



# Xarelto<sup>®</sup> (*rivaroxaban*)<sup>1</sup>

Version 2.1



<sup>1</sup> Image source: <https://borderfreehealth.com/shop/xarelto/>

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## Document version history

Version	Date	Description
<b>v1.0</b>	8/13/2025	Original Release
<b>v1.1</b>	8/18/2025	Added new public comment to the appendix table
<b>v1.2</b>	9/24/2025	Updated table numbers and references
<b>v2.0</b>	10/28/2025	30 day supply data added. 75 <sup>th</sup> and 95 <sup>th</sup> percentile data for cost per enrollee, and out of pocket costs added. Formatting changes.
<b>v2.1</b>	12/17/2025	Generic information added. Corrected exclusivity expiration.

## Review summary

Therapeutic alternatives<sup>2,3,4</sup>

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

Proprietary name	Non-proprietary name	Manufacturer	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
<b>Xarelto</b>	<i>rivaroxaban</i>	Jenssen Pharmaceuticals, Inc.	4	2025-2039	2024-2025 <sup>5</sup>	Yes
<b>Eliquis</b>	<i>apixaban</i>	Bristol-Myers Squibb Company	4	2026-2031	2028	Yes
<b>Pradaxa<sup>6</sup></b>	<i>dabigatran etexilate</i>	Boehringer Ingelheim Pharmaceuticals, Inc.	4	2025-2031		No
<b>Savaysa</b>	<i>edoxaban</i>	Daiichi Sankyo, Co., LTD.	2	2027-2028	2026	No

### Price history<sup>7,8</sup>

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:

<sup>2</sup> [Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations](#)

<sup>3</sup> Definitions of patents and exclusivity based on the U.S. Food & Drug Administration. [https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What\\_is\\_the\\_difference\\_between\\_patents\\_a](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a)

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

<sup>5</sup> Generic rivaroxaban at 2.5 mg only was approved by the FDA in March, 2025. U.S. Food & Drug Administration, March 10, 2025. <https://content.govdelivery.com/accounts/USFDA/bulletins/3d62f90> and GoodRx, November 20, 2025. <https://www.goodrx.com/xarelto/how-to-save-while-you-wait-for-xarelto-generic>

<sup>6</sup> No exclusivity information was listed for Pradaxa in the U.S. Food & Drug Administration Orange Book Database

<sup>7</sup> Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

<sup>8</sup> Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

- 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 (AAAC) for **Medicaid also increased by 15.4 percent** over the same period, reflecting broader trends in pricing escalation.

### Price concessions<sup>9</sup>

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**.

### Cost to the payer<sup>10</sup>

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

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

### Cost to enrollees<sup>11</sup>

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

Proprietary name	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
<b>Xarelto</b>	\$570	\$75	\$117	\$45
<b>Eliquis</b>	\$596	\$74	\$116	\$44
<b>Pradaxa</b>	\$91	\$20	\$23	\$20
<b>Savaysa</b>	\$647	\$94	\$140	\$75

<sup>9</sup> 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.

<sup>10</sup> 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>.

<sup>11</sup> Ibid.



# Rubric considerations

Domain	Consideration
<b>Utilization</b>	97,813
<b>Price evaluation</b>	Avg percent change in WAC between 4% to 4.99%, outpaced inflation for four years
<b>Price concessions</b>	25-50% of claims discounted
<b>System &amp; payer costs</b>	Total gross spend >\$50M, total net spend \$3M-\$10M
<b>Enrollee burden</b>	Total APAC OOP \$200-\$700
<b>Equity impact</b>	Yes
<b>Access restrictions</b>	No
<b>Therapeutic alternative fail to reduce system spending</b>	Yes
<b>Stakeholder input identify access or financial hardship?</b>	Yes
<b>Patent expirations more than 18 months from time of review?</b>	Yes
<b>Excluded from CMS Maximum Fair Price List (MFP)</b>	No

## 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<sup>12</sup>

<b>Drug proprietary name</b>	Xarelto®
<b>Non-proprietary name (active ingredient)</b>	<i>rivaroxaban</i>
<b>Manufacturer</b>	Janssen Pharmaceuticals, Inc.
<b>Treatment: Xarelto is a factor Xa inhibitor indicated:</b>	
	<ul style="list-style-type: none"> <li>• to reduce risk of stroke and systemic embolism in nonvalvular atrial fibrillation</li> <li>• for treatment of deep vein thrombosis (DVT)</li> <li>• for treatment of pulmonary embolism (PE)</li> <li>• for reduction in the risk of recurrence of DVT or PE</li> <li>• for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery</li> <li>• for prophylaxis of venous thromboembolism (VTE) in acutely ill medical patients</li> <li>• to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD)</li> <li>• 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</li> <li>• for treatment of VTE and reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years</li> <li>• for thromboprophylaxis in pediatric patients 2 years and older with congenital heart disease after the Fontan procedure.</li> </ul>
<b>Strength</b>	Tablet: 2.5mg; 10mg; 15mg; 20mg
<b>Dosage</b>	<ul style="list-style-type: none"> <li>• <u>Nonvalvular Atrial Fibrillation</u>: 15 or 20 mg once daily</li> <li>• <u>Treatment of DVT and/or PE</u>: 15 mg orally twice daily for the first 21 days followed by 20 mg orally once daily</li> </ul>

<sup>12</sup> 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022406s041lbl.pdf).

