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# Emgality®
# (*galcanezumab*)[1]

Version 4.0


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

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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 with an additional section for payer paid amounts |
| **v2.1** | 7/17/2025 | Added to the appendix table the public comment from the 7/16/2025 board meeting. |
| **V3.0** | 9/12/2025 | New tables added, format changes throughout the document |
| **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[2,3,4]

**Emgality® (*galcanezumab-gnlm*)** has the following therapeutic alternatives: **Aimovig, Ajovy, 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 |
|---|---|---|---|---|---|---|
| **Emgality**[5] | *Galcanazumab-gnlm* | Eli Lilly and Co. | | | | No |
| **Aimovig**[6] | *erenumab-aooe* | Amgen Inc. | | | | No |
| **Ajovy**[7] | *fremanezumab-vfrm* | Teva Pharmaceuticals | | | | No |
| **Nurtec ODT** | *rimegepant* | Pfizer Inc | 3 | 2030-2039 | 2025 | No |
| **Qulipta** | *atogepant* | Abbie Inc. | 6 | 2031-2043 | 2026 | No |
| **Vyepti**[8] | *eptinezumab* | Lundbeck Seattle BioPharmaceuticals, Inc. | | | | No |

[2] Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book. U.S. Food & Drug Administration, Aug. 8, 2025. https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

[3] Frequently Asked Questions on Patents and Exclusivity, U.S. Food & Drug Administration, Feb. 5, 2020. https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a.

[4] 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.

[5] No patent or exclusivity information was listed for Emgality in the U.S. Food & Drug Administration Purple Book Database

[6] No patent or exclusivity information was listed for Aimovig in the U.S. Food & Drug Administration Purple Book Database

[7] No patent or exclusivity information was listed for Ajovy in the U.S. Food & Drug Administration Purple Book Database

[8] No patent or exclusivity information was listed for Vyepti in the U.S. Food & Drug Administration Purple Book Database

## Price history[9,10]

**Emgality® (*galcanezumab-gnlm*) rose at an average annual rate of 2.8 percent** from 2018-2024

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

Additionally, the average annual rate exceeded inflation in 2020, 2023, and 2024. Pharmacy acquisition costs (AAAC) for **Medicaid also increased by 14.0 percent** over the same period, reflecting broader trends in pricing escalation.

## Price concessions[11]

Based on data received from healthcare carriers, Emgality in 2023 had the **gross spend of $790 per claim**, while the **spend net of discount was $465 per claim**. Price concession per claim was reported to be **$325**.

## Cost to payers[12]

*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 |
|---|---|---|---|---|
| **Emgality** | $9,896,376 | 15,130 | $5,085 | $642 |
| **Aimovig** | $10,990,158 | 15,271 | $5,893 | $710 |
| **Ajovy** | $6,566,875 | 10,307 | $4,097 | $639 |
| **Nurtec ODT** | $13,227,665 | 12,335 | $5,338 | $913 |
| **Qulipta** | $3,012,966 | 3,037 | $5,013 | $985 |
| **Vyepti** | $5,175 | 4 | $1,725 | $1,588 |

[9] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[10] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[11] 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.
[12] 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[13]

*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 |
|---|---|---|---|---|
| **Emgality** | $917 | $40 | $114 | $44 |
| **Aimovig** | $587 | $30 | $80 | $20 |
| **Ajovy** | $680 | $30 | $112 | $28 |
| **Nurtec** | $695 | $35 | $146 | $30 |
| **Qulipta** | $732 | $40 | $146 | $30 |
| **Vyepti** | $0 | $0 | $0 | $0 |

# Rubric considerations

| Domain | Consideration |
|---|---|
| **Utilization** | 15,130 |
| **Price evaluation** | change in WAC between 4-4.99% for 4 years, outpaces inflation for 3 years |
| **Price concessions** | High percentage of claims discounted (79%) |
| **System & payer costs** | Total gross spend < $10M, total net spend $3M-$10M |
| **Enrollee burden** | Total APAC OOP annual cost $700-$1,200 |
| **Equity impact** | Yes |
| **Access restrictions** | Yes |
| **Therapeutic alternative fail to reduce system spending** | Yes |
| **Stakeholder input identify access or financial hardship?** | Yes |
| **Patent expirations more than 18 months from time of review?** | Yes |
| **Excluded from CMS Maximum Fair Price List (MFP)** | Yes |

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

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

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

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

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

# Drug information[14]

| | |
|---|---|
| **Drug proprietary name** | Emgality® |
| **Non-proprietary name (active ingredient)** | *galcanezumab-gnlm* |
| **Manufacturer** | Eli Lilly and Company |
| **Pharmacologic Category** | Calcitonin Gene-Related Peptide (CGRP) Antagonist |
| **Treatment** | • preventive treatment of migraine<br>• treatment of episodic cluster headache in adults |
| **Dosage forms and strengths** | • Injection: 100 mg/mL solution in a single-dose prefilled syringe<br>• Injection: 120 mg/mL solution in a single-dose prefilled pen<br>• Injection: 120 mg/mL solution in a single-dose prefilled syringe |
| **Recommended dosing** | • Cluster headache: 300 mg SUBQ at the onset of the cluster and then once monthly until the end of the cluster period<br>• Migraine prevention: 240 mg SUBQ once, followed by 120 mg once monthly |
| **Route of administration:** | Subcutaneous |
| **Physician administered:** | No |

## FDA approval

Emgality was first approved by the FDA on  27, 2018.[15]

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

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

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

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

# Health inequities

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

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

The **Institute for Clinical and Economic Review (ICER)** highlighted similar concerns in its review of acute migraine treatments, noting that **trial enrollment did not reflect the real-world racial and ethnic diversity of people living with migraine**, particularly underrepresenting Black and Hispanic patients.[17] In contrast, the FDA's *Drug Trials Snapshot* for **Emgality** provides limited but promising subgroup data: pain relief rates were found to be **comparable across racial groups,** with **23.3 percent of Black participants and 21.2 percent of white participants** achieving pain freedom at 2 hours.[18] However, without consistent subgroup analysis across all CGRP-targeting therapies, disparities in both trial design and real-world access remain.

