Oregon Prescription Drug Affordability Board

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

Agenda

This is a regular meeting. *Date*: **August 20, 2025** | *Time*: **8 a.m.**

This is a draft agenda and subject to change

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

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

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

Purpose	Subject	Presenter
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 7/16/2025 minutes	Chair Shelley Bailey
Informational	PDAB program update	Staff
Informational	General public comment: limited to 3 minutes	Chair Shelley Bailey
Presentation	Executive session for legal advice pursuant to ORS 192.660(2)(f)	Pramela Reddi, Oregon Department of Justice
Review and discussion	Board review of methodology for drug reviews and scoring rubric and worksheet	Cortnee Whitlock, senior policy analyst
Review and discussion	Drug review: Trelegy – Antiasthmatic and Bronchodilator [1]	Cortnee Whitlock
Review and discussion	Drug review: Eliquis – Anticoagulants [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: Xarelto – Anticoagulants [1]	Cortnee Whitlock
Review and discussion	Drug review: Cosentyx – Dermatological [1]	Cortnee Whitlock
Review and discussion	Drug review: Creon – Digestive Aids [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 August 20 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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Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, July 16, 2025
Draft Minutes

Web link to the meeting video: https://youtu.be/wAl1u10eAM4
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20250716-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, Vice Chair Amy Burns, Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray
Absent: None

The board provided American Sign Language during the meeting. View at video minute **00:00:55**.

Declaration of conflict of interest, meetings with entities or individuals related to board activities, or testifying before the Legislature: John Murray provided a statement. View at video minute **00:01:13**.

Chair Bailey announced that PDAB meetings will start at 8 a.m. beginning Aug. 20, 2025 to provide more time for drug reviews. View at video minute **00:02:19**.

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. John Murray made a motion to approve the minutes and Lauri Hoagland provided a second. View the vote at video minute **00:02:54**.

MOTION to approve the June 18, 2025, minutes
Board Vote:
Yes: Dan Hartung, Lauri Hoagland, Chris Laman, John Murray, Chair Shelley Bailey
No: None
Abstain: Vice Chair Amy Burns, Dan Kennedy (due to being absent for the 6/18 meeting)
Absent: None
Motion passed 5-0

PDAB program update: Alex Cheng, deputy administrator, Division of Financial Regulation, provided a program update. View the video at minute **00:04:04**.

General public comment: Chair Bailey called on the people who signed up in advance to speak to the board: Ranier Simons, Community Access National Network, Lorren Sandt, Caring Ambassadors Program, Anne E Murray, Bristol Myers Squibb, Primo Castro, Biotechnology

Innovation Organization (BIO), Vanessa Lathan, Patient Inclusion Council (PIC) / Ensuring Access through Collaborative Health (EACH) Coalition, and Dharia McGrew, PhRMA. The board received 11 written comments, which are posted on the **PDAB website**. View the speakers at video minute **00:08:26**.

Board discussion about a process for measuring affordability to determine drug review cost impact: Cortnee Whitlock, senior policy analyst, led the board a discussion about the drug review process. View the **slide presentation** on Pages 6-12. View the discussion at video minute **00:27:35**.

Drug review: Antipsychotics & Antimanic agents – Vraylar: The board began discussions about drug reviews. View the Vraylar report on **Pages 13-44** posted on the PDAB website. View the discussion at video minute **00:40:06**.

Drug review: Migraine products – Ajovy, Emgality, Nurtec, Ubrelvy: The board continued the discussions about drug reviews. View the migraine products reports for Ajovy on **Page 75**, for Emgality on **Page 109**, for Nurtec on **Page 143**, and for Ubrelvy on **Page 178** posted on the PDAB website. View the discussion at video minute **01:26:50**.

Drug review: Cardiovascular agents – Entresto: The board continued the discussions about drug reviews. View the Entresto report on **Page 45** posted on the PDAB website. View the discussion at video minute **02:11:18**.

See board comments below.

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

Announcements: Chair Bailey announced the next meeting will be Aug. 20, 2025, at 8 a.m.

Adjournment: Chair Bailey adjourned the meeting at 11:30 a.m. with all board members in agreement. View at minute **02:27:26**.

Public comment speakers for review group 1 (Vraylar, Entresto, Ajovy, Emgality, Nurtec, and Ubrelvy)

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Lorren Sandt	Caring Ambassadors	Vraylar	Letter and speaking	7/16/2025	Exhibit A – letter Exhibit B – speaking
Courtney Piron	Novartis	Entresto	Letter	5/21/2025	Exhibit C
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Entresto	Letter	5/21/2025	Exhibit D
Alyss Patel	Novartis	Entresto	Letter	7/11/2025	Exhibit E
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Entresto	Letter	7/14/2025	Exhibit F
Sue Koob	Preventive Cardiovascular Nurses Association	Entresto	Letter	7/14/2025	Exhibit G
Lindsay Cox	The Headache & Migraine Policy Forum	Ajovy, Nurtec, Ubrelvy	Letter	7/14/2025	Exhibit H
Cynthia Ransom	Eli Lilly	Emgality	Letter	4/25/2025	Exhibit I
Lindsay Videnieks	The Headache & Migraine Policy Forum	Emgality	Letter	7/15/2025	Exhibit J
Tom Brown	Pfizer	Nurtec	Letter	6/18/25	Exhibit K
Tom Brown	Pfizer	Nurtec	Letter	7/11/25	Exhibit L
Dresden Skees-Gregory	PhD Candidate, Principal & CEO, Sustainable Environ-mental Services Corp	Nurtec	Letter	7/7/2025	Exhibit M
Katie Lukins	Public school teacher	Nurtec	Letter	7/8/2025	Exhibit N
David Gross	Pfizer, Inc	Nurtec	Speaking	7/16/2025	Exhibit O

Board comments about report

- Board could focus on a high-level summary of out-of-pocket costs for the drug compared with its therapeutic alternatives. – Dan Hartung
- It would be helpful to have a simple table with the average 30 day or annual price of the drug and its therapeutic alternatives. – Dan Hartung, Shelley Bailey
- Look at other state reports and how they have organized data. – Dan Hartung
- Board concern about review packets, process and volume of drugs. Review packets are overwhelming for board members. Some things in the packet are not relevant and should be removed. – Dan Hartung, Chris Laman
- Front load the report with critical information and put all the rest in an appendix. – Dan Hartung
- Have a summary section at the top of each review using APAC data showing number of patients on the prescription, number of claims, prescriptions dispensed, total cost to the system, total cost to patients, WAC over the last 3-5 years. – Chris Laman
- Patient quotes were very helpful. – Dan Hartung, John Murray
- The graphs about patient surveys were not as helpful and could be removed. – Dan Hartung
- In Tables 3 and 4, averages were miscalculated. In some places in the report, net cost was higher than the gross cost. – Dan Hartung
- Tables about CCO fee for service seem to be redundant with APAC summary data in multiple other tables. This is an example of ways to make the report more concise. – Dan Hartung
- Will the board have another meeting to discuss the drugs reviewed today? – Chris Laman
- Appreciates report information that sheds light on barriers to care, an important piece when looking at affordability. – Lauri Hoagland
- The Triptans have been omitted from the reports and they are an important comparison for migraine treatment. – Dan Hartung
- The reports could use WAC estimates of the monthly cost for migraine treatment versus prophylaxis based on WAC for a benchmark – Dan Hartung
- Narrow down what we think causes affordability issues for Oregonians and make that a focus in our packets. What is affecting the patient and out of pocket costs? – John Murray

Board comments about data

- How do we organize the data to help us make decisions? – Dan Hartung
- Board should lean on APAC data and use it mostly for review. The data call information has limitations. – Dan Hartung, Amy Burns
- Use APAC as the broader umbrella and refer to DPT in reviewing the drugs. – Shelley Bailey
- Use APAC and data call information. It will help see where the payments are going and how patients are impacted – John Murray
- I think it's important to include carrier data when we have it available. It sheds light on an important part of the state cost. – Lauri Hoagland

- Medicaid needs to be carved out of the overall, out-of-pocket estimate and presented separately in the reports – Dan Hartung

Board comments about drug reviews

Vraylar, Antipsychotics & Antimanic agents

- The board could use the three metrics it used to narrow the subset list: 1. Data call payer paid drug column filtered largest to smallest costs 2. APAC number of enrollees for all APAC claim line of business (Medicare, Medicaid, commercial) 3. Drugs with less than 1,000 APAC enrollees were removed. – Shelley Bailey
- Focus on cost to the healthcare system versus cost to patients. – Dan Hartung, Lauri Hoagland, Shelley Bailey
- Remember, payer expenses also impact patient costs. – Shelley Bailey
- Comparing prices with generics is important. – Dan Hartung
- The dashboard page showing APAC alternatives and biosimilars was helpful in reviewing each drug. – Shelley Bailey
- Entresto and Vraylar have substantially lower price concessions. Their small price concessions reflect the competitive environment of these drugs. – Dan Hartung

Entresto, cardiovascular agents – misc.

- Entresto has no drugs that have similar, therapeutic alternatives. The price concession is 11.5 percent, which is significantly less than the migraine products (in the mid-20s, with one being 41.2 percent.) Entresto and Vraylar have substantially lower price concessions. Their small price concessions reflect the competitive environment of these drugs. – Dan Hartung
- Entresto is not getting good rebates relative to the other drugs we've looked at. – Dan Hartung

Ajovy, migraine product

- Board should not be comparing and contrasting the four migraine products because we should be thinking about the world of therapeutic alternatives for each drug. – Dan Hartung

Emgality, migraine product

Nurtec, migraine product

- I was struck by how few people from minority groups are treated for migraine. It would be good to have a migraine product that was available to a broader group of patients. Nurtec, used to prevent migraines and also for acute pain, has a broader possible use. Oral medicines are perhaps a little more available for a broader population than injectables. – Lauri Hoagland
- There are differences in medications, some are injectable, some oral, and in dosing, and use. It's important to compare them accurately and to compare apples to apples. – Shelley Bailey, Amy Burns, Dan Hartung

- Nurtec dosing will be hard to tease out in a chart because patients take it both for prevention and pain relief. – Amy Burns
- Using a WAC cost per unit might be the best way to look at Nurtec, which has different dosing indications. – Amy Burns
- Another element of cost is looking at prior authorization (PA) requirements and percentage of approvals and the cost that goes out in the healthcare system with that. – Lauri Hoagland
- Most of the migraine products are on the non-preferred formulary and require prior authorization, which can be an access issue for those that need the medication. – Lauri Hoagland
- What's the difference in large group and small group in the descriptive titles? Is one a high-deductible type plan? It seems there are structural differences about those plans that led to vastly different out-of-pocket costs for employees or enrollees. – Dan Hartung

Ubrelvy, migraine product

DRAFT

Oregon Prescription Drug Affordability Board

Prescription Drug Affordability Board

2025 Drug Review Roadmap

August 20, 2025

2025 Drug Review (DR) Calendar

Rx Subset list

Board approval of preliminary list

Board approval of subset list

DR Group 1

DR Group 2

DR Group 3

Board discussion

Stakeholder RFI
(Request for Information)

Survey distribution

Analysis write-up and public comment

Results shared with board

Survey open for drugs under review

Insulin Subset list

Board approval of preliminary list

Board approval of subset list

DR Group 4

Board discussion

Data call

Rx

Analysis write-up

Insulin

Analysis write-up

Results shared with board

Annual Report

Draft Rx Report

Final Rx Report

Domain	Statutory* and Rule** References	Packet section	Key questions
Population impact & equity	*(2)(a) **(1)(a)-(b)	Health inequities; Residents prescribed; Relative financial impacts to health, medical or social services costs	• Are specific populations disproportionately affected (e.g. racial disparities, Medicaid reliance)? • How many Oregonians are using this drug, and through which payer line?
Price evaluation	*(2)(e) **(1)(c)	Price for the drug	• Has the WAC increased above inflation? • Are pharmacy acquisition costs or net costs diverging from WAC?
Price concessions[1]	*(2)(d) & (L) **(1)(d), (e) & (g)	Estimated average monetary price concessions; Estimated total amount of the price concessions; Estimated average price concession for therapeutic alternatives	• What percentage of claims receive discounts? • How do concessions affect net payer costs? • Are concessions for alternatives better or worse?
System & payer costs	**(1)(h)	Estimated costs to health insurance plans; Relative financial impacts to health, medical or social services costs	• What is the annual cost burden on Medicaid, Medicare, and commercial insurers? • How concentrated is use in one line of business?
Enrollee burdens	*(2)(g) & (j) **(1)(i) & (k)	Impact on patient access to the drug; Estimated average enrollee copayment or other cost-sharing; Access and equity considerations	• Are enrollees facing high OOP costs with the drug? • Is the drug non-preferred or subject to access barriers (e.g., prior authorization, step therapy)?
Therapeutic alternatives	*(2)(c) & (i) **(1)(f), (g), (j)	Estimated price for therapeutic alternatives; clinical information based on mfr material.	• Are there more affordable alternative that are equally or more effective? • Do those alternatives have fewer access restrictions?
Specified stakeholder input	*(3) **(2)(k)	Input from stakeholders	• What do patients and providers report about the affordability or access of the drug? • Are there unique cost burdens or value perceptions?

* All references are to ORS 646A.694.

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

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

1. Scoring Framework Overview

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

Score	Interpretation
0	Minimal impact
1	Moderate impact
2	High impact
3	Severe impact

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

Total score of 21

Suggested interpretations: 0-6 minimal impact; 7-13: moderate impact; 14-21 high impact

2. Sample Metrics:

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

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

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

Domain	Score 0 (Low Impact)	Score 1 (Moderate Impact)	Score 2 (High Impact)	Score 3 (Severe Impact)
Access and equity considerations	No disparities; widely preferred; minimal access barriers	Minor disparities or unclear data; modest impact on access 25%-49% plans listed drug as non-preferred	Clear disparities in access; significant impact on marginalized groups; 50%-74% plans listed drug as non-preferred	Systemic disparities; 75%-100% plans listed drug as non-preferred
Price evaluation	Stable WAC changes or rising below inflation for five years; minimal divergence from net cost	Average percent change in WAC between 0% to 3.99% for four years; out paces inflation four years	Average percent change in WAC between 4% to 4.99% for three years; out paced inflaction for three year	Average percent change in WAC between >5%; Outpaced inflation for four or more years
Price concessions	High % of claims discounted; net costs substantially reduced	50-75% of claims discounted; net costs modestly reduced	25-50% claims discounted; moderate payer relief	<25% of claims receive concessions; negligible payer relief
System & payer costs	Low total gross spend (<$10M); costs evenly spread across payers	Total gross spend $10M- $15M **and** total net spend <$3M	Total gross spend $15M-$50M **and** total net spend $3M-$10M	Total gross spend >$50M **and** total net spend >$10M
Enrollee burden	Total APAC OOP annual cost of < $200	Total APAC OOP annual cost $200-$700 **or** prior auth for <25% plans	Total APAC OOP $700-$1,200 **or** prior auth/step therapy >25%	Total APAC OOP >$1,200; drug excluded **or** majority of plans require prior auth/step therapy or over 50% denied prior-auth
Therapeutic alternatives	Cheaper and equally/more effective alternatives available; has a large number of TA/TE/Biosim	Somewhat more costly/effective; similar access; has six or more TA/TE/Biosim	More expensive alternatives; has 2-6 TA/TE/Biosim	No effective/affordable alternatives; has one or no TA/TE/Biosim
Specified stakeholder input	No concerns raised; positive feedback or minimal stakeholder input	Mixed views; moderate financial concerns noted	Significant concerns from providers/patients re: cost/affordability	Broad concern or consistent reports of high burden from multiple groups

Oregon Prescription Drug Affordability Board

Prescription drug review worksheet

For use by PDAB board members

Instructions:

For each domain, review the provided materials and assign a score based on the criteria below.
Use the comment section to justify your score or note uncertainties.

Drug name: Ajovy (fremanezumab-vfrm)

Board member: Amy Burns

Date of review:

Scoring Scale:

0 = Minimal impact / no relevant data
1 = Moderate impact / low concern
2 = High impact / mixed evidence
3 = Severe impact/ strong evidence of concern

Domains	Score 0 (minimal impact)	Score 1 (moderate impact)	Score 2 (high impact)	Score 3 (severe impact)	Domain notes
Access and equity considerations	○	○	○	○	
Price evaluation	○	○	○	○	
Price concessions	○	○	○	○	
System and payer costs	○	○	○	○	
Enrollee burden	○	○	○	○	
Therapeutic alternatives	○	○	○	○	
Specified stakeholder input	○	○	○	○	

Total scores

Total score (Max: 21): 0

Suggested interpretation:

- 0–6: Minimal impact concern
- 7–13: Moderate impact concern
- 14–21: High impact concern

Reviewer summary notes:

Oregon Prescription Drug
Affordability Board

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

Trelegy Ellipta®

(*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*)[1]

Version 1.0

[1] Image source: https://www.drugs.com/trelegy-ellipta.html

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Review summary

Price history

Trelegy Ellipta® (*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*) was first approved by the FDA in 2017. Since entering the market, the wholesale acquisition cost **(WAC) has risen at an average annual rate of 3.7 percent**, **exceeded inflation in 2019 and 2020**.[2,3] By late 2024, the **WAC reached approximately $10.96 per unit**. Pharmacy acquisition costs for **Medicaid also increased by 14.7 percent** over the same period, reflecting broader trends in pricing escalation.

Therapeutic alternatives

Trelegy Ellipta® (*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*) has the following therapeutic alternative: Breztri Aerosphere

Proprietary Name	Non-proprietary Name	Manufacturer	Year approved
Trelegy Ellipta	*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*	GlaxoSmithKline Research & Development	2017
Breztri Aerosphere	*budesonide, glycopyrrolate, and formoterol fumarate*	AstraZeneca	2020

Price history[4,5]

Trelegy rose at an **average annual rate of 3.7 percent** from 2018-2024.

- In the same time period, its therapeutic alternative rose at the rate:
    - Breztri Areosphere: 2.2 percent

Additionally, the average annual rate of Trelegy Ellipta exceeded inflation **in 2020, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 14.7 percent** over the same period, reflecting broader trends in pricing escalation.

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

Price concessions [6]

Based on data received from healthcare carriers, Trelegy Ellipta in 2023 had a **gross spend of $732 per claim**, while the **spend net of discount was $374 per claim**. Price concession per claim was reported to be $357.

Cost to the payer[7]

2023, APAC payer total expenditure, utilization, and cost per enrollee

Drug	Total Expenditure	Utilization	Cost per Enrollee	Cost per Enrollee, median
Trelegy Ellipta	$49,562,009	70,646	$4,684	$625
Breztri Aerophere	$4,627,756	7,218	$4,146	$609

Cost to enrollees[8]

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Trelegy Ellipta	$391	$30	$64	$10
Breztri Aerophere	$327	$35	$71	$10

[6] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[7] Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[8] 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. The 2023 drug affordability review selection included the following criteria: orphan-designated drugs were removed; drugs were reviewed based on payer-paid cost data from the data call submissions; and drugs reported to the APAC program across Medicare, Medicaid, and commercial lines of business were included. To ensure broader public impact, drugs with fewer than 1,000 enrollees reported in APAC reports were excluded from consideration.

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

Drug information[9]

Drug proprietary name(s)	Trelegy Ellipta®
Non-proprietary name	*fluticasone/umeclidinium/vilanterol*
Manufacturer	Glaxosmithkline (GSK)
Treatment: Trelegy Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for:	• the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
	• the maintenance treatment of asthma in patients aged 18 years and older.
Dosage and Strengths	• 100 mcg fluticasone furoate, 62.5 mcg umeclidinium, and 25 mcg vilanterol (100/62.5/25 mcg) per actuation.
	• 200 mcg fluticasone furoate, 62.5 mcg umeclidinium, and 25 mcg vilanterol (200/62.5/25 mcg) per actuation.
Form/Route	Powder/Inhalation

FDA approval

Trelegy was first approved by the FDA on September 18, 2017.[10]

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.

[9] U.S. Food & Drug Administration. *Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) Prescribing Information*. GSK, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209482s013lbl.pdf.

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

Health inequities

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

Black individuals with chronic obstructive pulmonary disease (COPD) are more likely than non-Hispanic whites to remain undiagnosed even at similar levels of airflow obstruction, resulting in delayed initiation of advanced therapies.[11] Even after diagnosis, minority patients are less likely to be referred for specialist care or preventive services such as smoking cessation , which contributes to underuse of combination therapies like Trelegy Ellipta (*fluticasone/umeclidinium/vilanterol*).[12]

Race adjusted spirometry equations decrease sensitivity for detecting COPD in Black patients, leading to underdiagnosis and treatment underutilization, including delayed access to newer respiratory therapies.[13] Cost also remains a major barrier as Trelegy is a branded therapy and often subject to higher out-of-pocket requirements under Medicare Part D or limited access with Medicaid and private plans, disproportionately affecting low-income populations.[14] Additionally, underrepresentation of minority patients in clinical trials may reduce clinician familiarity with Trelegy's effectiveness, further limiting equitable prescribing.[15]

Residents prescribed

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

Based on APAC claims, **70,646** Oregonians filled a prescription for Trelegy Ellipta in 2023.[16]

[11] Day, N. C., et al. (2020). Single-inhaler triple therapy fluticasone furoate/umeclidinium/vilanterol versus fluticasone furoate/vilanterol and umeclidinium/vilanterol in patients with COPD: results on cardiovascular safety from the IMPACT trial. *Respiratory research*, *21*(1), 139. https://doi.org/10.1186/s12931-020-01398-w.

[12] Grossi, Giuliana, "ATS 2024 Data Support Triple Therapy FF/UMEC/VI as Preferred Option for COPD." AJMC, Center on Health Equity & Access, The Center for Biosimilars, May 21, 2024. https://www.ajmc.com/view/ats-2024-data-support-triple-therapy-ff-umec-vi-as-preferred-option-for-copd.

[13] Davidson, Sean Richard, et al., "Race Adjustment of Pulmonary Function Tests in the Diagnosis and Management of COPD: A Scoping Review." International Journal of Chronic Obstructive Pulmonary Disease, April 29, 2024. https://pubmed.ncbi.nlm.nih.gov/38708410/.

[14] Ndugga, Nambi, et al. "Racial and Ethnic Disparities in Access to Medical Advancements and Technologies." KFF, Feb. 22, 2024. https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-and-ethnic-disparities-in-access-to-medical-advancements-and-technologies/.

[15] Ibid.

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

Price for the drug

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

This section examines the pricing dynamics of Trelegy Ellipta, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of 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 Trelegy Ellipta'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 WAC of Trelegy Ellipta, averaged across three NDCs reported, was approximately **$10.96 per unit** at the end of 2024.[17] Between 2018-2024, the unit WAC increased at an average annual rate of **3.7 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019 and 2019-2020 (see Figures 1 and 2).[18]

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

Table 1 Drug vs therapeutic alternatives and 2018-2024 WAC summary per 30-day supply

Year	Trelegy Ellipta	Breztri Aerosphere
2018	$8.83	
2019	$9.09	
2020	$9.55	$27.59
2021	$10.03	$27.59
2022	$10.33	$28,42
2023	$10.64	$29,27
2024	$10.96	$30,15
Avg. Annual % Change	3.7%	2.2%
% change 2018 between 2024	24.1%	

[17] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[18] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/.

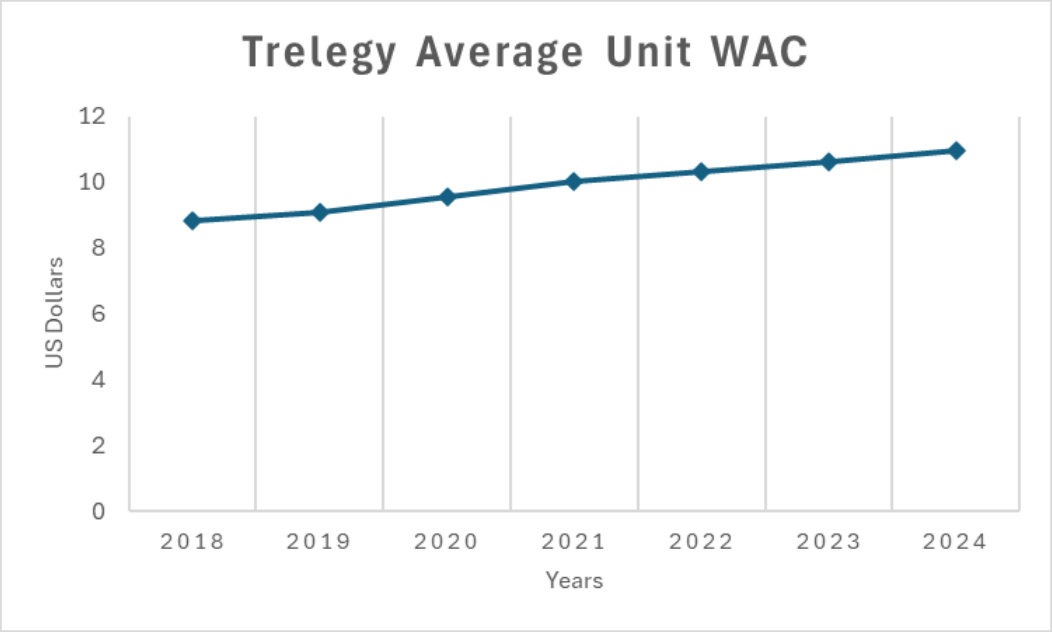


Figure 1 Trelegy Ellipta average unit WAC from 2018-2024

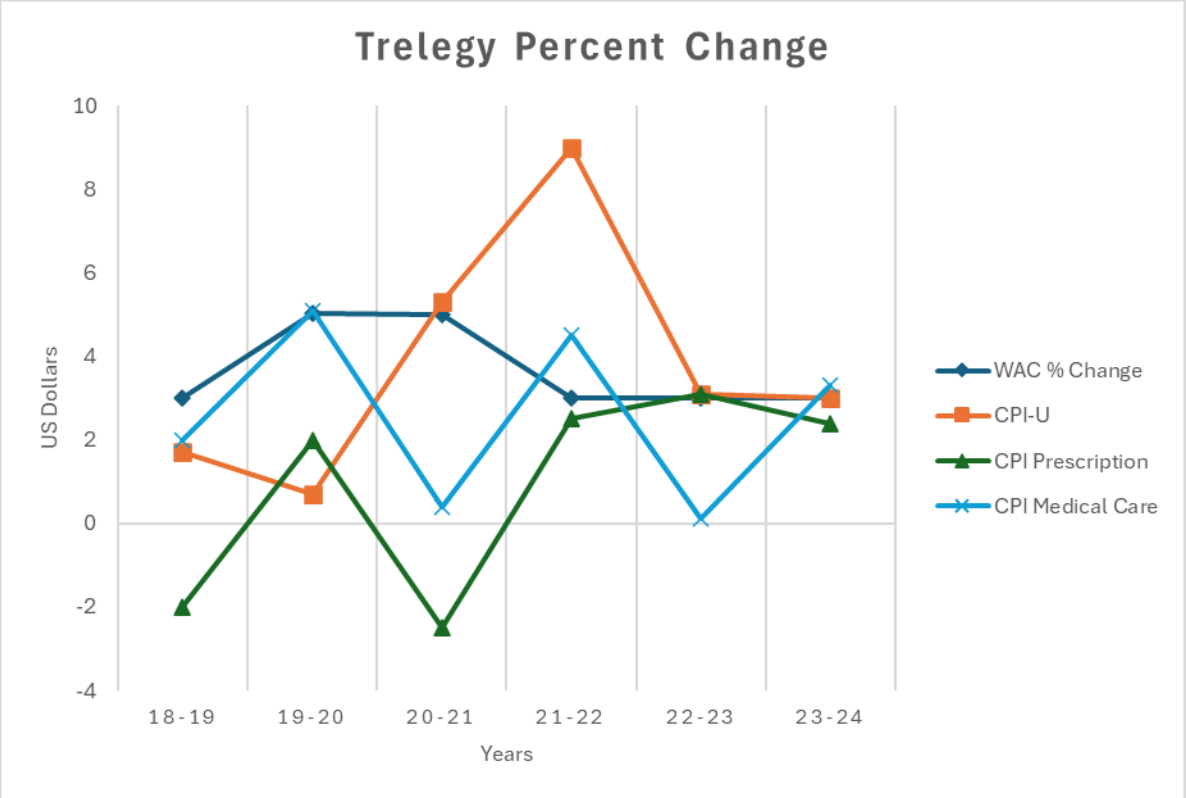


Figure 2 Year over year change in unit WAC compared to inflation rates[19]

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

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$9.16 per unit in Quarter 1 of 2020 to $10.51 per unit in Quarter 4 of 2024**, an approximate **14.7 percent increase** over the period (see Figure 3).[20] Relative to the **$10.97** WAC in end-of-year 2024 a **AAAC discount of 4.2 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 Trelegy Ellipta's price trajectory relative to inflation and affordability for public and private payers.

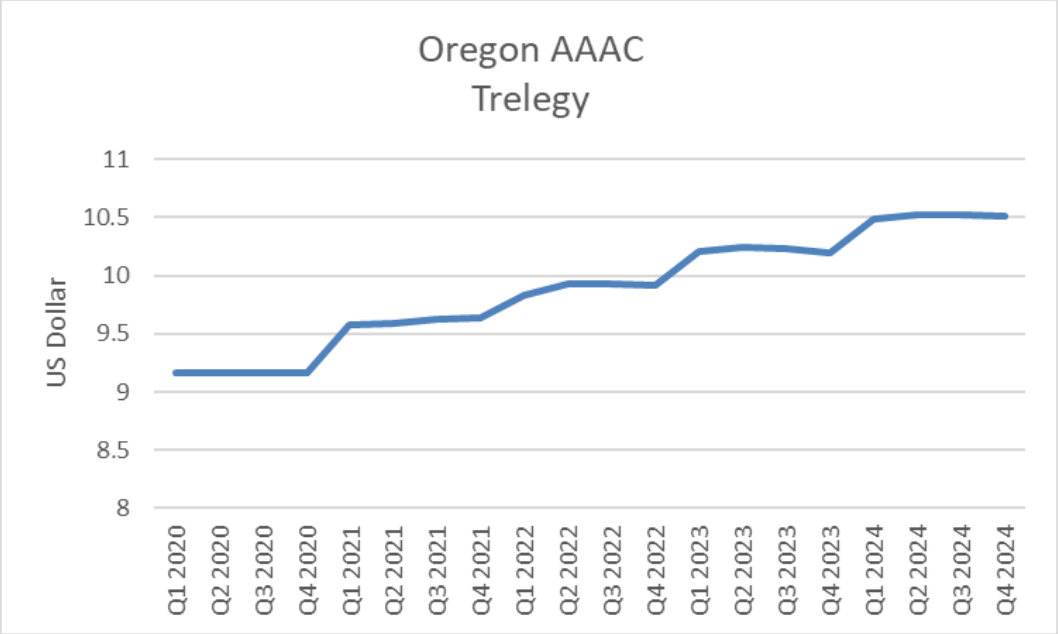


Figure 3 AAAC for Trelegy Ellipta from Q1 2020 to Q4 2024

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 Trelegy Ellipta claims in the commercial market. Drawing on data submitted through the 2023 carrier data call, it evaluates the extent to which these concessions

[20] 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 Trelegy Ellipta per enrollee in the commercial market was approximately $3,289**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $1,683**, reflecting an **estimated mean discount of 48.8 percent** relative to gross costs.