	<ul style="list-style-type: none"> <li>• <u>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</u></li> <li>• <u>Prophylaxis of DVT Following Hip or Knee Replacement Surgery: 10 mg once daily</u></li> <li>• <u>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</u></li> <li>• <u>CAD or PAD: 2.5 mg twice daily in combination with aspirin (75-100 mg) once daily</u></li> </ul>
<b>Route</b>	Oral

## FDA approval

Xarelto was first approved by the FDA on July 1, 2011.<sup>13</sup>

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.<sup>14</sup> Underrepresentation of these populations in major clinical trials limits generalizability and reinforces gaps in treatment equity, cost, and access.<sup>15</sup>

Provider bias, insurance formulary barriers, and structural social determinants contribute to these inequities. For instance, apixaban prescriptions are more frequently rejected for

<sup>13</sup> 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.

<sup>14</sup> 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.

<sup>15</sup> 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>.

Medicaid-insured and Black patients than for others, potentially delaying access to care.<sup>16</sup> 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 regional patterns particularly pronounced in the Southeast.<sup>17</sup>

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.<sup>18</sup> 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.<sup>19</sup>

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<sup>16</sup> 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>.

<sup>17</sup> 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>.

<sup>18</sup> 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>.

<sup>19</sup> 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 Xarelto, 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 Xarelto’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 3 30-day supply for Review Drug and its therapeutic alternatives*

	Xarelto	Eliquis	Pradaxa	Savaysa
<b>30-day supply</b>	30 units (30 pills)	60 units (60 pills)	60 units (60 pills)	30 units (30 pills)

*Table 4 Drug vs therapeutic alternatives and 2018-2024 WAC summary per 30-day supply<sup>20</sup>*

	Xarelto	Eliquis	Pradaxa	Savaysa
<b>2018</b>	\$389	\$419	\$401	\$337
<b>2019</b>	\$418	\$444	\$433	\$364
<b>2020</b>	\$439	\$471	\$459	\$389
<b>2021</b>	\$437	\$499	\$477	\$389
<b>2022</b>	\$458	\$529	\$496	\$389
<b>2023</b>	\$481	\$561	\$198	\$397
<b>2024</b>	\$505	\$594	\$159	\$404
<b>Avg. Annual % Change</b>	4.5%	6.0%	-9.6%	3.1%
<b>% change 2018 between 2024</b>	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.<sup>21</sup> Between 2018-2024, the unit WAC increased at an average annual rate

<sup>20</sup> Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

<sup>21</sup> Ibid

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 Table 5 and Figure 2).<sup>22</sup>

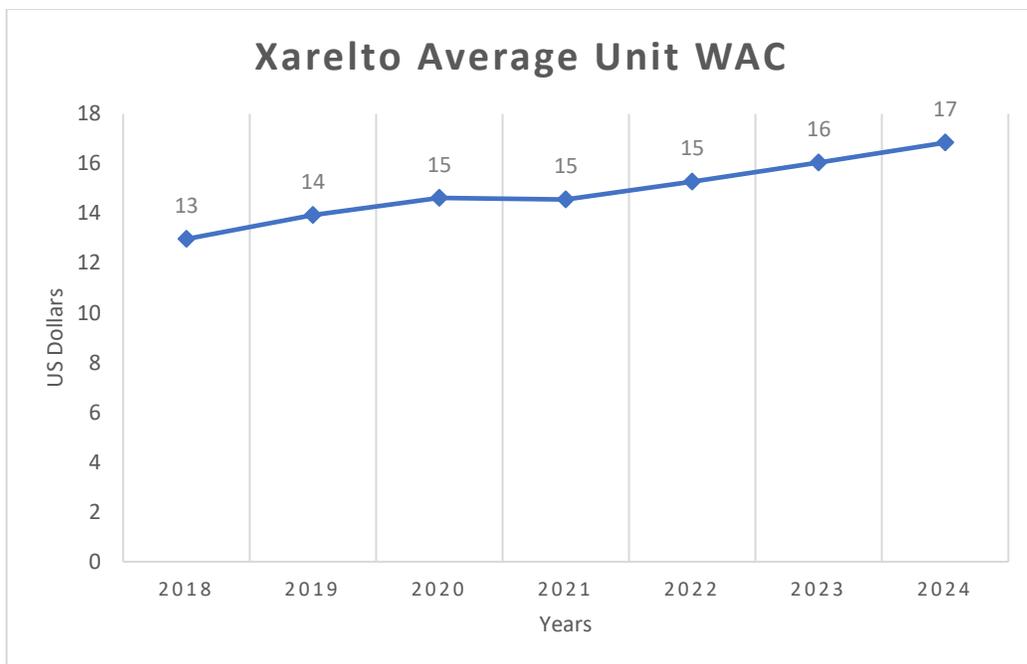


Figure 1 Xarelto average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison<sup>23</sup>