R**eal-world evidence** shows that **Black and Hispanic individuals are less likely to be diagnosed with migraine or prescribed advanced treatments**, even when accounting for socioeconomic status.[19] 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[20]—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.

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

[17] 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

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

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

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

# Residents prescribed

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

Based on APAC claims, **1,946** Oregonians filled a prescription for Emgality in 2023.[21]

# Price for the drug

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

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

## Price history

WAC per 30-day supply 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*

| | Emgality | Aimovig | Ajovy | Nurtec | Qulipta | Vyepti[22] |
|---|---|---|---|---|---|---|
| **30-day supply** | 1 unit (1 pen or 1 syringe of 1ml) | 1 unit (1 autoinjector or 1 syringe of 1ml) | 1 package (1 autoinjector or 1 syringe of 1.5ml) | 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[23]*

| Year | Emgality | Aimovig | Ajovy | Nurtec | Qulipta | Vyepti[24] |
|---|---|---|---|---|---|---|
| **2018** | $575 | $575 | $575 | | | |
| **2019** | $551 | $575 | $575 | | | |
| **2020** | $578 | $603 | $603 | $1,594 | | $493 |
| **2021** | $601 | $639 | $633 | $1,673 | $991 | $506 |
| **2022** | $626 | $697 | $665 | $1,724 | $991 | $531 |

[21] 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.
[22] Treatment of Vyepti consists of 1ml of infusion every 90 days.
[23] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[24] Treatment of Vyepti consists of 1ml of infusion every 90 days.

| Year | Emgality | Aimovig | Ajovy | Nurtec | Qulipta | Vyepti[24] |
|---|---|---|---|---|---|---|
| **2023** | $651 | $738 | $698 | $1,784 | $1,041 | $564 |
| **2024** | $677 | $753 | $733 | $1,873 | $1,093 | $603 |
| **Avg. Annual % Change** | 2.8% | 4.6% | 4.1% | 4.1% | 3.3% | 5.2% |
| **% change 2018 and 2024** | 17.7% | 31.0% | 27.5% | | | |

The WAC of Emgality, averaged across four NDCs reported, was approximately **$677 per unit** at the end of 2024.[25] Between 2018-2024, the unit WAC increased at an average annual rate of **2.8 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).[26]

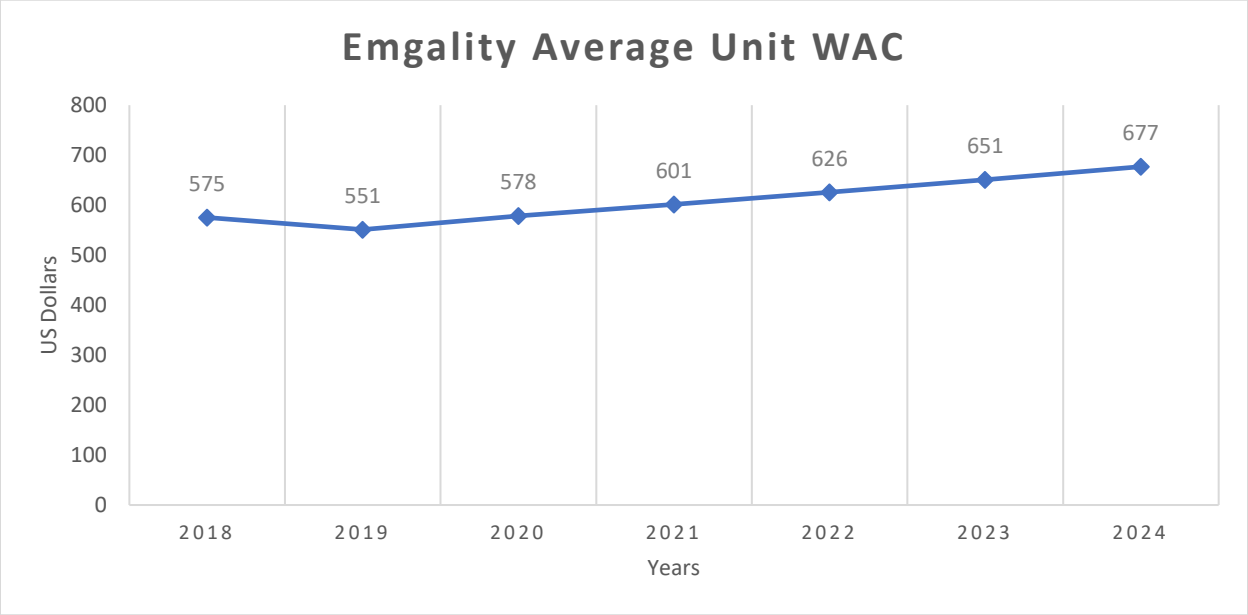


*Figure 1 Emgality average unit WAC from 2018-2024*

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

*Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison*[27]

| Year | Emgality | Aimovig | Ajovy | Nurtec | Qulipta | Vyepti | CPI-U |
|---|---|---|---|---|---|---|---|
| **2018-2019** | -4.2% | -33.3% | 0% | | | | 1.7% |
| **2019-2020** | 5.0% | 4.9% | 4.9% | | | 2.5% | 0.7% |
| **2020-2021** | 4.0% | 5.9% | 5.0% | 5.0% | | 5.1% | 5.3% |
| **2021-2022** | 4.0% | 9.1% | 5.0% | 3.0% | 0.0% | 6.1% | 9.0% |
| **2022-2023** | 4.0% | 5.9% | 5.0% | 3.5% | 5.0% | 7.0% | 3.1% |
| **2023-2024** | 4.0% | 2.0% | 5.0% | 5.0% | 5.0% | 5.2% | 3.0% |

