



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

Version 4.0



¹ Image source: <https://www.clinicaltrialsarena.com/projects/vraylar-cariprazine-for-the-treatment-of-bipolar-disorder-and-schizophrenia/>

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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.
v2.1	7/17/2025	Added to the appendix table the public comment from the 7/16/2025 board meeting.
v3.0	9/18/2025	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}

Vraylar® (*cariprazine*) has the following therapeutic alternatives: **Caplyta, Fanapt, Invega, Paliperidone, Risperdal, and Risperidone.**

Proprietary name	Non-proprietary name	Manufacturer	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
Vraylar	<i>capripazine hydrochloride</i>	Abbie Inc.	5	2028-2029	2025	Yes
Caplyta	<i>lumateperone tosylate</i>	Intra-Cellular Therapies Inc.	25	2028-2040		No
Fanapt	<i>iloperidone</i>	Vanda Pharmaceuticals Inc.	9	2025-2031	2027	No
Invega ⁵	<i>paliperidone</i>	Janssen Pharmaceuticals Inc.				No
Paliperidone	<i>Paliperidone</i>					No
Risperdal	<i>Risperdal</i>					No
Risperidone	<i>risperidone</i>					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](https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What%20is%20the%20difference%20between%20patents%20a).

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 Invega in the U.S. Food & Drug Administration Orange Book Database.

Price history^{6,7}

Vraylar® (*cariprazine*) increased at an average annual rate of 3.1 percent 2020, 2023, and 2024.

- In the same time period, its therapeutic alternatives rose at these rates:
 - Caplyta: **5.9** percent
 - Fanapt: **8.8** percent
 - Invega: **-10.2** percent
 - Paliperidone: **-19.9** percent
 - Risperdal: **-8.4** percent
 - Risperidone: **7.9** percent

Additionally, the average annual WAC rate exceeded inflation in 2020, 2023, and 2024. Pharmacy acquisition costs (AAAC) for **Medicaid increased by 18.0 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions⁸

Based on data received from healthcare carriers, Vraylar in 2023 had the **gross spend of \$1,505 per claim**, while the **spend net of discount was \$1,348 per claim**. Price concession per claim was reported to be **\$157**.

Cost to payers⁹

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
Vraylar	\$37,017,240	29,623	\$9,499	\$1,332
Caplyta	\$7,011,576	4,987	\$9,605	\$1,513
Fanapt	\$357,648	169	\$16,257	\$2,088
Invega	\$110,895	638	\$523	\$97
Paliperidone	\$2,295,103	13,523	\$1,213	\$75
Risperdal	\$10,953	20	\$5,477	\$563
Risperidone	\$174,008	10,511	\$135	\$11

⁶ Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

⁷ Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

⁸ Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.

⁹ Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

Cost to enrollees¹⁰

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
Vraylar	\$1,046	\$30	\$154	\$4
Caplyta	\$702	\$10	\$112	\$4
Fanapt	\$178	\$0	\$18	\$0
Invega	\$99	\$10	\$25	\$4
Paliperidone	\$95	\$1	\$12	\$0
Risperdal	\$5	\$0	\$0	\$0
Risperidone	\$22	\$1	\$3	\$0

Rubric considerations

Domain	Consideration
Utilization	29,623
Price evaluation	Avg change in WAC between 0-3.99% for three years and ≥ 5% for two years, outpaces inflation for 3 years
Price concessions	50-75% of claims discounted
System & payer costs	Total gross spend \$15M-\$50M, total net spend \$3M-\$10M
Enrollee burden	Total APAC OOP > \$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?	No
Excluded from CMS Maximum Fair Price List (MFP)	No

¹⁰ Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

Review background

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

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

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

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

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

Drug information¹¹

Drug proprietary name(s)	Vraylar®
Non-proprietary name (active ingredient)	<i>cariprazine</i>
Manufacturer	Forest Laboratories, LLC
Therapy class	Antipsychotics & Antimanic agents
Treatment	Vraylar is an atypical antipsychotic used in the treatment of schizophrenia, bipolar disorder, and as adjunctive therapy for major depressive disorder (MDD)
Dosage strength	Capsule, oral 1.5 mg, 3 mg, 4.5 mg, and 6 mg
Recommended dosing	<ul style="list-style-type: none">• Schizophrenia: 1.5 mg to 6 mg daily• Bipolar Mania: 3 mg to 6 mg daily• Bipolar Depression: 1.5 mg or 3 mg daily• Adjunctive therapy to antidepressants for MDD: 1.5 mg or 3 mg daily
Route of administration	By mouth
Physician administered	No

FDA approval

Vraylar was first approved by the FDA on Sept. 17, 2015.¹²

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.

Health inequities

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

Access to newer antipsychotic medications such as Vraylar (*cariprazine*) is marked by ongoing health disparities that disproportionately affect under-resourced communities and communities of color. Studies have shown that while racial and ethnic minorities are prescribed antipsychotics at similar rates to white patients, they are significantly less likely to receive

¹¹ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

¹² FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.

newer, second-generation agents like Vraylar.¹³ A comprehensive review found that African American patients had 38 percent lower odds, and Latino patients 23 percent lower odds, of being prescribed newer antipsychotics compared to white patients, even when controlling for diagnosis and healthcare access factors.¹⁴ This disparity is particularly concerning, given that newer antipsychotics tend to have improved side effect profiles and can support better adherence and outcomes.¹⁵

Cost and systemic barriers further reinforce this inequity. Although Vraylar is available to many Medicaid and Medicare beneficiaries, access is not consistent across states, as utilization is frequently subject to step therapy, prior authorization, or exclusion from preferred drug lists. Commercially insured patients may qualify for co-pay assistance through the manufacturer, but those without coverage or in transition between public programs can face list prices exceeding \$1,500 per month, depending on strength or monthly supply.¹⁶ These access restrictions, coupled with historical patterns of under prescribing newer agents in Black and Latino populations, contribute to treatment gaps and reinforce cycles of under-treatment in marginalized communities.¹⁷ As price negotiation reforms under the Inflation Reduction Act are implemented, patient advocacy groups have warned that cost containment measures must not come at the expense of equitable access to effective therapies.¹⁸

Residents prescribed

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

Based on APAC claims, **3,897** Oregonians filled a prescription for Vraylar in 2023.¹⁹

¹³ Puyat, J. H., Daw, J. R., Cunningham, C. M., Law, M. R., Wong, S. T., Greyson, D. L., & Morgan, S. G. (2013). Racial and ethnic disparities in the use of antipsychotic medication: a systematic review and meta-analysis. *Social psychiatry and psychiatric epidemiology*, 48(12), 1861–1872. <https://doi.org/10.1007/s00127-013-0753-4>.

