



# Mounjaro<sup>®</sup> (*tirzepatide*)<sup>1</sup>

Version 2.0



<sup>1</sup>Image source: <https://mylocalsurgery.co.uk/conditions/weight-loss-treatments/treatments/mounjaro/28>

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## Document version history

Version	Date	Description
<b>v1.0</b>	8/13/2025	Original Release
<b>v1.5</b>	9/18/2025	Added new public comment to the appendix table. Updated table numbers and table references.
<b>v1.6</b>	9/23/2025	Added new public comment to the appendix table
<b>v2.0</b>	10/30/2025	Updated table format and footnotes.

# Review summary

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

**Mounjaro® (tirzepatide)** has the following therapeutic alternatives: **Ozempic, Rybelsus, Trulicity,** and **Victoza.**

Proprietary name	Non-proprietary name	Manufacturer	Approved year	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
<b>Mounjaro</b>	<i>tirzepatide</i>	Eli Lilly and Co.	2022	4	2036-2041	2027	No
<b>Ozempic</b>	<i>semaglutide</i>	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027)
<b>Rybelsus<sup>5</sup></b>	<i>semaglutide</i>	Novo Nordisk Inc.	217	13	2026-2039		Yes (2027)
<b>Trulicity<sup>6</sup></b>	<i>dulaglutide</i>	Eli Lilly and Co.	2014				No
<b>Victoza<sup>7</sup></b>	<i>liraglutide</i>	Novo Nordisk Inc.	2010	4	2025-2037		No

<sup>2</sup> 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>.

<sup>3</sup> 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).

<sup>4</sup> Selected Drugs and Negotiated Prices. Centers for Medicare & Medicaid Services, May 23, 2025. <https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices>.

<sup>5</sup> No exclusivity was listed for Rybelsus. 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>.

<sup>6</sup> No patent or exclusivity information was listed for Trulicity. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration, Aug. 27, 2025. <https://purplebooksearch.fda.gov/>.

<sup>7</sup> No exclusivity was listed for Victoza. 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>.

## Price history<sup>8,9</sup>

Mounjaro rose at an **average annual rate of 4.7 percent** from 2022-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
  - Ozempic: **4.8 percent**
  - Rybelsus: **4.4 percent**
  - Trulicity: **5.0 percent**
  - Victoza: **-2.3 percent**

Additionally, the average annual rate of Mounjaro exceeded inflation in **2023 and 2024**. Pharmacy acquisition costs for **Medicaid also increased by 5.4 percent** over the same period, reflecting broader trends in pricing escalation.

## Price concessions<sup>10</sup>

Based on data received from healthcare carriers, Mounjaro in 2023 had the **gross spend of \$1,143 per claim**, while the **spend net of discount was \$608 per claim**. Price concession per claim was reported to be **\$535**.

## Cost to the payers<sup>11</sup>

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

Proprietary name	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
<b>Mounjaro</b>	\$24,384,519	22,658	\$5,672	\$974
<b>Ozempic</b>	\$81,017,647	78,032	\$4,427	\$902
<b>Rybelsus</b>	\$15,574,551	11,524	\$6,023	\$973
<b>Trulicity</b>	\$114,173,339	104,682	\$8,277	\$909
<b>Victoza</b>	\$26,835,206	20,794	\$6,963	\$1,089

<sup>8</sup> Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

<sup>9</sup> Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

<sup>10</sup> Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.

<sup>11</sup> Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

## Cost to enrollees<sup>12</sup>

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

Proprietary name	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
<b>Mounjaro</b>	\$520	\$35	\$100	\$30
<b>Ozempic</b>	\$360	\$40	\$89	\$30
<b>Rybelsus</b>	\$530	\$47	\$121	\$40
<b>Trulicity</b>	\$499	\$25	\$76	\$10
<b>Victoza</b>	\$367	\$10	\$78	\$4