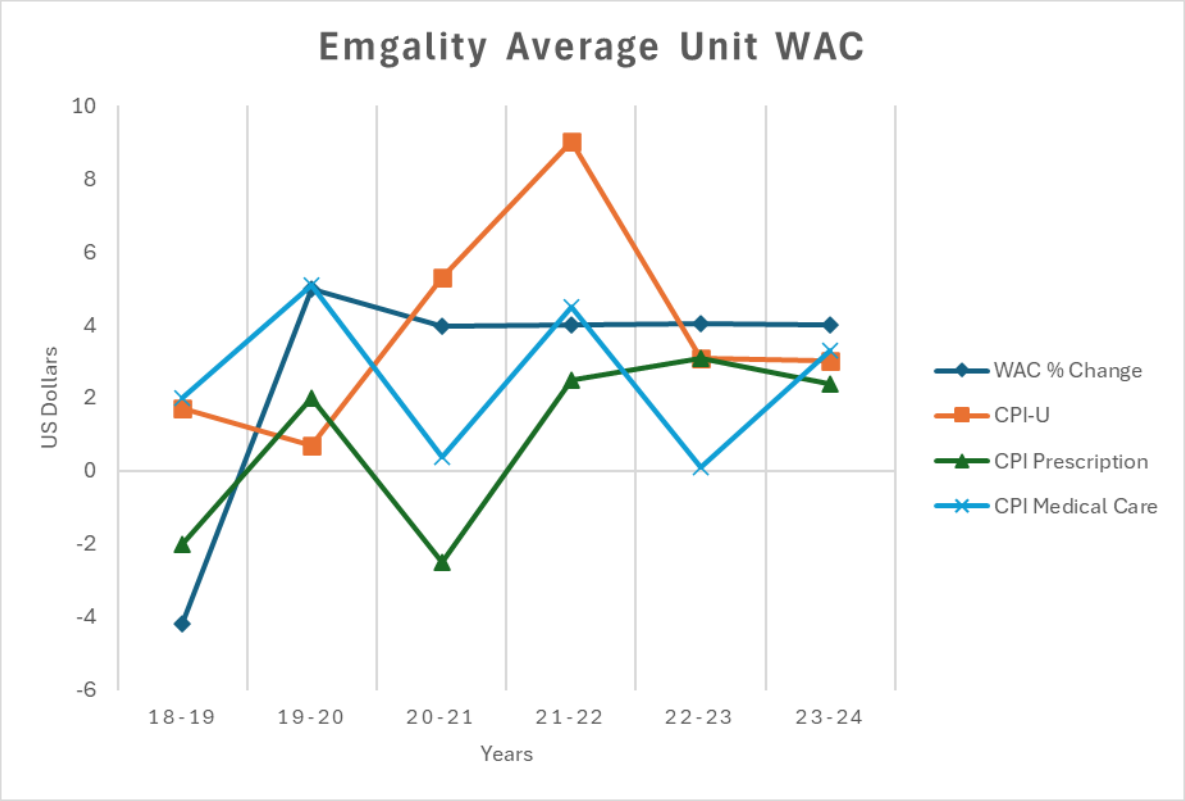


*Figure 2 Year over year change in unit WAC compared to inflation rates*[28]

## Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, **rose from $572 in Quarter 1 of 2020, to $642 in Quarter 4 of 2024, an increase of 14 percent**

[27] Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.
[28] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/

(see Table 6).[29] Relative to the **$677 WAC in end-of-year** 2024 an **AAAC discount of 5.45 percent** is indicated.

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

*Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices*

| Year | Quarter 1 | Quarter 2 | Quarter 3 | Quarter 4 | Average AAAC | Average WAC |
|---|---|---|---|---|---|---|
| **2020** | $572 | $583 | $583 | $582 | $580 | $578 |
| **2021** | $573 | $573 | $573 | $572 | $577 | $601 |
| **2022** | $594 | $597 | $597 | $595 | $596 | $626 |
| **2023** | $617 | $618 | $619 | $620 | $618 | $651 |
| **2024** | $644 | $643 | $643 | $642 | $643 | $677 |