¹⁴ Puyat, J. H., Daw, J. R., Cunningham, C. M., Law, M. R., Wong, S. T., Greyson, D. L., & Morgan, S. G. (2013). Racial and ethnic disparities in the use of antipsychotic medication: a systematic review and meta-analysis. *Social psychiatry and psychiatric epidemiology*, 48(12), 1861–1872. <https://doi.org/10.1007/s00127-013-0753-4>

¹⁵ Centers for Medicare & Medicaid Services. (2025) Public Input on Medicare Drug Price Negotiation – Session 2 Transcript. <https://www.cms.gov/files/document/session-2-redacted-transcript-pdf.pdf>

¹⁶ Vraylar (cariprazine) Cost & Savings, 2025. <https://www.vraylar.com/cost-and-savings>

¹⁷ Puyat, J. H., Daw, J. R., Cunningham, C. M., Law, M. R., Wong, S. T., Greyson, D. L., & Morgan, S. G. (2013). Racial and ethnic disparities in the use of antipsychotic medication: a systematic review and meta-analysis. *Social psychiatry and psychiatric epidemiology*, 48(12), 1861–1872. <https://doi.org/10.1007/s00127-013-0753-4>

¹⁸ Institute for Clinical and Economic Review (ICER). “2024 Update on Drug Access and Equity.” https://icer.org/wp-content/uploads/2024/12/UPI_2024_Report_121224.pdf

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

Price for the drug

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

This section examines the pricing dynamics of Vraylar, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of the wholesale acquisition cost (WAC) and the Oregon Actual Average Acquisition Cost (AAAC), compared to its therapeutic alternatives. Together, the data provides a comprehensive view of Vraylar’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

	Vraylar	Caplyta	Fanapt	Invega	Paliperidone	Risperdal	Risperidone
30-day supply	30 units (30 pills)	30-60 units	30-60 units				

Table 4 Drug vs. therapeutic alternatives for 2018-2024 WAC per 30-day supply²⁰

Year	Vraylar	Caplyta	Fanapt	Invega	Paliperidone	Risperdal	Risperidone
2018	\$1,201		\$671	\$1,108	\$733	\$946	\$72
2019	\$1,201		\$724	\$1,179	\$580	\$1,007	\$70
2020	\$1,225	\$1,320	\$852	\$1,202	\$437	\$1,007	\$70
2021	\$1,268	\$1,399	\$994	\$368	\$419	\$433	\$98
2022	\$1,312	\$1,482	\$1,079	\$368	\$271	\$433	\$98
2023	\$1,378	\$1,569	\$1,079	\$368	\$194	\$433	\$91
2024	\$1,447	\$1,662	\$1,100	\$368	\$181	\$433	\$107
Avg. Annual % Change	3.2%	5.9%	8.8%	-10.2%	-19.9%	-8.4%	7.9%
% change 2018 and 2024	20.5%		64.1%	-66.8%	-75.2%	-54.2%	48.2%

The WAC of Vraylar, averaged across seven NDCs reported, was approximately **\$48 per unit** at the end of 2024.²¹ Between 2018-2024, the unit WAC increased at an average annual rate

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

²¹ Ibid.

of **3.2 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).²²

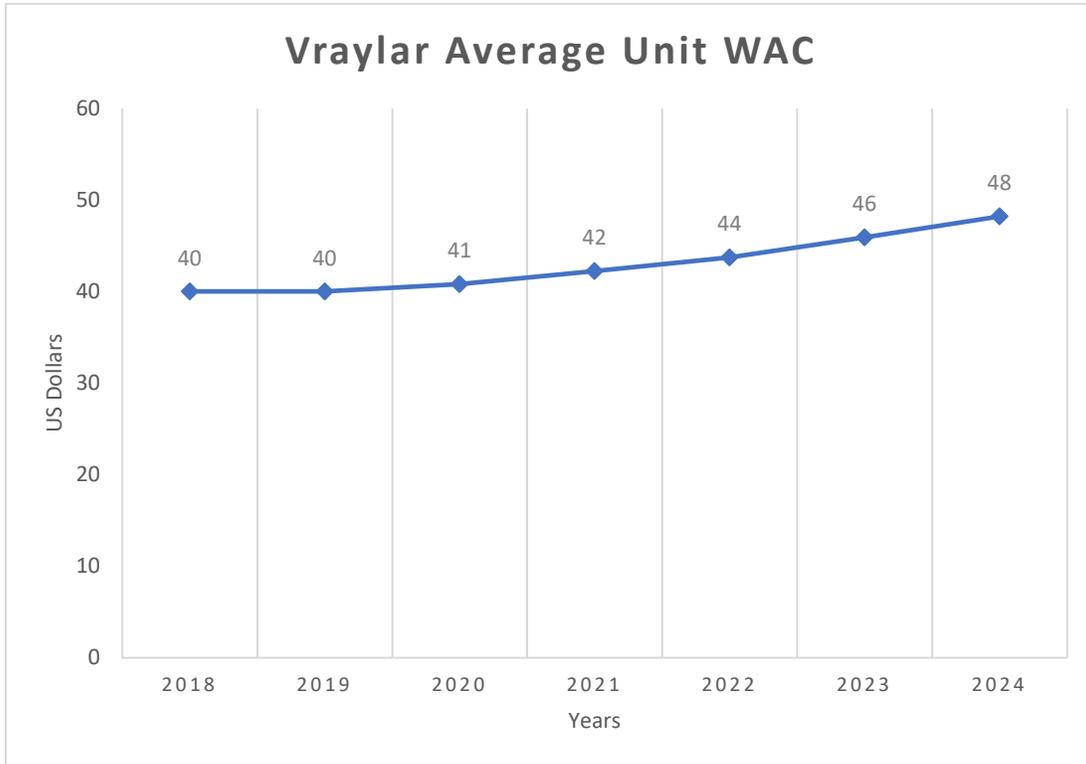


Figure 1 Vraylar average WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison²³

