



# Ajovy<sup>®</sup> (*Fremanezumab-vfrm*)<sup>1</sup>

Version 4.0



<sup>1</sup> <https://www.nsmedicaldevices.com/company-news/teva-canada-ajovy-subcutaneous-injection/>

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## Document version history

Version	Date	Description
v1.0	7/9/2025	Original Release
v2.0	7/11/2025	Updated gross spend amounts in the “Cost to the healthcare system” section; added a “Cost to payers” section; updated table 3 to reflect costs to the healthcare system; added table 4 for payer paid amounts; updated sections referencing patients to reference enrollees; added the drug name to the footer; Table 2 removed Total for paid/enrollee & claims and indicated the number as an average; separated rapid and long acting molecule drugs in the clinical review section for consistence with other drug review packets.
v2.1	7/17/2025	Added to the appendix table the public comment from the 7/16/2025 board meeting.
v3.0	9/3/2025	New tables added, table numbers updated, formatting changes
v4.0	10/21/2025	WAC data and 30 day supply data updated. New patent and exclusivity data added. Formatting changes.

## Review summary

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

**Ajovy (fremanezumab-vfrm)** has the following therapeutic alternatives: **Aimovig, Emgality, Nurtec ODT, Qulipta, and Vyepti.**

Proprietary name	Non-proprietary name	Manufacturer	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
<b>Ajovy</b> <sup>5</sup>	<i>fremanezumab-vfrm</i>	Teva Pharmaceuticals				No
<b>Aimovig</b> <sup>6</sup>	<i>erenumab-aooe</i>	Amgen Inc.				No
<b>Emgality</b> <sup>7</sup>	<i>Galcanazumab-gnlm</i>	Eli Lilly and Co.				No
<b>Nurtec ODT</b>	<i>rimegepant</i>	Pfizer Inc	3	2030-2039	2025	No
<b>Qulipta</b>	<i>atogepant</i>	Abbie Inc.	6	2031-2043	2026	No
<b>Vyepti</b> <sup>8</sup>	<i>eptinezumab</i>	Lundbeck Seattle BioPharmaceuticals, Inc.				No

<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%20is%20the%20difference%20between%20patents%20a)

<sup>4</sup> Selected drugs and negotiated prices. Centers for Medicare & Medicaid Services, May 23, 2025.

[https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices.](https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices)

<sup>5</sup> No patent or exclusivity information was listed for Ajovy in the U.S. Food & Drug Administration PurpleBook Database.

<sup>6</sup> No patent or exclusivity information was listed for Aimovig in the U.S. Food & Drug Administration PurpleBook Database.

<sup>7</sup> No patent or exclusivity information was listed for Emgality in the U.S. Food & Drug Administration PurpleBook Database.

<sup>8</sup> No patent or exclusivity information was listed for Vyepti in the U.S. Food & Drug Administration PurpleBook Database.

## Price history<sup>9,10</sup>

**Ajovy (fremanezumab-vfrm)** rose at an **average annual rate of 4.1 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
  - Aimovig: 4.6 percent
  - Emgality: 2.8 percent
  - Nurtec ODT: 4.1 percent
  - Qulipta: 3.3 percent
  - Vyepiti: 5.2 percent

Additionally, the average annual rate of Ajovy exceeded inflation in **2020, 2023, and 2024**. Pharmacy acquisition costs (AAAC) for **Medicaid also increased by 23.6 percent** over the same period, reflecting broader trends in pricing escalation.

## Price concessions<sup>11</sup>

Based on data received from commercial healthcare carriers, in 2023 Ajovy had a **gross spend of \$751 per claim**, while the **spend net of discount was \$535 per claim**. Price concession per claim was reported to be **\$216**.

## Cost to the payers<sup>12</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>Ajovy</b>	\$6,566,875	10,307	\$4,097	\$639
<b>Aimovig</b>	\$10,990,158	15,271	\$5,893	\$710
<b>Emgality</b>	\$9,896,376	15,130	\$5,085	\$642
<b>Nurtec ODT</b>	\$13,227,665	12,335	\$5,338	\$913
<b>Qulipta</b>	\$3,012,966	3,037	\$5,013	\$985
<b>Vyepiti</b>	\$5,175	4	\$1,725	\$1,588

<sup>9</sup> Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

<sup>10</sup> Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

<sup>11</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>12</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>.

## Cost to enrollees<sup>13</sup>

Table 2 2023 gross APAC 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>Ajovy</b>	\$680	\$30	\$112	\$28
<b>Aimovig</b>	\$587	\$30	\$80	\$20
<b>Emgality</b>	\$916	\$40	\$123	\$37
<b>Nurtec ODT</b>	\$695	\$35	\$146	\$30
<b>Qulipta</b>	\$732	\$40	\$146	\$30
<b>Vyepti</b>	\$0	\$0	\$0	\$0

## Rubric considerations

Domain	Consideration
<b>Utilization</b>	10,000 to \$24,999 patients on drug reported in APAC
<b>Price evaluation</b>	Avg change in WAC between 4-4.99% for five years, outpaces inflation for 3 years
<b>Price concessions</b>	25-50% claims discounted
<b>System &amp; payer costs</b>	Total gross spend < \$10M, total net spend \$3M-\$10M
<b>Enrollee burden</b>	Total APAC OOP annual cost \$200-\$700
<b>Equity impact</b>	Yes
<b>Access restrictions</b>	Yes
<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>	Yes

<sup>13</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>.

## Review background

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

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

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

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

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

## Drug information<sup>14</sup>

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

### FDA approval

Ajovy was first approved by the FDA on Sept. 14, 2018.<sup>15</sup>

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

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

## Health inequities

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

Clinical trials for migraine medications—including **Emgality (fremanezumab)**, **Emgality (galcanezumab)**, **Nurtec ODT (rimegepant)**, and **Ubrelvy (ubrogepant)**—have historically underrepresented racial and ethnic minority groups. A review of migraine clinical trials published in *Headache* found that **less than 15 percent** of participants across studies identified as non-white, with **Black Americans comprising less than 2 percent** of study cohorts in many trials—despite experiencing migraine at similar or greater rates than white populations.<sup>16</sup> This lack of diversity limits the generalizability of trial findings and raises concerns about whether these medications perform equally well across all demographic groups.