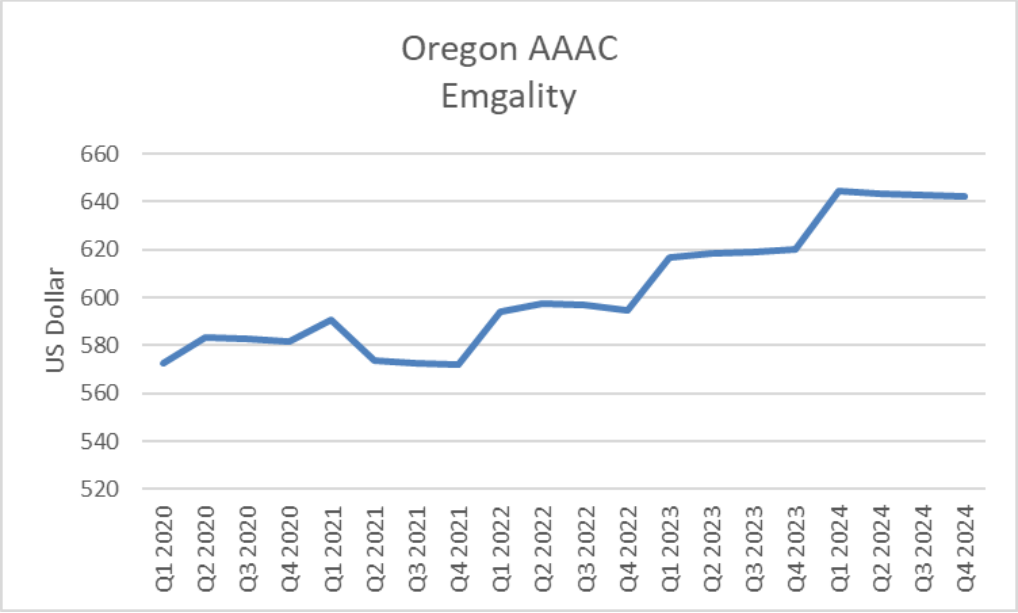


*Figure 3 AAAC for Emgality from Q1 2020 to Q4 2024*

[29] 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/

# Estimated average monetary price concession

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

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to Emgality claims in the commercial market. Drawing on 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 Emgality per enrollee in the commercial market was approximately $4,301**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $2,531**, reflecting an **estimated mean discount of 41.2 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Emgality before concessions was $4,021,432**, with total reported **price concessions amounting to approximately $1,655,143**, as detailed in Table 7. Notably, **79 percent of claims benefited from some form of price concession**, leaving **20 percent at full gross cost**.

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

| | |
|---|---|
| **Total number of enrollees** | 935 |
| **Total number of claims** | 5,088 |
| **Total number of claims with price concessions applied** | 4,020 |
| **Percentage of claims with price concessions applied** | 79% |
| **Percentage of cost remaining after concessions** | 58.8% |
| **Percentage of discount** | 41.2% |
| **Manufacturer price concessions for all market types** | $1,389,500 |
| **PBM price concessions for all market types** | $252,373 |
| **Other price reductions for all market types** | $13,271 |
| **Cost before price concessions across all market types** | $4,021,432 |
| **Total price concessions across all market types** | $1,655,143 |
| **Cost of after price concessions across all market types** | $2,366,289 |

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

Including all market segments, the **gross spend of Emgality per claim for commercial carriers was $790** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$465**, meaning that insurers reported a price concession of **$325** 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*[30]

| | Average | Individual market | Large market | Small market |
|---|---|---|---|---|
| **Spend per claim, gross** | $790 | $811 | $795 | $753 |
| **Spend per claim, net** | $465 | $432 | $499 | $390 |
| **Price concessions per claim** | $325 | $379 | $296 | $363 |

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

[30] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers.

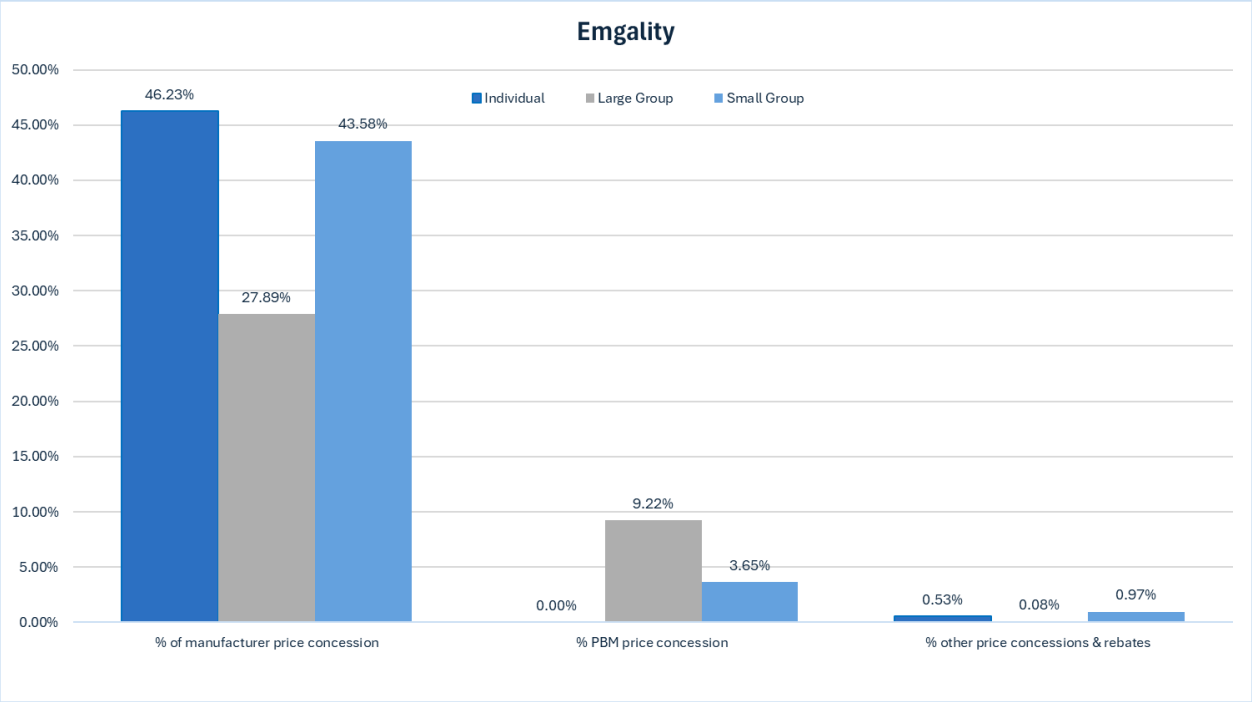


*Figure 4 Percent of price concession in each market type*[31,32]

# Estimated total amount of the price concession

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

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

The statutory and regulatory criteria call for consideration of such information to the extent practicable; however, due to limitations in available evidence and reporting, this analysis was not

[31] 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.