Year	Vraylar	Caplyta	Fanapt	Invega	Paliperidone	Risperdal	Risperidone	CPI-U
2018-2019	0.0%		8.0%	6.4%	-21.0%	6.4%	-3.2%	1.7%
2019-2020	2.0%		17.7%	2.0%	-24.7%	0.0%	0.0%	0.7%
2020-2021	3.5%	6.0%	16.6%	-69.4%	-3.9%	-57.0%	39.9%	5.3%
2021-2022	3.5%	5.9%	8.5%	0.0%	-35.3%	0.0%	0.0%	9.0%
2022-2023	5.0%	5.9%	0.0%	0.0%	-28.3%	0.0%	-6.5%	3.1%
2023-2024	5.0%	5.9%	2.0%	0.0%	-6.4%	0.0%	17.3%	3.0%

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

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

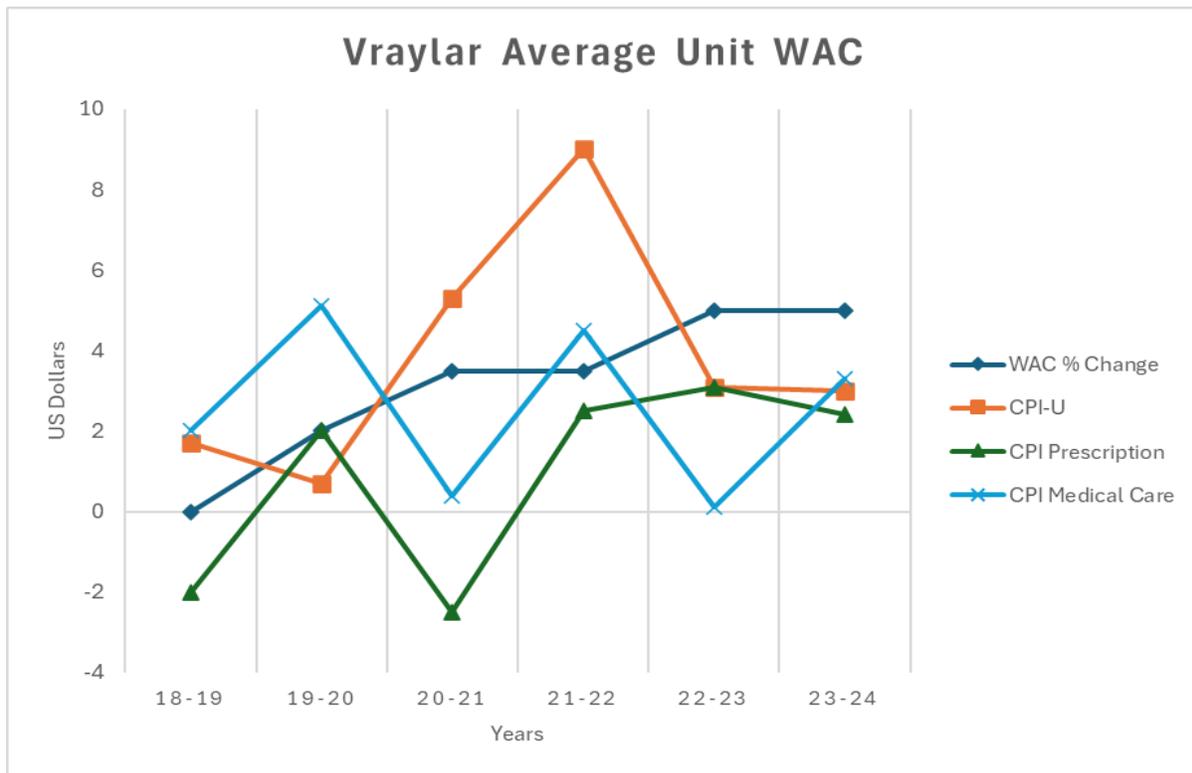


Figure 2 Year over year change in WAC compared to inflation rates²⁴

Pharmacy acquisition costs

The AAAC, which reflects pharmacies’ actual purchase prices for Medicaid fee-for-service claims, rose from **\$39 in Quarter 1 of 2020, to \$46 in Quarter 4 of 2024, an increase of 17.95 percent** over the period (see Table 6).²⁵ Relative to the **\$48 WAC** in end-of-year 2024, an **AAAC discount of 4.35 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 Vraylar’s price trajectory relative to inflation and informs the assessment of its affordability for public and private payers.

²⁴ Consumer Price Index, US Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/> Accessed May 20, 2025.

²⁵ Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2023. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. <https://myersandstauffer.com/client-portal/oregon/>.

Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Average AAAC	Average WAC
2020	\$39	\$39	\$39	\$39	\$39	\$41
2021	\$41	\$41	\$41	\$41	\$41	\$42
2022	\$42	\$42	\$42	\$42	\$42	\$44
2023	\$44	\$44	\$44	\$44	\$44	\$46
2024	\$46	\$46	\$46	\$46	\$46	\$48