## Rubric considerations

Domain	Consideration
<b>Equity impact</b>	Yes
<b>Access</b>	61.7% of plans listed as non-preferred, 64.2% require prior-auth
<b>Utilization</b>	22,658
<b>Price evaluation</b>	Avg percent change in WAC 4-4.99%, outpaced inflation for two years
<b>Price concessions</b>	25-50% of claims discounted
<b>System &amp; payer costs</b>	Total gross spend \$15M-\$50M, total net spend \$3M-\$10M
<b>Enrollee burden</b>	Total APAC OOP \$200-\$700
<b>Therapeutic alternative</b>	Subject Rx has 2-6 TA/TE/Biosim
<b>Stakeholder input</b>	Yes
<b>Patent expirations</b>	Yes
<b>On CMS Maximum Fair Price List (MFP)</b>	No

<sup>12</sup> Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

## Review background

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

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

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

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

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

## Drug information<sup>13</sup>

<b>Drug proprietary name(s)</b>	Mounjaro®
<b>Non-proprietary name</b>	<i>tirzepatide</i>
<b>Manufacturer</b>	Eli Lilly and Company
<b>Pharmacologic category</b>	Glucagon-like Peptide 1 (GLP-1) Receptor Agonist
<b>Treatment</b>	<ul style="list-style-type: none"><li>• As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).</li></ul>
<b>Dosage and strengths</b>	<ul style="list-style-type: none"><li>• 2.5 mg</li><li>• 5 mg</li><li>• 7.5 mg</li><li>• 10 mg</li><li>• 12.5 mg</li><li>• 15 mg per 0.5 mL in single-dose pen or single-dose vial</li></ul>
<b>Form/route</b>	Subcutaneous Injection
<b>Physician administered</b>	No

### FDA approval

Mounjaro was first approved by the FDA on May 13, 2022.<sup>14</sup>

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

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

## Health inequities

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

Glucagon-like peptide-1 or GLP-1 continues to expand, but data shows lower initiation and higher discontinuation among Black and Hispanic patients and those with lower income

<sup>13</sup> U.S. Food & Drug Administration. *Mounjaro (tirzepatide)* Prescribing information, May 2022.

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/215866s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf).

<sup>14</sup> FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.

patterns linked to affordability, insurance hurdles, and care fragmentation.<sup>15, 16</sup> The U.S. Food and Drug Administration (FDA) confirmed tirzepatide injection shortages were resolved in December 2024. However, utilization management and cost remain key access barriers that may differentially burden low-income and the Medicaid and Medicare populations.<sup>17,18</sup> Coverage for weight management indications remain limited in many programs. While this does not control diabetes indications directly, plan level policies and demand spillovers can indirectly affect access and continuity for people with type-2 diabetes.<sup>19</sup>

## Residents prescribed

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

Based on APAC claims, **22,658** Oregonians filled a prescription for Mounjaro in 2023.<sup>20</sup>

## Price for the drug

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

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

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<sup>15</sup> Moore, J., Iheme, N., Rebold, N. S., Kusi, H., Mere, C., Nwaogwugwu, U., Ettienne, E., Chaijamorn, W., & Rungkitwattanakul, D. (2025). Factors and Disparities Influencing Sodium-Glucose Cotransporter 2 Inhibitors and Glucagon-like Peptide 1 Receptor Agonists Initiation in the United States: A Scoping Review of Evidence. *Pharmacy (Basel, Switzerland)*, 13(2), 46. <https://doi.org/10.3390/pharmacy13020046>.

<sup>16</sup> Rodriguez, P. J., Zhang, V., Gratzl, S., Do, D., Goodwin Cartwright, B., Baker, C., Gluckman, T. J., Stucky, N., & Emanuel, E. J. (2025). Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity. *JAMA network open*, 8(1), e2457349. <https://doi.org/10.1001/jamanetworkopen.2024.57349>.

<sup>17</sup> Letter to Patty Donnelly, Eli Lilly and Company, from Dr. Patrizia Cavazzoni, Center for Drug Evaluation and Research. U.S. Food & Drug Administration, Dec. 19, 2024. [https://www.cfpr.org/files/2024.12.19\\_tirzepatide\\_declaratory\\_order.pdf](https://www.cfpr.org/files/2024.12.19_tirzepatide_declaratory_order.pdf).

<sup>18</sup> FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize. U.S. Food & Drug Administration, April 28, 2025. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize>.