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

<sup>14</sup> U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Revised 2021. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761089s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf).

<sup>15</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>16</sup> Robbins NM, Bernat JL. “Minority Representation in Migraine Treatment Trials.” *Headache*. 2017;57(3):525-533. PMID: 28127754.

Hispanic patients.<sup>172</sup> In contrast, the FDA's *Drug Trials Snapshot* for **Nurtec ODT** provides limited but promising subgroup data: pain relief rates were found to be **comparable across racial groups**, with **23.3 percent of Black participants and 21.2 percent of white participants** achieving pain freedom at 2 hours.<sup>18</sup> However, without consistent subgroup analysis across all CGRP-targeting therapies, disparities in both trial design and real-world access remain.

**Real-world evidence** shows that **Black and Hispanic individuals are less likely to be diagnosed with migraine or prescribed advanced treatments**, even when accounting for socioeconomic status.<sup>19</sup> This reflects broader systemic inequities in pain recognition, access to specialists, and treatment authorization. Compounding these disparities are **structural barriers** such as geographic isolation, lower health literacy, and provider bias<sup>20</sup>—all of which influence medication adherence, proper use of self-injection therapies, and management of side effects.

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

## Residents prescribed

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

Based on APAC claims, **10,307** Oregonians filled a prescription for Ajovy in 2023.<sup>21</sup>

## Price for the drug

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

This section examines the pricing dynamics of Ajovy, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the 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 Ajovy's list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

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<sup>17</sup> Institute for Clinical and Economic Review (ICER). "Acute Migraine Treatments – Final Evidence Report." January 2020. [https://icer.org/wp-content/uploads/2020/10/ICER\\_Acute-Migraine\\_Evidence\\_Report\\_011020\\_updated\\_011320\\_-2.pdf](https://icer.org/wp-content/uploads/2020/10/ICER_Acute-Migraine_Evidence_Report_011020_updated_011320_-2.pdf).

<sup>18</sup> FDA. "Drug Trials Snapshot: Nurtec ODT." <https://www.fda.gov/drugs/development-approval-process-drugs/drug-trials-snapshots-nurtec-odt>.

<sup>19</sup> Burch R et al. "The Prevalence and Burden of Migraine Across the U.S. Population." *Headache*. 2021. [PMID: 34108270](https://pubmed.ncbi.nlm.nih.gov/34108270/).

<sup>20</sup> Williams DR, Mohammed SA. "Discrimination and Racial Disparities in Health: Evidence and Needed Research." *J Behav Med*. 2009;32(1):20–47. [PMC2443411](https://pubmed.ncbi.nlm.nih.gov/192443411/).

<sup>21</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 history

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

*Table 3 30-day supply for review drug and its therapeutic alternatives*

	Ajovy	Aimovig	Emgality	Nurtec ODT	Qulipta	Vyepti <sup>22</sup>
<b>30-day supply</b>	1 package (1 auto injector or 1 syringe of 1.5ml)	1 unit (1 auto injector or 1 syringe of 1ml)	1 unit (1 pen or 1 syringe of 1ml)	15 units (15 pills)	30 units (30 pills)	0.3 package (0.3 ml of intravenous infusion)

*Table 4 Drug vs. therapeutic alternatives for 2018-2024 WAC per 30-day supply<sup>23</sup>*

Year	Ajovy	Aimovig	Emgality	Nurtec ODT	Qulipta	Vyepti
<b>2018</b>	\$575	\$575	\$575			
<b>2019</b>	\$575	\$575	\$551			
<b>2020</b>	\$603	\$603	\$578	\$1,594		\$493
<b>2021</b>	\$633	\$639	\$601	\$1,673	\$991	\$506
<b>2022</b>	\$665	\$697	\$626	\$1,724	\$991	\$531
<b>2023</b>	\$698	\$738	\$651	\$1,784	\$1,041	\$564
<b>2024</b>	\$733	\$753	\$677	\$1,873	\$1,093	\$603
<b>Avg. Annual % Change</b>	4.1%	4.6%	2.8%	4.1%	3.3%	5.2%
<b>% change 2018 and 2024</b>	27.5%	31.0%	17.7%			

The WAC of Ajovy, averaged across three NDCs reported, was approximately **\$489 per unit** at the end of 2024.<sup>24</sup> Between 2018-2024, the unit WAC increased at an average annual rate of **4.1 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2019–2020, 2022–2023, and 2023–2024 (see Table 5 and Figure 2).<sup>25</sup>

<sup>22</sup> Treatment of Vyepti consists of 1ml of infusion every 90 days.

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

<sup>24</sup> Ibid.