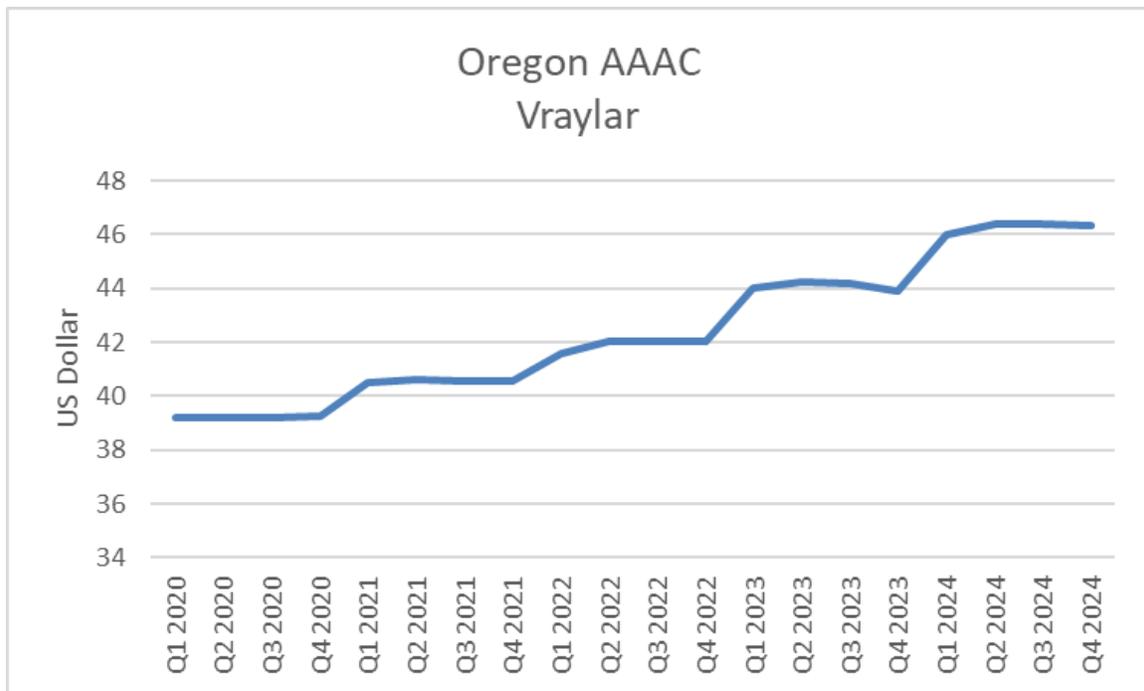


Figure 3 AAAC for Vraylar from Q1 2020 to Q4 2024

Estimated average monetary price concession

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

This section provides an analysis of the average monetary discounts, rebates, and other price concessions applied to Vraylar claims in the commercial market. Drawing on 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 manufacturers, pharmacy benefit managers (PBMs), and other negotiated price reductions.

Based on carrier-submitted data for 2023, the **average gross cost of Vraylar per enrollee in the commercial market was approximately \$4,932**. After accounting for manufacturer rebates, PBM discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$4,417**, reflecting an **estimated mean discount of 10.4 percent** relative to gross costs.

Across all reporting carriers and market segments, the total cost of Vraylar before concessions was **\$4,917,279**, with total reported price concessions amounting to approximately **\$513,113**, as detailed in Table 7. Notably, **74.7 percent of claims benefited from some form of price concession, leaving 25.3 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	997
Total number of claims	3,267
Total number of claims with price concessions applied	2,439
Percentage of claims with price concessions applied	74.7%
Percentage of cost remaining after concessions	89.6%
Percent of discount	10.4%
Manufacturer price concessions for all market types	\$397,892
PBM price concessions for all market types	\$108,423
Other price reductions for all market types	\$6,798
Cost before price concessions across all market types	\$4,917,279
Total price concessions across all market types	\$513,113
Cost of after price concessions across all market types	\$4,404,166
Avg. payer spend per enrollee without price concessions	\$4,932
Avg. payer spend per enrollee with price concessions	\$4,417

Including all market segments, the **gross spend of Vraylar per claim for commercial carriers was \$1,505** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$1,348**, meaning that insurers reported a price concession of **\$157** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types provided from Data Call²⁶

	Average	Individual market	Large market	Small market
Spend per claim, gross	\$1,505	\$1,685	\$1,527	\$1,247
Spend per claim, net	\$1,348	\$1,489	\$1,374	\$1,113
Price concessions per claim	\$157	\$197	\$153	\$135

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

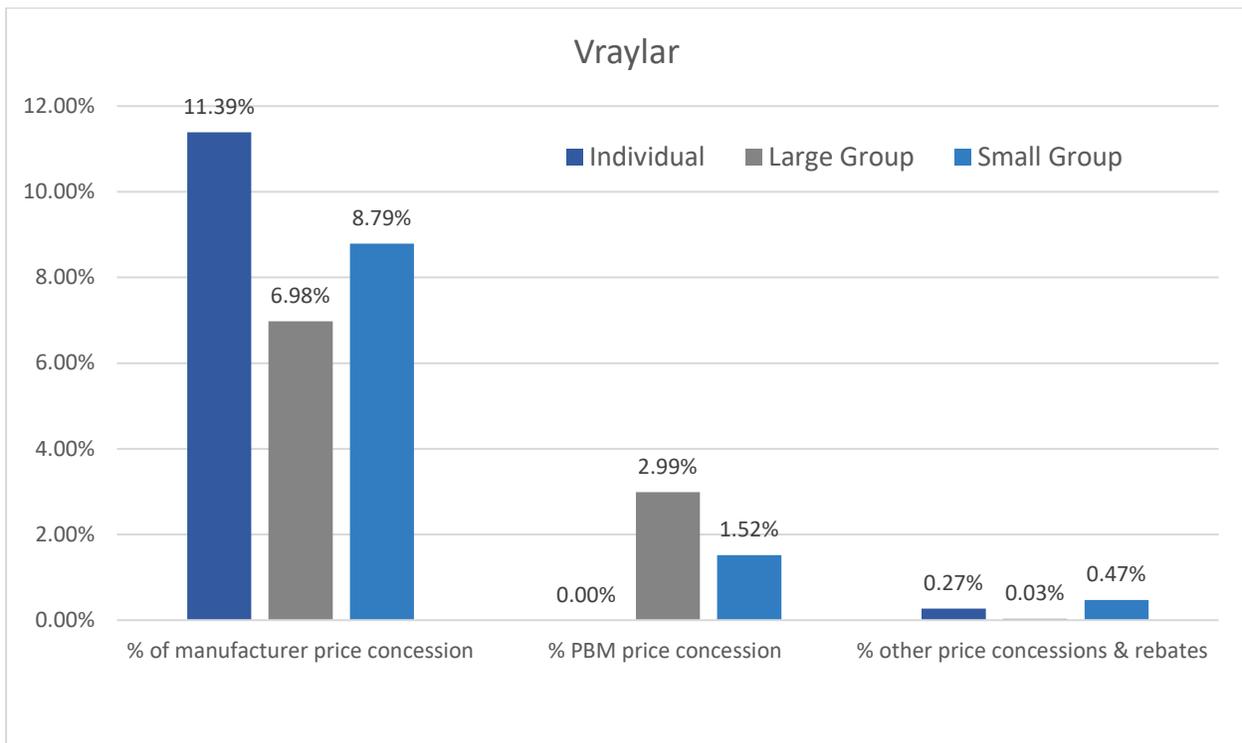


Figure 4 Percent of price concession in each market type^{27,28}

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

²⁷ 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).