Across all reporting carriers and market segments, the total cost of Trelegy Ellipta before concessions was **$3,532,805**, with total reported price concessions amounting to approximately **$1,725,195**, as detailed in Table 2. Notably, **95.2 percent of claims benefited from some form of price concession**, leaving **4.8 percent at full gross cost**.

Table 2 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,074
Total number of claims	4,827
Total number of claims with price concessions applied	4,595
Percentage of claims with price concessions applied	95.2%
Percentage of cost remaining after concessions	51.2%
Manufacturer price concessions for all market types	$1,364,864
PBM price concessions for all market types	$359,231
Other price reductions for all market types	$1,100
Cost before price concessions across all market types	$3,532,805
Total price concessions across all market types	$1,725,195
Cost of after price concessions across all market types	$1,807,610
Avg. payer spend per enrollee without price concessions	$3,289
Avg. payer spend per enrollee with price concessions	$1,683

Including all market segments, the **gross spend of Trelegy per claim for commercial carriers was $732** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$374**, meaning that insurers reported a price concession of **$357** per claim on the initial drug cost as shown in Table 3.

Table 3 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	$732	$742	$724	$754
Spend per Claim, net	$374	$384	$371	$378
Price Concession per Claim	$357	$359	$353	$376

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

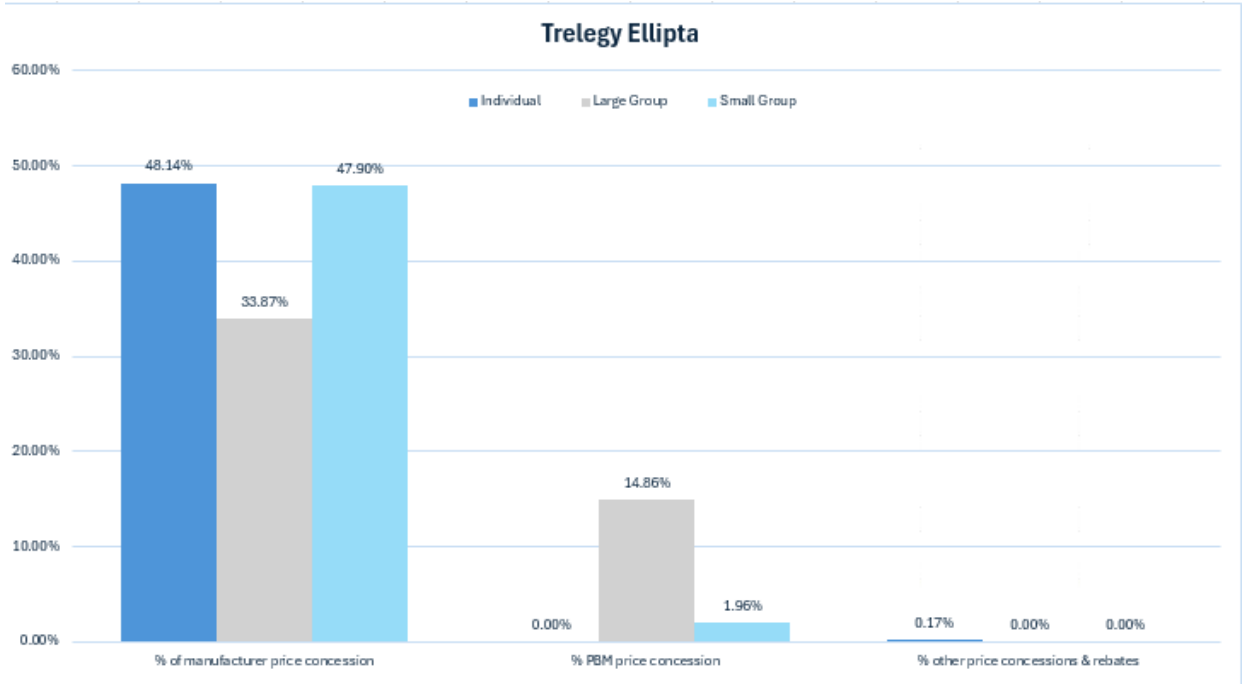


Figure 3 Percent of price concession in each market type[21, 22]

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

[22] Rebate refers to a discount that occurs after drugs are purchased from a pharmaceutical manufacturer and involves the manufacturer returning some of the purchase price of the purchaser. When drugs are purchased by a managed care organization, a rebate is based on volume, market share, and other factors. Academy of Managed Care Pharmacy. Managed Care Glossary | AMCP.org.

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 Trelegy Ellipta to each pharmacy benefit managers, expressed as a percentage of the drug's price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market.

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

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 Trelegy 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 submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concessions or rebates.

Trelegy Ellipta's gross total payer paid, based on APAC data, was $49.6 million, **while total net payer paid received from the carriers indicated a cost of $3.1 million. Trelegy Ellipta has the highest gross total pay in consideration with its therapeutic alternative,** which has the total gross payer paid of $4.6 million. **Notably, Trelegy has more utilization than its therapeutic alternative, at 70,646 claims**, as compared to Breztri Aerosphere, at 7,218 claims**. Trelegy Ellipta also has a higher payer paid per claim as compared to Breztri Aerosphere, $702 and $641 respectively.**

Trelegy also has the highest total enrollee paid at $3.8 million and Breztri Aerosphere follows behind with $462,080. Breztri Aerosphere has a patient paid per claim at $71, which is higher than **Trelegy's patient paid per claim at $55.**

[23] 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 4 Average healthcare and average patient OOP costs for Trelegy vs therapeutic alternatives

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid[24]	Payer paid/ claim	Patient paid/ claim[25]
Subject Drug **Trelegy (Data call)**	**1,074**	**4,827**	**$3,086,878**	**$318,465**	**$640**	**$66**
Subject Drug **Trelegy (APAC)**	**10,582**	**70,646**	**$49,562,009**	**$3,750,276**	**$702**	**$55**
Breztri Aerosphere	1,471	7,218	$4,627,756	$462,080	$641	$71

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 Trelegy, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

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 Trelegy 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

[24] The cost includes all lines of business.
[25] Ibid.

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 **70,646 total claims for Trelegy among 10,582 total enrollees**, corresponding to a **total payer expenditure of $49,562,009**.

Table 5 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Medicare** accounted for the largest share of utilization, with 46,375 claims from 7,722 enrollees and a total spend of **$34.9 million**.
- **Medicaid** and **commercial** payers reported smaller but notable expenditures of approximately **$7.5 million** and **$7.2 million**, respectively.

Table 5 Estimated 2023 APAC total gross costs to the payers [26]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial	1,960	11,859	$7,157,460	$3,652	$604
Medicaid	1,909	12,412	$7,486,718	$3,922	$603
Medicare	7,722	46,375	$34,917,832	$4,522	$753
Total	**10,582**	**70,646**	**$49,562,009**		

Table 6 provides utilization for the healthcare system for Trelegy and its therapeutic alternatives, distinguished by lines of business. **Trelegy had the most utilization** with **70,646 claims**. In all lines of business, Trelegy is the most utilized. **Breztri Aerosphere is the second most utilized at 7,218 claims**.

Table 6 Estimated 2023 APAC payer utilization of drug and its therapeutic alternatives[27]

Proprietary name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total claims[28]
Trelegy Ellipta	11,859	12,412	46,375	70,646
Breztri Aerosphere	981	711	5,526	7,218

[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.
[27] Ibid.
[28] Total is the sum of all utilization for the drug across all lines of business.

Table 7 shows the overall payer expenditure of Trelegy Ellipta and its therapeutic alternatives, distinguished by lines of business. Trelegy Ellipta has a **total expenditure of $49.6 million** with **Medicare being the biggest portion at $34.9 million**. The therapeutic alternative, Breztri Aerosphere, has less expenditure at $4.6 million.

Table 7 Estimated 2023 APAC payer expenditure of drug and its therapeutic alternatives[29]

Proprietary name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total[30]
Trelegy Ellipta	$7,157,460	$7,486,718	$34,917,832	$49,562,009
Breztri Aerosphere	$502,890	$421,270	$3,703,586	$4,627,756

Table 8 compares the overall payer cost per enrollee of Trelegy Ellipta and its therapeutic alternatives, distinguished by lines of business. **Trelegy Ellipta has the highest total cost per enrollee at $4,684**. Trelegy Ellipta has higher costs per enrollee in every line of business compared to Breztri Aerosphere. **The median cost per enrollee for Trelegy is $625**, which is higher than the median for the therapeutic alternative.

Table 8 Estimated 2023 APAC payer cost per enrollee of drug and its therapeutic alternatives[31]

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total cost/ enrollee	Cost per Enrollee, Median	IQR
Trelegy Ellipta	$3,652	$3,922	$4,522	$4,684	$625	$141
Breztri Aerosphere	$2,255	$2,790	$3,066	$3,146	$609	$164

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 (66% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $3.4 million**, with payer paying $3.1 million, and enrollees out-of-pocket estimating to be $318,465. Table 9 includes the

[29] 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.
[30] Total is the sum of all utilization for the drug across all lines of business.
[31] Ibid.

average plan costs per enrollee in the commercial market, ranging from **$3,309 (individual)** to **$2,983 (small group)** annually.

Table 9 Estimated 2023 data call total net costs to the healthcare system, payers and OOP/enrollee[32]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	858	192	$635,234	$542,183	$93,051
Large Group	3,238	711	$2,260,013	$2,071,688	$188,325
Small Group	731	171	$510,095	$473,006	$37,088
Total	**4,827**	**1,074**	**$3,405,342**	**$3,086,878**	**$318,465**

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	$740	$632	$108	$3,309	$2,824	$485
Large Group	$698	$640	$58	$3,179	$2,914	$265
Small Group	$698	$647	$51	$2,983	$2,766	$217

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

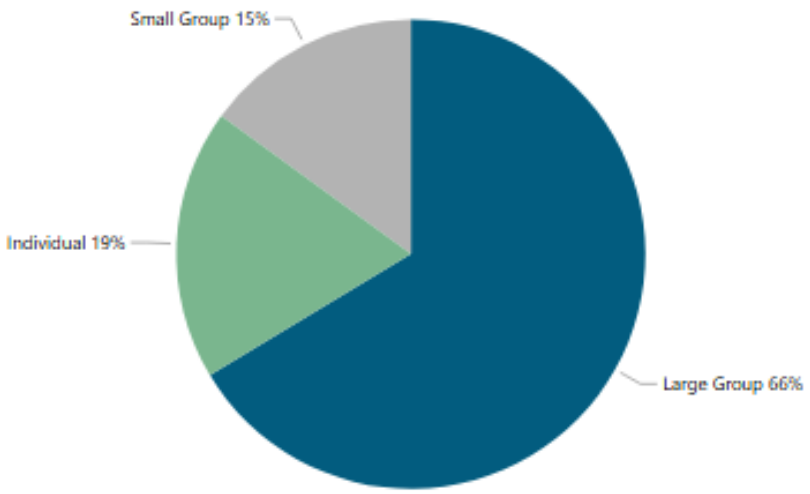


Figure 5 Data call total annual spend (payer paid)

Table 10 indicates CCOs that reported Trelegy as having an annual greatest increase from 2022-2023 (rebates not included) with about **$1.5 million in year-over-year increased cost growth**.

Table 10 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**
$5,547,915	$7,026,551	$1,478,636	0.1%

Impact on patient access to the drug

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

Review of rejected claims and drug benefit designs

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

Based on information reported through the carrier data call, the following plan design features were observed for Trelegy. In 2023, approximately **36.1 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.

For formulary placement, **37.2 percent of plans categorized Trelegy as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 11 Plan design analysis from 2023 data call

Percentage of Plans	
Required Prior Authorization	36.1%
Required Step Therapy	0.4%
On a non-preferred formulary	37.2%
Not covered	0.0%

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

Relative financial impacts to health, medical or social services costs

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

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

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

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

Estimated average patient copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Trelegy in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 12 and 13 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Medicare insured enrollees recorded higher average annual OOP costs**. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

Table 12 Drug vs. therapeutic alternatives and out-of-pocket cost per enrollee

Proprietary name	Medicare OOP Cost/Enrollee	Commercial OOP Cost/Enrollee	Total	Median	IQR
Trelegy Ellipta	$425	$239	$391	$30	$125
Breztri Aerosphere	$328	$296	$327	$35	$146

Table 13 Drug vs. therapeutic alternatives and out-of-pocket cost per claim

Proprietary name	Medicare OOP Cost/Claim	Commercial OOP Cost/Claim	Total	Median	IQR
Trelegy Ellipta	$71	$39	$64	$10	$47
Breztri Aerosphere	$72	$67	$71	$10	$47

Information from manufacturers

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

Drug indications

- FDA Approved:
  - the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
  - the maintenance treatment of asthma in patients aged 18 years and older.
- Limitations of Use
  - Not indicated for relief of acute bronchospasm.
- Off Label Uses:
  - None

Clinical efficacy

The clinical efficacy of Trelegy Ellipta *(Fluticasone Furoate/Umeclidinium/Vilanterol; FF/UMEC/VI)*, a once-daily combination inhaler containing fluticasone furoate (FF; an inhaled corticosteroid [ICS]), umeclidinium (UMEC; a long-acting muscarinic antagonist [LAMA]), and vilanterol (VV; a long-acting beta$_2$-agonist [LABA]), was established in multiple randomized, double-blind, controlled clinical trials evaluating both chronic obstructive pulmonary disease (COPD) and asthma. In COPD, two identical 12-week double blind studies compared UMEC + FF/VI to placebo + FF/VI in patients with COPD on change from baseline in FEV1 on day 85.[33] One study found a difference of 125 ml increase in trough FEV1 from baseline in patients receiving UMEC + FF/VI compared to patients receiving placebo + FF/VI and a difference of 122 ml in a second study. A large (n=10,355) randomized controlled trial (IMPACT) confirmed the efficacy of FF/UMEC/VI on moderate to severe exacerbations (Table 1) compared to FF/VI and UMEC/VI.

In 2022, Trelegy Ellipta received an expanded indication for maintenance treatment of asthma in adults and a new dosage form of FF/UMEC/VI 200mcg/62.5mcg/25mcg was approved. Approval was based on a 24-week, double blind, randomized, study comparing FF/UMEC/VI to FF/VI (Table 1). This trial demonstrated statistically significant improvements in trough FEV1with both doses compared to FF/VI. However, there was no significant difference in moderate or severe exacerbations with triple therapy compared to FF/VI.

[33] xSiler TM, Kerwin E, Sousa AR, Donald A, Ali R, Church A. Efficacy and safety of umeclidinium added to fluticasone furoate/vilanterol in chronic obstructive pulmonary disease: Results of two randomized studies. Respir Med. 2015 Sep;109(9):1155-63. doi: 10.1016/j.rmed.2015.06.006. Epub 2015 Jun 14. Erratum in: Respir Med. 2015 Nov;109(11):1493. PMID: 26117292.

Table 14 Clinical efficacy results

Trial / Population	Treatment Group	Comparator	Endpoint	Treatment Effect	p-value
COPD (IMPACT)	FF/UMEC/VI 100/62.5/25	FF/VI 100/25	Annual exacerbation rate	0.91/yr vs. 1.07/yr RR 0.85 (95% CI, 0.80 to 0.90)	<0.001
		UMEC/VI 62.5/25	Annual exacerbation rate	0.91/yr vs. 1.21/yr RR 0.75 (95% CI, 0.70 to 0.81)	<0.001
Asthma (CAPTAIN)	FF/UMEC/VI 100/62.5/25	FF/VI 100/25	Change from baseline in trough FEV1 at week 24	Difference 110 mL 95% CI 66 to 153)	<0.001
			Annual exacerbation rate	0.68/yr vs. 0.87/year RR 0.78 (95% CI 0.61 to 1.01)	0.06
	FF/UMEC/VI 200/62.5/25	FF/VI 100/25	Change from baseline in trough FEV1 at week 24	Difference 92 mL 95% CI 49 to 135)	<0.001
			Annual exacerbation rate	0.55/yr vs. 0.57/year RR 0.97 (95% CI 0.73 to 1.28)	0.08
Abbreviations: FEV1: Forced Expiratory Volume in one second, FF: fluticasone furoate; RR: rate ratio; UMEC: umeclidinium; VI: vilanterol					

Clinical safety

- <u>FDA safety warnings and precautions:</u>
  - Serious Asthma-Related Events with use of LABA monotherapy (without ICS) for asthma
  - Deterioration of disease and acute episodes if initiated in rapidly deteriorating or life-threatening episodes of COPD or asthma
  - Avoid excess use of Trelegy Ellipta and avoid use with other LABAs
  - Oropharyngeal candidiasis
  - Pneumonia
  - Immunosuppression and risk of infections
  - Hypercorticism and adrenal suppression, especially when transferring patients from systemic corticosteroid therapy
  - Drug interactions with strong cytochrome P450 3A4 inhibitors
  - Paradoxical Bronchospasm
  - Hypersensitivity reactions, including anaphylaxis

- Cardiovascular effects: beta agonists may cause elevations in blood pressure, heart rate, and arrythmias
- Reduction in bone mineral density
- Glaucoma and cataracts, worsening of narrow-angle glaucoma
- Worsening of urinary retention
- Hypokalemia and hyperglycemia
- Effect on growth in children and adolescents

- Contraindications:
  - Primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required.
  - Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients.
- Common side effects:
  - Nasopharyngitis and pharyngitis
  - Constipation, diarrhea, gastroenteritis, dysgeusia
  - Oral candidiasis
  - Headache
  - Voice disorder
  - Bronchitis, cough, respiratory tract infections, sinusitis
  - Back pain and arthralgia

Therapeutic alternatives:[34,35]

Triple therapy with a LABA/LAMA/ICS should be considered for patients with severe or very severe COPD with continued frequent and/or serious exacerbations despite optimized use of LABA and LAMA or LABA/ICS. There are currently two combination ICS/LAMA/LABA products available (Table 15). There are no randomized controlled trials directly comparing these agents or evidence demonstrating differences in efficacy or safety.

Table 15 FDA Approved Indications

Proprietary name	Non-proprietary name	Manufacturer (year approved)	FDA Approved Indications
Trelegy Ellipta	*fluticasone furoate, umeclidinium, and*	GlaxoSmithKline Research & Development (2017)	Maintenance treatment of COPD and asthma in adults

[34] U.S. Food & Drug Administration. *Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) Prescribing Information*. GSK, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209482s013lbl.pdf.

[35] U.S. Food & Drug Administration. *Breztri Aerosphere (budesonide, glycopyrrolate, and formoterol fumarate) Prescribing Information*. AstraZeneca, Action yr 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212122s000lbl.pdf.

Proprietary name	Non-proprietary name	Manufacturer (year approved)	FDA Approved Indications
	vilanterol inhalation powder		
Breztri Aerosphere	*budesonide, glycopyrrolate, and formoterol fumarate*	AstraZeneca (2020)	Maintenance treatment of COPD only

Table 16 Efficacy (clinical trials & practice)

Measure	Trelegy Ellipta	Breztri Aerosphere
Annual rate of moderate/severe exacerbations	Decreased 15–25% vs. FF/VI and UMEC/VI (p<0.001)	Decreased 15–20% vs. dual therapy (Hazard ratio ~0.85)
Trough FEV1 improvement (mL)	Increased 65–95 mL over dual therapy (p<0.001)	Increased 55–78 mL over dual therapy (p<0.001)
Quality of Life (SGRQ score improvement)	Clinically meaningful improvements (≥4-point SGRQ)	Modest improvements; sometimes not clinically meaningful
Abbreviations: SGRQ: St. George's Respiratory Questionnaire		

Table 17 Adverse effects profile

Adverse Effect Category	Trelegy Ellipta	Breztri Aerosphere
Common Adverse Effects	Nasopharyngitis, headache, URTI, pneumonia, back pain	URTI, pneumonia, back pain, oral candidiasis, influenza
Notable Risks	Increased risk of pneumonia, oral candidiasis, potential cardiovascular effects	Increased risk of pneumonia, oral candidiasis, systemic corticosteroid effects

Table 18 Dosing and route

Product	Trelegy Ellipta	Breztri Aerosphere
Route	Oral inhalation via dry powder inhaler (DPI)	Oral inhalation via pressurized metered dose inhaler (pMDI)
Strength per Inhalation	Fluticasone furoate/umeclidinium/vilanterol COPD 100/62.5/25 mcg. Asthma 100/62.5/25 mcg, or 200/62.5/25 mcg	Budesonide 160 mcg, glycopyrrolate 9 mcg, formoterol fumarate 4.8 mcg
Recommended Dose	1 inhalation once daily	2 inhalations twice daily

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 13 individuals** taking or having an association with Trelegy. According to the survey results, 10 respondents had insurance coverage for Trelegy.

There were no patients on Medicaid, 12 patients were on Medicare, and one patient had private health insurance but was on a patient assistance program because their prescription was not covered by insurance.

Individuals with scientific or medical training

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

Safety net providers

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

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

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

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

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

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

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

Table 19 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	10
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%

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 20 Amounts paid for drug under 340B discount program

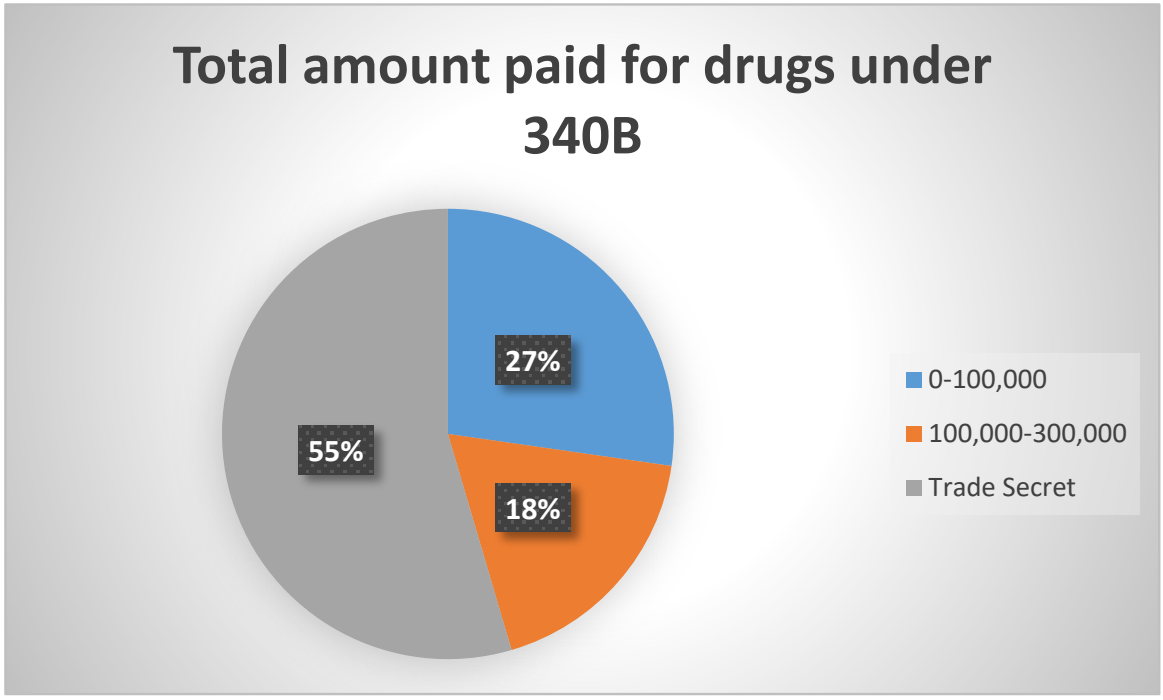
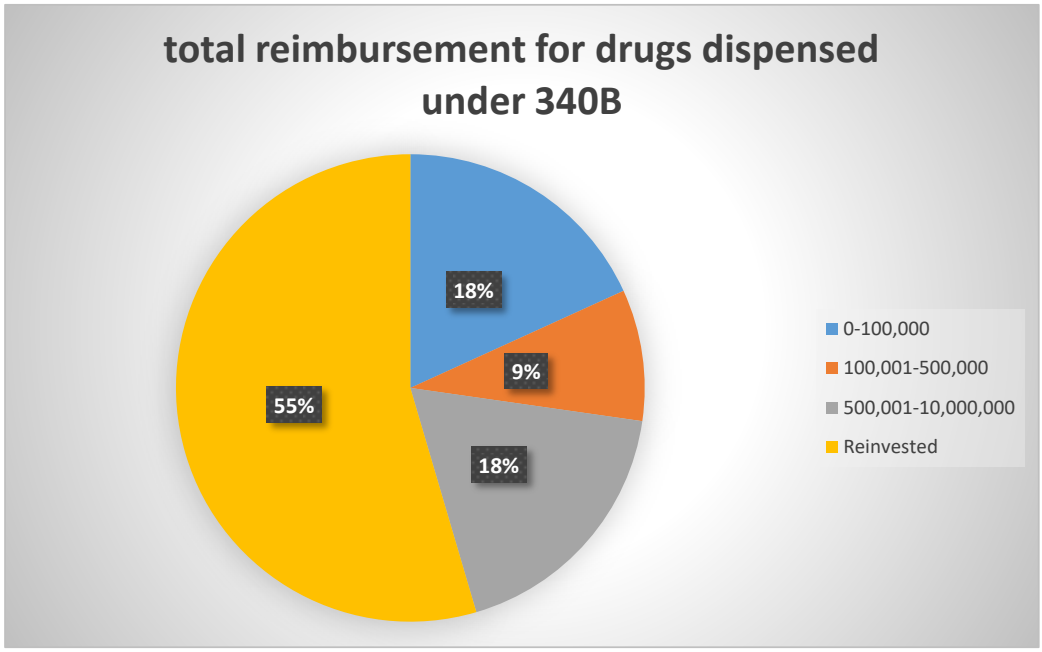


Table 21 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B discount program



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
Harmeet Dhillon	GSK	Trelegy	Letter	5/21/2025	Exhibit A
Linda Nelson	Oregon Coalition for Affordability Prescriptions	Trelegy	Letter	5/21/2025	Exhibit B
Molly Burich	GSK	Trelegy	Letter	8/15/2025	Exhibit C

Oregon Prescription Drug
Affordability Board

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

Eliquis®
(*apixaban*)[1]

Version 1.0

[1] Image source: https://meds90.com/products/eliquis/

Table of Contents

Review summary

Therapeutic alternatives

Eliquis (apixaban) has the following therapeutic alternatives: Pradaxa, Savaysa, and Xarelto.

Proprietary name	Non-proprietary name	Manufacturer	Year approved
Eliquis	*apixaban*	Bristol-Myers Squibb Company	2012
Pradaxa	*dabigatran etexilate*	Boehringer Ingelheim Pharmaceuticals, Inc.	2010
Savaysa	*edoxaban*	Daiichi Sankyo, Co., LTD.	2015
Xarelto	*rivaroxaban*	Jenssen Pharmaceuticals, Inc.	2011

Price history[2,3]

Eliquis rose at an **average annual rate of 6.0 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
    - Pradaxa: -9.6 percent
    - Savaysa: 3.1 percent
    - Xarelto: 5.2 percent

Additionally, the average annual rate of Eliquis exceeded inflation **in 2019, 2020, 2021, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 26.7 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions [4]

Based on data received from healthcare carriers, Eliquis in 2023 had the **gross spend of $872 per claim**, while the **spend net of discount was $601 per claim**. Price concession per claim was reported to be **$271**.

[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] 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 the payers[5]

2023, APAC payer total expenditure, utilization, and cost per enrollee

Drug	Total Expenditure	Utilization	Cost per Enrollee	Cost per Enrollee, median
Eliquis	$258,815,637	335,401	$4,331	$606
Pradaxa	$4,620,535	21,487	$840	$277
Savaysa	$88,003	140	$2,839	$761
Xarelto	$60,140,359	73,766	$4,343	$1,101

Cost to enrollees[6]

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Eliquis	$602	$70	$114	$44
Pradaxa	$91	$20	$23	$20
Savaysa	$647	$94	$140	$75
Xarelto	$591	$90	$122	$47

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

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

Review background

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

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

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

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

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

Drug information[7]

Drug proprietary name	Eliquis®
Active ingredient	*apixaban*
Manufacturer	Bristol-Myers Squibb
Treatment: A factor Xa inhibitor indicated:	
	• To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
	• For the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.
	• For the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy
Strength:	Tablets: 2.5 mg and 5 mg
Dosage	
Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation:	• 5 mg orally twice daily.
	• In patients with at least 2 of the following characteristics: age greater than or equal to 80 years, body weight less than or equal to 60 kg, or serum creatinine greater than or equal to 1.5 mg/dL, the recommended dose is 2.5 mg orally twice daily.
Prophylaxis of DVT following hip or knee replacement surgery	2.5 mg orally twice daily.
Treatment of DVT and PE	10 mg taken orally twice daily for 7 days, followed by 5 mg taken orally twice daily.
Reduction in the risk of recurrent DVT and PE following initial therapy	2.5 mg taken orally twice daily.
Route	Orally

FDA approval

Eliquis was first approved by the FDA on Dec. 28, 2012 to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.[8]

[7] U.S. Food & Drug Administration. *Eliquis (apixaban) Prescribing Information*. Bristol-Myers Squibb Company, Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202155s034lbl.pdf.

[8] 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.

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

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

Health inequities

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

Disparities exist in the prescribing and utilization of direct oral anticoagulants (DOACs), including Eliquis (*apixaban*) and Xarelto (*rivaroxaban*), among racial and ethnic minority patients, individuals with limited socioeconomic means, and residents of areas with constrained access to care. Black patients, along with Hispanic and Americans Indian/Alaska Native groups, remain consistently less likely than white patients to receive DOAC therapy despite comparable clinical indications for stroke prevention in atrial fibrillation (AF) or treatment of venous thromboembolism.[9] Underrepresentation of these populations in major clinical trials limits generalizability and reinforces gaps in treatment equity, cost, and access.[10]

Provider bias, insurance formulary barriers, and structural social determinants contribute to these inequities. For instance, apixaban prescriptions are more frequently rejected for Medicaid-insured and Black patients than for others, potentially delaying access to care.[11] Geographic and socioeconomic disparities further influence prescribing patterns; a large Medicare cohort demonstrated that counties with higher proportions of Black residents have markedly higher untreated AF rates, frequently exceeding 50 percent, with reginal patterns particularly pronounced in the Southeast.[12]

According to the Journal of American College of Cardiology (JACC), most significant AF studies disproportionately involved white participants, leaving Black, Hispanic, Asian, and Indigenous groups underrepresented.[13] The authors emphasize that advancing equitable care requires integrating social determinants of health into AF risk prediction, prevention, and treatment strategies, including anticoagulation therapy.