<sup>19</sup> Medicare Coverage of GLP-1 Drugs, H.R. 4818, S. 2407, P.L. 108-173, P.L. 117-169, Sept. 9, 2024. <https://www.congress.gov/crs-product/IF12758>

<sup>20</sup> Number of 2023 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data visit: <https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx>.

## Price history

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

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

	Mounjaro	Ozempic	Rybelsus	Trulicity	Victoza
<b>30-day supply</b>	1 package (4 pens of 0.5ml)	1 package (1 pen of 3ml)	30 units (30 pills)	1 package (4 pens of 0.5ml)	1 package (3 pens of 9ml)

Table 4 Drug vs therapeutic alternatives and 2018-2024 WAC per 30-day supply<sup>21</sup>

Year	Mounjaro	Ozempic	Rybelsus	Trulicity	Victoza
<b>2018</b>		\$729		\$730	\$870
<b>2019</b>		\$772		\$759	\$922
<b>2020</b>		\$811		\$797	\$968
<b>2021</b>		\$852	\$852	\$844	\$1,016
<b>2022</b>	\$974	\$892	\$892	\$887	\$1,065
<b>2023</b>	\$1,023	\$936	\$936	\$931	\$1,117
<b>2024</b>	\$1,069	\$969	\$969	\$977	\$677
<b>Avg. Annual % Change</b>	4.7%	4.8%	4.4%	5.0%	-2.3%
<b>% change 2018 between 2024</b>		32.8%		33.9%	-22.2%

The WAC of Mounjaro, averaged across six NDCs reported, was approximately **\$534.54 per unit** at the end of 2024.<sup>22</sup> Between 2022-2024, the unit WAC increased at an average annual rate of **4.7 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2022-2023 and 2023-2024**.<sup>23</sup>

<sup>21</sup> Medi-Span. Wolters Kluwer, 2025. <https://www.wolterskluwer.com/en/solutions/medi-span/medi-span>.

<sup>22</sup> Ibid

<sup>23</sup> Consumer Price Index. U.S. Bureau of Labor Statistics. <https://www.bls.gov/cpi/tables/supplemental-files/>.

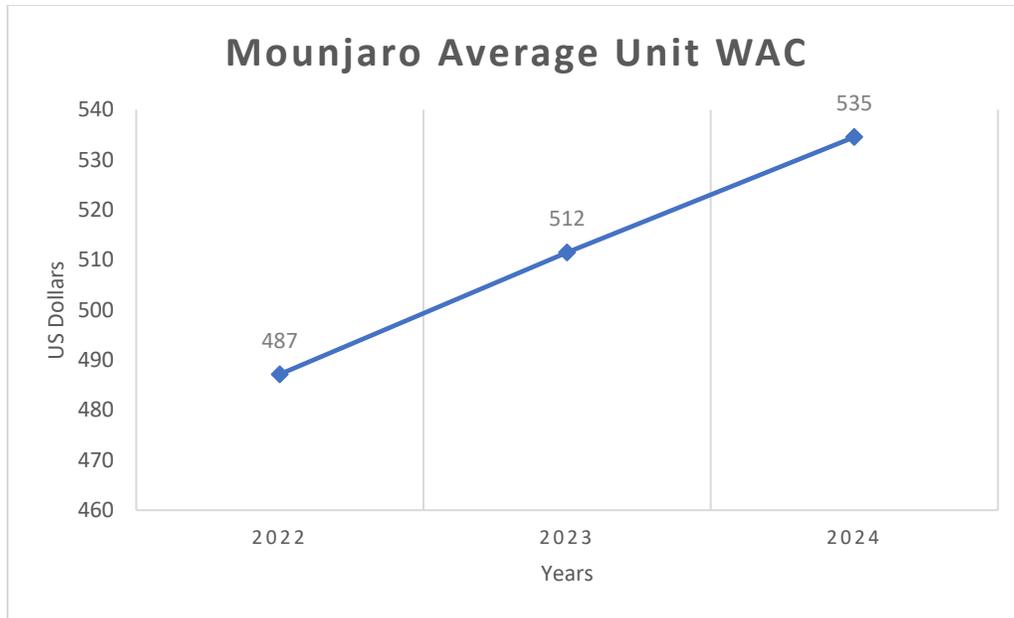


Figure 1 Mounjaro average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison<sup>24</sup>