²⁸ 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 Vraylar to each pharmacy benefit managers, expressed as a percentage of the drug's price. At the time of this review, there was no specific data available to PDAB to determine the total amount of such price concessions in the Oregon market.

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

Estimated price for therapeutic alternatives²⁹

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

This section presents information on the estimated spending associated with Vraylar and its therapeutic alternatives using data from APAC and 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.

Vraylar's **gross payer paid per claim, based on APAC data, was \$1,250**, while net cost data showed a comparable per-claim amount of \$1,288. Compared to Vraylar's gross cost per claim, Caplyta had a similar claim cost, while **Fanapt showed a higher cost per claim**, though it shows to have fewer claims. Risperidone and Paliperidone show lower per-claim costs with risperidone having the lowest average of \$17 per claim.

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

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

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

Table 9 Average healthcare and average enrollee OOP costs for Vraylar vs therapeutic alternatives³⁰

Proprietary name	No. of enrollees ³¹	No. of claims	Total payer paid	Total enrollees paid ³²	Payer paid/claim	Enrollee paid/claim ³³
<i>Subject drug</i> Vraylar (data call) ³⁴	997	3,267	\$4,207,403	\$909,046	\$1,288	\$278
<i>Subject drug</i> Vraylar (APAC)	3,897	29,623	\$37,017,240	\$1,640,648	\$1,250	\$55
Caplyta	730	4,987	\$7,011,576	\$210,672	\$1,406	\$42
Fanapt	22	169	\$357,648	\$2,310	\$2,116	\$14
Invega	212	638	\$110,895	\$1,889	\$174	\$3
Paliperidone	1,892	13,523	\$2,295,103	\$67,372	\$170	\$5
Risperdal	2	20	\$10,953	\$10	\$548	\$0
Risperidone	1,291	10,511	\$174,008	\$15,540	\$17	\$1

Estimated average price concession for therapeutic alternatives

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

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

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

³⁰ 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.

³¹ 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.

³² This cost includes all lines of business.

³³ Ibid.

³⁴ Information from the data call with the cost information after price concessions.

Estimated costs to health insurance plans

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

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

In 2023, the Oregon APAC database recorded **29,623 total claims for Vraylar among 4,085 total enrollees**, corresponding to a **total system gross expenditure of \$37 million**.

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

- **Medicaid** accounted for the largest share of utilization, with 18,799 claims from 2,480 enrollees and a total spend of **\$22.8 million**.
- **Medicare** and **commercial** payers reported smaller but notable expenditures of approximately **\$8.6 million** and **\$5.7 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers’ expenditure for total enrollees and total claims ³⁵

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	772	4,549	\$5,653,379	\$7,323	\$1,243
Medicaid	2,480	18,799	\$22,793,380	\$9,191	\$1,212
Medicare	833	6,275	\$8,570,481	\$10,289	\$1,366
Totals³⁶	4,085	29,623	\$37,017,240		

Table 11 provides APAC claims utilization across all lines of business with **29,623 total claims for Vraylar**. **Vraylar has the most utilization overall** and in each of the lines of business. Paliperidone has the second highest utilization with 13,523 claims.

³⁵ 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.

³⁶ 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 ³⁷

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims ³⁸
Vraylar	4,549	18,799	6,275	29,623
Caplyta	548	3,113	1,326	4,987
Fanapt	3	39	127	169
Invega	3	562	73	638
Paliperidone	605	8,069	4,849	13,523
Risperdal	0	0	20	20
Risperidone	560	4,546	5,405	10,511

Table 12 shows the overall payer expenditure of Vraylar and its therapeutic alternatives, distinguished by lines of business. **Vraylar has a total expenditure of \$37.0 million with Medicaid being the biggest portion at \$22.8 million.** The therapeutic alternative with the least expenditure is Risperdal, at \$10,953.

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

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total ⁴⁰
Vraylar	\$5,653,379	\$22,793,380	\$8,570,481	\$37,017,240
Caplyta	\$710,530	\$4,383,022	\$1,918,023	\$7,011,576
Fanapt	\$3,034	\$71,559	\$283,056	\$357,648
Invega	\$514	\$63,153	\$47,228	\$110,895
Paliperidone	\$76,933	\$619,682	\$1,598,489	\$2,295,103
Risperdal	\$0	\$0	\$10,953	\$10,953
Risperidone	\$4,699	\$72,175	\$97,135	\$174,008

Table 13 compares the overall payer cost per enrollee of Vraylar and its therapeutic alternatives, distinguished by lines of business. Fanapt has the highest total cost per enrollee at \$16,257. **Vraylar has a lower total cost per enrollee of \$9,499. The median cost per enrollee**

³⁷ 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.

³⁸ Total is the sum of all utilization for the drug across all lines of business.

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

for Vraylar is \$1,332.