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[9] Reynolds KR, Khosrow-Khavar F, Dave CV. Racial and Ethnic Disparities in Initiation of Direct Oral Anticoagulants Among Medicare Beneficiaries. JAMA Netw Open. 2024;7(5):e249465. doi:10.1001/jamanetworkopen.2024.9465.

[10] Norby, F. L., Benjamin, E. J., Alonso, A., & Chugh, S. S. (2021). Racial and Ethnic Considerations in Patients With Atrial Fibrillation: JACC Focus Seminar 5/9. Journal of the American College of Cardiology, *78*(25), 2563–2572. https://doi.org/10.1016/j.jacc.2021.04.110.

[11] Deitelzweig, S., Xie, L., Terasawa, E., Hood, D. W., Cato, M., Atreja, N., Kang, A., & Hines, D. M. (2023). Journey to anticoagulant access following payer rejection of apixaban. The American Journal of Managed Care, *29*(11), e330–e338. https://doi.org/10.37765/ajmc.2023.89459.

[12] Atwater, B.D., Singh, R., Parmar, S. *et al.* Geographic and Racial Variation in Oral Anticoagulant (OAC) Treatment Among Commercially Insured Patients with Non-valvular Atrial Fibrillation (NVAF) in the United States. American Journal of Cardiovascular Drugs (2025). https://doi.org/10.1007/s40256-025-00728-x.

[13] Norby, F. L., Benjamin, E. J., Alonso, A., & Chugh, S. S. (2021). Racial and Ethnic Considerations in Patients With Atrial Fibrillation: JACC Focus Seminar 5/9. Journal of the American College of Cardiology, *78*(25), 2563–2572. https://doi.org/10.1016/j.jacc.2021.04.110.

The JACC review also highlights that racial and ethnic minority status is sometimes associated with adverse AF outcomes, such as higher stroke incidence, but that access to anticoagulant therapy may reduce these risks. Studies support the importance of equitable DOAC access (Eliquis and Xarelto) to mitigate stroke disparities, particularly among Black patients whose adjusted stroke risk may remain elevated without anticoagulants.

No definitive studies show differential efficacy or safety of Eliquis compared to Xarelto across ethnic groups. The primary inequity lies in access and utilization. Economically and socially marginalized patients are more likely to be managed with older therapies (e.g., warfarin) even when guidelines indicate that DOAC therapies could yield better outcomes.

Residents prescribed

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

Based on APAC claims, **59,757** Oregonians filled a prescription for Eliquis in 2023.[14]

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

Price history

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

Table 1 Drug vs therapeutic alternatives and 2018-2024 WAC summary per 30-day supply[15]

Year	Eliquis	Pradaxa	Savaysa	Xarelto
2018	$419	$401	$337	$419
2019	$444	$433	$364	$448
2020	$471	$459	$389	$470
2021	$499	$477	$389	$492
2022	$529	$496	$389	$517

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

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

Year	Eliquis	Pradaxa	Savaysa	Xarelto
2023	$561	$198	$397	$542
2024	$594	$159	$404	$570
Avg. Annual % Change	6.0%	-9.6%	3.1%	5.2%
% change 2018 between 2024	41.9%	-60.3%	20.0%	35.9%

The WAC of Eliquis, averaged across six NDCs reported, was approximately **$9.91 per unit** at the end of 2024.[16] Between 2018-2024, the unit WAC increased at an average annual rate of **6.0 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019, 2019-2020, 2020-2021, 2022-2023, and 2023-2024 (see Figures 1 and 2).[17]

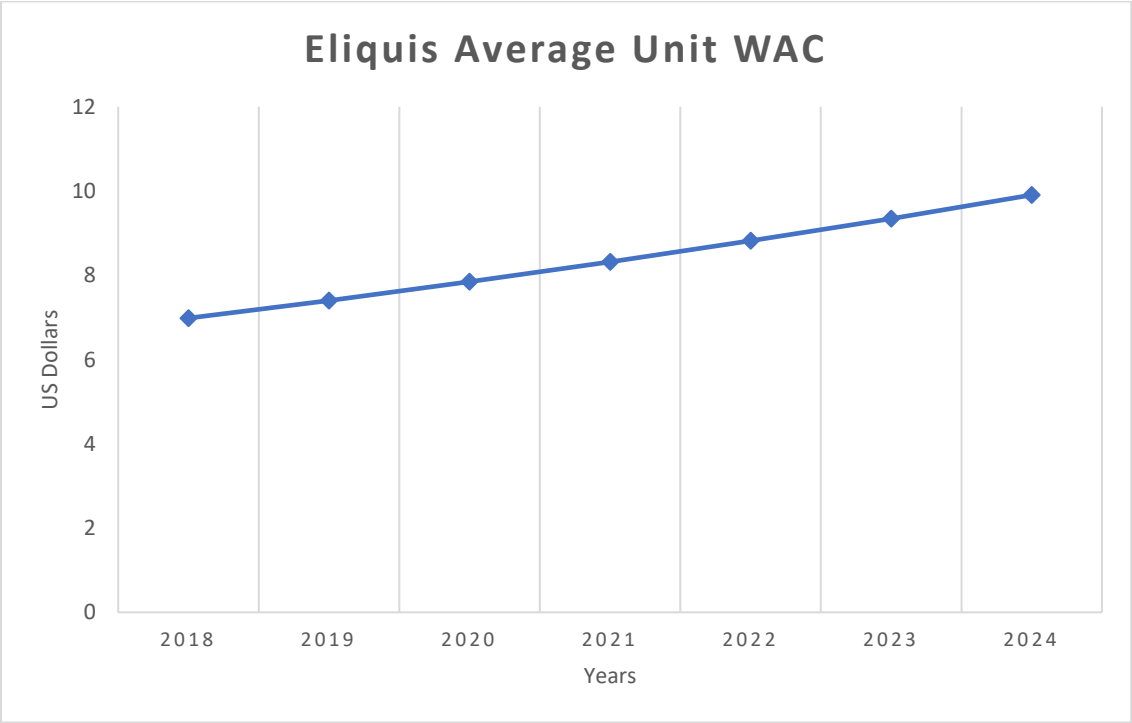


Figure 1 Eliquis average unit WAC from 2018-2024

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

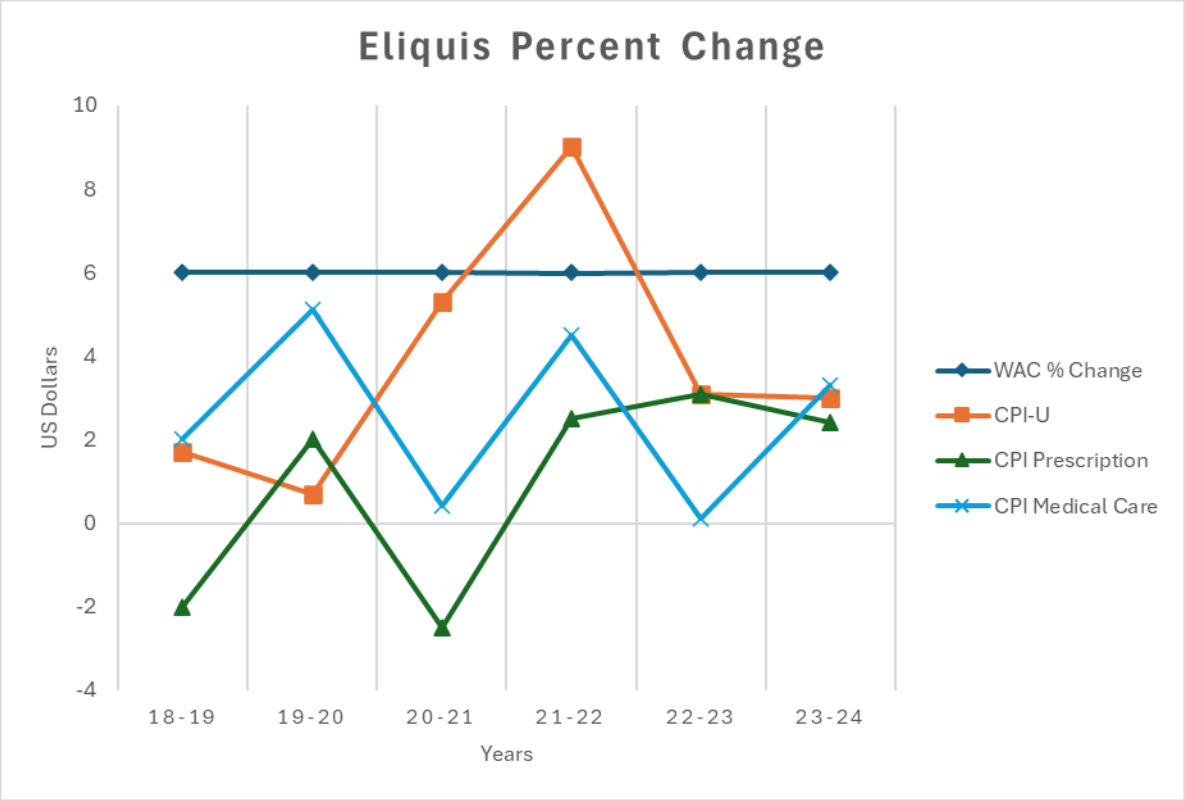


Figure 2 Year over year change in WAC compared to inflation rates[18]

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$7.51 per unit in Quarter 1 of 2020 to $9.53 per unit in Quarter 4 of 2024**, an approximate **26.7 percent increase** over the period (see Figure 3).[19] Relative to the **$9.91** WAC in end-of-year 2024 an **AAAC discount of 3.8 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 Eliquis's price trajectory relative to inflation and affordability for public and private payers.

[18] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[19] This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2024, available at https://myersandstauffer.com/client-portal/oregon/.

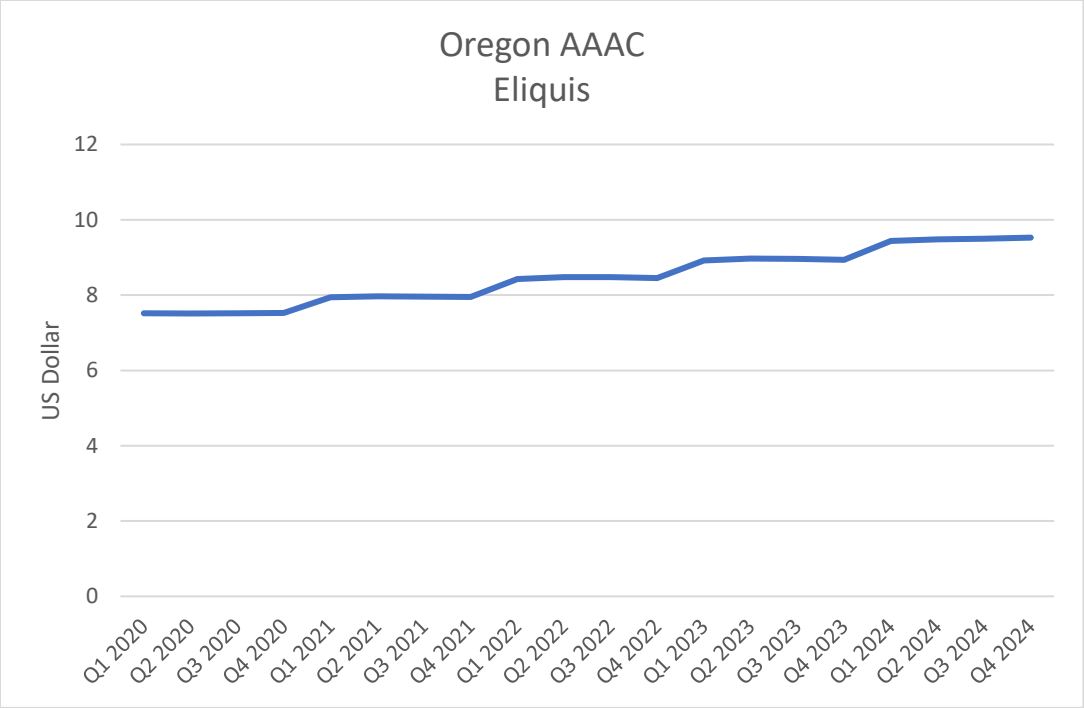


Figure 3 AAAC For Eliquis from Q1 2020 to Q4 2024

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 Eliquis 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 Eliquis per enrollee in the commercial market was approximately $3,191**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $2,198**, reflecting an **estimated mean discount of 31.1 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Eliquis before concessions was $19,091,230**, with total reported **price concessions amounting to approximately $5,939,900**, as detailed in Table 2. Notably, **93.1 percent of claims benefited from some form of price concession,** leaving **6.9 percent at full gross cost**.

Table 2 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	5,982
Total number of claims	21,891
Total number of claims with price concessions applied	20,382
Percentage of claims with price concessions applied	93.1%
Percentage of cost remaining after concessions	68.9%
Manufacturer price concessions for all market types	$5,015,041
PBM price concessions for all market types	$908,623
Other price reductions for all market types	$16,237
Cost before price concessions across all market types	$19,091,230
Total price concessions across all market types	$5,939,900
Cost of after price concessions across all market types	$13,151,330
Avg. payer spend per enrollee without price concessions	$3,191
Avg. payer spend per enrollee with price concessions	$2,198

Including all market segments, the **gross spend of Eliquis per claim for commercial carriers was $872** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$601**, meaning that insurers reported a price concession of **$271** per claim on the initial drug cost as shown in Table 3.

Table 3 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	$872	$892	$860	$894
Spend per Claim, net	$601	$620	$584	$636
Price Concessions per Claim	$271	$272	$275	$257

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

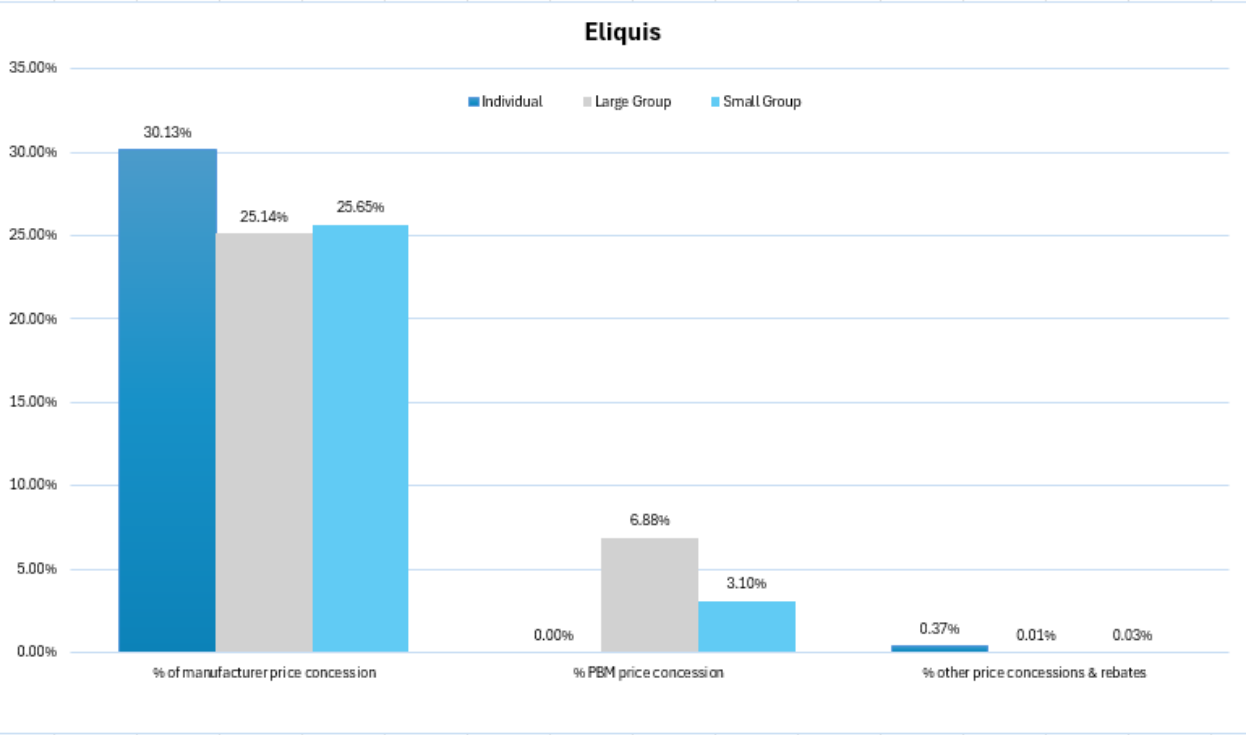


Figure 4 Percent of price concession in each market type[20, 21]

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

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

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[22]

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 Eliquis 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 submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concession or rebates.

Eliquis' gross total payer paid, based on APAC data, **was $258.8 million**, while total net payer paid received from the **carriers indicated a cost of $16.2 million. Eliquis has the highest gross total pay in consideration** with its therapeutic alternatives. The second highest is Xarelto, with $60.1 million. Notably, Eliquis has the **most utilization among the drugs, at 335,401 claims**, as compared to the second highest utilization of Xarelto, at 73,766 claims. Xarelto has a **higher payer paid per claim compared to Eliquis, which are $815 and $772 respectively**.

Eliquis also has the highest total enrollee paid at $33.3 million and Xarelto follows behind with $7.4 million. Savaysa has the highest patient paid per claim of $140, which is higher than both Xarelto at $122 and Eliquis at $99. The drug with the lowest patient paid per claim is Pradaxa, which is $23.

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

[22] 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).

Table 4 Average healthcare and average patient OOP costs for Eliquis vs therapeutic alternatives

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid[23]	Payer paid/ claim	Patient paid/ claim[24]
Subject Drug **Eliquis (Data call)**	**5,982**	**21,891**	**$16,168,736**	**$2,518,263**	**$739**	**$115**
Subject Drug **Eliquis (APAC)**	**59,757**	**335,401**	**$258,815,637**	**$33,319,981**	**$772**	**$99**
Pradaxa	5,501	21,487	$4,620,535	$478,268	$215	$23
Xarelto	13,849	73,766	$60,140,359	$7,442,476	$815	$122
Savaysa	31	140	$88,003	$19,417	$629	$140

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 Eliquis, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

[23] The cost includes all lines of business.
[24] Ibid.

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 Eliquis 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 **335,401 total claims for Eliquis among 63,449 total enrollees**, corresponding to a **total payer expenditure of $258,815,637**.

Table 5 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Medicare** accounted for the largest share of utilization, with 246,059 claims from 46,525 enrollees and a total spend of **$205.6 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **$30.7 million** and **$22.5 million**, respectively.

Table 5 Estimated 2023 APAC total gross costs to the payers [25]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	9,645	46,684	$30,683,588	$3,181	$657
Medicaid	7,279	42,658	$22,502,400	$1,091	$528
Medicare	46,525	246,059	$205,629,649	$4,420	$836
Totals	**63,449**	**335,401**	**$258,815,637**		

Table 6 provides utilization for the healthcare system for Eliquis and its therapeutic alternatives, distinguished by lines of business. **Eliquis has the most utilization** among the drugs, with **335,401 claims**. In all lines of business, Eliquis is the most utilized. **Xarelto is the second most utilized at 73,766 claims**.

[25] 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 6 Estimated 2023 APAC payer utilization of drug and its therapeutic alternatives[26]

Proprietary name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total claims[27]
Eliquis	46,684	42,658	246,059	335,401
Pradaxa	5,971	962	14,554	21,487
Savaysa	25	1	114	140
Xarelto	12,570	12,532	48,664	73,766

Table 7 shows the overall payer expenditure of Eliquis and its therapeutic alternatives, distinguished by lines of business. Eliquis has a **total expenditure of $258.8 million** with **Medicare being the biggest portion at $205.6 million**. The therapeutic alternative with the **least expenditure is Savaysa, at $88,003**.

Table 7 Estimated 2023 APAC payer expenditure of drug and its therapeutic alternatives[28]

Proprietary name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total[29]
Eliquis	$30,683,588	$22,502,400	$205,629,649	$258,815,637
Pradaxa	$1,176,190	$210,748	$3,233,597	$4,620,535
Savaysa	$17,033	$176	$70,794	$88,003
Xarelto	$9,274,654	$6,479,274	$44,386,431	$60,140,359

Table 8 compares the overall payer cost per enrollee of Eliquis and its therapeutic alternatives, distinguished by lines of business. **Xarelto has the highest total cost per enrollee at $4,343**. Eliquis has the **highest cost per enrollee in Medicare at $4,420**, though the cost per enrollee of the commercial line of business is comparable to its therapeutic alternative, Xarelto. **The median cost per enrollee for Eliquis is $606**, which is less than the median cost per enrollee for both Savaysa and Xarelto.

[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.
[27] Total is the sum of all utilization for the drug across all lines of business.
[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] Total is the sum of all expenditure for the drug across all lines of business.

Table 8 Estimated 2023 APAC payer cost per enrollee of drug and its therapeutic alternatives[30]

Proprietary name	Commercial Cost/Enrollee	Medicaid Cost/Enrollee	Medicare Cost/Enrollee	Total[31] Cost per Enrollee	Cost per Enrollee, Median	IQR
Eliquis	$3,181	$3,091	$4,420	$4,331	$606	$1,019
Pradaxa	$519	$747	$808	$840	$277	$202
Savaysa	$2,839	$176	$2,950	$2,839	$761	$667
Xarelto	$3,478	$3,510	$4,357	$4,343	$1,101	$997

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 (61% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $18.7 million**, with payer paying $16.2 million, and enrollees out-of-pocket estimating to be $2.5 million. Table 9 includes the average plan costs per enrollee in the commercial market, ranging from **$2,806 (large group)** to **$2,360 (individual)** annually.

Table 9 Estimated 2023 data call total net costs to the healthcare system, payers and OOP/enrollee[32]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	4,429	1,220	$3,946,404	$2,879,226	$1,067,179
Large Group	13,530	3,691	$11,461,137	$10,358,235	$1,102,902
Small Group	3,932	1,071	$3,279,458	$2,931,276	$348,182
Total	**21,891**	**5,982**	**$18,687,000**	**$16,168,736**	**$2,518,263**

[30] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[31] The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.
[32] Cost information from the data call is the cost of the drug after price concessions.

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$891	$650	$241	$3,235	$2,360	$875
Large Group	$847	$766	$82	$3,105	$2,806	$299
Small Group	$834	$745	$89	$3,062	$2,737	$325

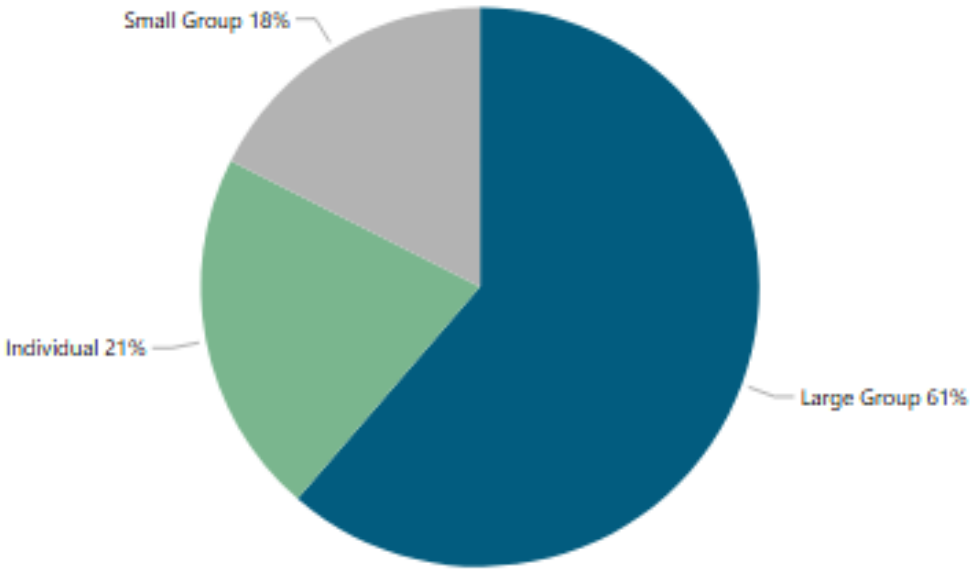


Figure 5 Data call percent of total annual spend (payer paid)

Table 10 indicates CCOs reported Eliquis as having an annual greatest increase from 2022-2023 (rebates not included) with a **$3,953,038 year-over-year increased cost growth**.

Table 10 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
$16,971,070	$20,924,108	$3,953,038	0.32%

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.

Review of rejected claims and drug benefit designs

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

Based on information reported through the carrier data call, the following plan design features were observed for Eliquis. In 2023, approximately **36.5 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.0 percent of plans required step therapy** before approving its use.

For formulary placement, **34.3 percent of plans categorized Eliquis as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 11 Plan design analysis from 2023 data call

Percentage of Plans	
Required Prior Authorization	36.5%
Required Step Therapy	0.0%
On a non-preferred formulary	34.3%
Not covered	0.0%

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

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria calls for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through carrier reporting, manufacturer disclosures, or other sources.
Future reviews may incorporate findings from real-world evidence, health technology assessments, or economic modeling as such data become available.

Estimated average patient copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Eliquis in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 12 and 13 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Medicare enrollees recorded higher average annual OOP costs** . Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

Table 12 Drug vs. therapeutic alternatives and out-of-pocket cost per enrollee[33]

Proprietary name	Medicare OOP Cost/Enrollee	Commercial OOP Cost/Enrollee	Total[34]	Median	IQR
Eliquis	$640	$368	$602	$70	$241
Pradaxa	$83	$64	$91	$20	$15
Savaysa	$626	$734	$647	$94	$272
Xarelto	$630	$385	$591	$90	$263

[33] 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.
[34] The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

Table 13 Drug vs. therapeutic alternatives and out-of-pocket cost per claim

Proprietary name	Medicare OOP Cost/Claim	Commercial OOP Cost/Claim	Total[35]	Median	IQR
Eliquis	$121	$76	$114	$44	$135
Pradaxa	$23	$24	$23	$20	$10
Savaysa	$132	$176	$140	$75	$191
Xarelto	$132	$82	$122	$47	$141

Information from manufacturers

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

Drug indications

- FDA Approved: apixaban (Eliquis) is a factor Xa inhibitor indicated:
  - To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
  - For the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.
- For the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy.
- Off Label Uses:
  - Heparin induced thrombocytopenia
  - Left ventricular thrombus

Clinical efficacy

The efficacy of *apixaban* (Eliquis), an oral factor Xa inhibitor, was demonstrated in six pivotal randomized, double-blind clinical trials across its approved indications, including stroke prevention in nonvalvular atrial fibrillation (NVAF), treatment and prevention of venous thromboembolism (VTE), and prophylaxis of deep vein thrombosis (DVT)following hip or knee replacement surgery.

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

Table 14 Clinical Efficacy Table – Eliquis vs Comparator

Indication (Study)	Comparator	Primary Endpoint	Eliquis Result	Comparator Result	Effect	Bleeding
NVAF (ARISTOTLE)	Warfarin	Stroke or systemic embolism	1.27%/ year	1.60%/ year	HR 0.79; p=0.01 (superior)	Fewer major bleeds
DVT/PE (AMPLIFY)	Enoxaparin/ Warfarin	Recurrent VTE or VTE-related death	2.3%	2.7%	Non-inferior	Fewer major bleeds
Extended VTE Prophylaxis (AMPLIFY-EXT)	Placebo	Recurrent VTE or death	3.8% (2.5 mg), 4.2% (5 mg)	11.6%	7.4% - 7.8% ARR reduction (p<0.001)	Low rates of major bleeding similar to placebo
VTE Prophylaxis post TKA (ADVANCE 1)	Enoxaparin 30 mg twice daily	Composite of DVT, PE, and death	9%	8.8%	Did not meet non-inferiority	Less major bleeding
DVT Prophylaxis post TKA (ADVANCE 2)	Enoxaparin 40 mg daily	Composite of DVT, PE, and death	15%	24%	p<0.001	Similar bleeding rates
DVT Prophylaxis post THA (ADVANCE 3)	Enoxaparin 40 mg daily	Composite of DVT, PE, and death	1.4%	3.9%	2.5% ARR p<0.001	Similar bleeding rates
Abbreviations: ARR: absolute risk reduction; DVT: deep vein thrombosis; HR: hazard ratio; PE: pulmonary embolism: TKA: total knee arthroplasty; THA: total hip arthroplasty; VTE: venous thromboembolism						

Clinical safety

- <u>FDA safety warnings and precautions:</u>
  - May cause serious, potentially fatal, bleeding.
  - Valvular disease: Not recommended with mechanical prosthetic heart valves, severe mitral stenosis, or significant rheumatic heart disease
  - Antiphospholipid syndrome: Not recommended in patients with triple positive antiphospholipid syndrome, may increase risk of thrombosis.
  - Spinal or epidural hematoma
- <u>Contraindications:</u>
  - Active pathological bleeding

- Severe hypersensitivity to Eliquis

- Common side effects:
  - Skin rash or severe allergic reactions
  - Bleeding-related events
  - Nausea

Therapeutic alternatives[36,37,38,39]

Table 15 FDA Approved Indications

Drug	Orthopedic VTE prophylaxis	DVT/PE Treatment	Stroke Prevention in NVAF	VTE Prevention in Acute Medical Illness	CAD and PAD
Xarelto (Rivaroxaban)	YES	YES	YES	YES	YES
Eliquis (apixaban)	YES	YES	YES	____	_____
Pradaxa (dabigatran)	YES	YES	YES	____	_____
Savaysa (edoxaban)	____	YES	YES	____	_____
Terms: CAD = coronary artery disease, DVT = deep vein thrombosis; NVAF: nonvalvular atrial fibrillation, PAD = peripheral artery disease; PE = pulmonary embolism; VTE = venous thromboembolism					

Comparative clinical efficacy

Direct oral anticoagulants (DOACs) have become standard of care and first line treatment for the treatment of stroke prevention in NVAF, and for the treatment and prevention of VTE. They are not recommended in patients with mechanical heart valves, in high-risk antiphospholipid syndrome, and in pregnant or breastfeeding. DOACs should be avoided in severe hepatic

[36] U.S. Food & Drug Administration. *Eliquis (apixaban) Prescribing Information*. Bristol-Myers Squibb Company, Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202155s034lbl.pdf.

[37] U.S. Food & Drug Administration. *Pradaxa (dabigatran etexilate) Prescribing Information*. Boehringer Ingelheim Pharmaceuticals, Inc., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022512s041lbl.pdf.

[38] U.S. Food & Drug Administration. *Savaysa (edoxaban) Prescribing Information*. Daiichi Sankyo, Co., LTD., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206316s017lbl.pdf.

[39] U.S. Food & Drug Administration. *Xarelto (rivaroxaban) Prescribing Information*. Jenssen Pharmaceuticals, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022406Orig1s039,202439Orig1s038correctedlbl.pdf

impairment and used cautiously with dose reduction in severe renal impairment. DOACs have been shown to be non-inferior or superior to warfarin in NVAF and non-inferior to low molecular weight heparin for the prevention and treatment of VTE.