Year	Mounjaro	Byetta	Ozempic	Trulicity	Rybelsus	Victoza	CPI-U
2018-2019			5.9%	4.0%		5.9%	1.7%
2019-2020		3.0%	5.0%	5.0%		5.0%	0.7%
2020-2021		3.5%	-21.3%	5.9%		5.0%	5.3%
2021-2022		3.0%	4.8%	5.0%	4.8%	4.8%	9.0%
2022-2023	5.0%	3.0%	4.9%	5.0%	4.9%	4.9%	3.1%
2023-2024	4.5%	3.0%	3.5%	5.0%	3.5%	-34.1%	3.0%

<sup>24</sup> Percentages might differ from Table 4 as Table 5 percentages are based on unit WAC only.

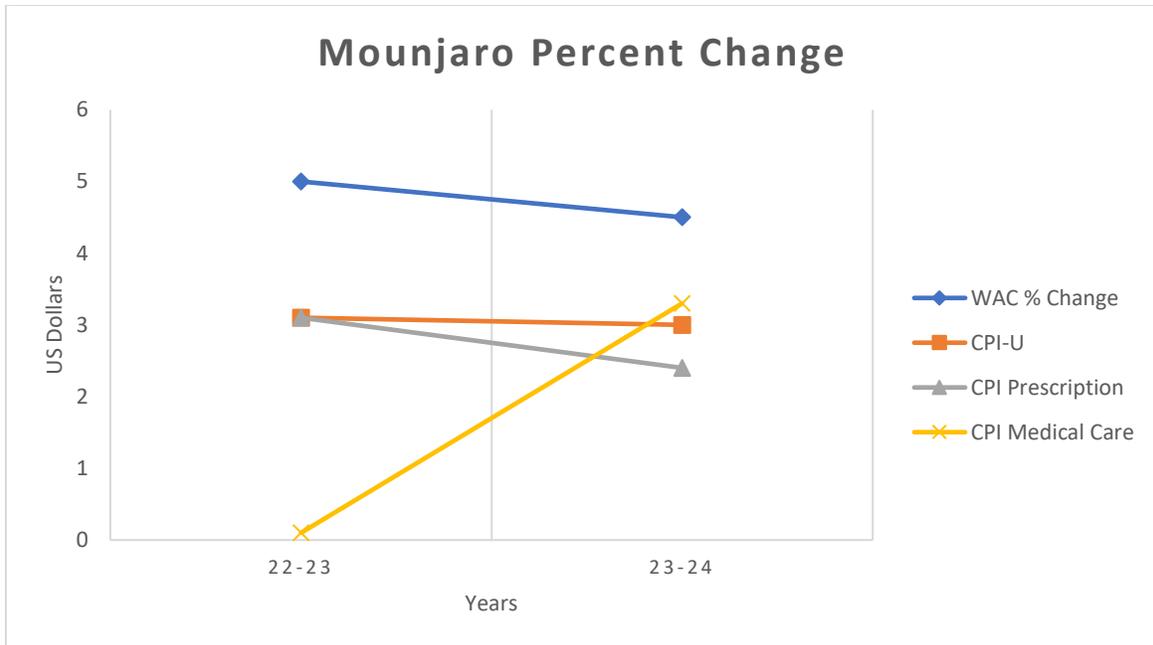


Figure 2 Year over year change in WAC compared to inflation rates<sup>25</sup>

### Pharmacy acquisition costs

The AAAC, which reflects pharmacies’ actual purchase prices for Medicaid fee-for-service claims, rose from **\$492.42 per unit in Quarter 1 of 2023 to \$513.80 per unit in Quarter 4 of 2024**, an approximate **5.4 percent increase** over the period (see Table 6).<sup>26</sup> Relative to the \$534.54 WAC in end-of-year 2024, an **AAAC discount of 4.0 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 Mounjaro’s price trajectory relative to inflation and affordability for public and private payers.

Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices for Mounjaro

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC average	Average unit WAC
2023	\$492	\$492	\$493	\$495	\$493	\$512
2024	\$517	\$516	\$515	\$514	\$515	\$535

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

<sup>26</sup> This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2024, available at <https://myersandstauffer.com/client-portal/oregon/>.