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

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total ⁴² cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee, 75 th percentile	Cost per enrollee, 95 th percentile
Vraylar	\$7,323	\$9,191	\$10,289	\$9,499	\$1,332	\$283	\$1,340	\$3,049
Caplyta	\$7,479	\$9,528	\$9,266	\$9,605	\$1,513	\$195	\$1,520	\$1,826
Fanapt	\$1,517	\$7,156	\$25,732	\$16,257	\$2,088	\$1,129	\$2,204	\$2,999
Invega	\$257	\$326	\$2,778	\$523	\$97	\$39	\$112	\$378
Paliperidone	\$583	\$502	\$2,766	\$1,213	\$75	\$99	\$144	\$687
Risperdal	\$0	\$0	\$5,477	\$5,477	\$563	\$9	\$568	\$570
Risperidone	\$40	\$115	\$165	\$135	\$11	\$7	\$13	\$41

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 \$5.1 million**, with payer paying \$4.2 million, and enrollees out-of-pocket estimating to be \$909,045. Table 14 includes the average plan costs per enrollee in the commercial market ranged from **\$4,968 (large group)** to **\$5,707 (individual)** annually.

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

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

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

⁴³ 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	\$1,678	\$1,096	\$583	\$5,707	\$3,725	\$1,982
Large Group	\$1,530	\$1,409	\$122	\$4,968	\$4,574	\$394
Small Group	\$1,589	\$1,024	\$566	\$5,206	\$3,353	\$1,853

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (**64% of total**), followed by small group and individual markets.

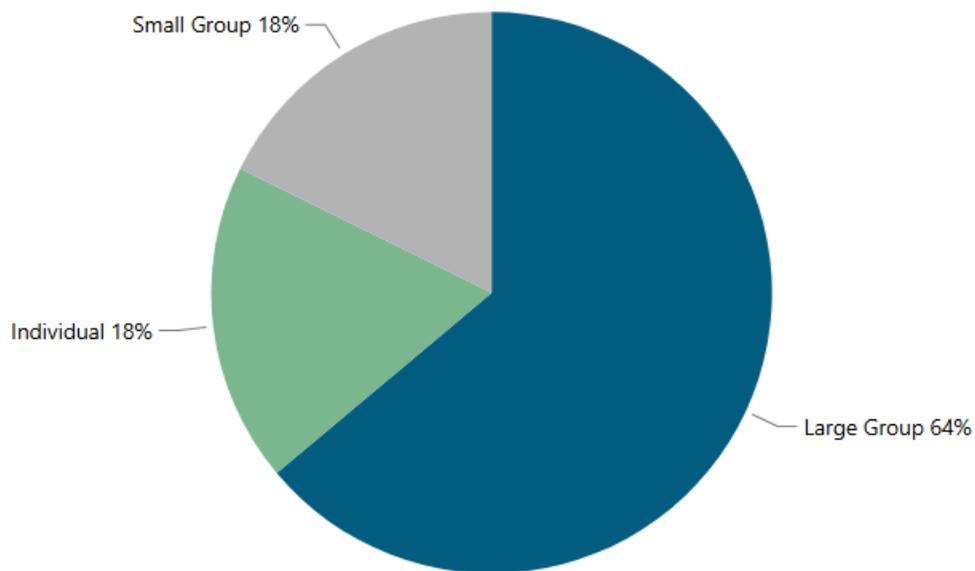


Figure 5 Data call total annual percent spend (payer paid) by market

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 Vraylar, 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 Vraylar. In 2023, approximately **51.1 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **3.0 percent of plans required step therapy** before approving its use.

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

Table 15 Plan design analysis from 2023 data

Percentage of Plan	
Required prior authorization	51.1%
Required step therapy	3.0%
On a non-preferred formulary	96.6%
Not covered	0.4%

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

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

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

Estimated average enrollee copayment or other cost-sharing

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

This section summarizes the average annual enrollee out-of-pocket (OOP) costs for Vraylar in Oregon, as reported in 2023 by the two data sources: the Oregon All Payers All Claims (APAC) database and the carrier data call.⁴⁴ These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type and commercial market segment.

Table 16 and 17 presents the average annual enrollee cost-sharing amounts derived from APAC and carrier-submitted data. The APAC data, which includes claims from commercial, Medicaid, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs that varied by payer line of business. For example, **commercially insured enrollees recorded higher average annual OOP costs** than Medicare enrollees. 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 enrollee⁴⁵

Proprietary name	Annual Medicare OOP cost/enrollee	Annual Commercial OOP cost/enrollee	Total ⁴⁶	Median	IQR	75 th percentile	95 th percentile
Vraylar	\$458	\$1,659	\$1,046	\$30	\$267	\$267	\$1,398
Caplyta	\$462	\$1,210	\$702	\$10	\$94	\$94	\$1,378
Fanapt	\$17	\$1,060	\$178	\$0	\$4	\$4	\$430
Invega	\$95	\$139	\$99	\$10	\$85	\$85	\$364
Paliperidone	\$87	\$131	\$95	\$1	\$10	\$10	\$220
Risperdal	\$5	--	\$5	\$0	\$0	\$0	\$6
Risperidone	\$21	\$28	\$22	\$1	\$4	\$4	\$21

⁴⁴ 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.

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.

Table 17 Review drug vs. therapeutic alternatives and gross out-of-pocket cost per claim⁴⁷

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total ⁴⁸	Median	IQR	75 th percentile	95 th percentile
Vraylar	\$61	\$282	\$154	\$4	\$75	\$75	\$835
Caplyta	\$72	\$210	\$112	\$4	\$60	\$60	\$761
Fanapt	\$1	\$707	\$18	\$0	\$4	\$4	\$10
Invega	\$22	\$93	\$25	\$4	\$4	\$4	\$164
Paliperidone	\$10	\$29	\$12	\$0	\$4	\$4	\$69
Risperdal	\$0	--	\$0	\$0	\$0	\$0	\$0
Risperidone	\$2	\$6	\$3	\$0	\$2	\$2	\$11

Clinical information based on manufacturer material⁴⁹

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

Drug indications

- FDA Approved:
 - Treatment of schizophrenia in adults
 - Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults
 - Treatment of depressive episodes associated with bipolar 1 disorder (bipolar depression) in adults
 - Adjunctive therapy to antidepressants for the treatment of MDD in adults.
- Off Label Uses: No off label uses determined

Clinical efficacy

- Schizophrenia in adults
 - The efficacy of cariprazine for schizophrenia was established in three, six-week randomized, placebo-controlled studies in 1,049 patients requiring hospitalization for active psychosis. The primary outcome was change from

⁴⁷ 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.