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

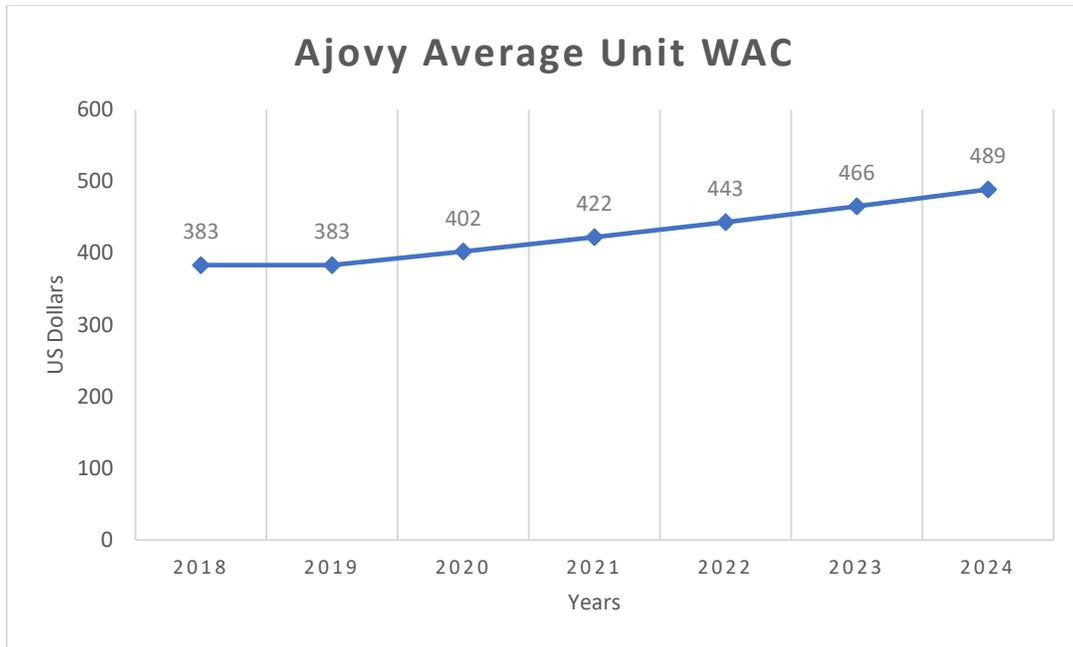


Figure 1 Ajoy average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison<sup>26</sup>

Year	Ajoy	Aimovig	Emgality	Nurtec ODT	Qulipta	Vyepti	CPI-U
<b>2018-2019</b>	0.0%	-33.3%	-4.2%				1.7%
<b>2019-2020</b>	4.9%	4.9%	5.0%			2.5%	0.7%
<b>2020-2021</b>	5.0%	5.9%	4.0%	5.0%		5.1%	5.3%
<b>2021-2022</b>	5.0%	9.1%	4.0%	3.0%	0.0%	6.1%	9.0%
<b>2022-2023</b>	5.0%	5.9%	4.0%	3.5%	5.0%	7.0%	3.1%
<b>2023-2024</b>	5.0%	2.0%	4.0%	5.0%	5.0%	5.2%	3.0%

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

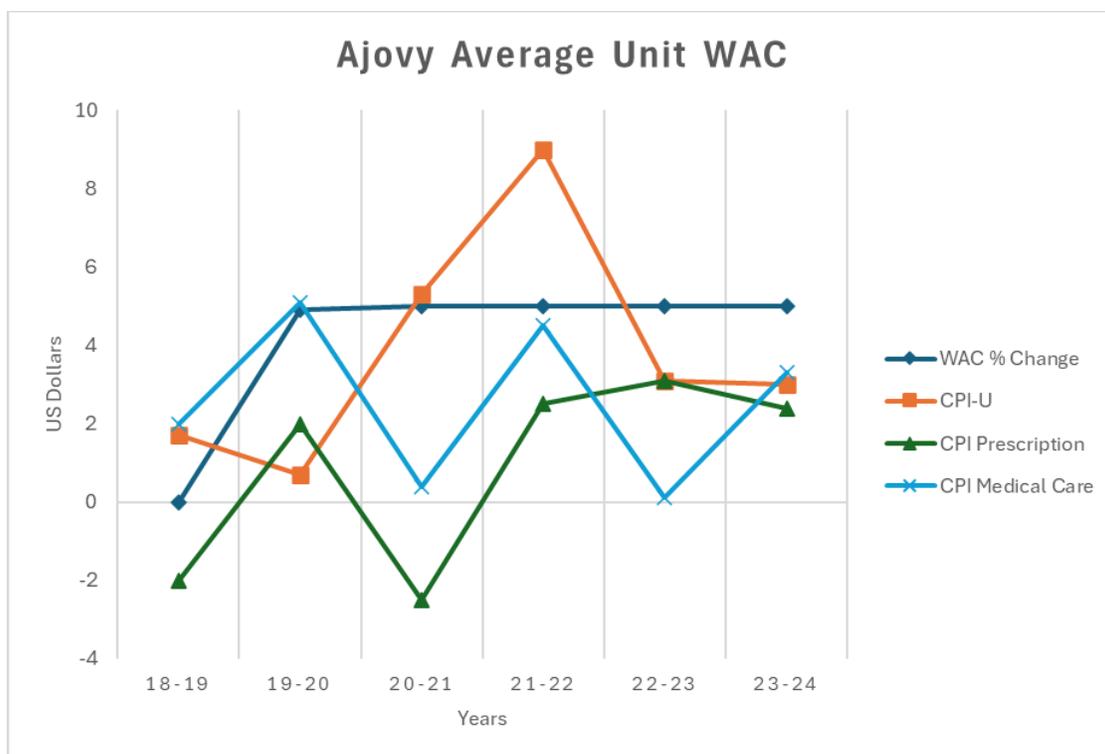


Figure 2 Year over year change in unit WAC compared to inflation rates<sup>27</sup>

### Pharmacy acquisition costs

The AAAC, which reflects pharmacies’ actual purchase prices for Medicaid fee-for-service claims, rose from **\$381 per unit in Q1 2020 to \$471 per unit in Q4 2024, an increase of 23.6 percent** over the period (see Table 6).<sup>28</sup> Relative to the **\$489 WAC in end-of-year 2024 a AAAC discount of 0.7 percent** is indicated.

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

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

<sup>28</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	\$381	\$387	\$387	\$388	\$386	\$402
2021	\$407	\$408	\$409	\$410	\$409	\$422
2022	\$429	\$430	\$429	\$428	\$429	\$443
2023	\$448	\$449	\$450	\$451	\$449	\$466
2024	\$472	\$471	\$471	\$471	\$471	\$489