[32] 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.

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[33]

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

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

Emgality's **gross payer paid per claim, based on APAC data, was $654**, while **net cost data showed a lower per-claim amount of $614**. Compared to Emgality's payer paid per claim, Ajovy has similar claim costs, while Nurtec and other therapeutic alternatives showed a higher cost per claim. Qulipta and Vyepti show lower numbers of enrollees and claims but have with elevated costs for payers in respect to the number of claims paid.

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

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

[33] 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).

*Table 9 Average healthcare and average enrollee OOP costs vs therapeutic alternatives*[34]

| Proprietary name | No. of enrollees [35] | No. of claims | Total payer paid | Total enrollees paid[36] | Payer paid/ claim | Enrollee paid/ claim[37] |
|---|---|---|---|---|---|---|
| *Subject drug* **Emgality (data call)**[38] | **935** | **5,088** | **$3,124,793** | **$752,054** | **$614** | **$148** |
| *Subject drug* **Emgality (APAC)** | **1,946** | **15,130** | **$9,896,376** | **$1,580,777** | **$654** | **$104** |
| **Aimovig** | 1,865 | 15,271 | $10,990,158 | $882,528 | $720 | $58 |
| **Ajovy** | 1,603 | 10,307 | $6,566,875 | $885,066 | $637 | $86 |
| **Nurtec ODT** | 2,478 | 12,335 | $13,227,665 | $1,503,175 | $1,072 | $122 |
| **Qulipta** | 601 | 3,037 | $3,012,966 | $400,332 | $992 | $132 |
| **Vyepti** | 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 Emgality, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

[34] 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.
[35] 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.
[36] This cost includes all lines of business.
[37] Ibid.
[38] Information from the data call with the costs 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 Emgality on health insurance plans in Oregon, based on claims and expenditure data from APAC and the carrier data call. Costs are delineated by payer type—including commercial, Medicaid, and Medicare—as well as by market segment within the commercial population. These estimates highlight the distribution of expenditures across different health coverage lines and inform assessments of the drug's budgetary implications for public and private payers.

In 2023, the Oregon APAC database recorded **15,130 total claims for Emgality among 2,084 total enrollees**, corresponding to a **total system gross expenditure of $9.9 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 8,715 claims from 1,112 enrollees and a total spend of **$5.2 million**.
- **Medicare** and **Medicaid** payers reported smaller but notable expenditures of approximately **$3.2 million** and **$1.5 million**, respectively.

*Table 10 Estimated 2023 APAC total annual gross payers' expenditure for total enrollees and total claims*[39]

| Payer line of business | Total enrollees | Total claims | Total payer paid | Average cost amount per enrollee | Average cost amount per claim |
|---|---|---|---|---|---|
| **Commercial** | 1,112 | 8,715 | $5,200,738 | $4,677 | $597 |
| **Medicaid** | 331 | 2,187 | $1,471,650 | $4,446 | $673 |
| **Medicare** | 641 | 4,228 | $3,223,988 | $5,030 | $763 |
| **Totals**[40] | **2,084** | **15,130** | **$9,896,376** | | |

Table 11 provides gross APAC claims utilization **across all lines of business** with **15,130 total claims for Emgality.** Emgality has the highest utilization in the commercial sector and has the second highest utilization overall. The drug with the highest utilization is Aimovig at 15,271 claims.

[39] 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.

[40] 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 [41]*

| Proprietary name | Commercial utilization | Medicaid utilization | Medicare utilization | Total claims[42] |
|---|---|---|---|---|
| **Emgality** | 8,715 | 2,187 | 4,228 | 15,130 |
| **Aimovig** | 5,785 | 4,188 | 5,298 | 15,271 |
| **Ajovy** | 6,224 | 2,373 | 1,710 | 10,307 |
| **Nurtec ODT** | 6,541 | 1,842 | 3,952 | 12,335 |
| **Qulipta** | 1,775 | 290 | 972 | 3,037 |
| **Vyepti** | 0 | 1 | 3 | 4 |

Table 12 shows the overall payer expenditure of Emgality and its therapeutic alternatives, distinguished by lines of business. Emgality has a **total expenditure of $9.9 million** with **commercial being the biggest portion at $5.2 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 [43]*

| Proprietary name | Commercial expenditure | Medicaid expenditure | Medicare expenditure | Total[44] |
|---|---|---|---|---|
| **Emgality** | $5,200,738 | $1,471,650 | $3,223,988 | $9,896,376 |
| **Aimovig** | $3,715,660 | $2,945,737 | $4,328,761 | $10,990,158 |
| **Ajovy** | $3,903,055 | $1,497,533 | $1,166,286 | $6,566,875 |
| **Nurtec ODT** | $6,396,237 | $2,024,678 | $4,806,730 | $13,227,665 |
| **Qulipta** | $1,658,305 | $274,690 | $1,079,971 | $3,012,966 |
| **Vyepti** | $0 | $266 | $4,909 | $5,175 |

Table 13 compares the overall payer cost per enrollee of Emgality and its therapeutic alternatives, distinguished by lines of business. Aimovig has the highest total cost per enrollee at $5,893. **Emgality had a total cost per enrollee at $5,030**. **The median cost per enrollee for Emgality is $642**.