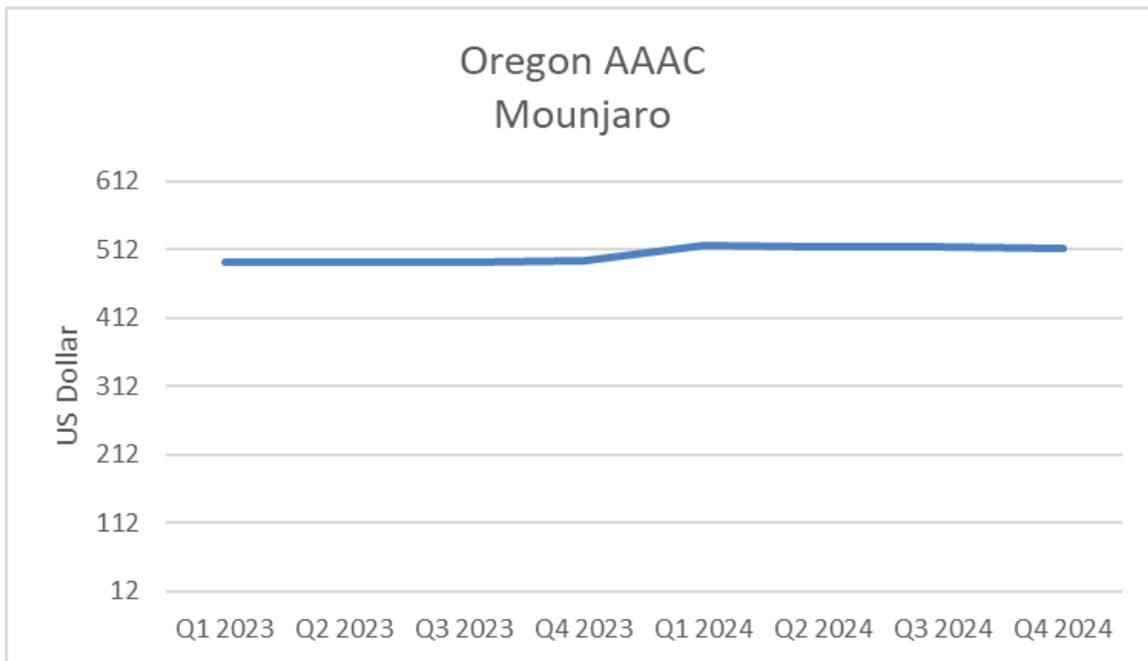


Figure 3 AAAC for Mounjaro from Q1 2023 to Q4 2024

## 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 Mounjaro 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 Mounjaro per enrollee in the commercial market was approximately \$2,480**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately \$1,319**, reflecting an **estimated mean discount of 46.8 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Mounjaro before concessions was \$9,166,321**, with total reported **price concessions amounting to approximately \$4,290,646**, as detailed in Table 7. Notably, **82.8 percent of claims benefited from some form of price concession**, leaving **17.2 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	3,696
Total number of claims	8,019
Total number of claims with price concessions applied	6,879

Percentage of claims with price concessions applied	85.8%
Percentage of cost remaining after concessions	53.2%
Percentage of discount	46.8%

Manufacturer price concessions for all market types	\$2,545,742
PBM price concessions for all market types	\$1,743,743
Other price reductions for all market types	\$1,161

Cost before price concessions across all market types	\$9,166,321
Total price concessions across all market types	\$4,290,646
Cost of after price concessions across all market types	\$4,875,675

Avg. payer spend per enrollee without price concessions	\$2,480
Avg. payer spend per enrollee with price concessions	\$1,319

Including all market segments, the **gross spend of Mounjaro per claim for commercial carriers was \$1,143** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **\$608**, meaning that insurers reported a price concession of **\$535** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types from data call<sup>27</sup>

	Average	Individual market	Large market	Small market
<b>Spend per claim, gross</b>	\$1,143	\$1,165	\$1,133	\$1,167
<b>Spend per claim, net</b>	\$608	\$604	\$612	\$596
<b>Price concessions per claim</b>	\$535	\$561	\$521	\$571