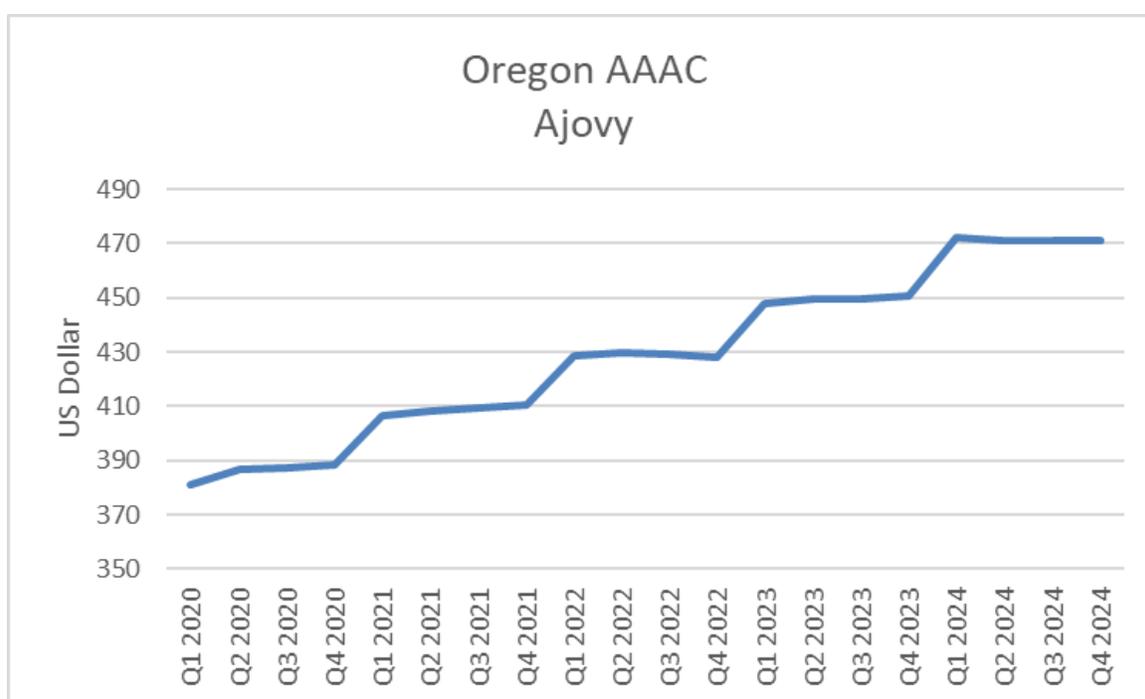


Figure 3 AAAC for Ajovy from Q1 2020 to Q4 2024

## Estimated average monetary price concession

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

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

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

Across all reporting carriers and market segments, the **total cost of Ajoy before concessions was \$3,987,390**, with total reported **price concessions amounting to approximately \$1,147,200**, as detailed in Table 7. Notably, **42.5 percent of claims benefited from some form of price concession**, leaving **57.5 percent at full gross cost**.

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

Total number of enrollees	1,057
Total number of claims	5,312
Total number of claims with price concessions applied	2,259
Percentage of claims with price concessions applied	42.5%
Percentage of cost remaining after concessions	71.2%
Percentage of discount	28.8%
Manufacturer price concessions for all market types	\$1,038,911
PBM price concessions for all market types	\$99,504
Other price reductions for all market types	\$8,786
Cost before price concessions across all market types	\$3,987,390
Total price concessions across all market types	\$1,147,200
Cost of after price concessions across all market types	\$2,840,190
Avg. payer spend per enrollee without price concessions	\$3,772
Avg. payer spend per enrollee with price concessions	\$2,687

Including all market segments, the **gross spend of Ajoy per claim for commercial carriers was \$751** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$535**, meaning that insurers reported a price concession of **\$216** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types provided from data call<sup>29</sup>

	Average	Individual market	Large market	Small market
<b>Spend per claim, gross</b>	\$751	\$807	\$748	\$682
<b>Spend per claim, net</b>	\$535	\$520	\$541	\$515
<b>Price concessions per claim</b>	\$216	\$287	\$208	\$167

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

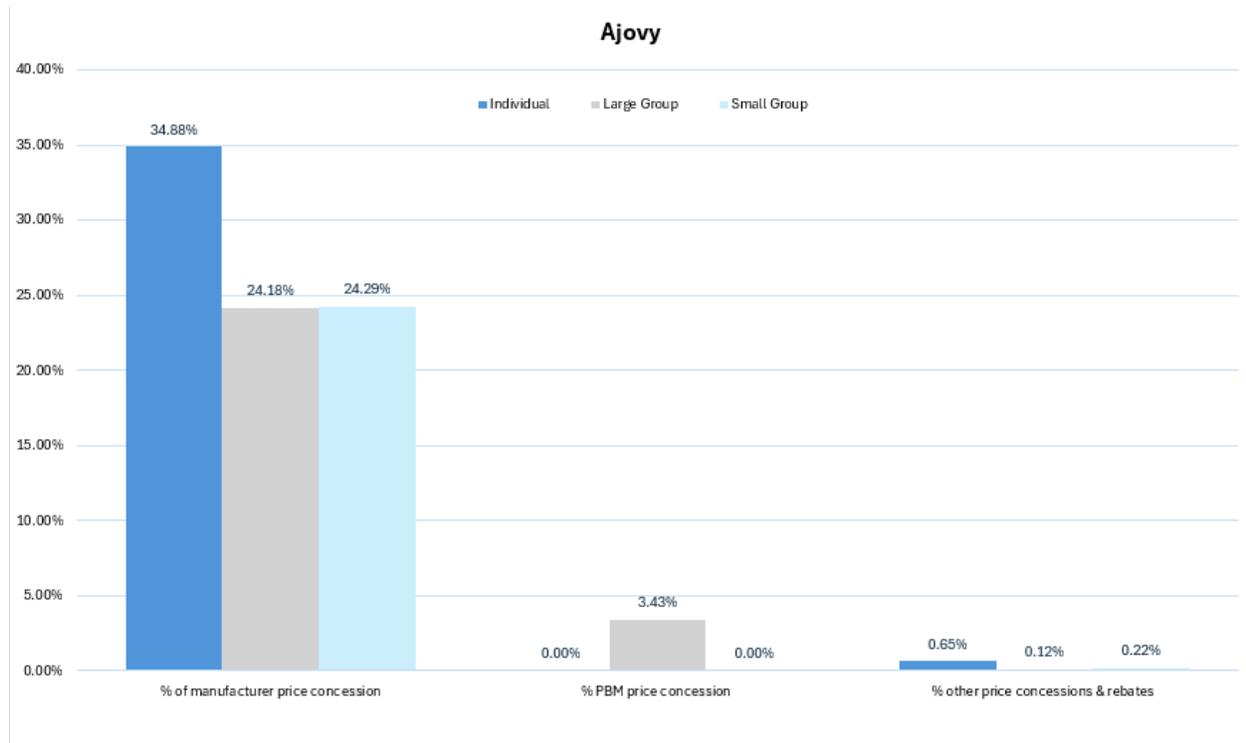


Figure 4 Percent of price concession in each market type<sup>30, 31</sup>

<sup>29</sup> Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon’s commercial insurance carriers.