[41] 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.
[42] Total is the sum of all utilization for the drug across all lines of business.
[43] 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.
[44] 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* [45]

| Proprietary name | Commercial cost/ enrollee | Medicaid cost/ enrollee | Medicare cost/ enrollee | Total[46] cost per enrollee | Cost per enrollee, median | IQR | Cost per enrollee, 75th percentile | Cost per enrollee, 95th percentile |
|---|---|---|---|---|---|---|---|---|
| **Emgality** | $4,677 | $4,446 | $5,030 | $5,085 | $642 | $258 | $752 | $1,900 |
| **Aimovig** | $4,941 | $5,298 | $5,688 | $5,893 | $710 | $161 | $774 | $2,059 |
| **Ajovy** | $3,819 | $3,626 | $3,787 | $4,097 | $639 | $289 | $700 | $1,979 |
| **Nurtec ODT** | $4,608 | $4,962 | $5,709 | $5,338 | $913 | $808 | $1,535 | $2,023 |
| **Qulipta** | $4,645 | $3,763 | $5,567 | $5,013 | $985 | $226 | $1,043 | $2,854 |
| **Vyepti** | $0 | $266 | $2,454 | $1,725 | $1,588 | $697 | $1,624 | $1,653 |

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 $3.9 million**, with **payer paying $3.1 million**, and **enrollees out-of-pocket estimating to be $752,054**. Table 14 includes the average plan costs per enrollee in the commercial market ranged from **$4,850 (individual)** to **$3,723 (small group)** annually.

*Table 14.a Estimated 2023 total net costs to the healthcare system, payers and OOP/enrollee*[47]

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

[45] 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.
[46] The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.
[47] Cost information from the data call is the net 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** | $755 | $3,131 | $268 | $4,850 | $488 | $1,719 |
| **Large Group** | $781 | $3,536 | $104 | $4,080 | $677 | $544 |
| **Small Group** | $706 | $2,894 | $157 | $3,723 | $549 | $829 |

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (62% of total), followed by individual and small group markets.

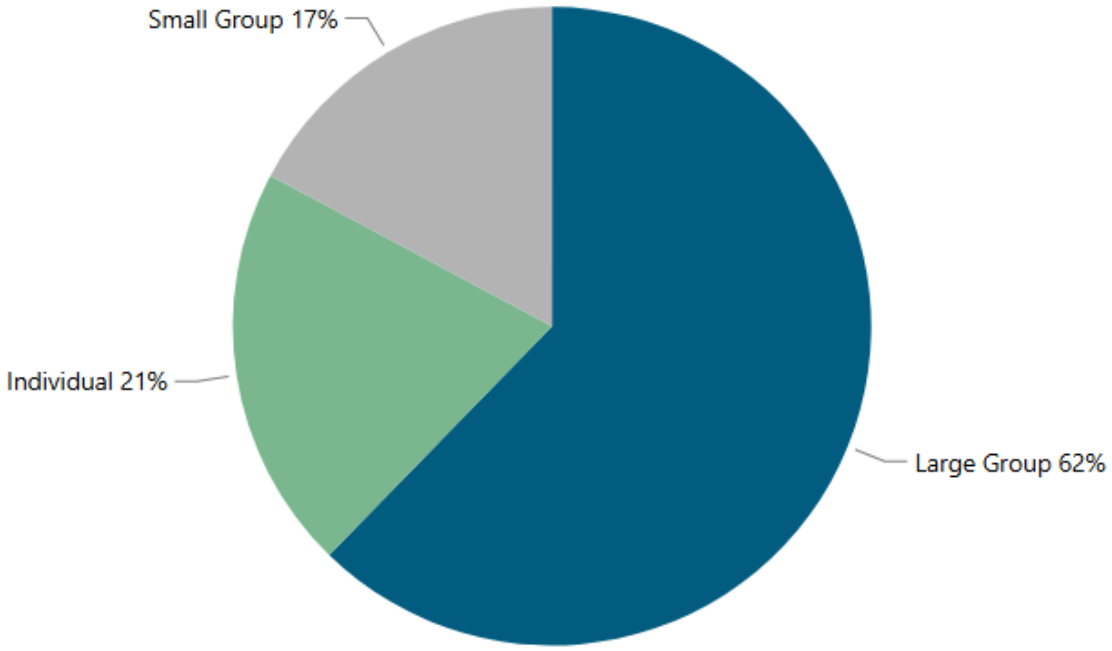


*Figure 5 Data call total annual percent spend (payer paid) by market*

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

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

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

*Table 15 Plan design analysis from 2023*

| Percentage of Plan | |
|---|---|
| **Required prior authorization** | 99.6% |
| **Required step therapy** | 0.4% |
| **On a non-preferred formulary** | 81.8% |
| **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 Emgality may affect broader health, medical, or social service costs, as compared to alternative treatments or no treatment. At the time of this review, there was no quantifiable data available to PDAB to assess these relative financial impacts in the Oregon population.

The statutory and regulatory criteria contemplate consideration of such impacts to the extent practicable. However, due to limitations in available evidence, data systems, and the challenges

inherent in isolating the indirect effects of a single drug on broader healthcare or social service costs, this analysis was not performed.

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

# Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Emgality in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).[48] 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. 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 [49]*

| Proprietary name | Annual Medicare OOP Cost/Enrollee | Annual Commercial OOP Cost/Enrollee | Total[50] | Median | IQR | 75th percentile | 95th percentile |
|---|---|---|---|---|---|---|---|
| **Emgality** | $590 | $1,090 | $917 | $40 | $253 | $253 | $900 |
| **Aimovig** | $514 | $653 | $587 | $30 | $123 | $123 | $705 |
| **Ajovy** | $455 | $729 | $680 | $30 | $250 | $250 | $838 |
| **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 |

[48] 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.
[49] 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.
[50] 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*[51]

| Proprietary name | Medicare OOP Cost/Claim | Commercial OOP Cost/Claim | Total[52] | Median | IQR | 75th percentile | 95th percentile |
|---|---|---|---|---|---|---|---|
| **Emgality** | $89 | $139 | $114 | $44 | $135 | $135 | $471 |
| **Aimovig** | $74 | $85 | $80 | $20 | $60 | $60 | $391 |
| **Ajovy** | $82 | $120 | $112 | $28 | $90 | $90 | $487 |
| **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[53]

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

## Drug indications

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

- Off Label Uses: None

## Clinical efficacy

**Efficacy in episodic migraine prevention**

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

[51] 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.
[52] The total is the overall cost per claim across commercial insurers, Medicaid, and Medicare.
[53] U.S. Food & Drug Administration. *Emgality (galcanezumb-gnlm) Prescribing Information*. Eli Lily, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf

galcanezumab resulted in statistically significant decreases in migraine days per month of about 2 days per month.