⁴⁸ The total is the overall cost per claim across commercial insurers, Medicaid, and Medicare.

⁴⁹ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

baseline in total positive and negative syndrome scale (PANSS), a tool to assess symptoms of schizophrenia. Cariprazine doses ranged from 1.5 to 9 mg daily.

- A statistically-significant difference in change in PANSS scores at week six were evident at all doses compared to placebo and was similar to aripiprazole in one trial.
- Effective dose range: 1.5 to 6 mg/day.
- Doses above 6 mg did not increase efficacy but increased risk of adverse events.
- Manic or mixed episodes in bipolar 1 disorder
 - The efficacy of cariprazine for bipolar mania/mixed episodes was established in three 3-week randomized, placebo-controlled studies at doses from 3 to 12 mg daily (n=962). The primary outcome was change from baseline in the Young Mania Rating Scale (YMRS).
 - A statistically significant difference in change in YMRS score at week three was observed in all trials.
 - Efficacy at daily doses up to 6 mg was demonstrated with no evidence to suggest higher daily doses are more efficacious.
- Depressive episodes in bipolar 1 disorder (bipolar depression)
 - The efficacy of cariprazine in bipolar depression is supported by two, phase three randomized, placebo-controlled, six-week trials. The primary outcome was change in the Montgomery-Asberg Depression Rating Scale (MADRS) total score.
 - A statistically significant change in MADRS score was observed with both 1.5 mg and 3 mg daily compared to placebo.
 - Effective doses: 1.5 mg and 3 mg/day, with most consistent benefits at 1.5 mg.
- Adjunctive therapy for major depressive disorder (MDD)
 - The efficacy of cariprazine as adjunctive treatment in MDD was evaluated in two, six-week and one, eight-week placebo-controlled trials on a change from baseline in MADRS. These trials demonstrated a statistically significant change in MADRS score with doses of 1.5 mg to 3 mg daily compared to placebo.
 - Another randomized, double-blind, placebo controlled study found no statistically significant difference between cariprazine 1.5 or 3 mg daily versus placebo on change in MADRS score.

Clinical safety⁵⁰

- FDA safety warnings and precautions:
 - Increased mortality in elderly patients with dementia-related psychosis
 - Suicidal thoughts and behaviors in children, adolescents, and young adults

⁵⁰ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

- Cerebrovascular adverse reactions in elderly patients with dementia-related psychosis
 - Neuroleptic malignant syndrome
 - Tardive dyskinesia
 - Late-occurring adverse reactions
 - Metabolic changes, including hyperglycemia, diabetes, dyslipidemia and weight gain
 - Leukopenia, neutropenia, and agranulocytosis
 - Falls due to somnolence, postural hypotension and motor instability
 - Orthostatic hypotension and syncope
 - Seizures
 - Potential for cognitive and motor impairment
 - Dysphagia
 - Body temperature dysregulation
- Contraindications:
 - Hypersensitivity to cariprazine
 - Common side effects:
 - Activating effects (e.g. akathisia, restlessness)
 - Sedating effects (e.g. drowsiness, somnolence)
 - Extrapyramidal symptoms
 - Hematologic abnormalities: leukopenia and neutropenia
 - Hyperglycemia
 - Weight gain
 - Nausea, abdominal pain, constipation, decreased appetite, diarrhea, dyspepsia

Comparative to therapeutic alternatives

Table 18 FDA-Approved Indications

Indication	Cariprazine (Vraylar) ⁵¹	Lumateperone (Caplyta) ⁵²
Schizophrenia	Yes (adults)	Yes (adults)
Bipolar depression	Yes	Yes
Bipolar mania	Yes	No
Adjunct in MDD	Yes (adjunctive)	No

⁵¹ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

⁵² U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf.

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

Table 19 Efficacy (Clinical Trials & Practice)

Comparison Point	Cariprazine (Vraylar) ⁵³	Lumateperone (Caplyta) ⁵⁴
Bipolar depression⁵⁵	Efficacy for moderate to severe symptoms	Strong efficacy, especially in Bipolar II
Mania/Hypomania	Proven in bipolar I mania ⁵⁶	Not approved or studied for mania ⁵⁷
Schizophrenia	Effective, especially on negative symptoms ⁵⁸	Effective, especially for cognitive/mood symptoms ⁵⁹
Adjunct for MDD	Proven efficacy	Not approved

Table 20 Side effect profile

Side Effect	Cariprazine (Vraylar) ⁶⁰	Lumateperone (Caplyta) ⁶¹
Weight gain	Moderate	Low
EPS (extrapyramidal symptoms)	Low	Very low
Akathisia	Common (up to 20%)	Rare
Metabolic risk	Mild	Very low risk

⁵³ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

⁵⁴ U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf.

⁵⁵ Calabrese, J. R., Durgam, S., Satlin, A., Vanover, K. E., Davis, R. E., Chen, R., Kozauer, S. G., Mates, S., & Sachs, G. S. (2021). Efficacy and Safety of Lumateperone for Major Depressive Episodes Associated With Bipolar I or Bipolar II Disorder: A Phase 3 Randomized Placebo-Controlled Trial. *The American Journal of Psychiatry*, 178(12), 1098–1106. <https://doi.org/10.1176/appi.ajp.2021.20091339>.

⁵⁶ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

⁵⁷ U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf.

⁵⁸ Scarff J. R. (2016). Cariprazine for Schizophrenia and Bipolar Disorder. *Innovations in clinical neuroscience*, 13(9–10), 49–52. <https://pmc.ncbi.nlm.nih.gov/articles/PMC5141596/>.

⁵⁹ Kane, J. M., Durgam, S., Satlin, A., Vanover, K. E., Chen, R., Davis, R., & Mates, S. (2021). Safety and tolerability of lumateperone for the treatment of schizophrenia: a pooled analysis of late-phase placebo- and active-controlled clinical trials. *International clinical psychopharmacology*, 36(5), 244–250. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8322041/>.

⁶⁰ U.S. Food & Drug Administration. Vraylar (cariprazine) Prescribing Information. AbbVie Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204370s009lbl.pdf.