There are no head-to-head randomized controlled trials directly comparing one DOAC to another and insufficient evidence that one is more effective or safer than another. Observational data and network meta-analysis suggests similar effectiveness between DOACs and a possible lower risk of major and gastrointestinal bleeding with apixaban compared to rivaroxaban and dabigatran. Choice of therapy is typically based on dosing, side effects, cost, drug-drug interactions, and indications.

Table 16 Safety and therapeutic considerations

Drug	Safety Considerations	Therapeutic Considerations
***rivaroxaban* (Xarelto)**	• Avoid for VTE if CrCl < 15 ml/min • Avoid with strong inducers and inhibitors of both P-gp and CYP3A4	• Short half-life of 5-9 hour • Administer doses > 10 mg with food • Only DOAC approved for CV Risk reduction in CAD/PAD (with aspirin)
***apixaban* (Eliquis)**	• Lowest risk of major and GI bleeding • Avoid with strong inducers of both P-gp and CYP3A4	• Preferred DOAC in renal impairment • Preferred DOAC if other risk factors for GI bleed present • Requires twice daily dosing
***dabigatran* (Pradaxa)**	• GI symptoms (dyspepsia) and gastritis-like symptoms (10%) • Caution if 75 years or older, poor kidney function, or underweight • Avoid if CrCl < 15 ml/min and < 30 ml/min for VTE	• More renally cleared • Dispense in original package and use within 4 months of opening • Requires twice daily dosing
***edoxaban* (Savaysa)**	• anemia, rash, abnormal liver function tests • Not recommended if CrCl < 15 ml/min • Avoid if CrCl > 95 ml/min	• Not approved for VTE prophylaxis
Abbreviations: CAD: coronary arter disease; CrCl: creatinine clearance; DOAC: direct oral anticoagulants; GI: gastrointestinal; PAD: peripheral artery disese; VTE: venous thromboembolism		

Table 17 17 Dosing and route

Drug	Route	Strength & dose		
		NVAF	**VTE Treatment**	**VTE Prevention**
***rivaroxaban* (Xarelto)**	Oral	20 mg daily	15 mg twice daily x21d then 20 mg daily	10 mg once daily
***apixaban* (Eliquis)**	Oral	5 mg twice daily *	10 mg twice daily ×7 days, then 5 mg twice daily	2.5 mg twice daily
***dabigatran* (Pradaxa)**	Oral	150 mg twice daily	150 mg twice daily after ≥ 5 days of parenteral therapy	220 mg once daily
***edoxaban* (Savaysa)**	Oral	60 mg daily	60 mg daily after ≥ 5 days of parenteral therapy	N/A
* SCr ≥1.5 mg/dL and either ≥80 years of age or body weight ≤60 kg: 2.5 mg twice daily.				

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 81 individuals** either currently taking or associated with the use of Eliquis. According to the survey results, seven respondents indicated that Eliquis was not covered by their insurance. Three respondents were enrolled in Medicaid, 59 were on Medicare, and 20 had private health insurance.

One Medicaid participants reported the drug was covered by their plan but was receiving assistance through a patient assistance program (PAP). Among the Medicare respondents, 50

patients had the drug covered with three being enrolled in a PAP. Of the private insurance participants, 18 had the drug covered, one was on a PAP.

In terms of out-of-pocket (OOP) costs, 21 respondents paid less than $49, six reported paying between $50 and $99, 20 were paying between $100-$199, 19 paid between $200-399, three were paying between $400-599, one was paying between $600-799, two were paying between $800-999, and nine respondents did not indicate if they had OOP cost.

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.

”Eliquis”

- This is a lifesaving drug that I will need for the rest of my life. I fear losing my insurance or them deciding not to cover it, in which case it would cost me around $900 a month. This would bankrupt me.
- I have applied to the Eliquis foundation and was refused due to my financial records as supplied by tax records, which I would agree to explain further.
- In 2024, my co-pay for the first two prescription fills/refills (90-day supply) was $135; by the end of 2024 it had gone up to just over $500, and this past March increased to $551 for same refill.
- High deductible made initial copay $310 for 30-day supply.
- This drug was $40 a month until 2025; now it’s $123 a month.
- The drug out of pocket was too expensive, so my doctor suggested I purchase it from Canada. I did and the price was less than half.
- This drug has helped me stay alive. Price would be prohibitive if not covered. Please do not allow this drug to be charged full price.
- I currently order this medication from Canada, after I paid $600 for the first month here. I can’t afford that amount on an ongoing basis. With the planned tariffs, I’m sure the price will go up.
- This drug is the most expensive one that I take, under my current Medicare Part D plan. I am hopeful that it will decrease in price as the drug becomes generic and Medicare limits on its cost go into effect.
- When my father had his first stroke in 2023 the hospitalist prescribed Eliquis and told us it was the newest and best anticoagulant available and was on the cutting edge. After being hospitalized for three months, we found the cost for Eliquis was too high to continue taking it once discharged and worked with the doctor to find a cheaper but similar medication. They noted that changing off Eliquis to Pradaxa (current medication) would work almost as well and was cheaper. It is frustrating that the cost of the best available medication was too high and we had to switch to something less effective.

- Now obtaining drug from mail-order Canadian pharmacy at far less cost than from Optum Rx domestic pharmacy.

Here is a compilation of consumers stories included in the Drug Price Transparency program's 2023 legislative report, lightly edited for readability and length. The term donut hole refers to a coverage gap in Medicare drug plans created by drug plan limitations.

- For 2024, my current Plan D with Cigna increased the annual deduction from $100 to $145, increased monthly premium from $54.70 to $65.20, and changed my Eliquis charge from a $47 monthly co-pay to 20 percent of total monthly cost. The current 3-month cost is $1,797. It is like being in the donut hole all year.
- Being new to Medicare this last year has been a real eye opener! Previously, while working and having commercial insurance, for the most expensive meds (i.e., Humira) you can use the company's $5 coupon, but not so on Medicare. Even with Part D, it is an astronomical cost. Same with Eliquis and many other drugs. We continue to let drug companies dictate and the government joins right in with them.
- My husband is on Medicare and a private insurance plan and he pays out of pocket $460 every 3 months for Jardiance and $400 for Eliquis. These are required to keep him alive per our primary doctor and not due to the ridiculous advertising we're subjected to non-stop while watching TV. We are both on a fixed income and cannot afford this. One step we should take as a nation is to ban prescription advertising to the public as is done in most countries except for the US and New Zealand. Only doctors should be made aware of their fabulous drugs. These ads must be very costly as they air in prime time and include an elaborate cast of actors with dancing and singing. Tell the drug companies to pass the cash savings on to those who really need these drugs. The Jardiance "little pill with the big story to tell" is particularly heinous given its cost to us.

Individuals with scientific or medical training

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

Safety net providers

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

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

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

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

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

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

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

Table 18 Safety net provider survey responses

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

Survey information	Response
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 19 Amounts paid for drug under 340B discount program

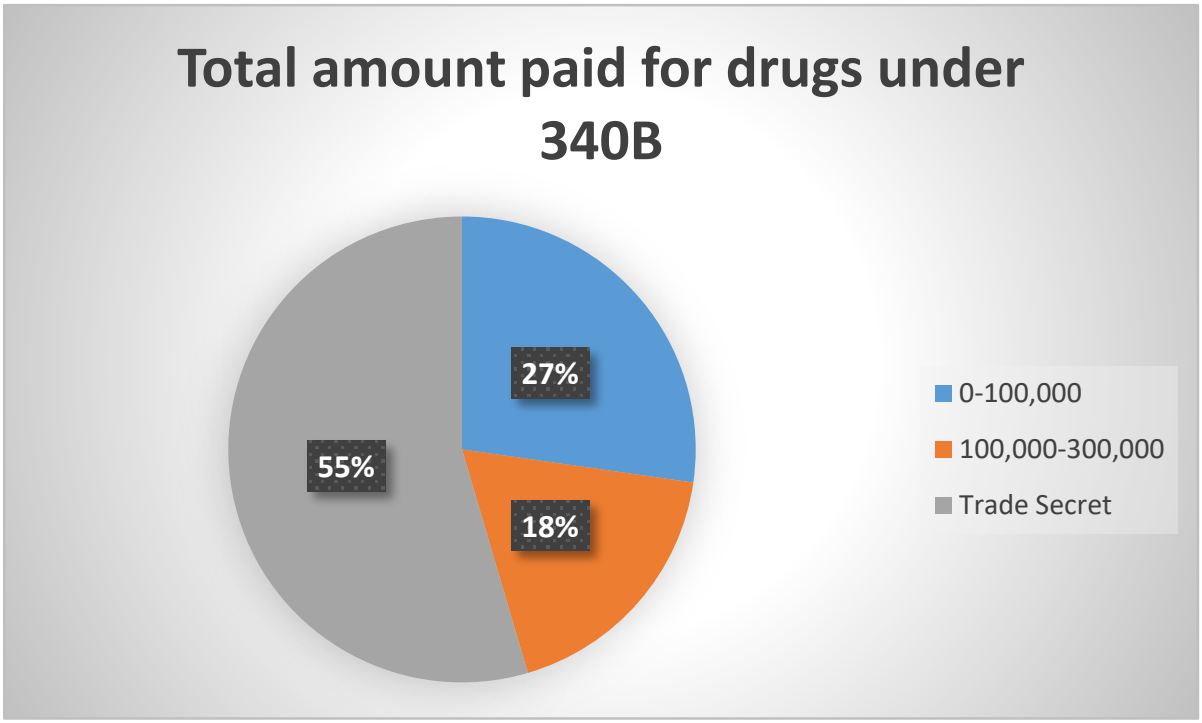
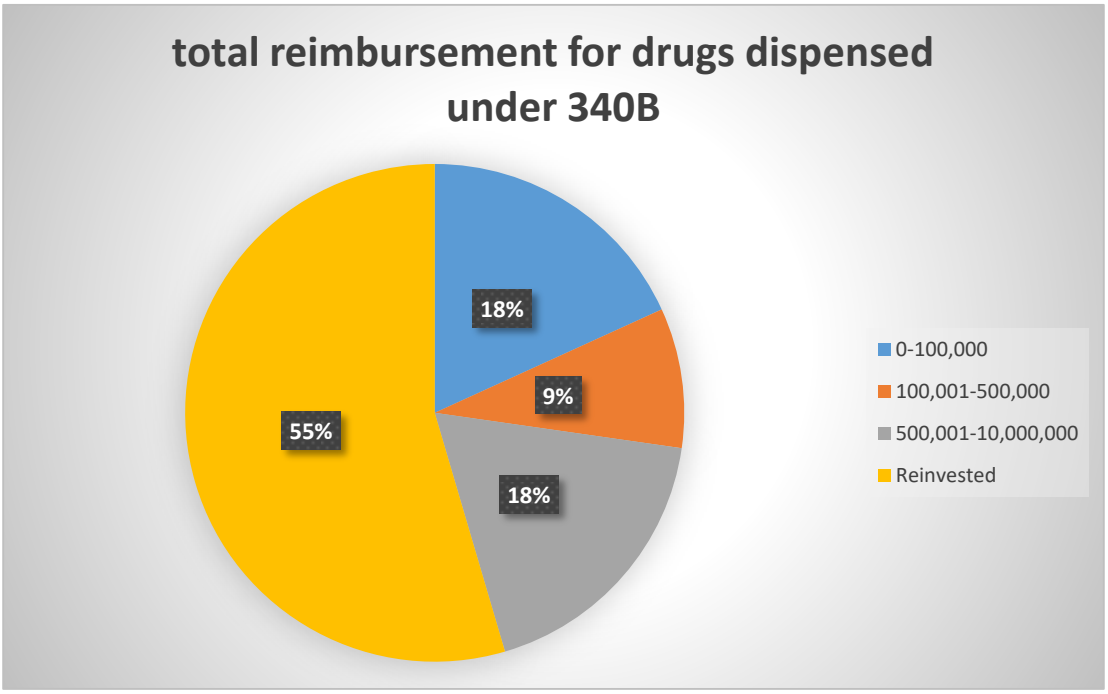


Table 20 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B programs



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
Anne Murray	Bristol Myers Squibb	Eliquis	Letter	5/21/2025	**Exhibit A**
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Eliquis	Letter	5/21/2025	**Exhibit B**
Anne Murray	Bristol Myers Squibb	Eliquis	Letter and speaker	7/13/2025	**Exhibit C** **Exhibit D**
Sue Koob	Preventive Cardiovascular Nurses Association	Eliquis	Letter	7/14/2024	**Exhibit E**

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

Xarelto®
(*rivaroxaban*)[1]

Version 1.0

[1] Image source: https://borderfreehealth.com/shop/xarelto/

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Review summary

Therapeutic alternatives

Xarelto (*rivaroxaban*) has the following therapeutic alternatives: Eliquis, Pradaxa, and Savaysa.

Proprietary name	Non-proprietary name	Manufacturer (year approved)	Year approved
Xarelto	*rivaroxaban*	Jenssen Pharmaceuticals, Inc.	2011
Eliquis	*apixaban*	Bristol-Myers Squibb Company	2012
Pradaxa	*dabigatran etexilate*	Boehringer Ingelheim Pharmaceuticals, Inc.	2010
Savaysa	*edoxaban*	Daiichi Sankyo, Co., LTD.	2015

Price history[2,3]

Xarelto rose at an **average annual rate of 4.5 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
    - Eliquis: 6.0 percent
    - Pradaxa: -9.6 percent
    - Savaysa: 3.1 percent

Additionally, the average annual rate of Xarelto exceeded inflation **in 2019, 2020, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 15.4 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions [4]

Based on data received from healthcare carriers, Xarelto in 2023 had the **gross spend of $917 per claim**, while the **spend net of discount was $649 per claim**. Price concessions per claim were reported to be $269.

[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] 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 the payer[5]

2023, APAC payer total expenditure, utilization, and cost per enrollee

Drug	Total Expenditure	Utilization	Cost per Enrollee	Cost per Enrollee, median
Xarelto	$76,917,196	97,813	$4,141	$1,005
Eliquis	$222,494,185	284,854	$4,312	$624
Pradaxa	$4,620,535	21,487	$840	$277
Savaysa	$88,003	140	$2,839	$761

Cost to enrollees[6]

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Xarelto	$570	$75	$117	$45
Eliquis	$596	$74	$116	$44
Pradaxa	$91	$20	$23	$20
Savaysa	$647	$94	$140	$75

[5] Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[6] 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. The 2023 drug affordability review selection included the following criteria: orphan-designated drugs were removed; drugs were reviewed based on payer-paid cost data from the data call submissions; and drugs reported to the APAC program across Medicare, Medicaid, and commercial lines of business were included. To ensure broader public impact, drugs with fewer than 1,000 enrollees reported in APAC reports were excluded from consideration.

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

Drug information[7]

Drug proprietary name	Xarelto®
Non-proprietary name (active ingredient)	*rivaroxaban*
Manufacturer	Janssen Pharmaceuticals, Inc.
Treatment: Xarelto is a factor Xa inhibitor indicated:	
	• to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation • for treatment of deep vein thrombosis (DVT) • for treatment of pulmonary embolism (PE) • for reduction in the risk of recurrence of DVT or PE • for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery • for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients • to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD) • to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD • for treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years • for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure.
Dosage	• Nonvalvular Atrial Fibrillation: 15 or 20 mg once daily • Treatment of DVT and/or PE: 15 mg orally twice daily for the first 21 days followed by 20 mg orally once daily • Reduction in the Risk of Recurrence of DVT and/or PE in patients at continued risk for DVT and/or PE: 10 mg once daily • Prophylaxis of DVT Following Hip or Knee Replacement Surgery: 10 mg once daily • Prophylaxis of VTE in Acutely Ill Medical Patients at Risk for Thromboembolic Complications Not at High Risk of Bleeding: 10 mg once daily for a total recommended duration of 31 to 39 days • CAD or PAD: 2.5 mg twice daily in combination with aspirin (75-100 mg) once daily
Strength	Tablet: 2.5mg; 10mg; 15mg; 20mg
Route	Oral

[7] U.S. Food & Drug Administration. *Xarelto (rivaroxaban)* Prescribing Information. Janssen Pharms, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022406s041lbl.pdf.

FDA approval

Xarelto was first approved by the FDA on July 1, 2011, for prophylaxis of DVT and PE in patients undergoing hip and knee replacement surgery.[8]

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

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.

Disparities exist in the prescribing and utilization of direct oral anticoagulants (DOACs), including Eliquis (*apixaban*) and Xarelto (*rivaroxaban*), among racial and ethnic minority patients, individuals with limited socioeconomic means, and residents of areas with constrained access to care. Black patients, along with Hispanic and Americans Indian/Alaska Native groups, remain consistently less likely than white patients to receive DOAC therapy despite comparable clinical indications for stroke prevention in atrial fibrillation (AF) or treatment of venous thromboembolism.[9] Underrepresentation of these populations in major clinical trials limits generalizability and reinforces gaps in treatment equity, cost, and access.[10]

Provider bias, insurance formulary barriers, and structural social determinants contribute to these inequities. For instance, apixaban prescriptions are more frequently rejected for Medicaid-insured and Black patients than for others, potentially delaying access to care.[11] Geographic and socioeconomic disparities further influence prescribing patterns; a large Medicare cohort demonstrated that counties with higher proportions of Black residents have markedly higher untreated AF rates, frequently exceeding 50 percent, with reginal patterns particularly pronounced in the Southeast.[12]

According to the Journal of American College of Cardiology (JACC), most significant AF studies disproportionately involved white participants, leaving Black, Hispanic, Asian, and Indigenous

[8] 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.
[9] Reynolds KR, Khosrow-Khavar F, Dave CV. Racial and Ethnic Disparities in Initiation of Direct Oral Anticoagulants Among Medicare Beneficiaries. *JAMA Netw Open.* 2024;7(5):e249465. doi:10.1001/jamanetworkopen.2024.9465.
[10] Norby, F. L., Benjamin, E. J., Alonso, A., & Chugh, S. S. (2021). Racial and Ethnic Considerations in Patients With Atrial Fibrillation: JACC Focus Seminar 5/9. Journal of the American College of Cardiology, *78*(25), 2563–2572. https://doi.org/10.1016/j.jacc.2021.04.110.
[11] Deitelzweig, S., Xie, L., Terasawa, E., Hood, D. W., Cato, M., Atreja, N., Kang, A., & Hines, D. M. (2023). Journey to anticoagulant access following payer rejection of apixaban. The American Journal of Managed Care, *29*(11), e330–e338. https://doi.org/10.37765/ajmc.2023.89459.
[12] Atwater, B.D., Singh, R., Parmar, S. *et al.* Geographic and Racial Variation in Oral Anticoagulant (OAC) Treatment Among Commercially Insured Patients with Non-valvular Atrial Fibrillation (NVAF) in the United States. American Journal of Cardiovascular Drugs (2025). https://doi.org/10.1007/s40256-025-00728-x.

groups underrepresented.[13] The authors emphasize that advancing equitable care requires integrating social determinants of health into AF risk prediction, prevention, and treatment strategies, including anticoagulation therapy.

The JACC review also highlights that racial and ethnic minority status is sometimes associated with adverse AF outcomes, such as higher stroke incidence, but that access to anticoagulant therapy may reduce these risks. Studies support the importance of equitable DOAC access (Eliquis and Xarelto) to mitigate stroke disparities, particularly among Black patients whose adjusted stroke risk may remain elevated without anticoagulants.

No definitive studies show differential efficacy or safety of Eliquis compared to Xarelto across ethnic groups. The primary inequity lies in access and utilization. Economically and socially marginalized patients are more likely to be managed with older therapies (e.g., warfarin) even when guidelines indicate that DOAC therapies could yield better outcomes.

Residents prescribed

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

Based on APAC claims, **97,813** Oregonians filled a prescription for Xarelto in 2023.[14]

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

Price history

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

[13] Norby, F. L., Benjamin, E. J., Alonso, A., & Chugh, S. S. (2021). Racial and Ethnic Considerations in Patients With Atrial Fibrillation: JACC Focus Seminar 5/9. *Journal of the American College of Cardiology*, *78*(25), 2563–2572. https://doi.org/10.1016/j.jacc.2021.04.110.

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

Table 1 Drug vs therapeutic alternatives and 2018-2024 WAC summary per 30-day supply

	Xarelto	Eliquis	Pradaxa	Savaysa
2018	$389	$419	$401	$337
2019	$418	$444	$433	$364
2020	$439	$471	$459	$389
2021	$437	$499	$477	$389
2022	$458	$529	$496	$389
2023	$481	$561	$198	$397
2024	$505	$594	$159	$404
Avg. Annual % Change	4.5%	6.0%	-9.6%	3.1%
% change 2018 between 2024	29.8%	41.9%	-60.3%	20.0%

The WAC of Xarelto, averaged across 16 NDCs reported, was approximately **$16.84 per unit** at the end of 2024.[15] Between 2018-2024, the unit WAC increased at an average annual rate of **4.5 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019, 2019-2020, 2022-2023, and 2023-2024 (see Figures 1 and 2).[16]

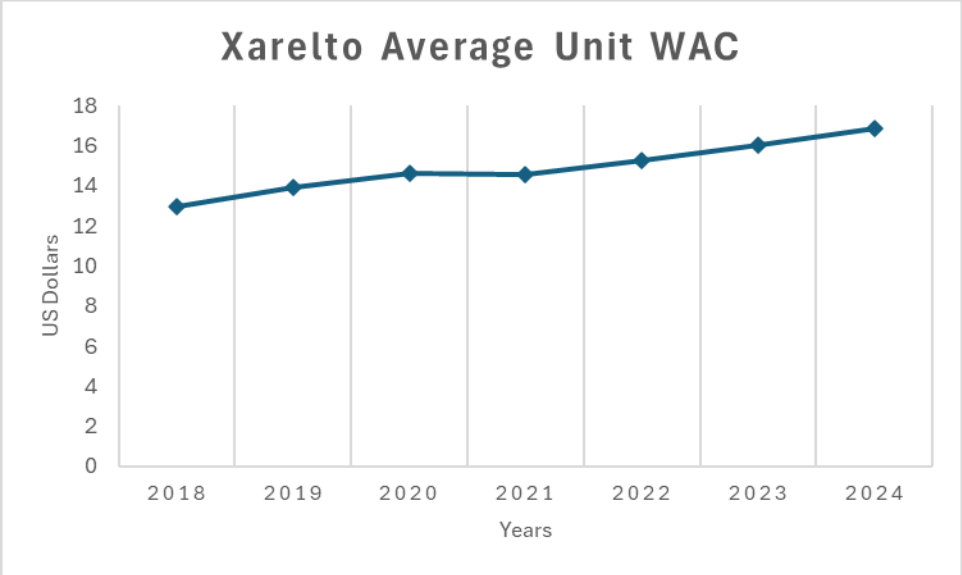

Figure 1 Xarelto average unit WAC from 2018-2024

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

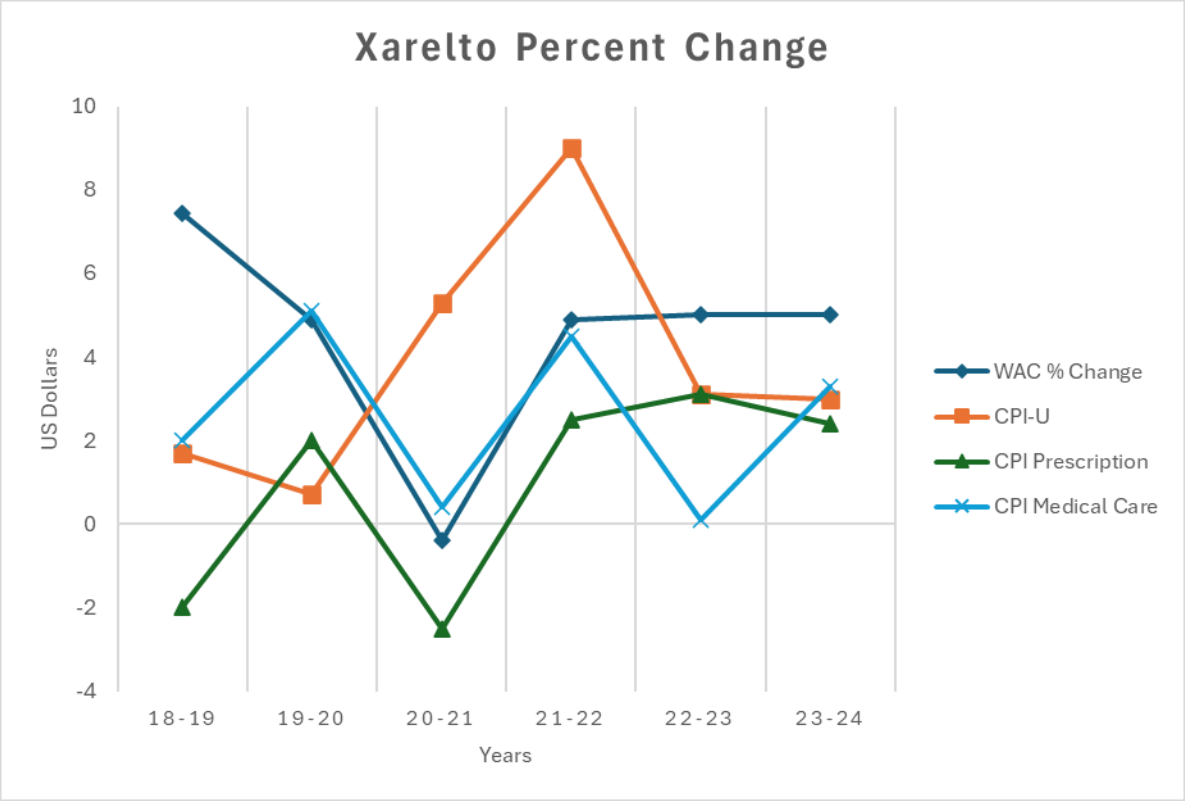

Figure 2 Year over year change in WAC compared to inflation rates[17]

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$14.16 per unit in Quarter 1 of 2020 to $16.39 per unit in Quarter 4 of 2024**, an approximate **15.4 percent increase** over the period (see Figure 3).[18] Relative to the **$16.84** WAC in end-of-year 2024 a **AAAC discount of 2.7 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 Xarelto's price trajectory relative to inflation and affordability for public and private payers.

[17] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[18] This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2024, available at https://myersandstauffer.com/client-portal/oregon/.

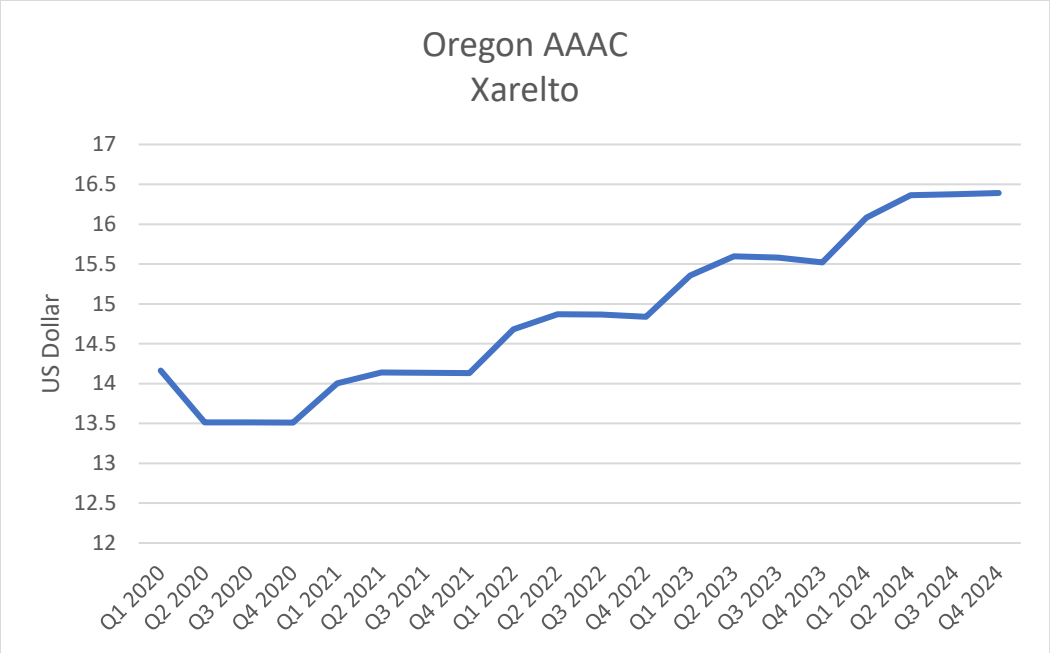

Figure 3 AAAC for Xarelto from Q1 2020 to Q4 2024

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 Xarelto 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 Xarelto per enrollee in the commercial market was approximately $2,764**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $1,955**, reflecting an **estimated mean discount of 29.3 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Xarelto before concessions was $8,275,127**, with total reported **price concessions amounting to approximately $2,423,131**, as detailed in Table 2. Notably, **78.1 percent of claims benefited from some form of price concession,** leaving **21.9 percent at full gross cost**.

Table 2 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	2,994
Total number of claims	9,021
Total number of claims with price concessions applied	7,041
Percentage of claims with price concessions applied	78.1%
Percentage of cost remaining after concessions	70.7%
Manufacturer price concessions for all market types	$1,949,542
PBM price concessions for all market types	$471,494
Other price reductions for all market types	$2,095
Cost before price concessions across all market types	$8,275,127
Total price concessions across all market types	$2,423,131
Cost of after price concessions across all market types	$5,851,996
Avg. payer spend per enrollee without price concessions	$2,764
Avg. payer spend per enrollee with price concessions	$1,955

Including all market segments, the **gross spend of Xarelto per claim for commercial carriers was $917** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$649**, meaning that insurers reported a price concession of **$269** per claim on the initial drug cost as shown in Table 3.