*Table 18 Clinical Efficacy in Prevention of Episodic Migraine*

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

**Efficacy in Chronic Migraine Prevention**

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

*Table 19 Efficacy in Chronic Migraine Prevention*

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

**Efficacy in episodic cluster headache**

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

*Table 20 Clinical Efficacy in Cluster Headache*

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

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

## Clinical safety

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

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

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

## Therapeutic alternatives:[54,55,56,57]

*Table 21 FDA Approved Indications*

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

*Table 22 Efficacy for Chronic or Episodic Migraine Prevention*

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

[54] U.S. Food & Drug Administration. *Emgality (galcanezumb-gnlm) Prescribing Information*. Eli Lily, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761063s006lbl.pdf.
[55] 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.
[56] 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.
[57] U.S. Food & Drug Administration. Vyepti (*eptinezumab-jjmr) Prescribing Information*. Lundback Seattle BioPharm, Action yr 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215206s004lbl.pdf.

*Table 23 Adverse Effects (AEs)*

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

*Table 24 Route and dosing*

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

### 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 two individuals taking or having an association with Emgality. For both respondents, insurance covered Emgality.

One patient had the drug covered under Medicare, was not on a patient assistant program (PAP), and paid between $100-$199 monthly for Emgality. One patient with private health insurance did not report an out-of-pocket cost or help from a PAP. Below are written answers from Oregon patients who responded to the PDAB survey in April 2025. Survey responses have been edited for readability, length and to protect patient privacy.

## ”Emgality”

- For the past three years, I take Emgality, 120mg, every 28 days to prevents migraines. I have tried many other drugs and they are not effective and/or have bad side effects. I'm fortunate to have private health insurance.

- I take Emgality, 120 mg, once a month and it prevents 80 percent of my migraines. I was having them four times a week from long covid. I have been taking Emgality 18 months and pay $127 for out-of-pocket per month. Botox worked best but my out of pocket cost was $650 every 90 days. I had fewer breakthrough migraines with Botox. I didn't like getting 30 injections all over my head but it sure worked. I don't qualify for patient assistance because I'm on Medicare. My Medicare plan this month said I didn't qualify anymore. I'm fighting it. It's truly messed up that since the age of 9, I have worked, paid into Social Security and Medicare, yet I pay about $520 a month for my advantage plan and co-pays. Medical dental and behavioral health coverage should be free for people making less than $100,000/year. Below are written answers from Oregon patients who responded to the PDAB survey in April 2025. Survey responses have been edited for readability, length and to protect patient privacy.

## Individuals with scientific or medical training

This section summarizes information reported by healthcare professionals with scientific or medical training who identified key barriers for patients in accessing the medications under review. One healthcare professional reported the **prior authorization process, step therapy, and cost** of Emgality as burdens for patients to access the medication.

### Reported benefits of the prescription drug compared to therapeutic alternatives:

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

### Reported disadvantages of the prescription drug compared to therapeutic alternatives:

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

## Safety net providers

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

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

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

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

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

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

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

*Table 25 Safety net provider survey responses*

| Survey information | Response |
|---|---|
| **Clinics responded** | 11 |
| **The drug is covered as a 340B eligible prescription in their program** | 4 |
| **Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.** | 91% |
| **Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.** | 64% |
| **Reported having a prescription savings program to improve patient access to prescription medications** | 82% |