<sup>30</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>31</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 Ajoy to each pharmacy benefit managers, expressed as a percentage of the drug's price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market.

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

## Estimated price for therapeutic alternatives<sup>32</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 Ajoy and its therapeutic alternatives using data from APAC and 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 data submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concession or rebates.

Ajoy's **gross payer paid per claim, based on APAC data, was \$637**, while **net cost data showed a comparable payer per-claim amount of \$638**. Compared to Ajoy's gross cost per claim, Emgality had a similar claim cost, while Vyepti showed a higher cost per claim. Vyepti had the lowest enrollee paid at \$0.

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

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

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<sup>32</sup> Therapeutic alternative means a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. [ORS 925-200-0020\(2\)\(c\)](#).

Table 9 Average healthcare and average patient OOP costs vs therapeutic alternatives<sup>33</sup>

Proprietary name	No. of enrollees <sup>34</sup>	No. of claims	Total payer paid	Total enrollees paid <sup>35</sup>	Payer paid/claim	Enrollee paid/claim <sup>36</sup>
Subject Drug <b>Ajovy (data call)</b> <sup>37</sup>	<b>1,057</b>	<b>5,312</b>	<b>\$3,391,205</b>	<b>\$602,467</b>	<b>\$638</b>	<b>\$113</b>
Subject Drug <b>Ajovy (APAC)</b>	<b>1,603</b>	<b>10,307</b>	<b>\$6,566,875</b>	<b>\$885,066</b>	<b>\$637</b>	<b>\$86</b>
<b>Aimovig</b>	1,865	15,271	\$10,990,158	\$882,528	\$720	\$58
<b>Emgality</b>	1,946	15,130	\$9,896,376	\$1,580,777	\$654	\$104
<b>Nurtec ODT</b>	2,478	12,335	\$13,227,665	\$1,503,175	\$1,072	\$122
<b>Qulipta</b>	601	3,037	\$3,012,966	\$400,332	\$992	\$132
<b>Vyepti</b>	3	4	\$5,175	\$0	\$1,294	\$0

## Estimated average price concession for therapeutic alternatives

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was

<sup>33</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>34</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, as compared to other totals indicated in this report.

<sup>35</sup> This cost includes all lines of business.

<sup>36</sup> Ibid.

<sup>37</sup> Information from the data call with the costs information after price concessions.

not performed. Future reviews may incorporate this information as additional data become available through carrier reporting, manufacturer disclosures, or other sources.

## Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **10,307 total claims for Ajovy among 1,743 total enrollees**, corresponding to a **total system gross expenditure of nearly \$6.6 million**.

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

- **Commercial** accounted for the largest share of utilization, with 6,224 claims from 1,022 enrollees and a total spend of **\$3.9 million**.
- **Medicaid** and **Medicare** payers reported smaller but notable expenditures of approximately **\$1.5 million** and **\$1.2 million**, respectively.

*Table 10 Estimated 2023 APAC total annual gross payers’ expenditure for total enrollees and total claims<sup>38</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>	1,022	6,224	\$3,903,055	\$3,819	\$627
<b>Medicaid</b>	413	2,373	\$1,497,533	\$3,626	\$631
<b>Medicare</b>	308	1,710	\$1,166,286	\$3,787	\$682
<b>Totals<sup>39</sup></b>	<b>1,743</b>	<b>10,307</b>	<b>\$6,566,875</b>		

Table 11 provides utilization for the healthcare system for Ajovy and its therapeutic alternatives, distinguished by lines of business. **Aimovig has the most utilization** all payer types,

<sup>38</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>39</sup> The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

with **15,271 claims**. **Ajovy has the fourth highest utilization, with 10,307 claims**. The drugs with the lowest claim of four is Vyepti.

*Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives <sup>40</sup>*

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims <sup>41</sup>
<b>Ajovy</b>	6,224	2,373	1,710	10,307
<b>Aimovig</b>	5,785	4,188	5,298	15,271
<b>Emgality</b>	8,715	2,187	4,228	15,130
<b>Nurtec ODT</b>	6,541	1,842	3,952	12,335
<b>Qulipta</b>	1,775	290	972	3,037
<b>Vyepti</b>	0	1	3	4

Table 12 shows the overall payer expenditure of Ajovy and its therapeutic alternatives, distinguished by lines of business. Ajovy has a **total expenditure of \$6.6 million** with **commercial being the biggest portion at \$3.9 million**. The therapeutic alternative with the **least expenditure is Vyepti, at \$5,175**.

*Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business <sup>42</sup>*

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total <sup>43</sup>
<b>Ajovy</b>	\$3,903,055	\$1,497,533	\$1,166,286	\$6,566,875
<b>Aimovig</b>	\$3,715,660	\$2,945,737	\$4,328,761	\$10,990,158
<b>Emgality</b>	\$5,200,738	\$1,471,650	\$3,223,988	\$9,896,376
<b>Nurtec ODT</b>	\$6,396,237	\$2,024,678	\$4,806,730	\$13,227,665
<b>Qulipta</b>	\$1,658,305	\$274,690	\$1,079,971	\$3,012,966
<b>Vyepti</b>	\$0	\$266	\$4,909	\$5,175

Table 13 compares the overall payer cost per enrollee of Ajovy and its therapeutic alternatives, distinguished by lines of business. Aimovig has the highest total cost per enrollee at \$5,893. **Ajovy has the second lowest total cost per enrollee at \$4,097. The median cost per enrollee**

<sup>40</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>41</sup> Total is the sum of all utilization for the drug across all lines of business.