Year	Xarelto	Eliquis	Pradaxa	Savaysa	CPI-U
<b>2018-2019</b>	7.4%	6.0%	8.0%	8.0%	1.7%
<b>2019-2020</b>	4.9%	6.0%	6.0%	7.0%	0.7%
<b>2020-2021</b>	-0.4%	6.0%	4.0%	0.0%	5.3%
<b>2021-2022</b>	4.9%	6.0%	4.0%	0.0%	9.0%
<b>2022-2023</b>	5.0%	6.0%	-60.0%	2.0%	3.1%
<b>2023-2024</b>	5.0%	6.0%	-19.8%	1.7%	3.0%

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

<sup>23</sup> Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

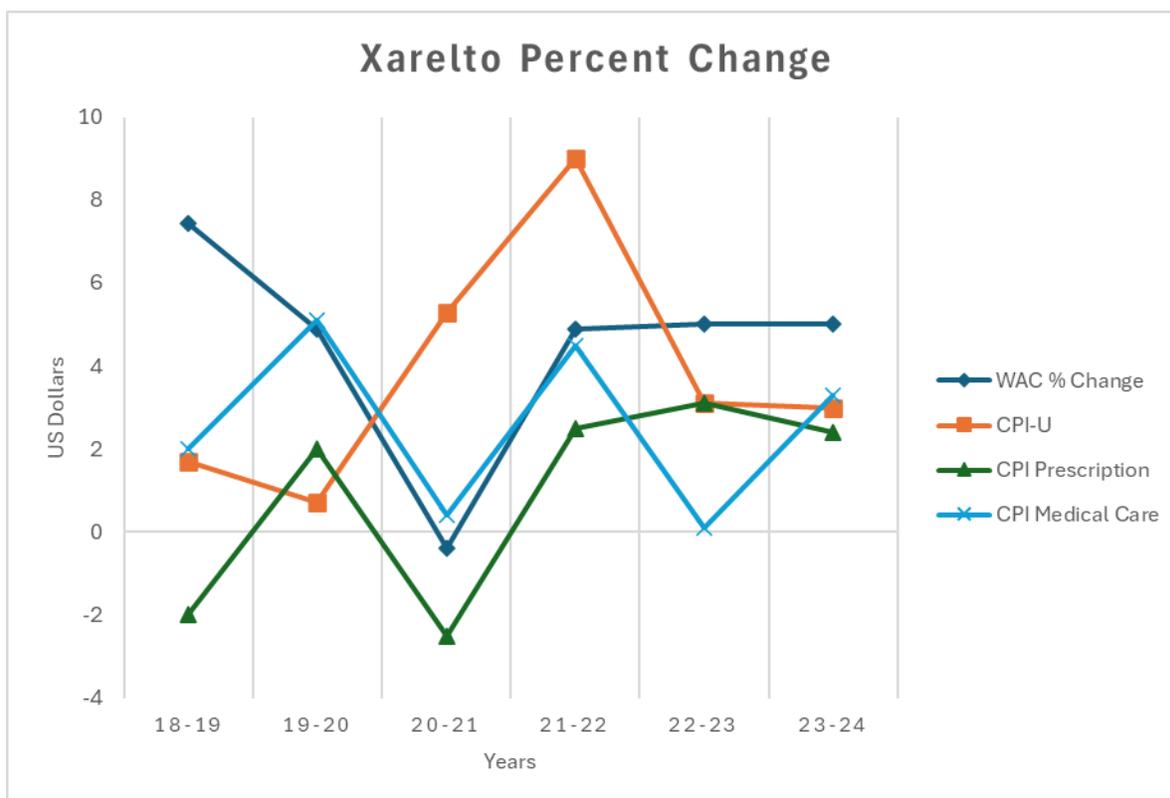


Figure 2 Year over year change in WAC compared to inflation rates<sup>24</sup>

### 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 Table 6).<sup>25</sup> Relative to the **\$16.84 WAC** in end-of-year 2024 an **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.

<sup>24</sup> Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>. \$15

<sup>25</sup> Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2024. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. <https://myersandstauffer.com/client-portal/oregon/>.

Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Average AAAC	Average WAC
2020	\$14	\$14	\$14	\$14	\$14	\$15
2021	\$14	\$14	\$14	\$14	\$14	\$15
2022	\$15	\$15	\$15	\$15	\$15	\$15
2023	\$15	\$16	\$16	\$16	\$16	\$16
2024	\$16	\$16	\$16	\$16	\$16	\$17