⁶¹ U.S. Food & Drug Administration. Caplyta (lumateperone) Prescribing Information. Intra-Cellular Therapies, Inc., Revised 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209500s011lbl.pdf.

Table 21 Dosing & tolerability

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

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 one individual taking or having an association with Vraylar. The survey response showed Vraylar was covered under the private insurance with no program assistance provided, and the patient's monthly out-of-pocket cost was between \$0-\$49.

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

” Vraylar ”

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

Individuals with scientific or medical training

This section summarizes information reported by healthcare professionals with scientific or medical training identified key barriers for patients in accessing medications. There was one healthcare professional that reported the prior authorization process of Vraylar was an administrative burden and laborious for patients to access the medication.

Safety net providers

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

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

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

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

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

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

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

Table 22 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	7
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340b compliance requirements	100%
Reported total amount paid for drug under 340B was between \$0-\$100,000	27%
Reported total amount paid for drug under 340B was between \$100,001-\$300,000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between \$0-\$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between \$100,001-\$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between \$500,000-\$10,000,000	18%

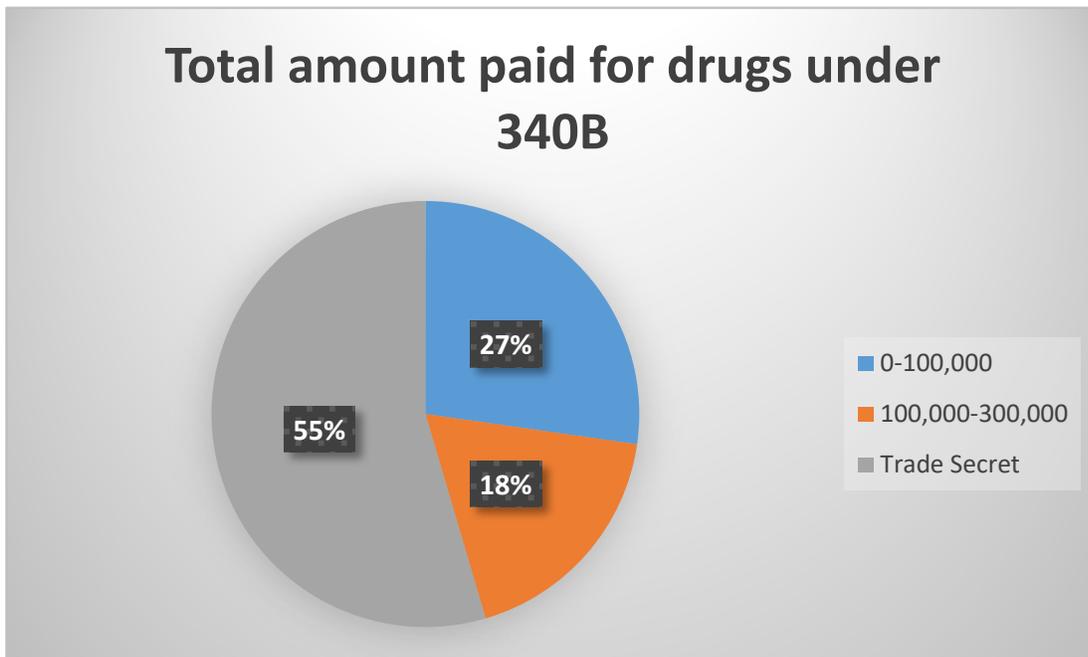


Figure 6 Amounts paid for drug under 340B discount program

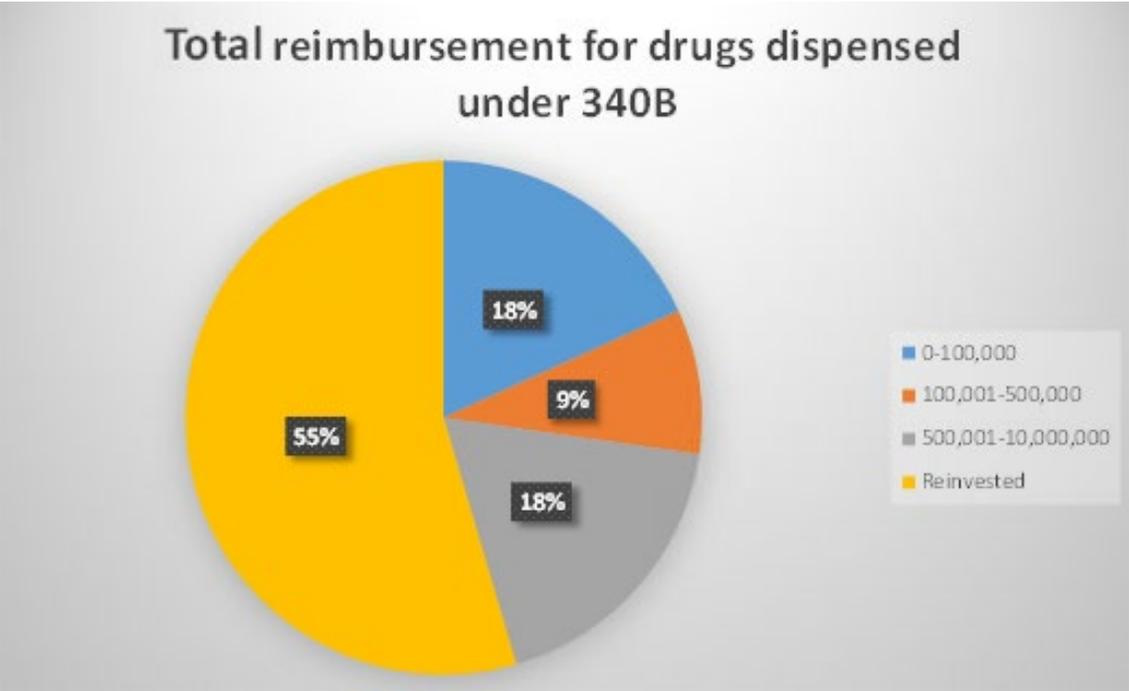


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

Payers

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

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

Appendix

Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Lorren Sandt	Caring Ambassadors	Vraylar	Letter, speaking	7/16/2025	Exhibit A Exhibit B