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

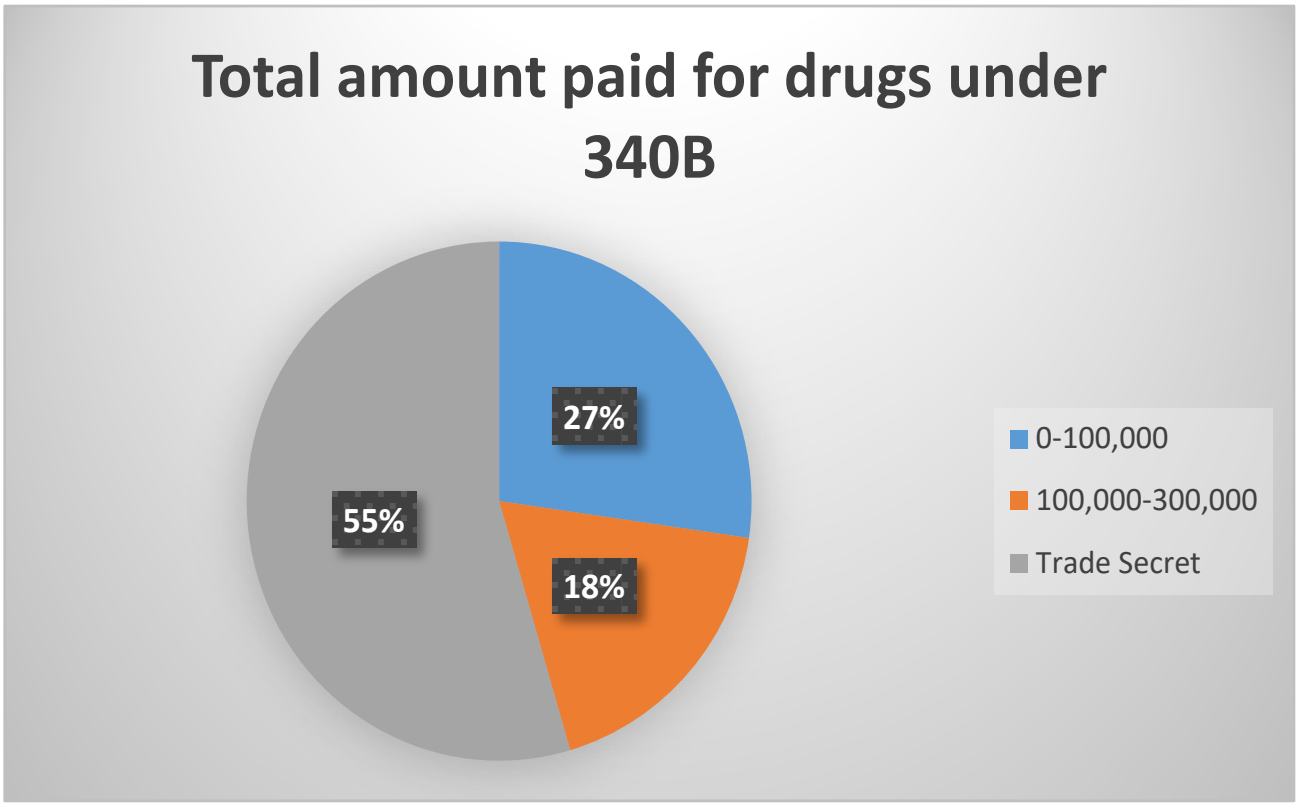


*Figure 6 Amounts paid for drug under 340B discount program*

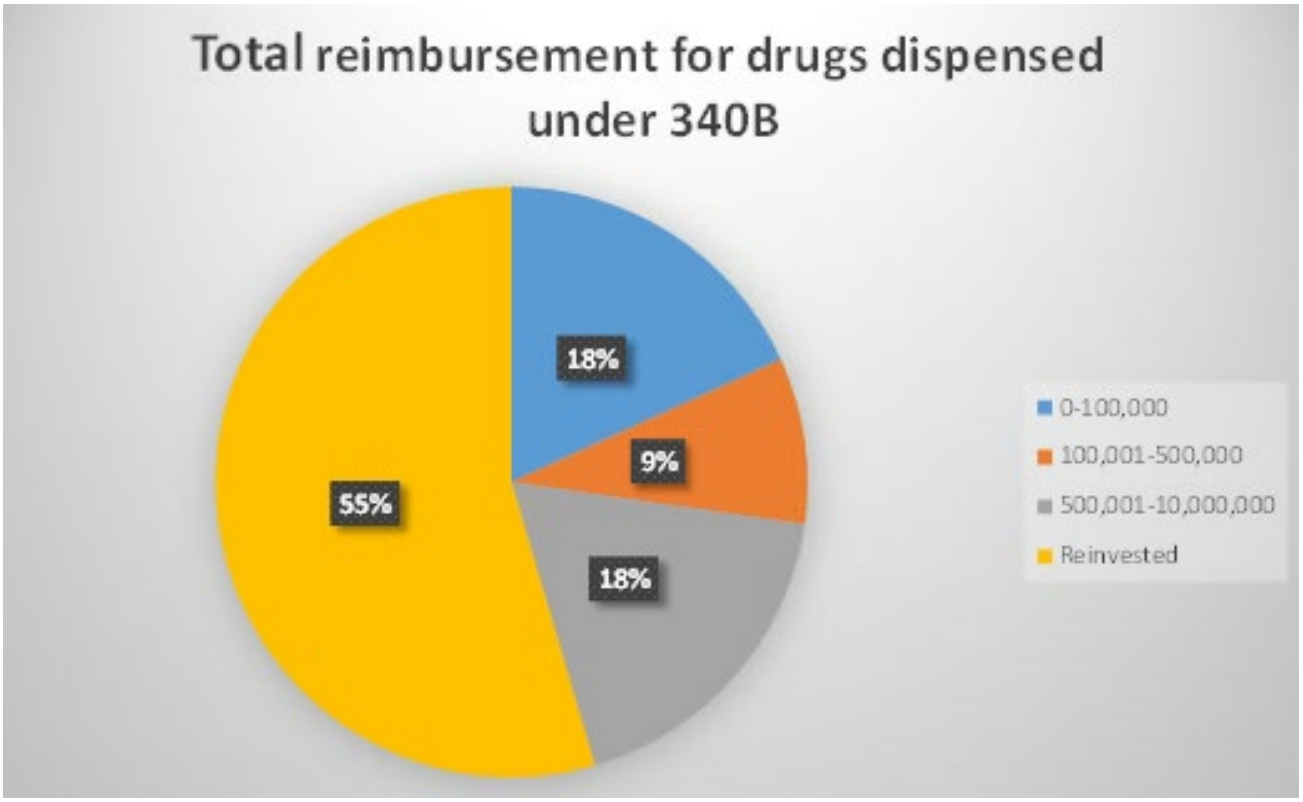


*Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program*

## 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**:

| Name of speaker | Association to drug under review | Drug | Format | Date | Exhibit website link |
|---|---|---|---|---|---|
| **Cynthia Ransom** | Eli Lilly | Emgality | Letter | 5/21/2025 | **Exhibit A** |
| **Lindsay Videnieks** | The Headache & Migraine Policy Forum | Emgality | Letter | 7/14/2025 | **Exhibit B** |