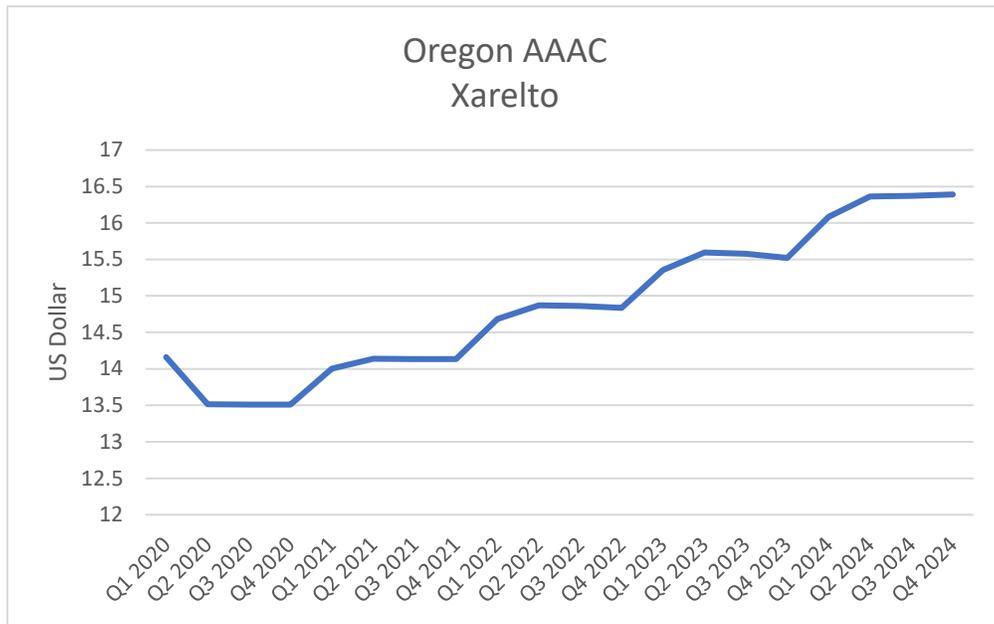


Figure 3 AAAC for Xarelto from Q1 2020 to Q4 2024

## 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 7. Notably, **78.1 percent of claims benefited from some form of price concession**, leaving **21.9 percent at full gross cost**.

*Table 7 Net cost estimate based on carrier submitted 2023 data*

<b>Total number of enrollees</b>	2,994
<b>Total number of claims</b>	9,021
<b>Total number of claims with price concessions applied</b>	7,041
<b>Percentage of claims with price concessions applied</b>	78.1%
<b>Percentage of cost remaining after concessions</b>	70.7%
<b>Percentage of discount</b>	29.3%
<b>Manufacturer price concessions for all market types</b>	\$1,949,542
<b>PBM price concessions for all market types</b>	\$471,494
<b>Other price reductions for all market types</b>	\$2,095
<b>Cost before price concessions across all market types</b>	\$8,275,127
<b>Total price concessions across all market types</b>	\$2,423,131
<b>Cost of after price concessions across all market types</b>	\$5,851,996
<b>Avg. payer spend per enrollee without price concessions</b>	\$2,764
<b>Avg. payer spend per enrollee with price concessions</b>	\$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 8.

Table 8 The average price concessions across market types from Data Call<sup>26</sup>

	Average	Individual market	Large market	Small market
<b>Spend per claim, gross</b>	\$917	\$968	\$881	\$1,010
<b>Spend per claim, net</b>	\$649	\$686	\$623	\$714
<b>Price concession per claim</b>	\$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.

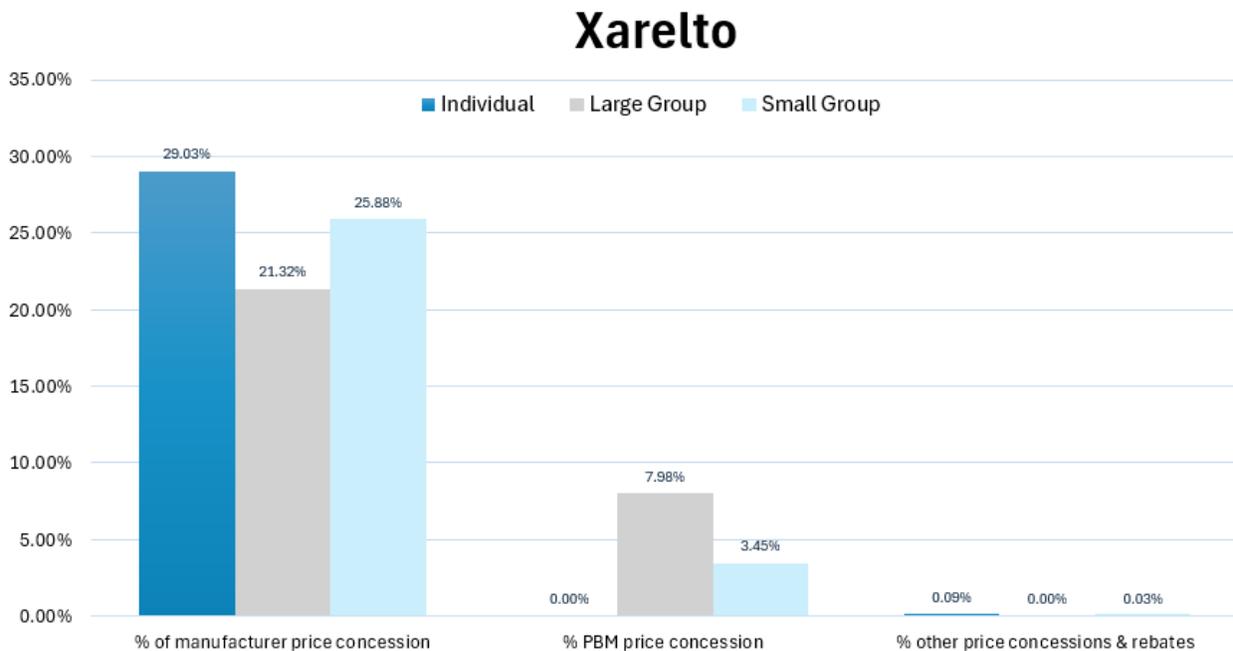


Figure 4 Percent of price concession in each market type<sup>27, 28</sup>

<sup>26</sup> Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon’s commercial insurance carriers.