<sup>42</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>43</sup> Total is the sum of all expenditure for the drug across all lines of business.

for **Ajovy** is **\$639**, the lowest median of the total cost per enrollee, though it is comparable to the median of the total cost per enrollee for **Emgality**, which is **\$642**.

*Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives <sup>44</sup>*

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total <sup>45</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>Ajovy</b>	\$3,819	\$3,626	\$3,787	\$4,097	\$639	\$289	\$700	\$1,979
<b>Aimovig</b>	\$4,941	\$5,298	\$5,688	\$5,893	\$710	\$161	\$774	\$2,059
<b>Emgality</b>	\$4,677	\$4,446	\$5,030	\$5,085	\$642	\$258	\$752	\$1,900
<b>Nurtec ODT</b>	\$4,608	\$4,962	\$5,709	\$5,338	\$913	\$808	\$1,535	\$2,023
<b>Qulipta</b>	\$4,645	\$3,763	\$5,567	\$5,013	\$985	\$226	\$1,043	\$2,854
<b>Vyepti</b>	\$0	\$266	\$2,454	\$1,725	\$1,588	\$697	\$1,624	\$1,653

Data for plan year 2023 submitted via the carrier data call further stratifies commercial expenditures by market segment. The collected **total net cost from reporting market types was around \$4 million**, with **payer paying \$3.4 million**, and enrollees out-of-pocket estimated to be **\$602,467**. Table 14 includes the average plan costs per enrollee in the commercial market ranged from **\$3,344 (large group)** to **\$2,496 (small group)** annually.

*Table 14.a Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee <sup>46</sup>*

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

<sup>44</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>45</sup> The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

<sup>46</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	\$802	\$587	\$215	\$4,205	\$3,079	\$1,126
Large Group	\$755	\$669	\$86	\$3,772	\$3,344	\$428
Small Group	\$659	\$510	\$149	\$3,228	\$2,496	\$732

Figure 5 shows the **large group market segment** represented most of the commercial spending (73% of total), followed by individual and small group markets.

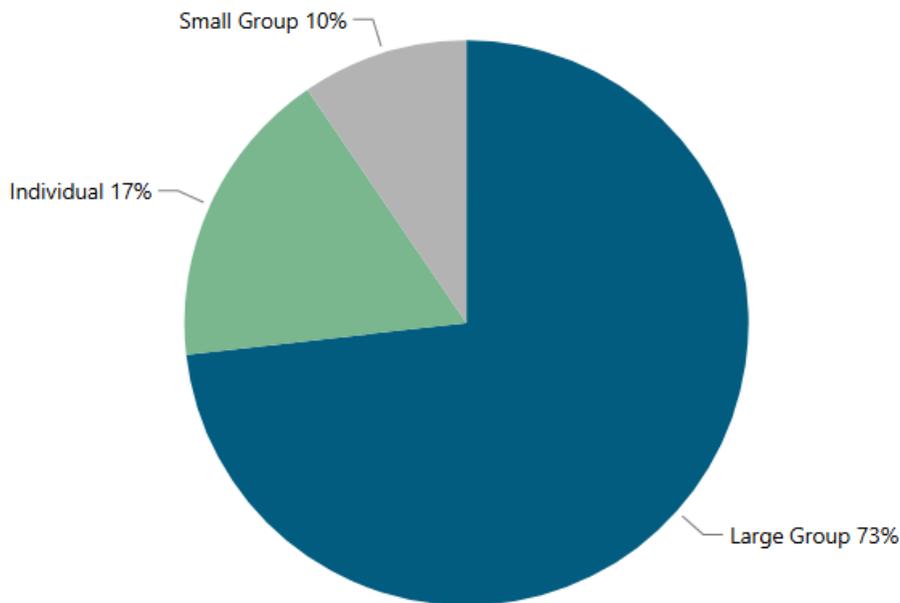


Figure 5 Data call total annual percent spend (payer paid) by market

## Impact on enrollee access to the drug

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

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

Based on information reported through the carrier data call, the following plan design features were observed for Ajovy. In 2023, approximately **99.6 percent of reporting plans required prior**

**authorization (PA)** for coverage of the drug, and **3.0 percent of plans required step therapy** before approving its use.

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

*Table 15 Plan design analysis from 2023*

Percentage of plans	
<b>Required prior authorization</b>	99.6%
<b>Required step therapy</b>	3.0%
<b>On a non-preferred formulary</b>	23.6%
<b>Not covered</b>	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 Ajoyv may affect broader health, medical, or social service costs, as compared to alternative treatments or no treatment. At the time of this review, there was no quantifiable data available to PDAB to assess these relative financial impacts in the Oregon population.

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

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

## Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Ajovy in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).<sup>47</sup> These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance lines of business of Medicare and commercial health care carriers.

Table 16 and 17 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Commercial 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>48</sup>*

Proprietary name	Annual Medicare OOP Cost/ Enrollee	Annual Commercial OOP Cost/ Enrollee	Total <sup>49</sup>	Median	IQR	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
Ajovy	\$455	\$729	\$680	\$30	\$250	\$250	\$838
Aimovig	\$514	\$653	\$587	\$30	\$123	\$123	\$705
Emgality	\$589	\$1,090	\$916	\$40	\$252	\$252	\$900
Nurtec ODT	\$505	\$797	\$695	\$35	\$226	\$226	\$950
Qulipta	\$414	\$896	\$732	\$40	\$246	\$240	\$1,024
Vyepti	\$0	\$0	\$0	\$0	\$0	\$0	\$0

<sup>47</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>48</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>49</sup> The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

Table 17 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim<sup>50</sup>

Proprietary name	Medicare OOP Cost/ Claim	Commercial OOP Cost/ Claim	Total <sup>51</sup>	Median	IQR	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
Ajovy	\$82	\$120	\$112	\$28	\$90	\$90	\$487
Aimovig	\$74	\$85	\$80	\$20	\$60	\$60	\$391
Emgality	\$89	\$139	\$123	\$37	\$132	\$132	\$632
Nurtec ODT	\$108	\$169	\$146	\$30	\$100	\$100	\$900
Qulipta	\$83	\$180	\$146	\$30	\$104	\$104	\$847
Vyepti	\$0	\$0	\$0	\$0	\$0	\$0	\$0

## Clinical information based on manufacturer material<sup>52</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: preventive treatment of migraine in adults
- Off Label Uses: None

### Clinical efficacy

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

In both studies, there was a statistically-significant reduction in migraine days from baseline and responder rates ( $\geq 50\%$  reduction from baseline) with both monthly and quarterly doses compared to placebo (Table 18 and 19).