Table 3 The average price concessions across market types

	Average	Individual market	Large market	Small market
Spend per Claim, gross	$917	$968	$881	$1,010
Spend per Claim, net	$649	$686	$623	$714
Price Concession per Claim	$269	$282	$258	$297

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

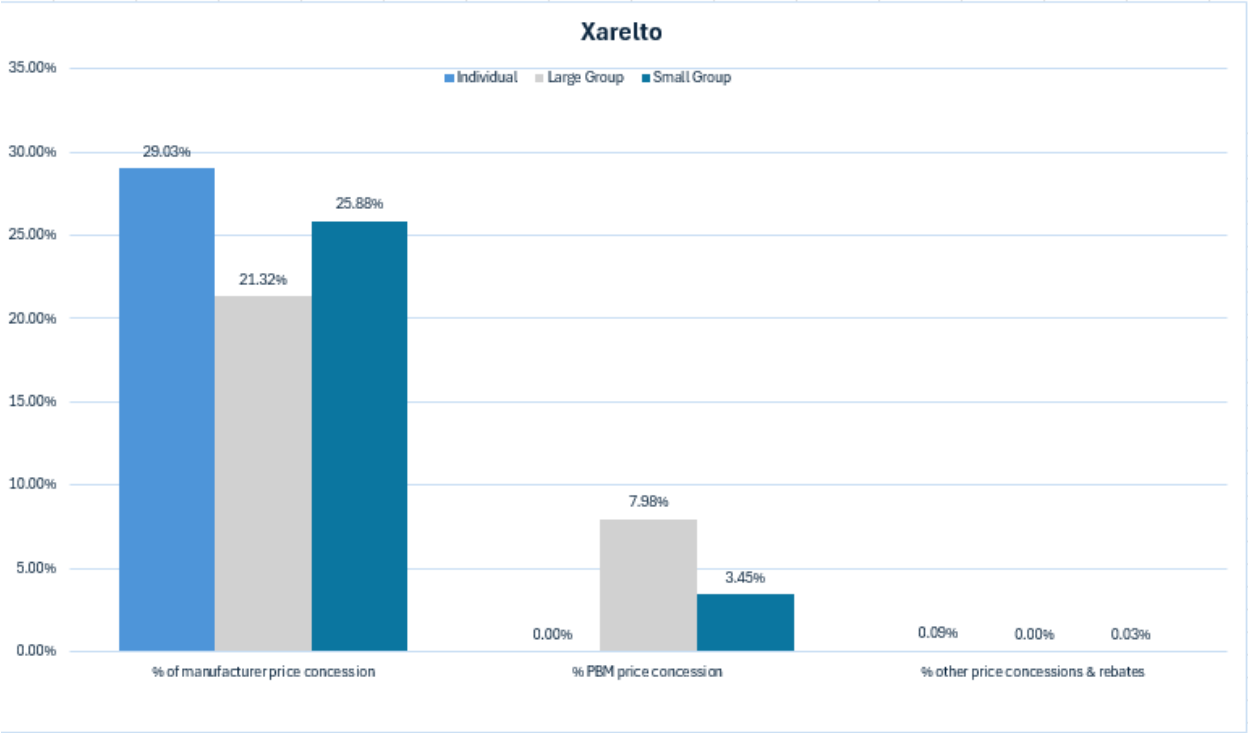

Figure 4 Percent of price concession in each market type[19, 20]

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

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

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[21]

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 Xarelto 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 submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concession or rebates.

Xarelto's gross total payer paid, based on APAC data, was $76.9 million, while net total payer paid, based on carrier reporting, was $7.8 million. **Eliquis has the highest gross total pay in consideration with Xarelto and its therapeutic alternatives**. The second highest is Xarelto, with $76.9 million. **Notably, Eliquis has the most utilization amongst the drugs, at 284,854 claims**, as compared to the second highest utilization of Xarelto, at 97,831 claims**. Xarelto also has a lower payer paid per claim as compared to Eliquis, $781 and $791 respectively**.

Eliquis also has the highest total enrollee paid at $28.4 million and Xarelto follows behind with $9.6 million. Savaysa has the highest patient paid per claim of $140, which is higher than both Xarelto at $117 and Eliquis at $116. The drug with the lowest patient paid per claim is Pradaxa, which is $23.

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

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

Table 4 Average healthcare and average patient OoP costs for Xarelto vs therapeutic alternatives

Drug	No. of enrollees[22]	No. of claims	Total payer paid	Total enrollees paid[23]	Payer paid/ claim	Patient paid/ claim[24]
Subject Drug **Xarelto (data call)**	**2,994**	**9,021**	**$7,805,072**	**$932,172**	**$787**	**$103**
Subject Drug **Xarelto (APAC)**	**18,565**	**97,813**	**$76,885,552**	**$9,619,157**	**$781**	**$117**
Eliquis	51,600	284,854	$222,494,185	$28,396,627	$791	$116
Pradaxa	5,501	21,487	$4,620,535	$478,268	$215	$23
Savaysa	31	140	$88,003	$19,417	$629	$140

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 Xarelto, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

[22] 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.
[23] The cost includes all lines of business.
[24] Ibid.

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 Xarelto 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 **97,813 total claims for Xarelto among 18,565 total enrollees**, corresponding to a **total payer expenditure of $76,885,552**.

Table 5 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Medicare** accounted for the largest share of utilization, with 65,167 claims from 13,508 enrollees and a total spend of **$56.8 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **$11.9 million** and **$8.1 million**, respectively.

Table 5 Estimated 2023 APAC total gross costs to the payers [25]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	3,712	16,810	$11,917,196	$3,210	$709
Medicaid	2,460	15,836	$8,131,530	$3,306	$513
Medicare	13,508	65,167	$56,836,825	$4,208	$872
Totals	**18,565**	**97,813**	**$76,885,552**		

Table 6 provides utilization for the healthcare system for Xarelto and its therapeutic alternatives, distinguished by lines of business. **Eliquis has the most utilization** among the drugs, with **284,854 claims**. In all lines of business, Eliquis is the most utilized. **Xarelto is the second most utilized at 97,813 claims**.

[25] 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 6 Estimated 2023 APAC payer utilization of drug and its therapeutic alternatives[26]

	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total[27]
Xarelto	16,810	15,836	65,167	97,813
Eliquis	41,612	39,255	203,987	284,854
Pradaxa	5,971	962	14,554	21,487
Savaysa	25	1	114	140

Table 7 shows the overall payer expenditure of Xarelto and its therapeutic alternatives, distinguished by lines of business. Xarelto has a **total expenditure of $76.9 million** with **Medicare being the biggest portion at $56.8 million**. The therapeutic alternative with the **least expenditure is Savaysa, at $88,003**.

Table 7 Estimated 2023 APAC payer expenditure of drug and its therapeutic alternatives[28]

	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total
Xarelto	$11,917,196	$8,131,530	$56,836,825	$76,885,551
Eliquis	$27,794,424	$20,708,944	$173,990,817	$222,494,185
Pradaxa	$1,176,190	$210,748	$3,233,597	$4,620,535
Savaysa	$17,033	$176	$70,794	$88,003

Table 8 compares the overall payer cost per enrollee of Xarelto and its therapeutic alternatives, distinguished by lines of business. **Xarelto has the second highest total cost per enrollee at $4,141** and the highest cost per enrollee for Medicaid lines of business with $3,306. The Medicare cost per enrollee for Xarelto is the second highest to Eliquis. **The median cost per enrollee for Xarelto is $804**, which is the highest amongst the therapeutic alternatives.

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

Table 8 Estimated 2023 APAC payer cost per enrollee of drug and its therapeutic alternatives[29]

	Commercial Cost/Enrollee	Medicaid Cost/Enrollee	Medicare Cost/Enrollee	Total	Median	IQR
Xarelto	$3,210	$3,306	$4,208	$4,141	$804	$1,005
Eliquis	$3,240	$3,152	$4,373	$4,312	$624	$1,011
Pradaxa	$519	$747	$808	$840	$277	$202
Savaysa	$2,839	$176	$2,950	$2,839	$761	$667

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 individual and small group markets. The collected **total net cost to the healthcare system was around $8 million**, with payer paying $7.1 million, and enrollees out-of-pocket estimating to be $900,000. Table 9 includes the average plan costs per enrollee in the commercial market ranged from **$2,455 (small group)** to **$2,257 (individual)** annually.

Table 9 Estimated 2023 data call total net costs to the healthcare system, payers and OOP/enrollee[30]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	533	1,220	$1,530,870	$1,202,921	$327,948
Large Group	1,973	3,691	$5,164,641	$4,702,132	$462,509
Small Group	488	1,071	$1,339,957	$1,198,243	$141,714
Total	**2,994**	**9,021**	**$8,035,468**	**$7,103,296**	**$932,172**

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	$966	$759	$207	$2,872	$2,257	$615

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

Market	Avg. plan spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plan spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Large Group	$863	$786	$77	$2,618	$2,383	$234
Small Group	$922	$824	$97	$2,746	$2,455	$290

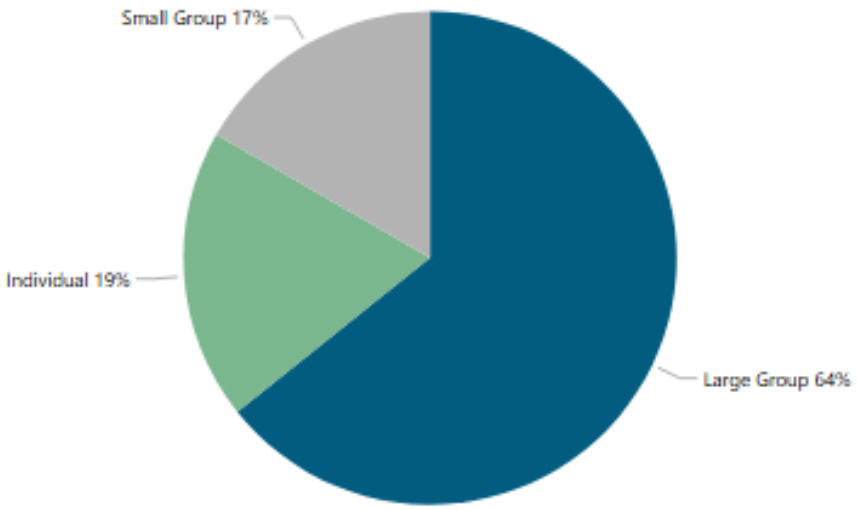

Figure 5 Data call total annual spend (payer paid)

Impact on patient access to the drug

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

Review of rejected claims and drug benefit designs

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Xarelto, including prior authorization requirements, step therapy

protocols, and formulary placement. The data describes how the drug is positioned within insurance benefit designs and the extent to which utilization management processes were applied during the reporting period.

Based on information reported through the carrier data call, the following plan design features were observed for Xarelto. In 2023, approximately **35.5 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.0 percent of plans required step therapy** before approving its use.

For formulary placement, **0.0 percent of plans categorized Xarelto as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 10 Plan design analysis from 2023 data call

Percentage of Planes	
Required Prior Authorization	35.5%
Required Step Therapy	0.0%
On a non-preferred formulary	0.0%
Not covered	0.0%

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

Relative financial impacts to health, medical or social services costs

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

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

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

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

Estimated average patient copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Xarelto in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 11 and 12 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **Medicare insured enrollees recorded higher average annual OOP costs**. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

Table 11 Drug vs. therapeutic alternatives and out-of-pocket cost per enrollee

	Medicare OOP Cost/Enrollee	Commercial OOP Cost/Enrollee	Total[31]	Median	IQR
Xarelto	$612	$365	$570	$75	$252
Eliquis	$633	$375	$596	$74	$244
Pradaxa	$83	$64	$91	$20	$15
Savaysa	$626	$734	$647	$94	$272

Table 12 Drug vs. therapeutic alternatives and out-of-pocket cost per claim

	Medicare OOP Cost/Claim	Commercial OOP Cost/Claim	Total[32]	Median	IQR
Xarelto	$127	$81	$117	$45	$136
Eliquis	$123	$77	$116	$44	$137
Pradaxa	$23	$24	$23	$20	$10
Savaysa	$132	$176	$140	$75	$191

[31] The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.
[32] Ibid.

Information from manufacturers

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

Drug indications

- FDA Approved:

  Xarelto is a factor Xa inhibitor indicated:
  - to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation
  - for treatment of deep vein thrombosis (DVT)
  - for treatment of pulmonary embolism (PE)
  - for reduction in the risk of recurrence of DVT or PE
  - for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery
  - for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients
  - to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD)
  - to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD
  - for treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years
  - for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure.
- Off Label Uses:
  - Atrial fibrillation with native valve disease
  - Acute coronary syndrome
  - Heparin-induced thrombocytopenia
  - Thrombosis of superficial vein of lower limb

Clinical efficacy

The clinical efficacy of *rivaroxaban* (Xarelto) has been established through multiple large-scale randomized trials across a range of thromboembolic conditions. The studies evaluated *rivaroxaban* in the prevention of stroke and systemic embolism in nonvalvular atrial fibrillation, treatment prevention of venous thromboembolism and prophylaxis of VTE following orthopedic surgery. R*ivaroxaban* demonstrated non-inferiority or superiority to standard therapies such as warfarin and enoxaparin, offering a fixed dose oral anticoagulant option without the need for routine coagulation monitoring. More recently, low dose rivaroxaban (2.5 mg twice daily) was approved to reduce the risk of major cardiovascular events in patients with CAD and PAD when used in combination with aspirin.

Table 13 Summary table: Rivaroxaban (Xarelto) clinical efficacy trials

Trial	Indication	Comparator	Outcome	Result	Bleeding
ROCKET AF	NVAF	Warfarin	Stroke and systemic embolism	Non-inferior	No difference in major bleeding, fewer ICH
EINSTEIN-DVT/PE	Acute DVT and PE	Enoxaparin/ Warfarin	Recurrent VTE	Non-inferior	Fewer major bleeding events
EINSTEIN-Extension	Extended VTE Prophylaxis	Placebo	Recurrent VTE	Superior	No difference
MAGELLAN	VTE Prophylaxis (Acutely Ill)	Enoxaparin	VTE	Non-inferior	More bleeding events
RECORD 1–4	Post-Op VTE Prophylaxis after TKA and THA	Enoxaparin	VTE	Non-inferior or Superior	No difference
COMPASS*	CAD	Aspirin	Major CV events	Superior	More major bleeding
VOYAGER*	PAD	Aspirin	CV and limb events	Superior	No difference
***rivaroxaban 2.5 mg twice daily in combination with aspirin studied**					
Abbreviations: CV: cardiovascular; DVT: deep vein thrombosis; ICH: intracranial hemorrhage; NVAF: nonvalvular atrial fibrillation, PE: pulmonary embolism; VTE: venous thromboembolism; THA: total hip arthroplasty; TKA: total knee arthroplasty					

Clinical safety

- FDA safety warnings and precautions:
  - Risk of bleeding
  - Pregnancy-related hemorrhage
  - Prosthetic heart valves: Rivaroxaban use not recommended.

- Increased Risk of Thrombosis in Patients with Triple Positive Antiphospholipid Syndrome: Rivaroxaban use not recommended.
- Spinal/epidural anesthesia or puncture
- Use with P-gp and strong CYP3A4 inhibitors or inducers
- Severe renal or liver impairment

- Contraindications:
  - Active pathological bleeding
  - Severe hypersensitivity reaction to Rivaroxaban

- Common side effects:
  - The most common adverse reaction (>5%) in adult patients was bleeding.
  - The most common adverse reactions (>10%) in pediatric patients were bleeding, cough, vomiting, and gastroenteritis.

Therapeutic alternatives[33,34,35,36]

Table 14 FDA approved indications

Drug	Orthopedic VTE prophylaxis	DVT/PE Treatment	Stroke Prevention in NVAF	VTE Prevention in Acute Medical Illness	CAD and PAD
Xarelto (Rivaroxaban)	YES	YES	YES	YES	YES
Eliquis (apixaban)	YES	YES	YES	____	_____
Pradaxa (dabigatran)	YES	YES	YES	____	_____
Savaysa (edoxaban)	____	YES	YES	____	_____

[33] U.S. Food & Drug Administration. *Xarelto (rivaroxaban) Prescribing Information*. Jenssen Pharmaceuticals, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022406Orig1s039,202439Orig1s038correctedlbl.pdf

[34] U.S. Food & Drug Administration. *Eliquis (apixaban) Prescribing Information*. Bristol-Myers Squibb Company, Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202155s034lbl.pdf.

[35] U.S. Food & Drug Administration. *Pradaxa (dabigatran etexilate) Prescribing Information*. Boehringer Ingelheim Pharmaceuticals, Inc., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022512s041lbl.pdf.

[36] U.S. Food & Drug Administration. *Savaysa (edoxaban) Prescribing Information*. Daiichi Sankyo, Co., LTD., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206316s017lbl.pdf.

Drug	Orthopedic VTE prophylaxis	DVT/PE Treatment	Stroke Prevention in NVAF	VTE Prevention in Acute Medical Illness	CAD and PAD
Terms: CAD = coronary artery disease, DVT = deep vein thrombosis; NVAF: nonvalvular atrial fibrillation, PAD = peripheral artery disease; PE = pulmonary embolism; VTE = venous thromboembolism					

Comparative clinical efficacy

Direct oral anticoagulants (DOACs) have become standard of care and first line treatment for the treatment of stroke prevention in NVAF, and for the treatment and prevention of VTE. They are not recommended in patients with mechanical heart valves, in high-risk antiphospholipid syndrome, and in pregnant or breastfeeding. DOACs should be avoided in severe hepatic impairment and used cautiously with dose reduction in severe renal impairment. DOACs have been shown to be non-inferior to warfarin in NVAF and non-inferior to low molecular weight heparin for the prevention and treatment of VTE.

There are no head-to-head randomized controlled trials directly comparing one DOAC to another and insufficient evidence that one is more effective or safer than another. Observational data and network meta-analysis suggest similar effectiveness between DOACs and a possible lower risk of major and gastrointestinal bleeding with apixaban compared to rivaroxaban and dabigatran. Choice of therapy is typically based on dosing, side effects, cost, drug-drug interactions, and indications.

Table 15 DOAC dosing

Drug	Route	Strength & dose		
		NVAF	**VTE Treatment**	**VTE Prevention**
***rivaroxaban* (Xarelto)**	Oral	20 mg daily	15 mg twice daily x21d then 20 mg daily	10 mg once daily
***apixaban* (Eliquis)**	Oral	5 mg twice daily *	10 mg twice daily ×7 days, then 5 mg twice daily	2.5 mg twice daily
***dabigatran* (Pradaxa)**	Oral	150 mg twice daily	150 mg twice daily after ≥ 5 days of parenteral therapy	220 mg once daily

Drug	Route	Strength & dose		
***edoxaban* (Savaysa)**	Oral	60 mg daily	60 mg daily after ≥ 5 days of parenteral therapy	N/A
* SCr ≥1.5 mg/dL and either ≥80 years of age or body weight ≤60 kg: 2.5 mg twice daily.				

Table 16 Efficacy (Clinical trials & practice)

Drug	Efficacy Summary
***rivaroxaban* (Xarelto)**	Rocket AF (NVAF): *rivaroxaban* was non-inferior to warfarin in preventing stroke and systemic embolism in patients with nonvalvular atrial fibrillations (NVAF) and elevated stroke risk. Einstein-DVT and Einstein-PE (VTE treatment): *rivaroxaban* was non-inferior to enoxaparin/warfarin for the treatment of DVT and PE, and prevention of recurrent VTE.
***apixaban* (Eliquis)**	Two evaluations, the Aristotle and Averroes studies, demonstrated *apixaban* significantly reduced the rate of stroke, death, and bleeding compared to warfarin (Aristotle) and Aspirin (Averroes), indicating *apixaban* is a superior anticoagulant for patients with atrial fibrillation.
***dabigatran* (Pradaxa)**	The RE-LY (Randomized Evaluation of Long-term Anticoagulant Therapy) showed lower stroke risk vs warfarin. The RE-COVER and RE-COVER II trials showed to be non-inferior to warfarin.
***edoxaban* (Savaysa)**	Engage AF-TIMI 48 (AF): non-inferior to warfarin for stroke and systemic embolism. Hokusai-VTE study showed *edoxaban* non-inferior to warfarin and reduced bleeding with 30 mg does

Table 17 Safety and Therapeutic Considerations of DOACs

Drug	Safety Considerations	Therapeutic Considerations
***rivaroxaban* (Xarelto)**	• Avoid for VTE if CrCl < 15 ml/min • Avoid with strong inducers and inhibitors of both P-gp and CYP3A4	• Short half-life of 5-9 hours • Administer doses > 10 mg with food • Only DOAC approved for CV Risk reduction in CAD/PAD (with aspirin)
***apixaban* (Eliquis)**	• Lowest risk of major and GI bleeding	• Preferred DOAC in renal impairment

Drug	Safety Considerations	Therapeutic Considerations
	• Avoid with strong inducers of both P-gp and CYP3A4	• Preferred DOAC if other risk factors for GI bleed present • Requires twice daily dosing
***dabigatran* (Pradaxa)**	• GI symptoms (dyspepsia) and gastritis-like symptoms (10%) • Caution if 75 years or older, poor kidney function, or underweight • Avoid if CrCl < 15 ml/min and < 30 ml/min for VTE	• More renally cleared • Dispense in original package and use within 4 months of opening • Requires twice daily dosing
***edoxaban* (Savaysa)**	• anemia, rash, abnormal liver function tests • Not recommended if CrCl < 15 ml/min • Avoid if CrCl > 95 ml/min	• Not approved for VTE prophylaxis
Abbreviations: CAD: coronary arter disease; CrCl: creatinine clearance; DOAC: direct oral anticoagulants; GI: gastrointestinal; PAD: peripheral artery disese; VTE: venous thromboembolism		

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 collected from 18 individuals taking or having an association with Xarelto. Two patients had the drug covered under Medicaid with none being on a patient assistance program. The patient out of pocket cost ranged from $0-49. Medicare covered 14 patients, with two having cost coverage from PAPs. Six responses indicated paying monthly out of pocket costs over $100. Two patients with private health insurance had coverage with no PAP.

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

"Xarelto"

- There is a $1,000 deductible on the plan, so the first couple of months it's more expensive.
- Without this medication I would probably be dead.
- This is a very expensive drug and before the year is up, I use Medicare benefits and the price more than doubles.
- This medication has been on the market for many years, but the cost is still very high and there is no generic form available.
- The U.S. is one of the only countries to not have a generic version of Xarelto.
- I am on Xarelto for life and the price keeps going up.

Individuals with scientific or medical training

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

Safety net providers

The information reported by safety net providers describes their experience dispensing Xarelto, 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 Xarelto was covered as a 340B-eligible prescription** within their programs. Most clinics (91%) reported operating an internal pharmacy for dispensing 340B-eligible medications, and 64 percent reported using one or more contract pharmacies for this purpose.

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

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

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

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

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

Table 18 Safety net provider survey responses

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

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
Sarah Hoffman	Partnership to Advance Cardiovascular Health	Xarelto	Letter	5/21/25	**Exhibit A**
Silas Martin	Johnson and Johnson	Xarelto	Speaker	5/21/25	**Exhibit B**
Michael Valenta	Johnson and Johnson	Xarelto	Letters	3/30/25 6/18/25 8/14/25	**Exhibit C** **Exhibit D** **Exhibit E**
Sue Koob	Preventive Cardiovascular Nurses Association	Xarelto	Letter	7/14/25	**Exhibit F**
Lisa Pulver	Johnson and Johnson	Xarelto	Speaker	8/20/25	**Exhibit G** Video will be posted 8/21

Oregon Prescription Drug
Affordability Board

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

Cosentyx®
(*secukinumab*)[1]

Version 1.0

[1] Image source: https://kuludonline.com/products/cosentyx-150-mg-ml-solution-for-injection-in-prefilled-pen-2-pens

Table of Contents

Review summary

Therapeutic alternatives

Cosentyx® (*secukinumab*) has the following therapeutic alternatives.

Proprietary name	Non-proprietary name	Manufacturer	Year
Cosentyx	*secukinumab*	Novartis Pharmaceuticals Corp.	2015
Ilumya	*tildrakizumab*	Sun Pharmaceutical Industries Limited	2018
SIliq	*brodalumab*	Bausch Health Ireland, Limited	2017
Skyrizi	*risankizumab-rzaa*	AbbVie, Inc.	2019
Stelara	*ustekinumab*	Janssen Biotech, Inc.	2016
Taltz	*ixekizumab*	Eli Lilly and Company	2016
Tremfya	*guselkumab*	Janssen Biotech, Inc.	2017

Price history[2,3]

Cosentyx rose at an **average annual rate of 6.7 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
    - Ilumya: -1.3 percent
    - Siliq: 7.0 percent
    - Skyrizi: 7.3 percent
    - Stelara: 5.2 percent
    - Taltz: 5.0 percent
    - Tremfya: 5.0 percent

Additionally, the average annual rate of Cosentyx **exceeded inflation in 2019, 2020, 2021, 2023, and 2024**.

[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/.

Price concessions [4]

Based on data received from healthcare carriers, Cosentyx in 2023 had the **gross spend of $6,032 per claim**, while the **spend net of discount was $3,462 per claim**. Price concession per claim were reported to be **$2,569**.

Cost to the payer[5]

2023, APAC payer total expenditure, utilization, and cost per enrollee

Drug	Total Expenditure	Utilization	Cost per Enrollee	Cost per Enrollee, median
Cosentyx	$74,284,016	11,830	$53,751	$6,520
Ilumya	$1,181,860	79	$73,866	$17,648
Siliq	$754,850	139	$44,403	$4,656
Skyrizi	$102,839,237	6,176	$62,440	$18,353
Stelara	$195,809,214	9,536	$113,909	$24,379
Taltz	$6,210,391	767	$36,318	$9,516
Tremfya	$24,941,463	2,337	$48,524	$12,114

Cost to enrollees[6]

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Cosentyx	$2,422	$15	$293	$5
Ilumya	$2,600	$0	$796	$0
Siliq	$3,168	$0	$389	$0
Skyrizi	$4,011	$125	$1,093	$99
Stelara	$4,235	$15	$797	$5
Taltz	$3,302	$40	$800	$0
Tremfya	$3,065	$35	$677	$27

[4] 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.
[5] Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[6] Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

Review background

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

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

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

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

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

Drug information[7]

Drug proprietary name(s)	**Cosentyxz®**
Active ingredient	*secukinumab*
Manufacturer	Novartis Pharmaceuticals Corporation
Treatment: Cosentyx is a human interleukin-17A antagonist indicated for:	
	• moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy.
	• active psoriatic arthritis (PsA) in patients 2 years of age and older. adults with active ankylosing spondylitis (AS).
	• adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
	• active enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older.
	• adults with moderate to severe hidradenitis suppurativa (HS)
Dosage/Strength:	
• **Injection:**	• 300 mg/2 mL solution in a single-dose UnoReady® pen and in a single-dose prefilled syringe.
	• 150 mg/mL solution in a single-dose Sensoready® pen and in a single-dose prefilled syringe.
	• 75 mg/0.5 mL solution in a single-dose prefilled syringe (for pediatric patients).
• **Infusion:**	• 125 mg/5 mL solution in a single-dose vial.
Form/Route:	Subcutaneous Injection, Intravenous Infusion

FDA approval

Cosentyx was first approved by the FDA on Jan. 21, 2025.[8]

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

At 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.

[7] U.S. Food & Drug Administration. Cosentyx (*secukinumab*) Prescribing Information. Teva Pharms., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125504s000lbl.pdf.

[8] 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.

Racial and ethnic minority patients are less likely to receive advanced biologic therapies such as Cosentyx (secukinumab). Studies have shown that minority patients, including Black, Hispanic, and Asian individuals, are more often treated with older systemic medications like methotrexate or corticosteroids, which have less favorable efficacy and side effect profiles.[9] This pattern is due to systemic barriers, provider bias, and lower awareness of familiarity with newer treatment options within these communities.[10] Additionally, culturally appropriate education and decision-making in clinical settings can further limit access to secukinumab.[11]

Insurance and financial barriers also pay a critical role. High out-of-pocket costs, restrictive formularies, and prior authorization requirements are common obstacles for Medicaid and Medicare enrollees.[12] Because racial and ethnic minorities are overrepresented in public insurance programs and lower-income populations, these administrative burdens disproportionately hinder access to high-cost specialty medication.[13]

Psoriasis often presents differently on darker skin tones and these differences are frequently inadequately captured in medical training and research literature which can further limit equitable treatment.[14] Additionally, geographic barriers, such as limited access to dermatologist or biologic prescribing clinics can further perpetuate disparities. Rural areas, safety-net clinics, and publicly funded health systems may lack the infrastructure or provider familiarity required to support biologics therapy monitoring.[15] Access to specialty drug programs have been implemented successfully in urban settings, but access models are not as broadly available to the communities that would benefit most.[16]

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[9] Hash MG, et al. (2025). Racial Disparities in Psoriasis Treatment: A Review of Prescription Patterns and Outcomes Across White and Skin of Color Populations. Dermis. 5(1):28. https://www.jdermis.com/full-text/racial-disparities-in-psoriasis-treatment-a-review-of-prescription-patterns-and-outcomes-across-white-and-skin-of-color-populations.

[10] Takeshita, J., Eriksen, et al. (2019). Racial Differences in Perceptions of Psoriasis Therapies: Implications for Racial Disparities in Psoriasis Treatment. *The Journal of investigative dermatology*, *139*(8), 1672–1679.e1. https://doi.org/10.1016/j.jid.2018.12.03.

[11] Desai RM, McCune M, Olsen R, Tong L, Davis MS. An analysis of racial disparities in systemic treatments for psoriasis and their pharmacologic consequences. Arch Clin Toxicol. 2025;7(1):71-76.

[12] Wan V, et al. "Disparities and barriers to the access of biologics in moderate-to-severe adult psoriasis." International Journal of Dermatology. 2024 Oct;63(10):1293-1301. doi: 10.1111/ijd.17236. Epub 2024 Jun 6. PMID: 38845122.

[13] Ibid.

[14] Gkini, M.-A., et al. (2025). "Psoriasis in People With Skin of Color: An Evidence-Based Update." International Journal of Dermatology, 64(4), 667–677. https://doi-org.slo.idm.oclc.org/10.1111/ijd.17651.

[15] Patel, A.A., Ferrante, S.A., Lin, I. *et al.* Racial and Ethnic Disparities in Treatment Initiation Among Patients with Newly Diagnosed Psoriatic Arthritis: A Retrospective Medicaid Claims Database Study. Rheumatol Ther 10, 1241–1253 (2023). https://doi.org/10.1007/s40744-023-00580-y.

[16] Patel, A.A., Ferrante, S.A., Lin, I. *et al.* Racial and Ethnic Disparities in Treatment Initiation Among Patients with Newly Diagnosed Psoriatic Arthritis: A Retrospective Medicaid Claims Database Study. Rheumatol Ther 10, 1241–1253 (2023). https://doi.org/10.1007/s40744-023-00580-y.

Residents prescribed

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

Based on APAC claims, Oregonians filled **11,830 prescriptions** for Cosentyx in 2023.[17]

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 Cosentyx, to characterize its historical price trends and implications for affordability. It includes an analysis of the drug's wholesale acquisition cost (WAC) compared to its therapeutic alternatives. Cosentyx was not on the Oregon Actual Average Acquisition Cost (AAAC) list. The WAC data provides a comprehensive view of Cosentyx's list price trajectory, and the degree to which the list price impacts costs.