<sup>27</sup> Price concession refers to any form of discount, directed or indirect subsidy, or rebate received by the carriers or its intermediary contracting organization from any source that serves to decrease the costs incurred under the health plan by the carriers. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on purchase agreement, coupons, free or reduced-price services, and goods in kind. Definition adapted from Code of Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 423, Subpart C. See more at: [CFR-2024-title42-vol3-sec423-100.pdf](https://www.ecfr.gov/current/title-42-chapter-iv-subchapter-b-part-423-subpart-c).

<sup>28</sup> 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 call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through improved reporting or additional disclosures from manufacturers, PBMs, and payers.

## Estimated price for therapeutic alternatives<sup>29</sup>

*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 data call collection for 2023 information. 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.

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<sup>29</sup> Therapeutic alternative to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. [ORS 925-200-0020\(2\)\(c\)](#).

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

*Table 9 Average healthcare and average patient OOP costs vs therapeutic alternatives<sup>30</sup>*

Proprietary name	No. of enrollees <sup>31</sup>	No. of claims	Total payer paid	Total enrollees paid <sup>32</sup>	Payer paid/claim	Patient paid/claim <sup>33</sup>
<i>Subject Drug</i> <b>Xarelto (data call)<sup>34</sup></b>	<b>2,994</b>	<b>9,021</b>	<b>\$7,805,072</b>	<b>\$932,172</b>	<b>\$787</b>	<b>\$103</b>
<i>Subject Drug</i> <b>Xarelto (APAC)</b>	<b>18,565</b>	<b>97,813</b>	<b>\$76,885,552</b>	<b>\$9,619,157</b>	<b>\$781</b>	<b>\$117</b>
<b>Eliquis</b>	51,600	284,854	\$222,494,185	\$28,396,627	\$791	\$116
<b>Pradaxa</b>	5,501	21,487	\$4,620,535	\$478,268	\$215	\$23
<b>Savaysa</b>	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 call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

<sup>30</sup> The therapeutic alternative information is based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>31</sup> The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 9, as compared to other totals indicated in this report.

<sup>32</sup> The cost includes all lines of business.

<sup>33</sup> Ibid.

<sup>34</sup> Information from the data call with the cost information after price concessions.

# Estimated costs to health insurance plans

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

This section quantifies the financial impact of 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 \$76.9 million**.

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

- **Medicare** accounted for the largest share of utilization, with 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 10 Estimated 2023 APAC total annual gross payers’ expenditure for total enrollees and total claims <sup>35</sup>*

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
<b>Commercial</b>	3,712	16,810	\$11,917,196	\$3,210	\$709
<b>Medicaid</b>	2,460	15,836	\$8,131,530	\$3,306	\$513
<b>Medicare</b>	13,508	65,167	\$56,836,825	\$4,208	\$872
<b>Totals<sup>36</sup></b>	<b>18,565</b>	<b>97,813</b>	<b>\$76,885,552</b>		

Table 11 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**.

<sup>35</sup> 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.

<sup>36</sup> The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives<sup>37</sup>

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims <sup>38</sup>
<b>Xarelto</b>	16,810	15,836	65,167	97,813
<b>Eliquis</b>	41,612	39,255	203,987	284,854
<b>Pradaxa</b>	5,971	962	14,554	21,487
<b>Savaysa</b>	25	1	114	140

Table 12 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 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business<sup>39</sup>

Proprietary Name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total <sup>40</sup>
<b>Xarelto</b>	\$11,917,196	\$8,131,530	\$56,836,825	\$76,885,551
<b>Eliquis</b>	\$27,794,424	\$20,708,944	\$173,990,817	\$222,494,185
<b>Pradaxa</b>	\$1,176,190	\$210,748	\$3,233,597	\$4,620,535
<b>Savaysa</b>	\$17,033	\$176	\$70,794	\$88,003

Table 13 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.

<sup>37</sup> 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.

<sup>38</sup> Total is the sum of all utilization for the drug across all lines of business.

<sup>39</sup> 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.

<sup>40</sup> Total is the sum of all expenditure for the drug across all lines of business.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives<sup>41</sup>

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total <sup>42</sup> cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee, 75 <sup>th</sup> percentile	Cost per enrollee, 95 <sup>th</sup> percentile
<b>Xarelto</b>	\$3,210	\$3,306	\$4,208	\$4,141	\$804	\$1,005	\$1,455	\$1,742
<b>Eliquis</b>	\$3,240	\$3,152	\$4,373	\$4,312	\$624	\$1,011	\$1,500	\$1,816
<b>Pradaxa</b>	\$519	\$747	\$808	\$840	\$277	\$202	\$303	\$323
<b>Savaysa</b>	\$2,839	\$176	\$2,950	\$2,839	\$761	\$667	\$1,035	\$1,229

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. 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 14 includes the average plan costs per enrollee in the commercial market ranged from **\$2,455 (small group) to \$2,257 (individual)** annually.