<sup>50</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>51</sup> The total is the overall cost per claim across commercial insurers, Medicaid, and Medicare.

<sup>52</sup> U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Action yr 2021. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761089s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf).

Table 18 Key Findings (Study 1) in episodic migraine (n=875) over 3 months:

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

Table 19 Key Findings (Study 2) in chronic migraine (n=1121) over 3 months:

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

Table 20 Pharmacokinetics

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

## Clinical safety<sup>53</sup>

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

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<sup>53</sup> U.S. Food & Drug Administration. *Ajovy (fremanezumab-vfrm) Prescribing Information*. Teva Pharms., Action yr 2021. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/761089s013lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761089s013lbl.pdf).

Therapeutic alternatives:<sup>54,55,56,57,58,59</sup>

Table 21 FDA Approved Indications

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

<sup>54</sup> Ibid.

<sup>55</sup> U.S. Food & Drug Administration. *Aimovig (erenumab-aooe) Prescribing Information*. Amgen Inc., Action yr 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/761077s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761077s015lbl.pdf).

<sup>56</sup> U.S. Food & Drug Administration. *Emgality (galcanezumab-gnlm) Prescribing Information*. Eli Lilly, Action yr 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/761063s006lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf).

<sup>57</sup> U.S. Food & Drug Administration. *Nurtec ODT (imegepant) Prescribing Information*. Pfizer, Action yr 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/761063s006lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf).

<sup>58</sup> U.S. Food & Drug Administration. *Qulipta (atogepant) Prescribing Information*. Abbvie, Action yr 2023. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/215206s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf).

<sup>59</sup> U.S. Food & Drug Administration. *Vyepti (eptinezumab-jjmr) Prescribing Information*. Lundbeck Seattle BioPharm, Action yr 2023. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/215206s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf).

Table 22 Efficacy: Migraine days decreased & responder rates

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

**Comparative effectiveness:**

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

Table 23 Adverse effect profile

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

Table 24 Route and dosing

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

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

**Safety summary:**

- The monoclonal antibody CGRP antagonists (fremanezumab, erenumab, eptinezumab, and galcanezumab) are administered parenterally and include common side effects of injection site reactions and hypersensitivity reactions. Hypersensitivity reactions requiring discontinuation or steroid treatment have been reported within hours to one month after fremanezumab administration. There is a theoretical concern for cardiovascular side effects and erenumab has been associated with hypertension.
- The oral CGRP antagonists (rimegepant, atogepant) have common GI side effects associated with them (nausea, abdominal pain, dyspepsia) and atogepant can cause constipation. They should be avoided in severe liver impairment and with strong CYP3A34 inhibitors and inducers.

## Input from specified stakeholders

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

**See appendix page for all stakeholder feedback.**

**Patients and caregivers:**

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

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

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

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

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

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

## “ Ajovy ”

- Doctors, neurologist have tried everything and nothing is stopping the migraines. They wanted to try Ajovy but insurance denied it. The medications I take only help with some of the pain but they do not reduce the amount of chronic, complex migraines with aura I am having. Doctors have appealed, but insurance coverage is still denied for Ajovy. I have several other medical conditions, but the migraines, by far, limit by ability to function.
- The doctor prescribed it and it works. I used Emgality, but insurance stopped covering it, so I switched to Ajovy.
- Ajovy decreases the number of migraine days per month. I pay \$15 a month with an assistance program. I had a bad reaction to Aimovig with site pain and swelling but it did help decrease the number of migraine days.
- Ajovy has reduced severity and frequency of really bad, 48-hour migraines to 12 hours. I pay \$11 per month through the Medicare Part D Extra Help program. I also take several other drugs. Mirtazapine as a preventative has also reduced severity and frequency.

Oxycodone and Butalbital at the same time when I have significant pain that is uncontrollable. Maxalt aborts most migraines that I still have.

-  Ajovy reduces and lessens migraines. My most recent, monthly, out-of-pocket cost for Ajovy was \$91. I have tried many, many other remedies. I tried to get on a patient assistance program but was unsuccessful. At one point they lost all my information and I had to start over. I would send everything in and when I would eventually contact them about the process, they would add something to the list of requirements. Finally they denied me, but gave no reason. When I went on Medicare, the price skyrocketed.
-  Ajovy lessens migraines. My most recent monthly, out-of-pocket expense was \$150. I have tried other medications that worked, but insurance quit paying for them.
-  Ajovy reduces migraines from 25 per month to two per month or less. My most recent, monthly, out-of-pocket cost was \$28. I have 75 percent medical financial assistance. I tried Aimovig and Emgality but Ajovy is more effective. Ajovy radically improved my life. I do not want to go back to 25 migraines per month.
-  Ajovy has stopped chronic migraines. I tried multiple medications and they only helped sometimes. Nothing helped as well as Ajovy. It was covered until this year. My most recent, monthly, out-of-pocket cost was \$174.26. I now am trying Aimovig 70 ML INJ that is covered by my insurance through Medicare Advantage. The cost is \$47 but it is not as effective.

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

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

## Individuals with scientific or medical training

This section summarizes information reported by healthcare professionals with scientific or medical training who identified key barriers for patients in accessing the medications under review. Among survey respondents, one healthcare professional cited each of the following as administrative burdens: **prior authorization, step therapy, and cost**. In contrast, **quantity limits**, PBM/formulary restrictions, and first-line therapy status were not reported as notable barriers to access for this medication.