Price history

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

Table 1 Drug vs therapeutic alternatives and 2018-2024 WAC summary per 30-day supply[18]

	Cosentyx	Ilumya	Siliq	Skyrizi	Stelara	Taltz	Tremfya
2018	$3,534	$4,419	$2,333		$6,861	$5,162	
2019	$3,884	$4,638	$2,333		$7,335	$5,368	$5,430
2020	$4,156	$4,870	$2,473		$7,694	$5,690	$5,696
2021	$4,447	$5,162	$2,622	$5,671	$8,064	$5,974	$5,969
2022	$4,853	$5,162	$2,881	$6,091	$8,499	$6,273	$6,292
2023	$4,846	$5,472	$3,167	$6,578	$8,839	$6,586	$6,606
2024	$5,186	$3,839	$3,480	$7,006	$9,281	$6,916	$6,936
Avg. Annual % Change	6.7%	-1.3%	7.0%	7.3%	5.2%	5.0%	5.0%
% change 2018 between 2024	46.7%	-13.3%	49.1%		35.3%	34.0%	

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

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

The WAC of Cosentyx, averaged across five NDCs , was approximately **$5,186.27 per unit** at the end of 2024.[19] Between 2018-2024, the unit WAC increased at an average annual rate of **6.7 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019, 2019-2020, 2020-2021, and 2023-2024 (see Figures 1 and 2).[20]

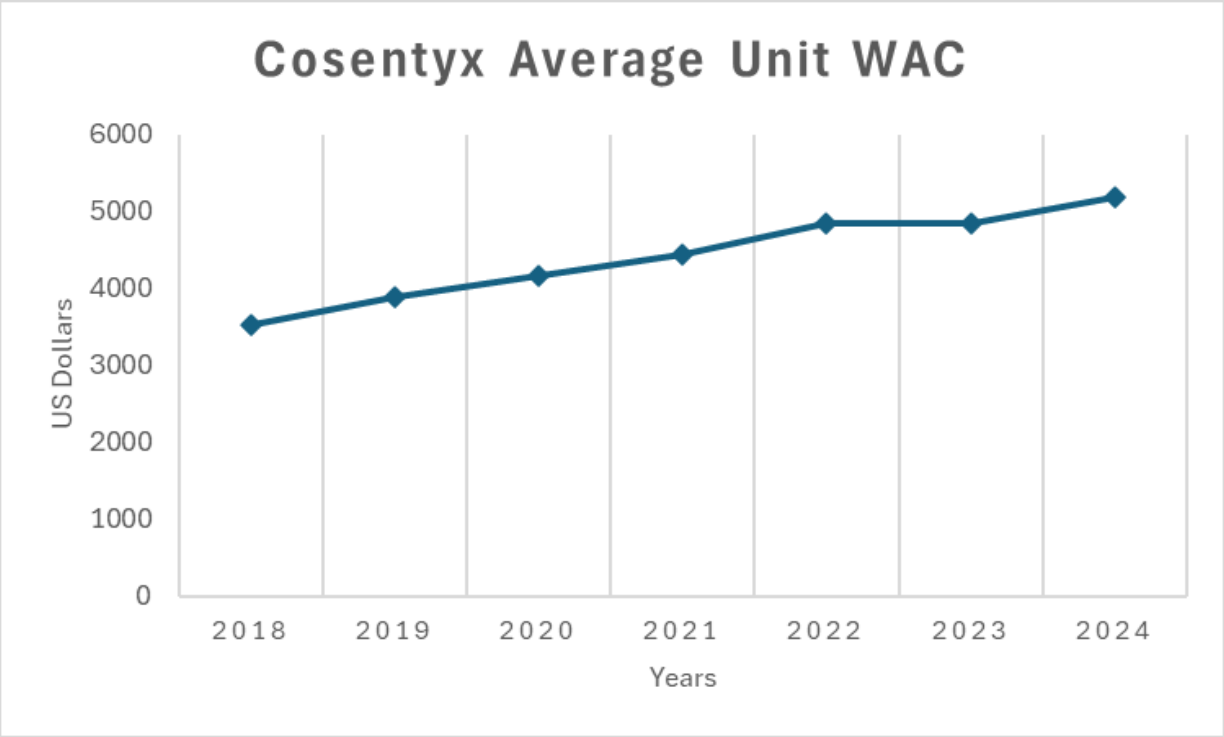


Figure 1 Cosentyx average unit WAC from 2018-2024

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

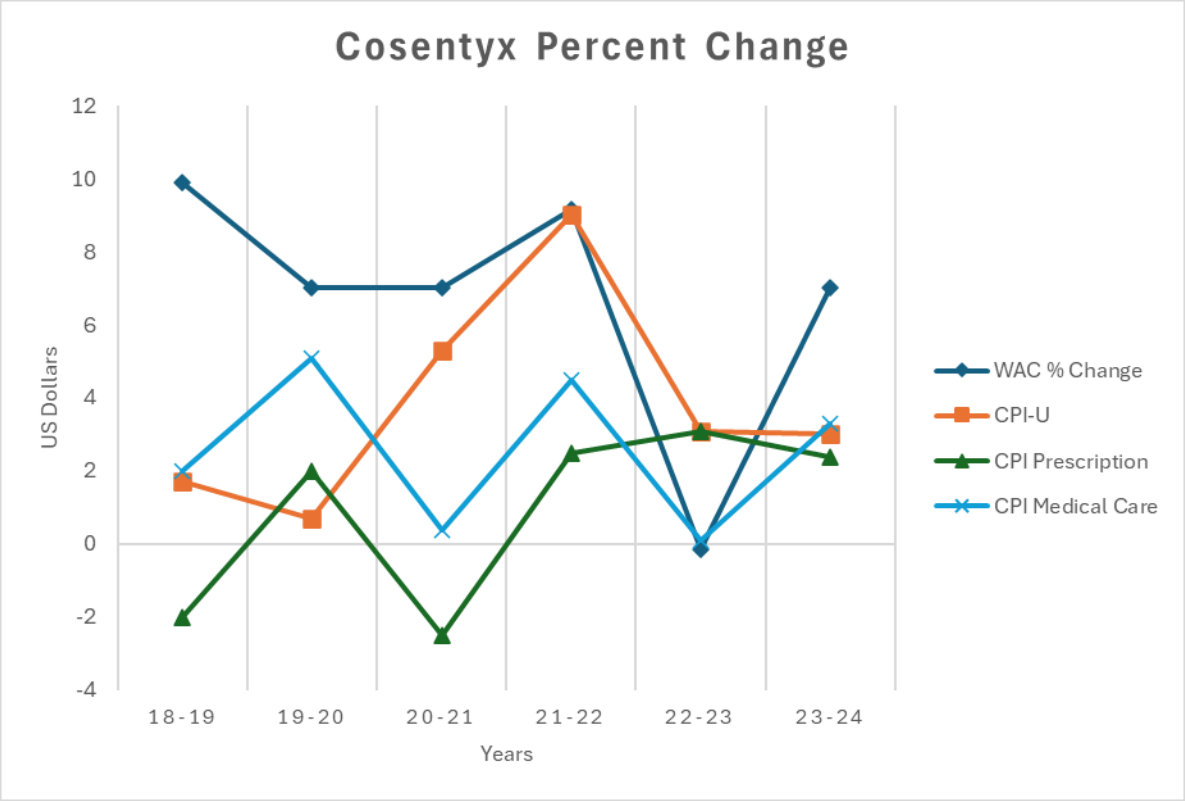


Figure 2 Year over year change in WAC compared to inflation rates[21]

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 Cosentyx 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 Cosentyx per enrollee in the commercial market was approximately $39,882**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $22,894**, reflecting an **estimated mean discount of 42.6 percent** relative to gross costs.

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

Across all reporting carriers and market segments, the **total cost of Cosentyx before concessions was $36,093,372**, with total reported **price concessions amounting to approximately $15,374,304**, as detailed in Table 2. Notably, **54.8 percent of claims benefited from some form of price concession,** leaving **45.2 percent at full gross cost**.

Table 2 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	905
Total number of claims	5,984
Total number of claims with price concessions applied	3,280
Percentage of claims with price concessions applied	54.8%
Percentage of cost remaining after concessions	57.4%
Manufacturer price concessions for all market types	$12,997,231
PBM price concessions for all market types	$1,104,178
Other price reductions for all market types	$1,272,895
Cost before price concessions across all market types	$36,093,372
Total price concessions across all market types	$15,374,304
Cost of after price concessions across all market types	$20,719,068
Avg. payer spend per enrollee without price concessions	$39,882
Avg. payer spend per enrollee with price concessions	$22,894

Including all market segments, the **gross spend of Cosentyx per claim for commercial carriers was $6,032** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$3,462**, meaning that insurers reported a price concession of **$2,569** per claim on the initial drug cost as shown in Table 3.

Table 3 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	$6,032	$6,477	$5,797	$6,681
Spend per Claim, net	$3,462	$3,015	$3,701	$2,798
Price Concession per Claim	$2,569	$3,463	$2,096	$3,882

Figure 3 shows manufacturer concessions comprised the largest share, supplemented by PBM discounted price arrangements and other adjustments across the payer types.

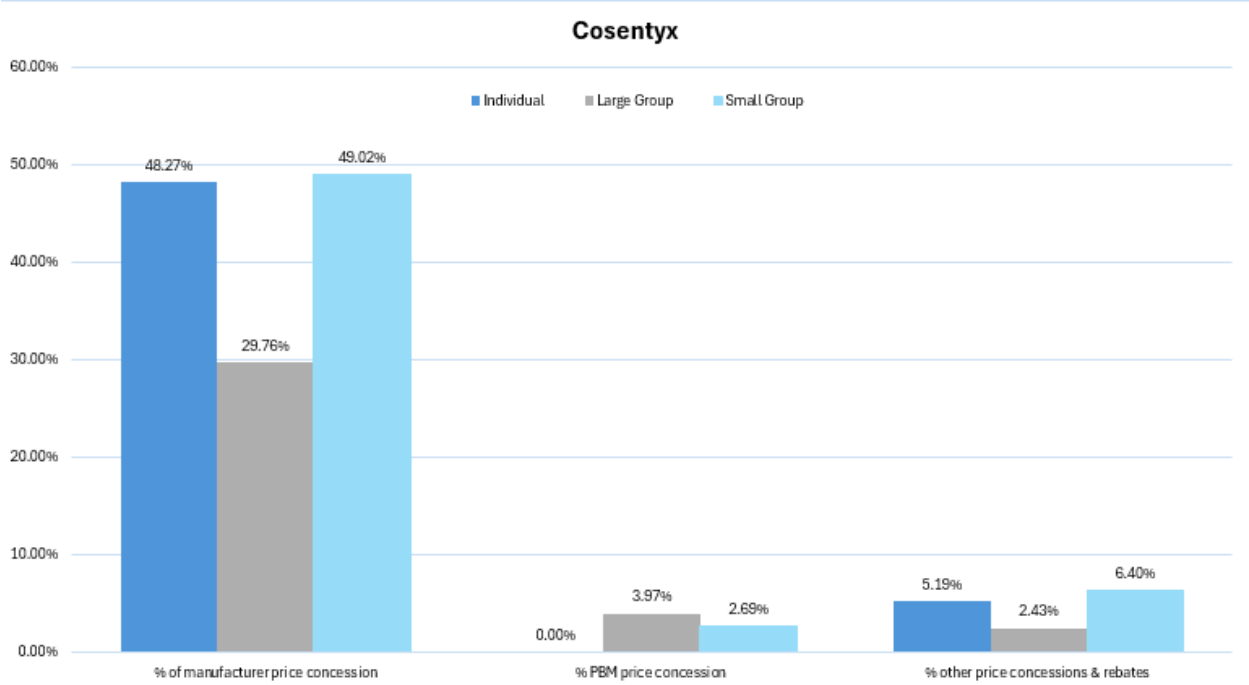


Figure 3 Percent of price concession in each market type[22,23]

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

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

Estimated total amount of the price concession

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

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

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

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 Cosentyx 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 submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concessions or rebates.

Cosentyx's total gross payer paid, based on APAC data, was $74.3 million, while **total net payer paid received from the carriers indicated a cost of $32.7 million**. Two of its therapeutic alternatives, **Skyrizi and Stelara, had a higher gross payer paid amount than Cosentyx, at $102.8 million and $195.8 million respectively**, despite Cosentyx having the highest utilization of the group. The drug with the lowest gross total payer paid expenditure was Siliq with $753,850. **Cosentyx had $6,279 payer paid per claim**, which is the second lowest when compared to its therapeutic alternatives.

Skyrizi and Stelara continue to top the group with total enrollee paid cost, at $6.2 million and $6.5 million. **Cosentyx follows behind them, with $2.7 million in total enrollees paid**. However, considering the high utilization of Cosentyx**, the drug has the lowest patient paid per claim among the group.**

[24] 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. https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf.

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

Table 4 Average healthcare and average patient OoP costs for Cosentyx vs therapeutic alternatives

Drug	No. of enrollees[25]	No. of claims	Total payer paid	Total enrollees paid[26]	Payer paid/ claim	Patient paid/ claim[27]
Subject Drug **Cosentyx (data call)**	905	5,984	$32,652,235	$2,346,683	$5,457	$392
Subject Drug **Cosentyx (APAC)**	1,382	11,830	$74,284,016	$2,712,109	$6,279	$293
Illumya	16	79	$1,181,860	$39,002	$14,960	$796
Siliq	17	139	$754,850	$44,354	$5,431	$389
Skyrizi	1,647	6,176	$102,839,237	$6,204,274	$16,651	$1,093
Stelara	1,719	9,536	$195,809,214	$6,467,256	$20,534	$797
Taltz	171	767	$6,210,391	$525,064	$8,097	$800
Tremfya	514	2,337	$24,941,463	$1,406,683	$10,672	$677

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 Cosentyx, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

[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.
[26] The cost includes all lines of business.
[27] Ibid.

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 Cosentyx 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 **11,830 total claims for Cosentyx among 1,382 total enrollees**, corresponding to a **total payer expenditure of $74,284,016**.

Table 5 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Commercial** accounted for the largest share of utilization, with 6,862 claims from 849 enrollees and a total spend of **$38.9 million**.
- **Medicaid** and **Medicare** payers reported smaller but notable expenditures of approximately **$17.9 million** and **$17.5 million**, respectively.

Table 5 Estimated 2023 APAC total gross costs 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	849	6,862	$38,903,515	$45,823	$5,669
Medicaid	338	2,571	$17,871,007	$52,873	$6,951
Medicare	295	2,397	$17,509,493	$59,354	$7,305
Totals	**1,382**	**11,830**	**$74,284,016**		

Table 6 provides utilization for the healthcare system for Cosentyx and its therapeutic alternatives, distinguished by lines of business. **Cosentyx has the most utilization** among the drugs, with **11,840 claims**. In all lines of business, Cosentyx is the most utilized. **Stelara is the second most utilized at 9,536 claims**.

[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.

Table 6 Estimated 2023 APAC payer utilization of drug and its therapeutic alternatives[29]

Proprietary Name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total Claims[30]
Cosentyx	6,862	2,571	2,397	11,830
Ilumya	37	30	12	79
Siliq	57	25	57	139
Skyrizi	3,912	499	1,765	6,176
Stelara	5,791	1,419	2,326	9,536
Taltz	418	111	238	767
Tremfya	1,596	260	481	2,337

Table 7 shows the overall payer expenditure of Cosentyx and its therapeutic alternatives, distinguished by lines of business. Cosentyx has a **total expenditure of $74.3 million** with **commercial being the biggest portion at $38.9 million**. Two therapeutic alternatives had greater total expenditure than Cosentyx, with **Skyrizi at $102.8 million and Stelara at $195.8 million.**

Table 7 Estimated 2023 APAC payer expenditure of drug and its therapeutic alternatives[31]

Proprietary Name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total
Cosentyx	$38,903,515	$17,871,007	$17,509,493	$74,284,016
Ilumya	$440,240	$529,024	$212,596	$1,181,860
Siliq	$204,237	$118,319	$432,293	$754,850
Skyrizi	$63,057,039	$8,948,218	$30,833,980	$102,839,237
Stelara	$113,193,622	$30,728,479	$51,887,113	$195,809,214
Taltz	$2,982,811	$1,054,618	$2,172,962	$6,210,391
Tremfya	$16,540,440	$2,830,035	$5,570,988	$24,941,463

[29] 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.
[30] Total is the sum of all expenditure for the drug across all lines of business.
[31] Ibid.

Table 8 compares the overall payer cost per enrollee of Cosentyx and its therapeutic alternatives, distinguished by lines of business. **Stelara has the highest total cost per enrollee at $113,909**. Cosentyx has comparable cost per enrollee as compared to its therapeutic alternatives in all lines of business; the total **cost per enrollee for Cosentyx is $53,751**, which makes it the fourth most expensive out of seven drugs compared. **The median cost per enrollee for Cosentyx is $6,520**, which is only more than the median cost per enrollee for Siliq.

Table 8 Estimated 2023 APAC payer cost per enrollee of drug and its therapeutic alternatives[32]

Proprietary Name	Commercial Cost/Enrollee	Medicaid Cost/Enrollee	Medicare Cost/Enrollee	Total Cost per Enrollee	Cost per Enrollee, Median	IQR
Cosentyx	$45,823	$52,873	$59,354	$53,751	$6,520	$2,585
Ilumya	$40,022	$52,902	$53,149	$73,866	$17,648	$2,392
Siliq	$34,040	$39,440	$54,037	$44,403	$4,656	$1,870
Skyrizi	$60,112	$64,842	$60,459	$62,440	$18,353	$4,100
Stelara	$104,615	$104,875	$110,164	$113,909	$24,379	$13,272
Taltz	$33,515	$47,937	$31,042	$36,318	$9,516	$7,870
Tremfya	$48,506	$42,879	$46,815	$48,524	$12,114	$3,044

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. As shown in Figure 4, the **large group market segment** represented the majority of commercial spending (66% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $35.0 million**, **with payer paying $32.7 million**, and **enrollees out -of-pocket estimating to be $2.3 million**. Table 9 includes the average plan costs per enrollee in the commercial market ranged from **$36,353 (large group)** to **$45,613 (individual)** annually.

[32] 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 9 Estimated 2023 data call total net costs to the healthcare system, payers and OOP/enrollee[33]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	1,002	142	$6,477,039	$5,506,330	$970,709
Large Group	4,163	639	$23,229,479	$22,317,982	$911,497
Small Group	819	124	$5,292,401	$4,827,924	$464,477
Total	**5,984**	**905**	**$34,998,919**	**$32,652,235**	**$2,346,683**

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	$6,464	$5,495	$969	$45,613	$38,777	$6,836
Large Group	$5,580	$5,361	$219	$36,353	$34,926	$1,426
Small Group	$6,462	$5,895	$567	$42,681	$38,935	$3,746

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

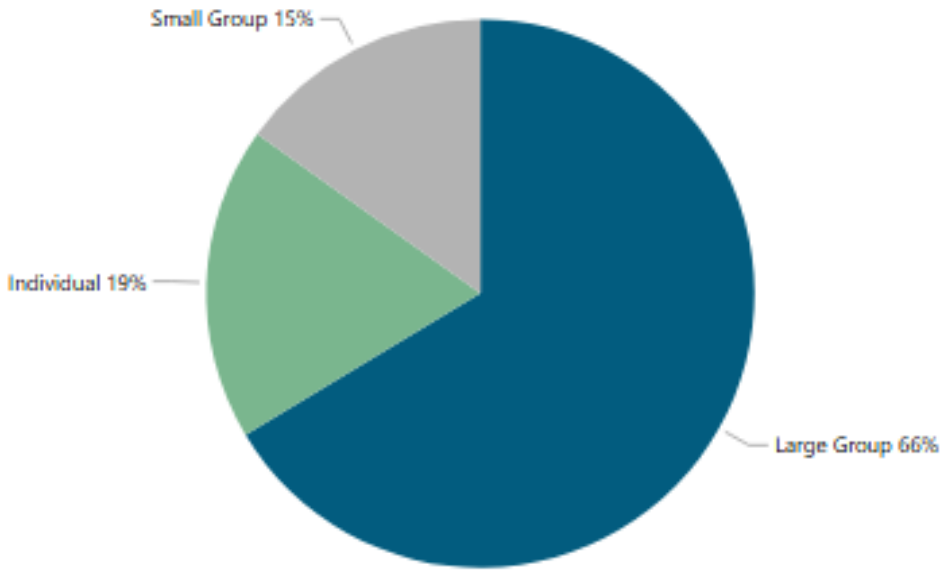


Figure 4 Data call percent of total annual spend (payer paid)

Table 10 indicates CCOs reported Cosentyx as having an annual greatest increase from 2022-2023 (rebates not included) with a **$1,726,378 year-over-year increased cost growth**.

Table 10 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**
$10,807,478	$12,533,856	$1,726,378	0.1%

Impact on patient access to the drug

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

Review of rejected claims and drug benefit designs

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

Based on information reported through the carrier data call, the following plan design features were observed for Cosentyx. In 2023, approximately **100 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.

For formulary placement, **1.4 percent of plans categorized Cosentyx as a non-preferred drug** and **0.7 percent of plans excluded it entirely from the formulary**.

Table 11 Plan design analysis from 2023 data call

Percentage of Plans	
Required Prior Authorization	100%
Required Step Therapy	0.4%
On a non-preferred formulary	1.4%
Not covered	0.7%

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

Relative financial impacts to health, medical or social services costs

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

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

The statutory and regulatory criteria calls for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through carrier reporting, manufacturer disclosures, or other sources.
Future reviews may incorporate findings from real-world evidence, health technology assessments, or economic modeling as such data become available.

Estimated average patient copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Cosentyx in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 12 and 13 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

Table 12 Drug vs. therapeutic alternatives and out-of-pocket cost per enrollee[34]

Proprietary Name	Medicare OOP Cost/Enrollee	Commercial OOP Cost/Enrollee	Total	Median	IQR
Cosentyx	$1,821	$2,562	$2,422	$15	$211
Ilumya	$1,689	$2,932	$2,600	$0	$85
Siliq	$537	$6,676	$3,168	$0	$1,104
Skyrizi	$3,802	$4,066	$4,011	$125	$2,106
Stelara	$6,055	$3,341	$4,235	$15	$1,000
Taltz	$3,499	$3,147	$3,302	$40	$1,951
Tremfya	$3,168	$3,020	$3,065	$35	$814

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

Table 13 Drug vs. therapeutic alternatives and out-of-pocket cost per claim

Proprietary Name	Medicare OOP Cost/Claim	Commercial OOP Cost/Claim	Total	Median	IQR
Cosentyx	$224	$317	$293	$5	$150
Ilumya	$563	$872	$796	$0	$120
Siliq	$75	$703	$389	$0	$20
Skyrizi	$1,099	$1,090	$1,093	$99	$620
Stelara	$1,226	$624	$797	$5	$300
Taltz	$1,029	$670	$800	$0	$400
Tremfya	$784	$645	$677	$27	$400

Information from manufacturers[35]

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:
  - Cosentyx is a human interleukin-17A (IL-17) antagonist indicated for the treatment of:
    - moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy.
    - active psoriatic arthritis (PsA) in patients 2 years of age and older. adults with active ankylosing spondylitis (AS).
    - adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
    - active enthesitis-related arthritis (ERA) in pediatric patients 4 years of age and older.
    - adults with moderate to severe hidradenitis suppurativa (HS)
- Off Label Uses:
  - Rheumatoid Disease
    - IL-17 antagonists belong to a group of medicines called biological DMARDs (disease-modifying anti-rheumatic drugs) and reduces the inflammation effects of interleukin 17. Though Cosentyx is approved by the FDA for other diseases with symptoms of inflammation,

[35] U.S. Food & Drug Administration. Cosentyx (Secukinumab) Prescribing Information. Teva Pharms., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125504s000lbl.pdf.

secukinumab and other IL-17 antagonists are used in off label uses to treat rheumatoid diseases such as rheumatoid arthritis.[36, 37]

Clinical efficacy

The efficacy of secukinumab for moderate to severe plaque psoriasis was established in two pivotal randomized, double-blind, placebo-controlled trials (ERASURE [trial 2302] and FIXTURE [trial 2303]) (Table 15). Across these studies, secukinumab demonstrated statistically significant improvements in disease activity, measured by the psoriasis area and severity index (PASI) and the proportion of patients achieving a response of 0 or 1 on the modified investigator's global assessment (mIGA) compared to placebo and etanercept (active comparator) at week 12. Secukinumab has also demonstrated efficacy across additional indications including psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis.

Table 14 Adult plaque psoriasis response study measured by PASI 75 and IGA 0/1 Response at Week 12

Study	Treatment	Comparator	PASI 75 Response (%)	ARR / P value	mIGA 0/1 Response (%)	ARR/ P value
ERASURE (2302)	secukinumab (SK) 300 mg	Placebo (PB)	SK: 81.6% PB: 4.5%	77% / <0.001	SK: 65.3% PB: 2.4%	63%/ <0.001
FIXTURE (2303)	secukinumab (SK) 300 mg	Placebo (PB) Etanercept (EUE)	SK: 77.1% EUE: 44% PB: 4.9%	72%/ <0.001 33% <0.001	SK: 62.5% EUE: 27.2% PB: 2.8%	60% <0.001 35% <0.001
Abbreviations: ARR: absolute risk reduction; EUE: etanercept; mIGA = modified investigator's global assessment with 0=clear, 1=almost clear, 2=mild disease, 3=moderate disease, 4=severe disease; PASI: psoriasis area and severity index on a scale of 0 to 72 with higher scores indicating more severe disease; PASI 75 = a reduction of ≥75% in baseline PASI score; PB: placebo; SK: secukinumab						

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

[37] Stefania, S., et al. (2021). Off-label use of anti-IL-1 drugs in rheumatic diseases. International journal of immunopathology and pharmacology, 35, 20587384211006584. https://doi.org/10.1177/20587384211006584.

Table 15 Adult psoriatic arthritis (Week 24 response)

Study	Treatment	Comparator	ACR20 (%)	P value (vs placebo)	ACR50 (%)	P value
FUTURE1	secukinumab (SK) 75 mg and 150 mg	Placebo (PB)	SK75: 50.5% SK150: 50.0% PB: 17.3%	<0.001*	SK75: 30.7% SK150: 34.7% PB: 7.4%	<0.001*
FUTURE2	secukinumab (SK) 75 and 150 mg and 300 mg	Placebo (PB)	SK75: 29% SK150: 51% SK300: 54% PB: 15%	0·0399 <0·0001 <0·0001	SK75: 18% SK150: 35% SK300: 35% PB: 7%	0·9195 0·0555 0·0040
Abbreviations: ACR: American college of rheumatology; ACR20: proportion of patients with at least a 20% improvement from baseline in the number of tender and swollen joints and at least three other domains; ACR50: proportion of patients with at least a 50% improvement from baseline in ACR; PB: placebo; SK: secukinumab						
*for all doses compared to placebo						

Table 16 Ankylosing Spondylitis Response (Week 16 ASAS20)

Study	Treatment	Comparator	ASAS20 (%)	P value (vs placebo)	ASAS40 (%)	P value
MEASURE1	secukinumab (SK) 75 mg and 150 mg	Placebo (PB)	SK75: 60% SK150: 61% PB: 29%	<0.001*	SK75: 33% SK150: 41% PB: 13%	<0.001*
MEASURE2	secukinumab (SK) 75 and 150 mg	Placebo (PB)	SK75: 41% SK150: 61% PB: 28%	0·10 <0·0001	SK75: 26% SK150: 36% PB: 11%	0·10 <0·0001
Abbreviations: ASAS20: Assessment of Spondyloarthritis International Society; ASAS20: proportion of patients with at least a 20% improvement from and absolute improvement of ≥1 unit [on a 10-unit scale] in at least three of the four main ASAS domains; ASAS40: improvement of ≥40% and absolute improvement of ≥2 units [on a 10-unit scale] in at least three of the four main ASAS domains; PB: placebo; SK: secukinumab						
*for all doses compared to placebo						

Clinical safety[38]

- FDA safety warnings and precautions:
  - Infections
  - Tuberculosis
  - Inflammatory Bowel Disease
  - Eczematous Eruptions
  - Risk of Hypersensitivity in Latex-Sensitive Individuals
  - Immunizations: patients should be up to date before initiating therapy. Live vaccines should not be given concurrently during therapy.
- Contraindications:
  - Serious hypersensitivity reaction to secukinumab or to any of the excipients.
- Common side effects:
  - Gastrointestinal: diarrhea, exacerbation of Crohn's disease, ulcerative colitis
  - Infections, nasopharyngitis, upper respiratory tract infections
  - Urticaria
  - Headache

[38] U.S. Food & Drug Administration. Cosentyx (Secukinumab) Prescribing Information. Teva Pharms., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125504s000lbl.pdf.

Therapeutic alternatives:[39,40,41,42,43,44,45]

Table 17 FDA Approved Indications

Non-proprietary (*proprietary*) name	Manufacturer (year approved)	Plaque Psoriasis	Psoriatic Arthritis (PsA)	Ankylosing Spondylitis (AS)	Non-Radiographic Axial SpA	Other Indications
***secukinumab* (Cosentyx)**	Novartis Pharmaceuticals Corp. (2015)	≥6 yo	≥2 yo	≥ 18 yo	≥ 18 yo	Enthesitis-Related Arthritis (≥4 yo)
***tildrakizumab* (Ilumya)**	Sun Pharmaceutical Industries Limited (2018)	≥ 18 yo	No	No	No	—
***brodalumab* (Siliq)**	Bausch Health Ireland, Limited (2017)	≥ 18 yo	No	No	No	—
***guselkumab* (Tremfya)**	Janssen Biotech, Inc. (2017)	≥ 18 yo	≥ 18 yo	No	No	—
***ixekizumab* (Taltz)**	Eli Lilly and Company (2016)	≥6 yo	≥ 18 yo	≥ 18 yo	≥ 18 yo	—

[39] U.S. Food & Drug Administration. *Cosentyx (secukinumab) Prescribing Information*. Novartis Pharm. Corp., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125504_S050_S051lbl.pdf.
[40] U.S. Food & Drug Administration. *Ilumya (tildrakizumab-asmn) Prescribing Information*. Sun Pharma. Ind. Limited., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761067s014lbl.pdf.
[41] U.S. Food & Drug Administration. *Siliq (brodalumab)Prescribing Information*. Bausch Health Ireland, Limited, Action yr 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761032lbl.pdf.
[42] U.S. Food & Drug Administration. *Tremfya (guselkumab) Prescribing Information*. Janssen Biotech, Inc., Action yr 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761061s007lbl.pdf.
[43] U.S. Food & Drug Administration. *Taltz (ixekizumab) Prescribing Information*. Eli Lilly and Company, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125521s024lbl.pdf.
[44] U.S. Food & Drug Administration. *Stelara (Ustekinumab) Prescribing Information*. Janssen Biotech, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761044s010lbl.pdf.
[45] U.S. Food & Drug Administration. *Skyrizi (risankizumab-rzaa)Prescribing Information.* AbbVie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761105s018lbl.pdf.

Non-proprietary (*proprietary*) name	Manufacturer (year approved)	Plaque Psoriasis	Psoriatic Arthritis (PsA)	Ankylosing Spondylitis (AS)	Non-Radiographic Axial SpA	Other Indications
***ustekinumab* (Stelara)**	Janssen Biotech, Inc. (2016)	≥6 yo	≥6 yo	No	No	Crohn's Disease, Ulcerative Colitis
***risankizumab* (Skyrizi)**	AbbVie, Inc. (2019)	≥ 18 yo	≥ 18 yo	No	No	Crohn's Disease, Ulcerative Colitis

Comparative clinical efficacy

Secukinumab has shown to be superior to etanercept and ustekinumab in achieving clear or almost clear skin in patients with plaque psoriasis. One small, open-label, trial found no difference in clinical improvement between guselkumab and secukinumab at 16 weeks and another trial found no difference in disease remission between risankizumab and secukinumab at 16 weeks. There is no evidence of difference in harms between secukinumab and other targeted immune modulators for the treatment of plaque psoriasis.