Table 14.a Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee<sup>43</sup>

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

<sup>41</sup> 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.

<sup>42</sup> The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

<sup>43</sup> Cost information from the data call is the cost of the drug after price concessions.

Table 14.b Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee

Market	Avg. plans spend/claim	Avg. payer paid/claim	Avg. enrollee paid/claim	Avg. plans spend/enrollee	Avg. payer paid/enrollee	Avg. OOP/enrollee
Individual	\$966	\$759	\$207	\$2,872	\$2,257	\$615
Large Group	\$863	\$786	\$77	\$2,618	\$2,383	\$234
Small Group	\$922	\$824	\$97	\$2,746	\$2,455	\$290

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.

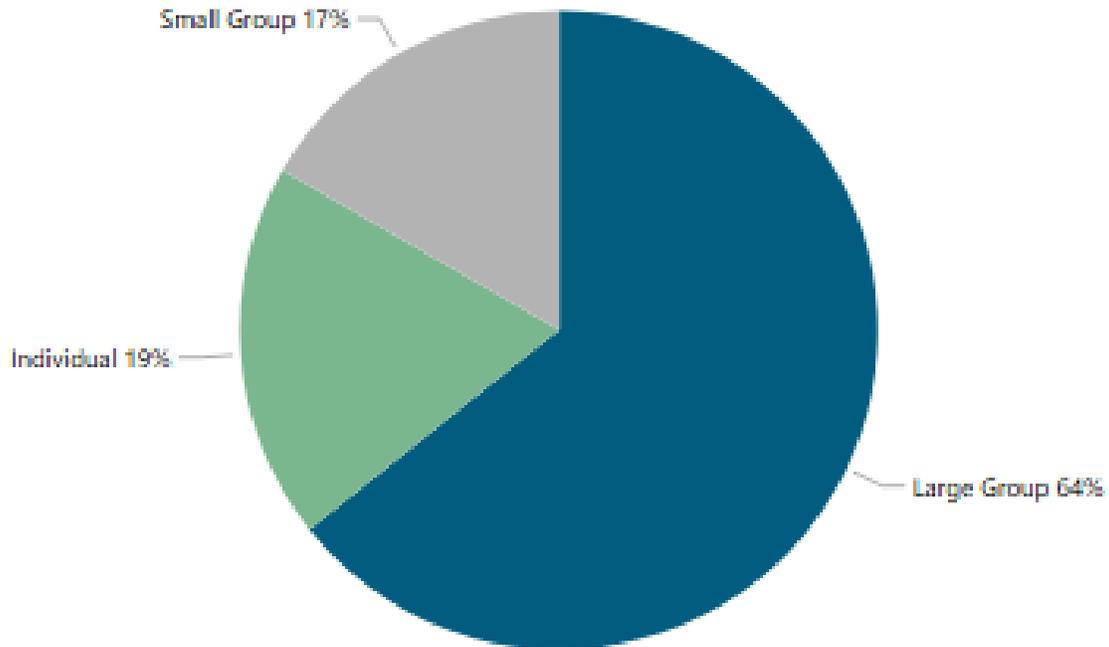


Figure 5 Data call total annual spend (payer paid) by market

# Impact on patient access to the drug

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

## Review of rejected claims and drug benefit designs

This section summarizes information reported by carriers regarding plan design features that relate to coverage of 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 15 Plan design analysis from 2023

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 contemplate 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 enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Xarelto in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).<sup>44</sup> These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 16 and 17 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs 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 16 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee<sup>45</sup>*

Proprietary name	Annual Medicare OOP cost/enrollee	Annual commercial OOP cost/enrollee	Total <sup>46</sup>	Median	IQR	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
<b>Xarelto</b>	\$612	\$365	\$570	\$75	\$252	\$256	\$848
<b>Eliquis</b>	\$633	\$375	\$596	\$74	\$244	\$248	\$979
<b>Pradaxa</b>	\$83	\$64	\$91	\$20	\$15	\$25	\$67
<b>Savaysa</b>	\$626	\$734	\$647	\$94	\$272	\$282	\$823

<sup>44</sup> Gross costs from the APAC database are prior to any price concessions such as discounts or coupons. Net cost information from the data call is the cost of the drug after price concessions.

<sup>45</sup> Based on 2023 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>46</sup> The total is the overall cost per enrollee across commercial insurers and Medicare.

Table 17 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim<sup>47</sup>

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total <sup>48</sup>	Median	IQR	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
<b>Xarelto</b>	\$127	\$81	\$117	\$45	\$136	\$136	\$506
<b>Eliquis</b>	\$123	\$77	\$116	\$44	\$137	\$137	\$483
<b>Pradaxa</b>	\$23	\$24	\$23	\$20	\$10	\$20	\$45
<b>Savaysa</b>	\$132	\$176	\$140	\$75	\$191	\$195	\$529

## Clinical information based on manufacturer material<sup>49</sup>

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.

<sup>47</sup> 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.

<sup>48</sup> The total is the overall cost per claim across commercial insurers and Medicare.