## Safety net providers

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

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

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

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

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

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

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

Table 25 Safety net provider survey responses

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

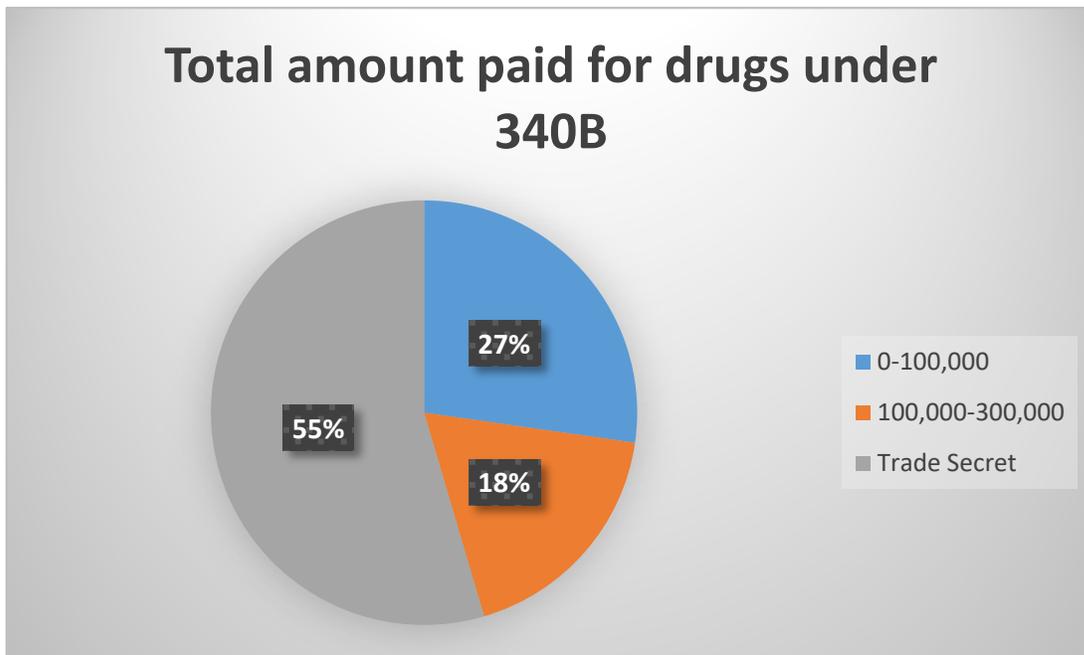
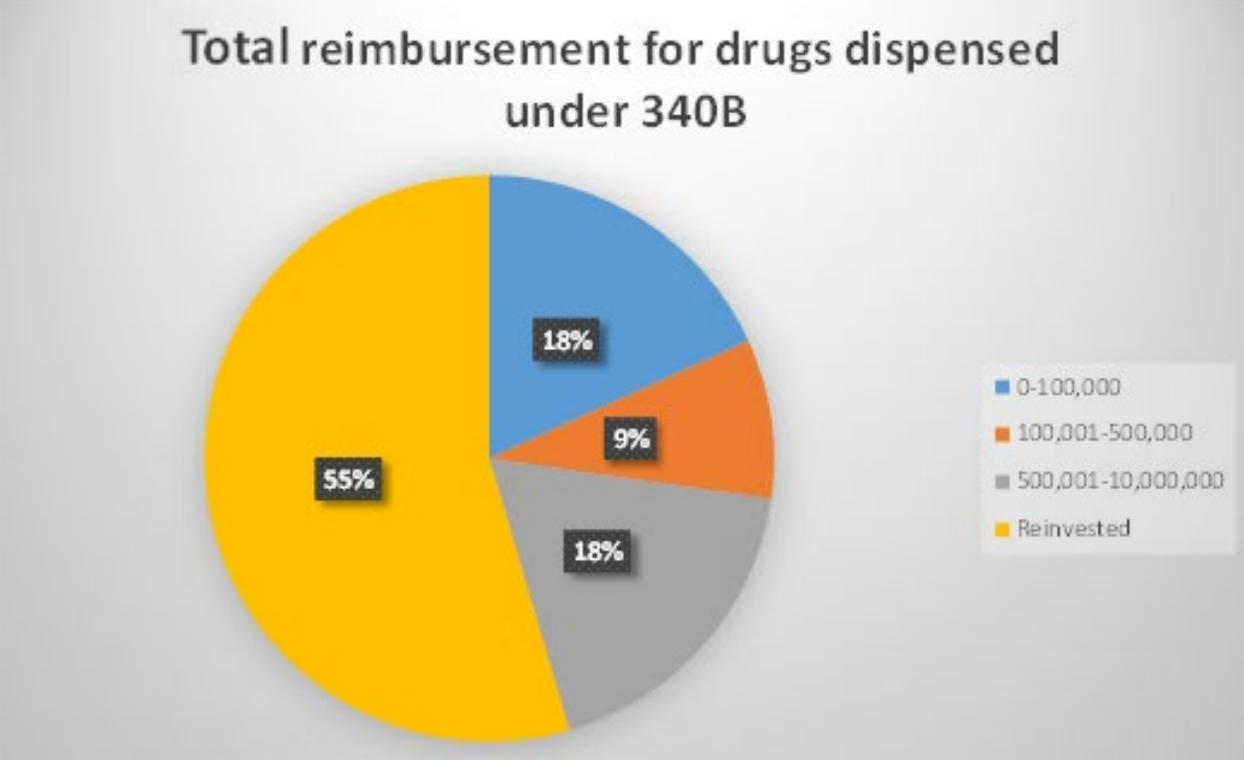


Figure 6 Amounts paid for drug under 340B discount program



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

### Payers

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

The data provided through the carrier data call serves as a comprehensive source of payer input and reflects 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:

<b>Name of speaker</b>	<b>Association to drug under review</b>	<b>Drug</b>	<b>Format</b>	<b>Date</b>	<b>Exhibit website link</b>
Lindsay Videnieks	The Headache & Migraine Policy Forum	Ajovy	Letter	7/14/2025	<a href="#">Exhibit A</a>