Table 18 Adverse effects comparison

Drug	Common AEs	Serious Risks / Warnings
***secukinumab* (Cosentyx)**	Nasopharyngitis, URTI, Diarrhea	Risk of infections, tuberculosis, IBD flare, hypersensitivity
***tildrakizumab-asmn* (Ilumya)**	URTI, injection site reactions	Risk of infections, tuberculosis
***brodalumab* (Siliq)**	Arthralgia, headache	Risk of infections, tuberculosis, suicidal ideation (boxed warning)
***guselkumab* (Tremfya)**	URTI, headache, injection site rxns	Risk of infections, TB screening advised
***ixekizumab* (Taltz)**	Injection site reactions, URTI	Risk of infections, tuberculosis, IBD exacerbation
***ustekinumab* (Stelara)**	Nasopharyngitis, fatigue	Malignancy, risk of infections, tuberculosis
***risankizumab-rzaa* (Skyrizi)**	URTI, headache, fatigue	Risk of infections, tuberculosis, risk of hypersensitivity

Table 19 Route and dosing

Drug	Route	Initial Dosing	Maintenance Dosing
***secukinumab* (Cosentyx)**	SubQ	300 mg weekly × 5 weeks	300 mg Q4W (can use 150 mg in some)
***tildrakizumab-asmn* (Ilumya)**	SubQ	100 mg at Weeks 0 and 4	100 mg Q12W
***brodalumab* (Siliq)**	SubQ	210 mg at Weeks 0, 1, and 2	210 mg Q2W
***guselkumab* (Tremfya)**	SubQ	100 mg at Weeks 0 and 4	100 mg Q8W
***ixekizumab* (Taltz)**	SubQ	160 mg at Week 0, then 80 mg Q2W ×12W	80 mg Q4W
***ustekinumab* (Stelara)**	SubQ	Weight-based at Weeks 0 and 4	Q12W
***risankizumab-rzaa* (Skyrizi)**	SubQ	150 mg at Weeks 0 and 4	150 mg Q12W

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 three individuals** taking or having an association with Cosentyx. According to the survey results, 67 percent of respondents had insurance coverage for Cosentyx.

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

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

” Cosentyx ”

- For the past year, the patient has taken Cosentyx every four weeks by injection for psoriasis. It clears up skin issues. The patient was on Humira for a number of years, but it lost its effectiveness. They have billed him over $7,000 per monthly dose for Cosentyx and then told him he no longer qualified for the patient assistance program. The patient is on Medicaid. (Submitted by a caregiver.)
- I take Cosentyx Sensoready 150MG / ML - 2 pack, self-administered every 30 days for psoriasis and psoriatic arthritis. I have been taking it for about four years. My monthly, out-of-pocket cost is $45 through private insurance and a patient assistance program. This drug eliminates all my symptoms with 100 percent reliability and no unpleasant side effects. In the past, I have tried Humira, Enbril, and Taltz with much lower efficacy and/or with very unpleasant side effects. My monthly premium for health insurance for two people is high enough ($1,500) to make me eligible to purchase cheaper insurance on the marketplace. However, because this drug is classified as a tiered specialty medication, it is not covered by any plans I can afford. I made the mistake of buying a plan on the marketplace a few years ago and the copay for Cosentyx was $4,500 per month, with the patient assistance program offering to cover $100 of that. I went unmedicated for about seven months.
- I take Cosentyx 300 mg once every 30 days for psoriasis. I have no out-of-pocket costs for this drug. Cosentyx works excellently in treating my condition. I tried other drugs with poor results and worse side effects. If I didn’t qualify for the patient assistance program through Novartis, I would not be able to afford this drug. The co-pay with my Medicare Advantage plan is prohibitively high.

Individuals with scientific or medical training

A survey of healthcare professionals with scientific or medical training identified key barriers for patients accessing medications.

There were **three healthcare professionals that reported** the prior authorization, step therapy, cost, and formulary issues with Cosentyx was an administrative burden and laborious for patients to access the medication.

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

Below are selected written responses about Cosentyx from the survey for individuals with scientific or medical training, edited for length and to protect their privacy.

- Cosentyx reduces skin and joint inflammation and often results in disease remission. Obtaining prior authorizations are time consuming and frustrating, often resulting in back and forth with PBMs and submitting appeal for denials. PBMs will often deny coverage in favor of formulary alterative. Same concerns apply for other rheumatology specialty meds. PBMs have taken away our autonomy and the ability to best care for our patients, not to mention the undue administrative burden and hand wringing caused by their stonewalling and excessive (and often redundant) paperwork. – Oregon rheumatologist

- Cosentyx treats Psoriasis, hidradenitis suppurativa. It blocks a key cytokine called IL-17 to reduce inflammation. Medicaid is burdensome and often requires multiple layers of step therapy. Benefits of Cosentyx compared to therapeutic alternatives? Improved efficacy compared to methotrexate and adalimumab. Safer option than infliximab as it is more targeted and does not broadly suppress the immune system. Higher cost than methotrexate. Not used as much for psoriasis as there are many more effective options. Is considered second-line therapy for hidradenitis suppurativa. Medicaid has recommended several other step therapy options that led to patient never getting their psoriasis treated. -OHSU dermatology professor

- In general, the goal of therapy in treating the various conditions Cosentyx is FDA-approved for, involves improvement in symptom control and disease activity from baseline, whether that is a reduction of PASI score in dermatologic conditions or response to treatment using clinical measuring tool/scores in rheumatologic conditions (e.g., AS20, ASA20, etc.). Dosing: requires loading dose for most indications. Frequency: monthly dosing (depending on the indication) compared to multi-month dosing for other IL blockers. Warning: can worsen existing IBD. Storage: requires refrigeration and stability at room temperature is not as good as Enbrel (4 days vs. 14 days). – manager of an Oregon specialty pharmacy

Safety net providers

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

A total of **11 safety net clinics** responded to the survey. Among respondents, **2 clinics indicated that Cosentyx was covered as a 340B-eligible prescription** within their programs.

Most clinics (91%) reported operating an internal pharmacy for dispensing 340B-eligible medications, and 64 percent reported using one or more contract pharmacies for this purpose.

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

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

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

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

These results suggest that while Cosentyx 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	2
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between $0-$100,000	27%
Reported total amount paid for drug under 340B was between $100,001-$300-000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between $0-$100,000	18%

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

Table 21 Amounts paid for drug under 340B discount program

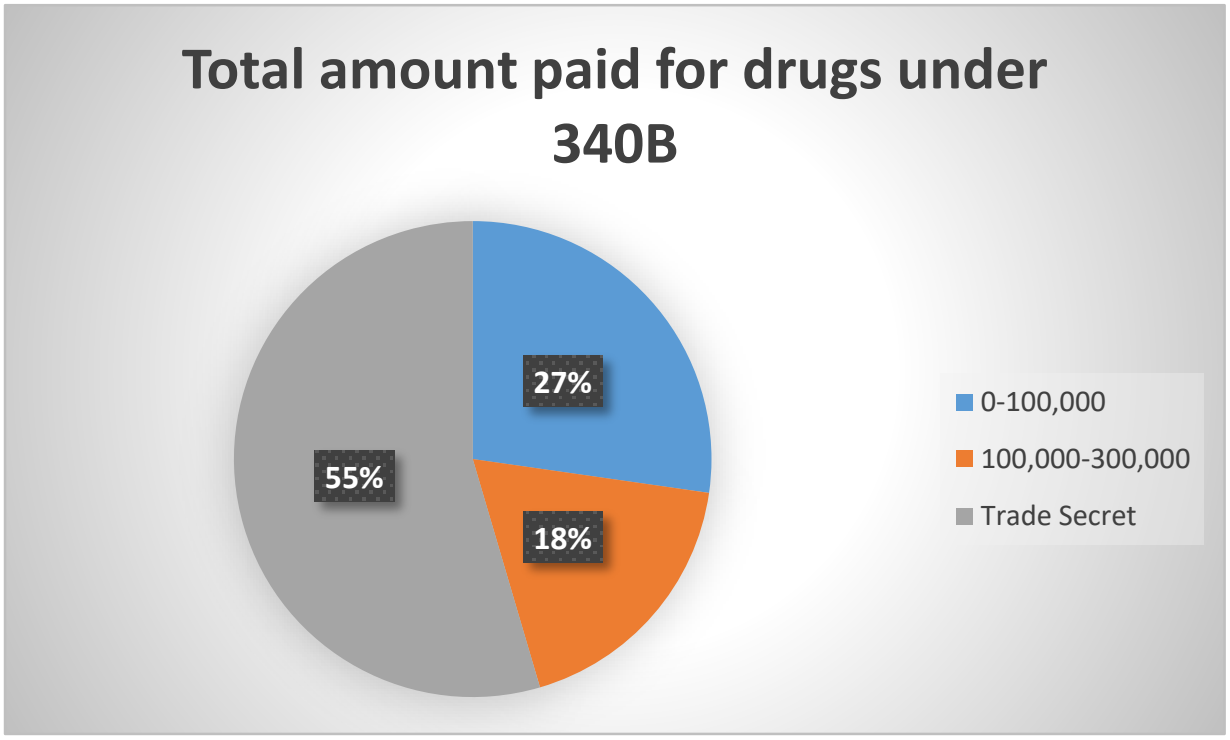
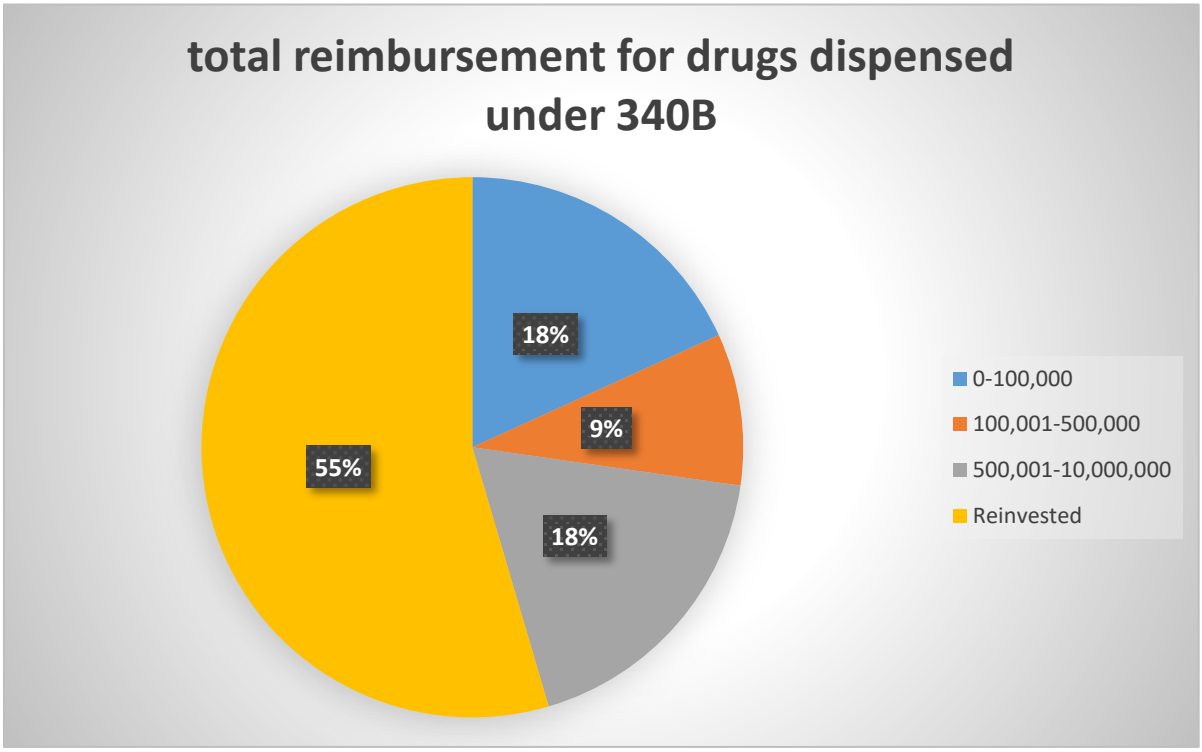


Table 22 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



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 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:

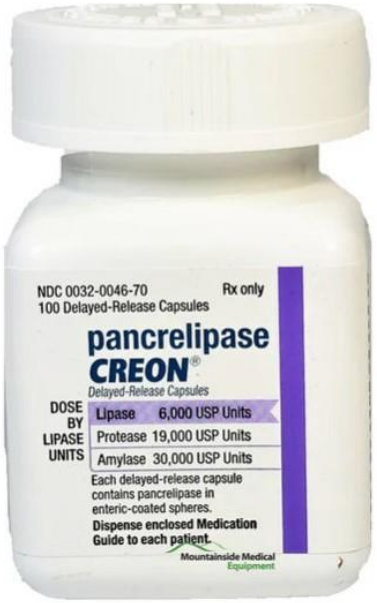
Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Courtney Piron	Novartis	Cosentyx	Letter	5/21/2025	Exhibit A
Courtney Piron	Novartis	Cosentyx	Letter	8/12/2025	Exhibit B

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

Creon®

(*pancrelipase*)[1]

Version 1.0



[1] Image source: https://www.mountainside-medical.com/products/creon-dr-pancrelipase-capsules-6000-usp

Table of Content

Review summary

Therapeutic alternatives

Creon® (*pancrelipase*) has the following therapeutic alternatives:

Proprietary name	Non-proprietary name	Manufacturer	Year approved
Creon	*pancrelipase*	Abbvie Inc.	2009
Pancreaze	*pancrelipase*	Vivus, Inc.	2010
Pertzye	*pancrelipase*	Digestive Care, Inc.	2012
Viokace	*pancrelipase*	Viokace, LLC	2012
Zenpep	*pancrelipase*	Zenpep, LLC	2009

Price history[2,3]

Creon rose at an **average annual rate of 6.0 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
    - Pancreaze: 13.1 percent
    - Pertyze: 3.5 percent
    - Viokace: 6.3 percent
    - Zenpep: 3.3 percent

Additionally, the average annual rate of Creon **exceeded inflation in 2019, 2020, 2021, 2023, and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 13.6 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions [4]

Based on data received from healthcare carriers, Creon in 2023 had the **gross spend of $2,674 per claim**, while the **spend net of discount was $2,130 per claim**. Price concessions per claim were reported to be **$545**.

[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] 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 the payers[5]

2023, APAC payer total expenditure, utilization, and cost per enrollee

Drug	Total Expenditure	Utilization	Cost per Enrollee	Cost per Enrollee, median
Creon	$32,874,312	18,427	$10,280	$1,292
Pancreaze	$456,954	339	$5,573	$955
Pertzye	$25,567	21	$8,522	$2,368
Viokace	$70,729	49	$3,723	$557
Zenpep	$10,504,953	3,669	$14,631	$1,934

Cost to enrollees[6]

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

Drug	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Creon	$451	$25	$90	$8
Pancreaze	$600	$80	$158	$37
Pertzye	$188	$38	$25	$0
Viokace	$297	$0	$154	$0
Zenpep	$751	$35	$161	$20

[5] Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[6] 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. The 2023 drug affordability review selection included the following criteria: orphan-designated drugs were removed; drugs were reviewed based on payer-paid cost data from the data call submissions; and drugs reported to the APAC program across Medicare, Medicaid, and commercial lines of business were included. To ensure broader public impact, drugs with fewer than 1,000 enrollees reported in APAC reports were excluded from consideration.

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

Drug information[7]

Drug proprietary name(s)	Creon®
Non-proprietary name	*pancrelipase*
Manufacturer	ABBVIE
Treatment: Creon is a combination of porcine-derived lipases, proteases, and amylases indicated for:	• the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.
Dosage and Strengths	• Delayed-Release Capsules: 3,000 USP units of lipase; 9,500 USP units of protease; and 15,000 USP units of amylase.
	• Delayed-Release Capsules: 6,000 USP units of lipase; 19,000 USP units of protease; and 30,000 USP units of amylase.
	• Delayed-Release Capsules: 12,000 USP units of lipase; 38,000 USP units of protease; and 60,000 USP units of amylase.
	• Delayed-Release Capsules: 24,000 USP units of lipase; 76,000 USP units of protease; and 120,000 USP units of amylase.
	• Delayed-Release Capsules: 36,000 USP units of lipase; 114,000 USP units of protease; and 180,000 USP units of amylase.
Form/Route	Oral capsule

FDA approval

Creon was first approved by the FDA on April 30, 2009.[8]

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

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

[7] U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.

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

Health inequities

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

Equity in pancreatic enzyme replacement therapy for exocrine pancreatic insufficiency (EPI) remains a challenge. Creon (*pancrelipse*) is underutilized in underserved populations, where EPI is frequently underdiagnosed and dosing titration is delayed, leading to avoidable malabsorption and nutrient deficits.[9] Delays often stem from limited access to gastroenterology specialists and insufficient clinical follow-up in lower-resourced communities.

Additionally, racial and socioeconomic disparities influence treatment initiation and continuity. Evidence demonstrates that minority patients face structural barriers to care in pancreatic related conditions, including delays in treatment and limited specialty referrals.[10] Shortages of Creon have further exacerbated access gaps, disproportionately affecting those who cannot easily switch products or afford alternatives.[11]

Creon represents a high-cost therapy within an already inequitable health system. While no single pricing metric is universally available, the economic burden of treating chronic conditions like EPI disproportionately falls on public insured or uninsured patients, many of whom are from marginalized communities. This contributes to the larger systemic cost of racial and ethnic health inequities, estimated in the hundreds of billions annually.[12]

Residents prescribed

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

Based on APAC claims, **18,427 Oregonians** filled a prescription for Creon in 2023.[13]

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[9] Barkin, Jodie A. MD∗; Harb, Diala PharmD, PhD†; Kort, Jens MD, PhD†; Barkin, Jamie S. MD, MACG. Real-World Patient Experience With Pancreatic Enzyme Replacement Therapy in the Treatment of Exocrine Pancreatic Insufficiency. Pancreas 53(1):p e16-e21, January 2024. | DOI: 10.1097/MPA.0000000000002273 .

[10] Reddy, K., Patrick, C., Liaquat, H., Rodriquez, E., Stocker, A., Cave, B., Cave, M. C., Smart, L., Cutts, T., & Abell, T. (2018). Differences in Referral Access to Care Between Gastrointestinal Subspecialty Patients: Barriers and Opportunities. *Health equity*, *2*(1), 103–108. https://doi.org/10.1089/heq.2018.0001.

[11] "National Patient Safety Alert: Shortage of Pancreatic enzyme replacement therapy (PERT) – Additional actions." Community Pharmacy England, Dec. 18, 2024. https://cpe.org.uk/our-news/national-patient-safety-alert-shortage-of-pancreatic-enzyme-replacement-therapy-pert-additional-actions/.

[12] Cacari Stone, L., Wallerstein, N., Gonzales, M., Martin, R., Boursaw, B., Kim, E., Simmons, J., & Verney, S. (2025). Evaluating the Translation of Research Evidence Into Practice and Policy for Behavioral Health Equity. Health Education & Behavior, 52(1_suppl), 66S-73S. https://doi.org/10.1177/10901981251346742.

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

Price for the drug

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

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

Price history

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

Table 1 Drug vs therapeutic alternatives and 2018-2024 WAC summary per 30-day supply

Year	Creon	Pancreaze	Pertzye	Viokace	Zenpep
2018	$1,044		$650		
2019	$1,109	$747	$684		
2020	$1,191	$747	$714		
2021	$1,265	$1,179	$739	$1,257	$1,535
2022	$1,344	$1,179	$775	$1,376	$1,596
2023	$1,411	$1,238	$797	$1,507	$1,644
2024	$1,479	$1,299	$797	$1,507	$1,694
Avg. Annual % Change	6.0%	13.1%	3.5%	6.3%	3.3%
% change 2018 between 2024	41.6%		22.8%		

The WAC of Creon, averaged across nine NDCs reported, was approximately **$6.16 per unit** at the end of 2024.[14] Between 2018-2024, the unit WAC increased at an average annual rate of **6.0 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019, 2019-2020, 2020-2021, 2022-2023, and 2023-2024 (see Figures 1 and 2).[15]

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

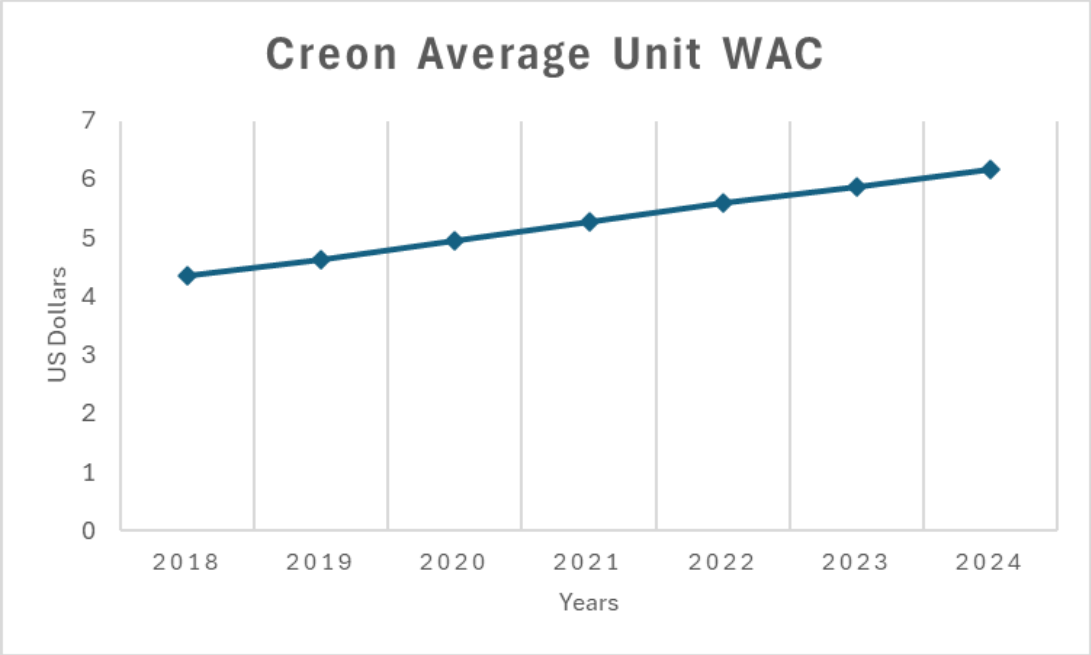


Figure 1 Creon average unit WAC from 2018-2024

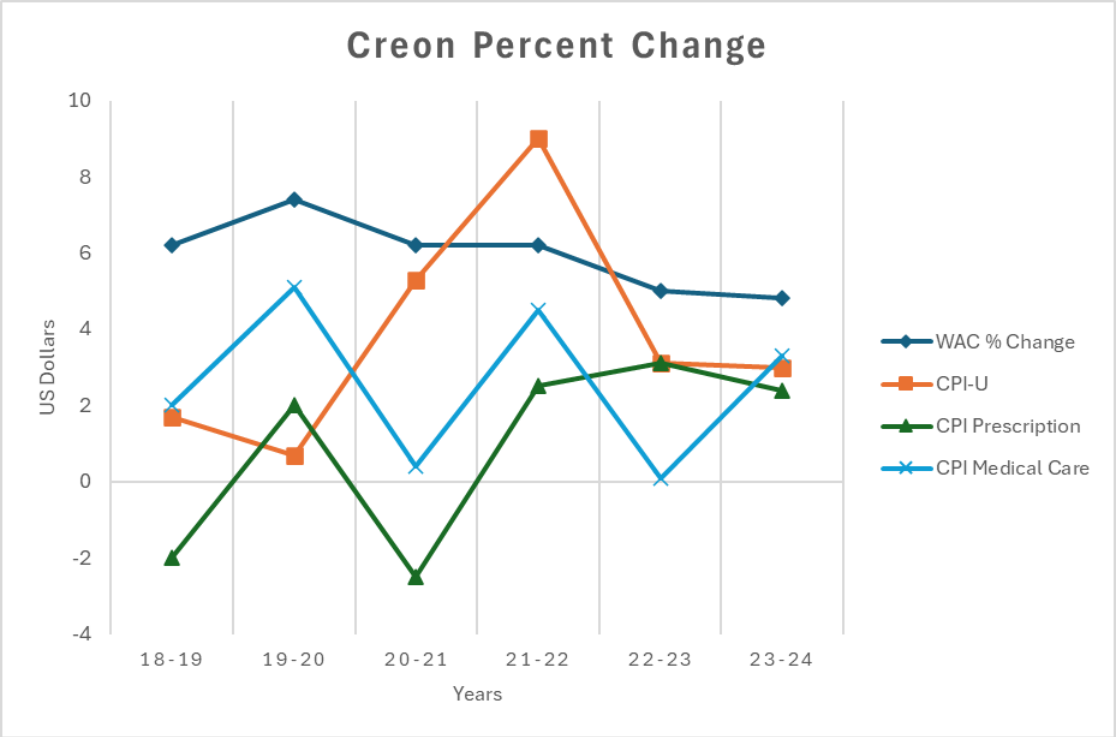


Figure 2 Year over year change in unit WAC compared to inflation rates[16]

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

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$4.84 per unit in Quarter 1 of 2020 to $5.50 per unit in Quarter 4 of 2024**, an approximate **13.6 percent increase** over the period (see Figure 3).[17] Relative to the **$6.16** WAC in end-of-year 2024 an **AAAC discount of 10.7 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 Creon's price trajectory relative to inflation and affordability for public and private payers.

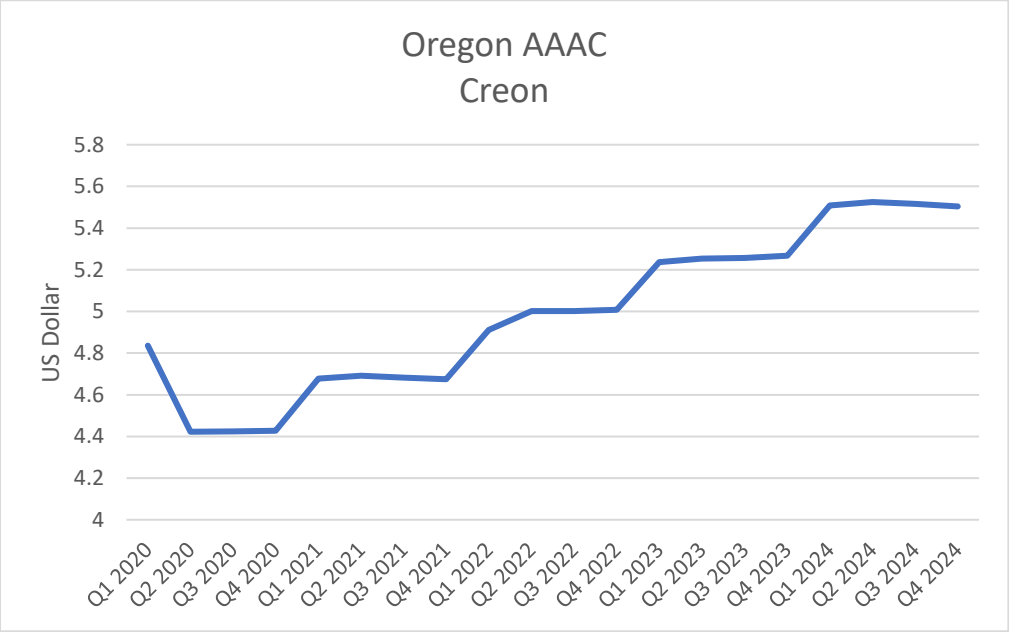


Figure 3 AAAC for Creon from Q1 2020 to Q4 2024

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 Creon 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

[17] 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/.

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 Creon per enrollee in the commercial market was approximately $8,242**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $6,563**, reflecting an **estimated mean discount of 20.4 percent** relative to gross costs.

Across all reporting carriers and market segments, the total cost of Creon before concessions was **$6,131,905**, with total reported price concessions amounting to approximately **$1,248,787**, as detailed in Table 2. Notably, **92.4 percent of claims benefited from some form of price concession**, leaving **7.6 percent at full gross cost**.

Table 2 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	744
Total number of claims	2,293
Total number of claims with price concessions applied	2,119
Percentage of claims with price concessions applied	92.4%
Percentage of cost remaining after concessions	79.6%
Manufacturer price concessions for all market types	$1,098,093
PBM price concessions for all market types	$148,856
Other price reductions for all market types	$1,838
Cost before price concessions across all market types	$6,131,905
Total price concessions across all market types	$1,248,787
Cost of after price concessions across all market types	$4,883,118
Avg. payer spend per enrollee without price concessions	$8,242
Avg. payer spend per enrollee with price concessions	$6,563

Including all market segments, the **gross spend of Creon per claim for commercial carriers was $2,674** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$2,130**, meaning that insurers reported a price concession of **$545** per claim on the initial drug cost as shown in Table 3.

Table 3 The average price concessions across market types

	Average	Individual Market	Large Market	Small Market
Spend per Claim, gross	$2,674	$2,376	$2,698	$2,911
Spend per Claim, net	$2,130	$1,803	$2,202	$2,231
Price Concession per Claim	$545	$573	$495	$680

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

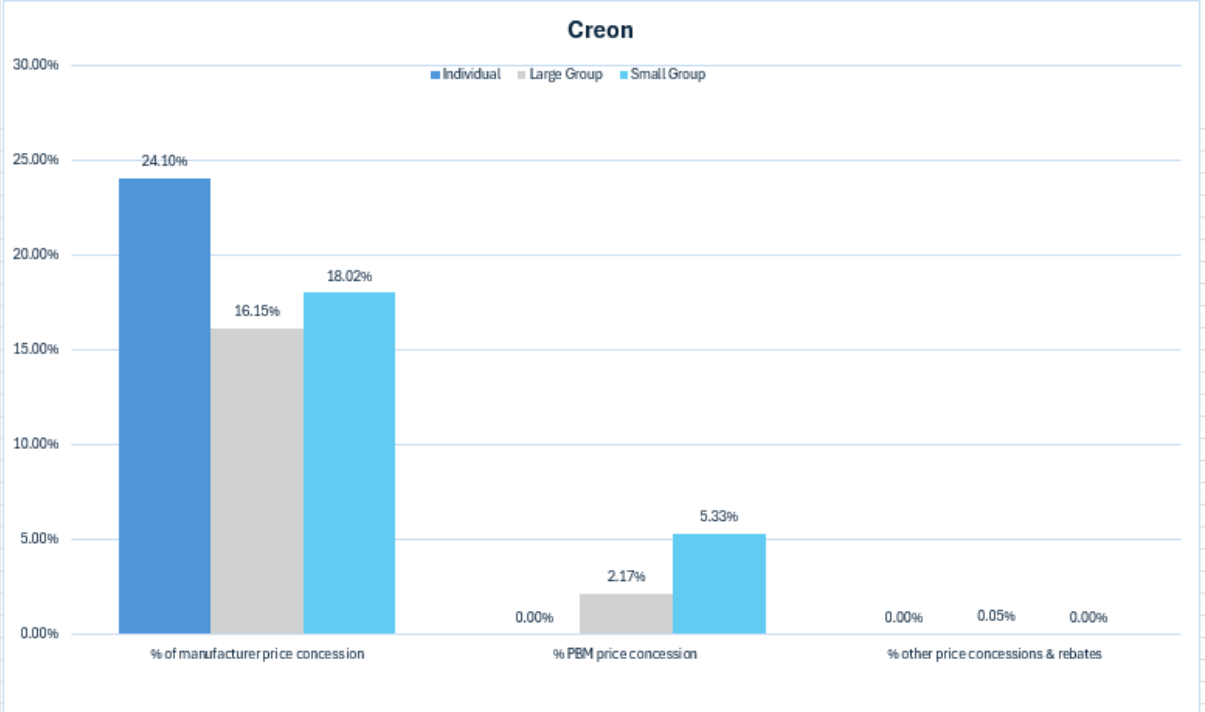


Figure 4 Percent of price concession in each market type[18, 19]

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

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

Estimated total amount of the price concession

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

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

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

Estimated price for therapeutic alternatives[20]

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

This section presents information on the estimated spending associated with Creon 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 submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concessions or rebates.