<sup>49</sup> 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022406s041lbl.pdf)

- 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. *Rivaroxaban* 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 18 Summary table: *Rivaroxaban (Xarelto) clinical efficacy trials*

Trial	Indication	Comparator	Outcome	Result	Bleeding
<b>ROCKET AF</b>	NVAF	Warfarin	Stroke and systemic embolism	Non-inferior	No difference in major bleeding, fewer ICH
<b>EINSTEIN-DVT/PE</b>	Acute DVT and PE	Enoxaparin/Warfarin	Recurrent VTE	Non-inferior	Fewer major bleeding events
<b>EINSTEIN-Extension</b>	Extended VTE Prophylaxis	Placebo	Recurrent VTE	Superior	No difference
<b>MAGELLAN</b>	VTE Prophylaxis (Acute III)	Enoxaparin	VTE	Non-inferior	More bleeding events
<b>RECORD 1–4</b>	Post-Op VTE Prophylaxis after TKA and THA	Enoxaparin	VTE	Non-inferior or Superior	No difference
<b>COMPASS*</b>	CAD	Aspirin	Major CV events	Superior	More major bleeding

Trial	Indication	Comparator	Outcome	Result	Bleeding
VOYAGER*	PAD	Aspirin	CV and limb events	Superior	No difference
<b>*rivaroxaban 2.5 mg twice daily in combination with aspirin studied</b>					
<b>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</b>					

## 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<sup>50,51,52,53</sup>

Table 19 FDA approved indications

Drug	Orthopedic VTE prophylaxis	DVT/PE treatment	Stroke prevention in NVAF	VTE prevention in acute medical illness	CAD and PAD
<b>Xarelto (Rivaroxaban)</b>	Yes	Yes	Yes	Yes	Yes
<b>Eliquis (apixaban)</b>	Yes	Yes	Yes	—	—
<b>Pradaxa (dabigatran)</b>	Yes	Yes	Yes	—	—
<b>Savaysa (edoxaban)</b>	—	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 impairment and used cautiously with dose reduction in severe renal impairment. DOACs have

<sup>50</sup> U.S. Food & Drug Administration. *Xarelto (rivaroxaban) Prescribing Information*. Janssen Pharmaceuticals, Inc., Action yr 2022.

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/022406Orig1s039,202439Orig1s038correctedlbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022406Orig1s039,202439Orig1s038correctedlbl.pdf)

<sup>51</sup> 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202155s034lbl.pdf).

<sup>52</sup> 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022512s041lbl.pdf).

<sup>53</sup> 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](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/206316s017lbl.pdf).

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 20 DOAC dosing*

Drug	Route	Strength & dose		
		NVAf	VTE Treatment	VTE Prevention
<b>rivaroxaban (Xarelto)</b>	Oral	20 mg daily	15 mg twice daily x21d then 20 mg daily	10 mg once daily
<b>apixaban (Eliquis)</b>	Oral	5 mg twice daily *	10 mg twice daily x7 days, then 5 mg twice daily	2.5 mg twice daily
<b>dabigatran (Pradaxa)</b>	Oral	150 mg twice daily	150 mg twice daily after ≥ 5 days of parenteral therapy	220 mg once daily
<b>edoxaban (Savaysa)</b>	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 21 Efficacy (clinical trials & practice)

Drug	Efficacy summary
<b>rivaroxaban (Xarelto)</b>	Rocket AF (NVAF): <i>rivaroxaban</i> 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): <i>rivaroxaban</i> was non-inferior to enoxaparin/warfarin for the treatment of DVT and PE, and prevention of recurrent VTE.
<b>apixaban (Eliquis)</b>	Two evaluations, the Aristotle and Averroes studies, demonstrated <i>apixaban</i> significantly reduced the rate of stroke, death, and bleeding compared to warfarin (Aristotle) and Aspirin (Averroes), indicating <i>apixaban</i> is a superior anticoagulant for patients with atrial fibrillation.
<b>dabigatran (Pradaxa)</b>	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.
<b>edoxaban (Savaysa)</b>	Engage AF-TIMI 48 (AF): non-inferior to warfarin for stroke and systemic embolism.  Hokusai-VTE study showed <i>edoxaban</i> non-inferior to warfarin and reduced bleeding with 30 mg does

Table 22 Safety and Therapeutic Considerations of DOACs

Drug	Safety considerations	Therapeutic considerations
<b>rivaroxaban (Xarelto)</b>	<ul style="list-style-type: none"> <li>• Avoid for VTE if CrCl &lt; 15 ml/min</li> <li>• Avoid with strong inducers and inhibitors of both P-gp and CYP3A4</li> </ul>	<ul style="list-style-type: none"> <li>• Short half-life of 5-9 hours</li> <li>• Administer doses &gt; 10 mg with food</li> <li>• Only DOAC approved for CV Risk reduction in CAD/PAD (with aspirin)</li> </ul>
<b>apixaban (Eliquis)</b>	<ul style="list-style-type: none"> <li>• Lowest risk of major and GI bleeding</li> <li>• Avoid with strong inducers of both P-gp and CYP3A4</li> </ul>	<ul style="list-style-type: none"> <li>• Preferred DOAC in renal impairment</li> <li>• Preferred DOAC if other risk factors for GI bleed present</li> <li>• Requires twice daily dosing</li> </ul>
<b>dabigatran (Pradaxa)</b>	<ul style="list-style-type: none"> <li>• GI symptoms (dyspepsia) and gastritis-like symptoms (10%)</li> <li>• Caution if 75 years or older, poor kidney function, or underweight</li> <li>• Avoid if CrCl &lt; 15 ml/min and &lt; 30 ml/min for VTE</li> </ul>	<ul style="list-style-type: none"> <li>• More renally cleared</li> <li>• Dispense in original package and use within 4 months of opening</li> <li>• Requires twice daily dosing</li> </ul>

Drug	Safety considerations	Therapeutic considerations
<b>edoxaban (Savaysa)</b>	<ul style="list-style-type: none"> <li>• anemia, rash, abnormal liver function tests</li> <li>• Not recommended if CrCl &lt; 15 ml/min</li> <li>• Avoid if CrCl &gt; 95 ml/min</li> </ul>	<ul style="list-style-type: none"> <li>• Not approved for VTE prophylaxis</li> </ul>
Abbreviations: CAD: coronary artery disease; CrCl: creatinine clearance; DOAC: direct oral anticoagulants; GI: gastrointestinal; PAD: peripheral artery disease; 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 23 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%

## Total amount paid for drugs under 340B

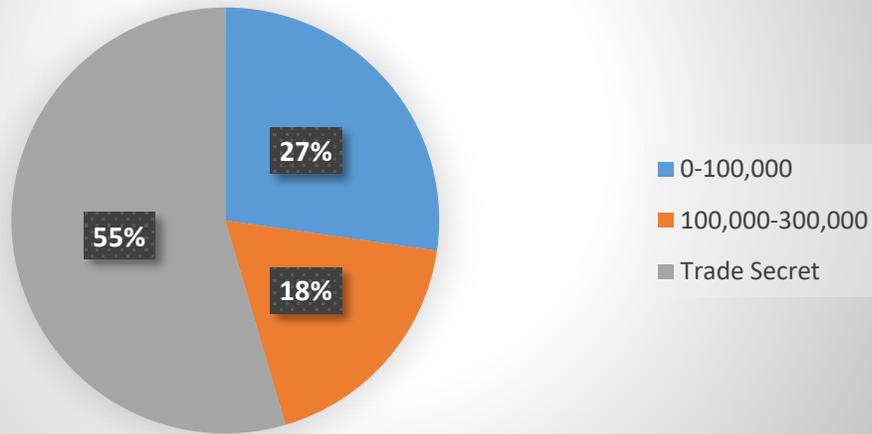


Figure 6 Amounts paid for drug under 340B discount program

## Total reimbursement for drugs dispensed under 340B

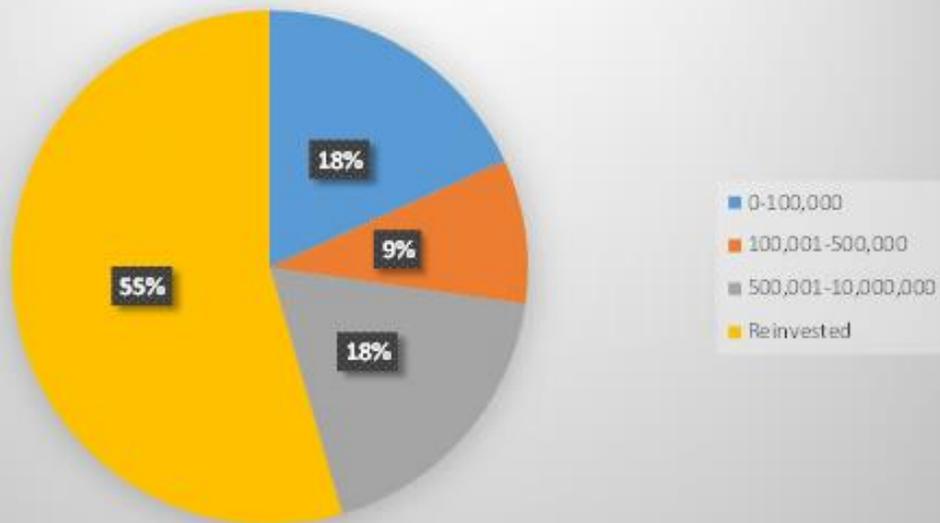


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

## Payers

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

The data provided through the carrier data call serves as a comprehensive source of payer input and reflects 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	<a href="#">Exhibit A</a>
Silas Martin	Johnson and Johnson	Xarelto	Speaker	5/21/25	<a href="#">Exhibit B</a>
Michael Valenta	Johnson and Johnson	Xarelto	Letters	3/30/25 6/18/25 8/14/25	<a href="#">Exhibit C</a> <a href="#">Exhibit D</a> <a href="#">Exhibit E</a>
Sue Koob	Preventive Cardiovascular Nurses Association	Xarelto	Letter	7/14/25	<a href="#">Exhibit F</a>
Lisa Pulver	Johnson and Johnson	Xarelto	Speaker	8/20/25	<a href="#">Exhibit G</a>