Creon's **gross total payer paid**, based on APAC data, was **$32.9 million**, while total net payer paid received from the **carriers indicated a cost of $5.7 million. Creon has the highest gross total pay in consideration** with its therapeutic alternatives. The second highest is Zenpep, with $10.5 million. Notably, **Creon has the most utilization** among the drugs, **at 18,427 claims**, as compared to the second highest utilization of Zenpep, at 3,669 claims**.** Zenpep also has a higher payer paid per claim as compared to Creon, $2,863 and $1,784 respectively.

Creon also has th**e highest total enrollee paid at $1.2 million** and Zenpep follows behind with $459 thousand. Zenpep has the highest patient paid per claim of $161. **Creon's patient paid per claim, at $90**, is the lowest, just above Pertzye at $75.

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

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

Table 4 Average healthcare and average patient OOP costs for Creon vs therapeutic alternatives

Drug	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid[21]	Payer paid/ claim	Patient paid/ claim[22]
Subject Drug **Creon** (Data call)	**744**	**2,293**	**$5,707,517**	**$211,955**	**$2,489**	**$92**
Subject Drug **Creon** (APAC)	**3,198**	**18,427**	**$32,874,312**	**$1,218,960**	**$1,784**	**$90**
Pancreaze	82	339	$456,954	$20,387	$1,348	$158
Pertzye	3	21	$25,567	$375	$1,217	$75
Viokace	19	49	$70,729	$4,455	$1,443	$154
Zenpep	718	3,669	$10,504,953	$459,505	$2,863	$161

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 Creon, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

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 Creon 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

[21] The cost includes all lines of business.
[22] Ibid.

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 **18,427 total claims for Creon among 3,198 total enrollees**, corresponding to a **total payer expenditure of $32,874,312**.

Table 5 provides gross cost estimates by the total APAC payer spend across all lines of business:

- **Medicare** accounted for the largest share of utilization, with 8,321 claims from 1,735 enrollees and a total spend of **$13.8 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **$10.5 million** and **$8.6 million**, respectively.

Table 5 Estimated 2023 APAC total gross costs to the payers[23]

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	1,026	5,264	$10,475,268	$10,210	$1,990
Medicaid	873	4,842	$8,550,295	$9,794	$1,766
Medicare	1,735	8,321	$13,848,749	$7,982	$1,664
Totals	**3,198**	**18,427**	**$32,874,312**		

Table 6 provides utilization for the healthcare system for Creon and its therapeutic alternatives, distinguished by lines of business. **Creon has the most utilization** among the drugs, with **18,427 claims**. In all lines of business, Creon is the most utilized. **Zenpep is the second most utilized at 3,669 claims**.

Table 6 Estimated 2023 APAC payer utilization of drug and its therapeutic alternatives[24]

Proprietary Name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total Claims[25]
Creon	5,264	4,842	8,321	18,427
Pancreaze	68	210	61	339
Pertzye	15	6	0	21

[23] 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.
[24] Ibid.
[25] Total is the sum of all utilization for the drug across all lines of business.

Proprietary Name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total Claims[25]
Viokace	9	20	20	49
Zenpep	1,175	815	1,679	3,669

Table 7 shows the overall payer expenditure of Creon and its therapeutic alternatives, distinguished by lines of business. Creon has a **total expenditure of $32.9 million** with **edicare being the biggest portion at $13.8 million**. The therapeutic alternative with the **least expenditure is Pertyze, at $25,567**.

Table 7 Estimated 2023 APAC payer expenditure of drug and its therapeutic alternatives[26]

Proprietary Name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total[27]
Creon	$10,475,268	$8,550,295	$13,848,749	$32,874,312
Pancreaze	$133,486	$260,090	$63,378	$456,954
Pertzye	$22,191	$3,376	$0	$25,567
Viokace	$15,441	$14,565	$40,723	$70,729
Zenpep	$3,571,823	$2,470,824	$4,462,306	$10,504,953

Table 8 compares the overall payer cost per enrollee of Creon and its therapeutic alternatives, distinguished by lines of business. **Creon has the second highest total cost per enrollee at $10,280**. Creon has the **second highest cost per enrollee in Medicare at $7,982**, though the cost per enrollee of the commercial line of business is lower than therapeutic alternatives, Pertyze and Zenpep. **The median cost per enrollee for Creon is $1,292**, which is less than the median cost per enrollee for Pertyze and Zenpep.

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

Table 8 Estimated 2023 APAC payer cost per enrollee of drug and its therapeutic alternatives[28]

Proprietary Name	Commercial Cost/Enrollee	Medicaid Cost/Enrollee	Medicare Cost/ Enrollee	Total Cost per Enrollee	Cost per Enrollee, Median	IQR
Creon	$10,210	$9,794	$7,982	$10,280	$1,292	$2,263
Pancreaze	$7,416	$5,308	$3,961	$5,573	$955	$1,285
Pertzye	$11,096	$1,688	$0	$8,522	$2,368	$1,853
Viokace	$2,573	$2,428	$4,525	$3,723	$577	$1,708
Zenpep	$13,685	$15,158	$12,192	$14,631	$1,934	$3,387

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 (63% of total), followed by small group and individual markets. The collected **total net cost to the healthcare system was around $18.7 million**, with payer paying $16.2 million, and enrollees out-of-pocket estimating to be $2.5 million. Table 9 includes the average plan costs per enrollee in the commercial market, ranging from **$8,558 (small group)** to **$6,600 (individual)** annually.

Table 9 Estimated 2023 data call total net costs to the healthcare system, payers and OOP/enrollee[29]

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	449	148	$1,057,076	$976,811	$80,265
Large Group	1,419	464	$3,688,738	$3,601081	$98,657
Small Group	425	132	$1,162,658	$1,129,625	$33,033
Total	**2,293**	**744**	**$5,919,472**	**$5,7807,517**	**$211,955**

[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.

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	$2,354	$2,176	$179	$7,142	$6,600	$542
Large Group	$2,607	$2,538	$70	$7,974	$7,761	$213
Small Group	$2,736	$2,658	$78	$8,808	$8,558	$250

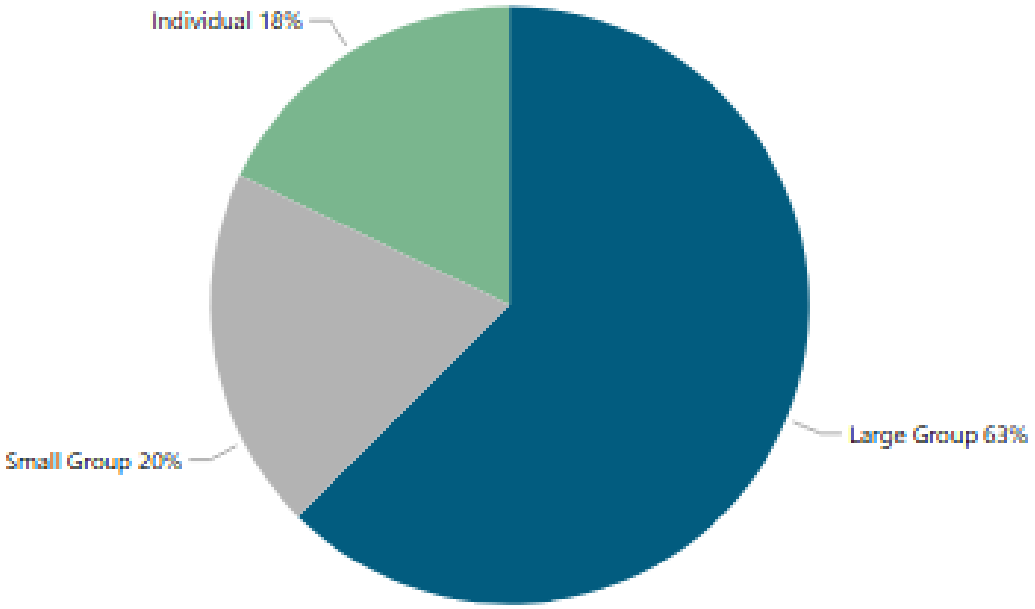


Figure 5 Data call total annual spend (payer paid)

Impact on patient access to the drug

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

Review of rejected claims and drug benefit designs

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

Based on information reported through the carrier data call, the following plan design features were observed for Creon. In 2023, approximately **1.2 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.0 percent of plans required step therapy** before approving its use.

For formulary placement, **0.4 percent of plans categorized Creon as a non-preferred drug** and **no plans excluded it entirely from the formulary**.

Table 10 Plan design analysis from 2023 data call

Percentage of Plans	
Required Prior Authorization	1.2%
Required Step Therapy	0.0%
On a non-preferred formulary	0.4%
Not covered	0.0%

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

Relative financial impacts to health, medical or social services costs

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

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

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

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

Estimated average patient copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Creon in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Tables 11 and 12 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Medicare enrollees recorded higher average annual OOP costs**. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

Table 11 Drug vs. therapeutic alternatives and out-of-pocket cost per enrollee

Proprietary Name	Medicare OOP Cost/Enrollee	Commercial OOP Cost/Enrollee	Total	Median	IQR
Creon	$507	$331	$451	$25	$100
Pancreaze	$870	$359	$600	$80	$250
Pertzye	$0	$188	$188	$38	$38
Viokace	$485	$15	$297	$0	$72
Zenpep	$716	$757	$751	$35	$173

Table 12 Drug vs. therapeutic alternatives and out-of-pocket cost per claim

Proprietary Name	Medicare OOP Cost/Claim	Commercial OOP Cost/Claim	Total	Median	IQR
Creon	$106	$64	$90	$8	$47
Pancreaze	$228	$95	$158	$37	$196
Pertzye	$0	$25	$25	$0	$75
Viokace	$218	$10	$154	$0	$80
Zenpep	$156	$168	$161	$20	$90

Information from manufacturers

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

Drug indications

- FDA Approved:
  - The treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.

- Off Label Uses: None

Clinical efficacy

Pancrelipase (Creon) is a pancreatic enzyme replacement therapy (PERT) consisting of lipase, protease, and amylase. It is indicated for the treatment of exocrine pancreatic insufficiency (EPI) due to conditions such as cystic fibrosis, chronic pancreatitis, pancreatectomy, pancreatic cancer, or other conditions. This is typically lifelong therapy for patients who require pancreatic enzyme replacement.

The clinical efficacy of *pancrelipase* was demonstrated in two pivotal randomized, double-blind, placebo-controlled trials, both of which measured the Coefficient of Fat Absorption (CFA) as the primary efficacy endpoint.

Table 13- Clinical efficacy pancrelipase vs placebo[30]

Study Population	Endpoint	Pancrelipase Result	Placebo Result	Treatment Difference	p-value
Study 1: Adults & children (>7 yrs)	Primary: Coefficient of Fat Absorption (CFA)	88.6%	49.3%	+39.3%	<0.001
	Secondary: Coefficient of Nitrogen Absorption (CNA)	85.1%	58.0%	+27.1%	<0.001
Study 2: Children (7–11 yrs)	Primary: Coefficient of Fat Absorption (CFA)	83.0%	51.7%	+31.3%	<0.001
	Secondary: Coefficient of Nitrogen Absorption (CNA)	81.0%	54.1%	+26.9%	<0.001

Clinical safety

- FDA safety warnings and precautions:

[30] U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.

    - Fibrosing Colonopathy
    - Mucosal irritation
    - Potential for Risk of Hyperuricemia
    - Potential Porcine Viral Exposure from the Product Source
    - Hypersensitivity
- Contraindications:
    - None
- Common side effects:
    - Headache (> 10%)
    - Peripheral edema
    - Hyperglycemia, hypoglycemia
    - Gastrointestinal symptoms (abdominal pain, abnormal stools, constipation, diarrhea, flatulence, gastritis, nausea)
    - Cough, nasopharyngitis

Therapeutic alternatives:[31,32,33,34,35]

Table 14 FDA approved indications

Proprietary	Non-proprietary name	Indications	Available Strengths
Creon	*pancrelipase*	exocrine pancreatic insufficiency.	• 3,000 units lipase, 9,500 units protease, 15,000 units amylase • 6,000 units lipase, 19,000 units protease, 30,000 units amylase • 12,000 units lipase, 38,000 units protease, 60,000 units amylase • 24,000 units lipase, 76,000 units protease, 120,000 units amylase • 36,000 units lipase, 114,000 protease, 180,000 amylase
Pancreaze	*pancrelipase*	exocrine pancreatic insufficiency.	• 2,600 units lipase, 6,200 units protease, 10,850 units amylase

[31] U.S. Food & Drug Administration. *Creon (pancrelipase) Prescribing Information*. Abbvie, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020725s028lbl.pdf.
[32] U.S. Food & Drug Administration. *Pancreaze (pancrelipase) Prescribing Information*. Vivus, Inc., Action yr 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022523s016lbl.pdf.
[33] U.S. Food & Drug Administration. *Pertzye (pancrelipase) Prescribing Information*. Digestive Care, Inc., Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022175s008lbl.pdf.
[34] U.S. Food & Drug Administration. *Viokace (pancrelipase) Prescribing Information*. Viokace, LLC, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022542Orig1s007CorrectedLbl.pdf.
[35] U.S. Food & Drug Administration. *Zenpep (pancrelipase) Prescribing Information*. Zenpep, LLC, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022210Orig1s024_CorrectedLbl.pdf.

Proprietary	Non-proprietary name	Indications	Available Strengths
			• 4,200 units lipase, 14,200 units protease, 24,600 units amylase • 10,500 units lipase, 35,500 units protease, 61,500 units amylase • 16,800 units lipase, 56,800 units protease, 98,400 units amylase • 21,000 units lipase, 54,700 units protease, 83,900 units amylase
Pertzye	*pancrelipase*	exocrine pancreatic insufficiency.	• 4,000 units lipase, 14,375 units protease, 15,125 units amylase • 8,000 units lipase, 28,750 units protease, 30,250 units amylase • 16,000 units lipase, 57,500 units protease, 60,500 units amylase • 24,000 units lipase, 86,250 units protease, 90,750 units amylase
Viokace	*pancrelipase*	exocrine pancreatic insufficiency.	• 10,440 units lipase, 39,150 units protease, 39,150 units amylase • 20,880 units lipase, 78,300 units protease, 78,300 units amylase
Zenpep	*pancrelipase*	exocrine pancreatic insufficiency.	• 3,000 units lipase, 10,000 units protease, 14,000 units amylase • 5,000 units lipase, 17,000 units protease, 24,000 units amylase • 10,000 units lipase, 32,000 units protease, 42,000 units amylase • 15,000 units lipase, 47,000 units protease, 63,000 units amylase • 20,000 units lipase, 63,000 units protease, 84,000 units amylase • 25,000 units lipase, 79,000 units protease, 105,000 units amylase • 40,000 units lipase, 126,000 protease, 168,000 units amylase

Comparative efficacy and safety:

There is no high-quality evidence from randomized controlled trials providing data that one *pancrelipase* product is more effective than another. There is insufficient evidence to determine any differences in efficacy or safety between products. Pancreatic enzyme agents are not automatically interchangeable since enzyme amounts can vary. The most important

factor to consider when treating exocrine pancreatic insufficiency is administering the appropriate amount of lipase units to each individual patient based on diet. The recommended dose is individualized based on clinical symptoms and dietary fat content.

They are all derived from porcine pancreatic glands and have similar safety profiles. Agents that are not enteric coated (e.g. Viokace) need to be given in combination with a proton pump inhibitor. All agents include a warning for the rare but serious complication of fibrosing colonopathy from lipase administration. Selection of a *pancrelipase* product is based on cost, insurance coverage, and formulation characteristics.

Table 15 Efficacy: Treatment vs placebo and percent change for Coefficient of fat absorption (CFA)

Proprietary name	Non-proprietary name	Treatment CFA %	Placebo CFA %	Mean % Change
Creon	*pancrelipase*	89.0	49.0	41.0
Pancreaze	*pancrelipase*	87.0	56.0	37.1
Pertzye	*pancrelipase*	83.8	46.0	32.6
Viokace	*pancrelipase*	86.0	58.0	28.0
Zenpep	*pancrelipase*	88.3	63.0	26.0

Table 16 Efficacy: Treatment vs placebo and percent change for Coefficient of nitrogen absorption (can)

Proprietary name	Non-proprietary name	Treatment CNA %	Placebo CNA %	Mean % Change
Creon	*pancrelipase*	86.0	49.0	37.0
Pertzye	*pancrelipase*	79.0	47.0	32.0

Table 17 Adverse effects comparison

Proprietary name	Non-proprietary name	Type	Clinical Considerations
Creon	*pancrelipase*	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow
Pancreaze	*pancrelipase*	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow
Pertzye	*pancrelipase*	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow
Viokace	*pancrelipase*	Non-enteric coated	Must be used with proton pump inhibitor Tablets must be swallowed whole
Zenpep	*pancrelipase*	Delayed release/enteric coated	Capsules can be opened for patients unable to swallow

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 collected from **nine individuals** taking or having an association with Creon. According to the survey results, 89 percent of respondents had insurance coverage for Creon.

Three patients were on Medicaid, zero patients were on Medicare, and six patients had private health insurance. One patient reported their prescription was not covered, although they were under private health insurance. Three patients reported being on patient assistance programs.

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

"Creon"

- The patient takes Creon, two capsules before every meal or snack, for cystic fibrosis. She has taken it since birth for the past seven years. Creon allows her food to digest so that she can get the nourishment she needs to live and grow. This is the only option that works for her. She is covered by private health insurance. (Submitted by a caregiver.)
- The patient takes Creon 6000, 3 capsules with every meal, 15 capsules per day for cystic fibrosis and has since birth. It allows digestion of food, otherwise it would be impossible to get nutrition. It Is life supporting. The patient has private insurance and Oregon Health Plan/Medicaid as secondary. Medicaid covers the co-pays. (Submitted by a caregiver.)
- The patient took Creon, one capsule right before every meal or snack. He took it for six months and it helped his body absorb fat and nutrition, which helped him start gaining weight. The patient is on Medicaid. (Submitted by a caregiver.)
- The patient took Creon 24,000, five capsules with all meals and snacks, 25/day, for cystic fibrosis, for the past 21 years. The patient's monthly out-of-pocket cost is $120. In cystic fibrosis, the pancreas is no longer able to provide necessary digestive enzymes to the

body. Any time anything is consumed, replacement digestive enzymes are necessary to both digest the food and facilitate nutrient absorption. Without these replacement enzymes, the body would simply waste away, with body systems unable to function leading to extreme weight loss, malnutrition, and death. In the past, the patient tried Pancreaze, Pertzye, and Ultrace, all resulting in inadequate system support and health decline. The patient has private health insurance. It is not on the standard formulary but my employer brokered a separate agreement to have it covered. When I first began with this employer and discovered it was not covered, the patient was required to try the other versions listed above and "fail" on those medications before it would be covered. For the record, "failing" on a digestive enzyme is miserable (think horrible indigestion, gas, bloating, awful loose stool, etc). Creon is the medication that has allowed my child to grow and thrive when the alternatives were causing, not only extreme discomfort and pain, but an actual inability to function in everyday life. It is absolutely an essential part of their every day care. While there are other enzymes on the market, not every one works for every person and it is imperative that there be multiple options for patients of all ages. (Submitted by a caregiver.)

- I just got a letter in the mail this month from Oregon Health Plan/Medicaid telling me that I need to switch to Creon because Pancreaze DR will no longer be covered by my insurance. So I don't yet know what my dosage will be for Creon. I have been diagnosed with pancreatic insufficiency. The medications help make me able to pass stool. Without it, I end up severely constipated and in the emergency room. I was originally prescribed Creon, but the pharmacy said that OHP wouldn't cover it. So, I started taking Pancreaze, which worked fine, but now it is no longer covered and I need to switch to Creon next month because I am told that it is now covered. I wish this was easier! Thank you for your help.
- I take Creon six capsules of 12,000 USP units each with meals (three times per day), with additional capsules with snacks (usually three to four). I take it for cystic fibrosis-related pancreatic insufficiency. I have been taking it for 14 years. Creon assists the digestive system in breaking down nutrients in food when the pancreas is unable to make the chemicals itself. I have private health insurance and have no out-of-pocket costs for Creon. Without the effect of this medication, eating and nutrition are arduous processes, with unnecessary chronic abdominal pain to the point it often interferes with everyday life. Additionally, it is difficult to gain and maintain a healthy body weight, putting a patient at greater risk for long term health issues and susceptibility to complications from minor illnesses.
- I take Creon 2400UNT two to three capsules per day for enzyme deficiency and have been taking it for three years. My recent monthly out-of-pocket cost is $175 with private health insurance. I had to get approval and it took forever. But I can digest food now.
- I take Creon 24,000-unit EC Caps five times per day for pancreatic insufficiency and have been taking it for two years. My recent monthly, out-of-pocket cost was $24 with insurance through the Veteran’s Administration. Creon allows food to be properly digested and nutrients absorbed.

Individuals with scientific or medical training

A survey of healthcare professionals with scientific or medical training identified key barriers for patients accessing medications. There were six healthcare professionals that reported the prior authorization, step therapy, and formulary issues with Creon was an administrative burden and laborious for patients to access the medication, even though it is considered a first line of therapy.

Drug	Prior Authorization	Step Therapy	Quantity Limit	Cost	PBM/ formulary issues	Considered first line of therapy
Creon	Y	Y			Y	Y

Below are selected written responses about Creon from the survey for individuals with scientific or medical training, edited for length and to protect their privacy.

- Usually requires a lengthy and involved prior authorization process despite being the gold standard for CF-related malabsorption for the last 50 years. Many times we have to fight insurance companies for approval of Creon. RN, cystic fibrosis, from OHSU
- Prior authorization is nearly always necessary. While there are different brands which are formulated slightly differently, individuals will tolerate some brands better than others, so it is often necessary to "try and fail" a patient hasn't done well with in order to keep the medication that is known to work. Sometimes recurrent pancreatitis can be treated with this therapy as supplementation of pancreatic enzymes can cause feedback inhibition to reduce pancreatic stimulation and reduce chronic pain associated with pancreatitis, even if there is pancreatic insufficiency. This reduces the need for opiate therapy, missed days of work/school, and greatly improves quality of life. Sometimes the medication has not been approved by insurance leading to missed doses. - Associate Professor of Medicine, Pulmonary Medicine, Cystic Fibrosis, OHSU
- Some patients will have better fat absorption and less G.I. discomfort and bloating on Creon versus the other available alternatives. The other alternatives are typically priced in a similar range and there is no generic available. There are non-FDA approved, herbal formulations that are unregulated, medically not appropriate and contraindicated. One advantage of Creon is that there are many different dosing strengths measured in numbers of international units of lipase per capsule to accommodate all ages, sizes to include newborns all the way up to adults. – Representative of the Cystic Fibrosis Foundation and Inova Fairfax Hospital, Maryland
- Without this drug, CF pancreatic insufficient patients will develop malnutrition. Malnutrition leads to poor lung health, decline in health and earlier death. – MD Pediatrics, Kaiser Permanente
- This drug is first-line therapy for those with Exocrine Pancreatic Insufficiency. It is essential for nutrient absorption to support life. This drug is essential and irreplaceable. - MD, MS; Pediatric Gastroenterologist with a focus in Nutrition, OHSU

Safety net providers

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

A total of **11 safety net clinics** responded to the survey. Among respondents, **10 clinics indicated that Creon was covered as a 340B-eligible prescription** within their programs.

Most clinics (91%) reported operating an internal pharmacy for dispensing 340B-eligible medications, and 64 percent reported using one or more contract pharmacies for this purpose.

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

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

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

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

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

Table 18 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	10
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%

Survey information	Response
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

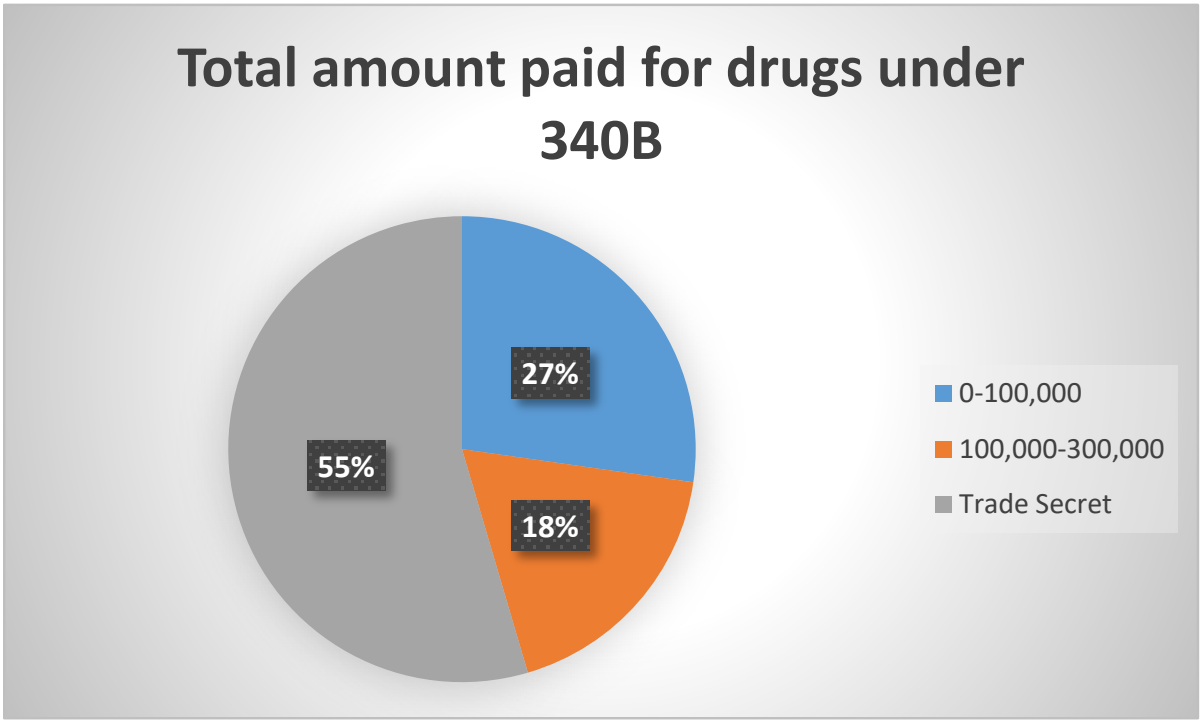
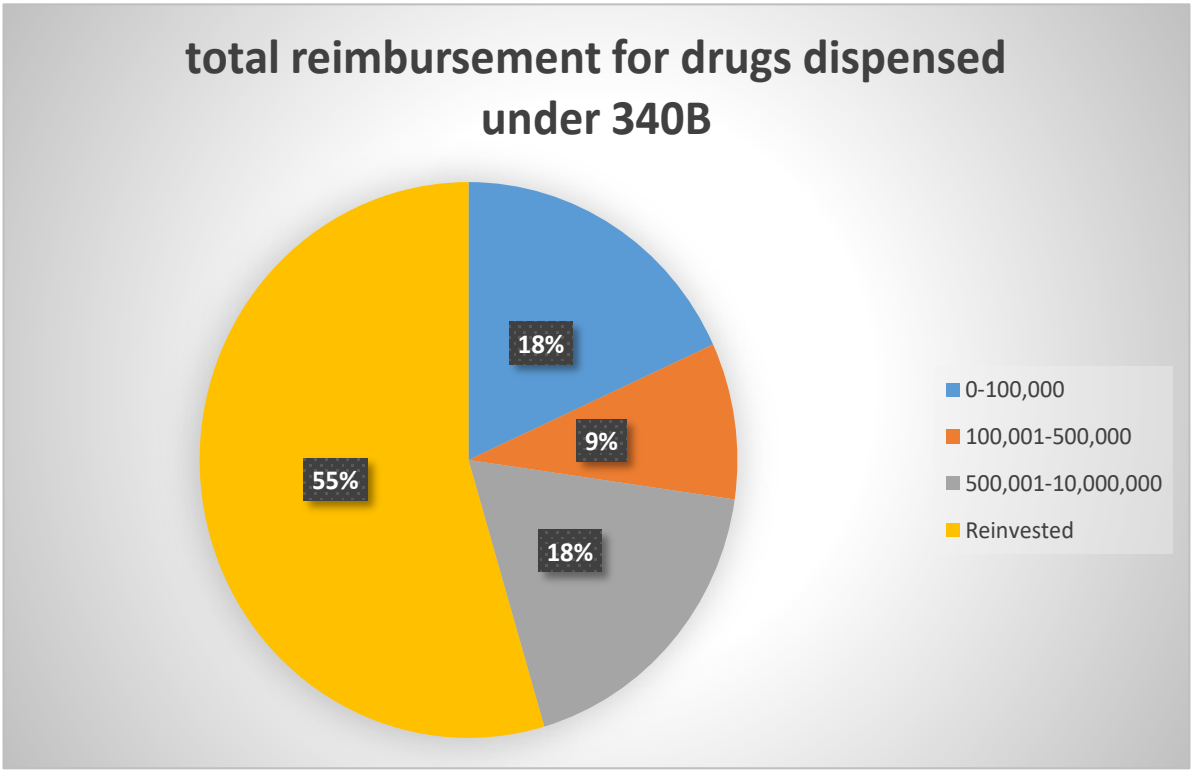


Table 19 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program



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 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
Albert Faro et al	Cystic Fibrosis Foundation	Creon	Letter	5/21/2025	Exhibit A
Lindsay Silva	Mother/primary care giver to someone living with Cystic Fibrosis	Creon	Speaker	5/21/2025	Exhibit B