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

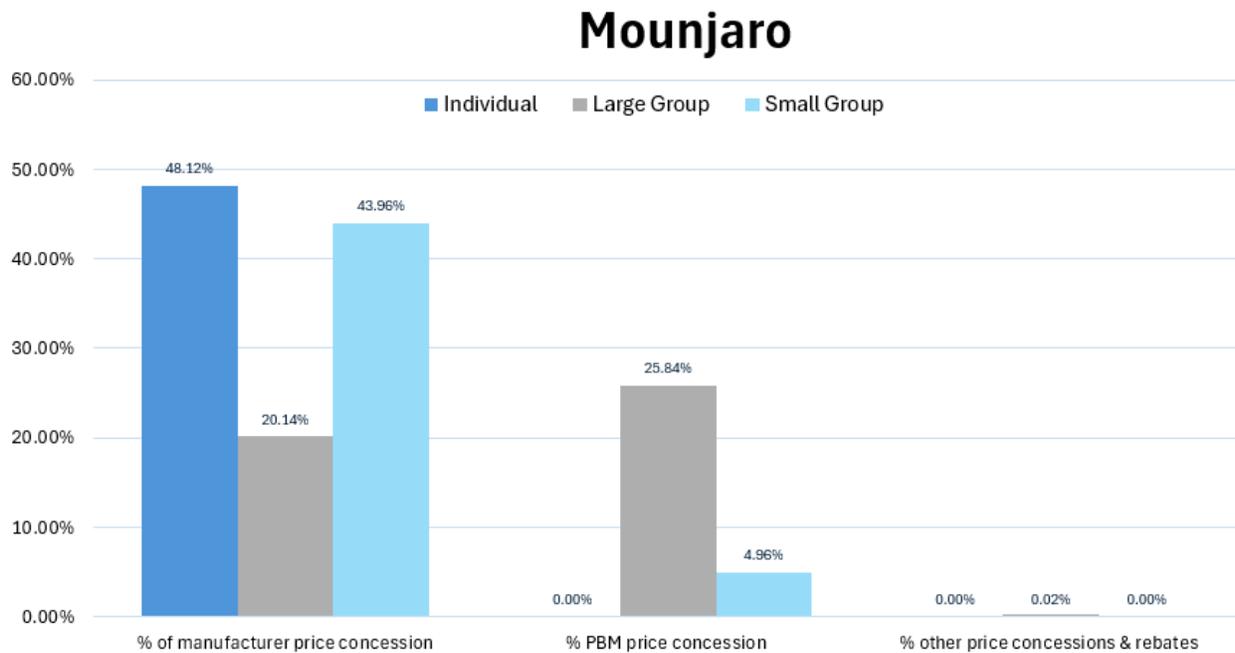


Figure 4 Percent of price concession in each market type<sup>28, 29</sup>

<sup>27</sup> Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon’s commercial insurance carriers.

<sup>28</sup> Price concession refers to any form of discount, directed or indirect subsidy, or rebate received by the carriers or its intermediary contracting organization from any source that serves to decrease the costs incurred under the health plan by the carriers. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on purchase agreement, coupons, free or reduced-price services, and goods in kind. Definition adapted from Code of Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 423, Subpart C. See more at: [CFR-2024-title42-vol3-sec423-100.pdf](https://www.ecfr.gov/current/title-42-chapter-iv-subchapter-b-part-423-subpart-c).

<sup>29</sup> Rebate refers to a discount that occurs after drugs are purchased from a pharmaceutical manufacturer and involves the manufacturer returning some of the purchase price of the purchaser. When drugs are purchased by a managed care organization, a rebate is based on volume, market share, and other factors. Academy of Managed Care Pharmacy. <https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary>.

## Estimated total amount of the price concession

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

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

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

## Estimated price for therapeutic alternatives<sup>30</sup>

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

This section presents information on the estimated spending associated with [drug] and its therapeutic alternatives using 2023 data from APAC and the data call. APAC data reflects gross spending across Medicare, Medicaid, and commercial health plans in Oregon, while the data call includes net spending submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concession or rebates.

**Mounjaro' gross total payer paid, based on APAC data, was \$24.4 million, while total net payer paid received from the carriers indicated a cost of \$7.8 million. Trulicity has the highest gross total pay in consideration with its therapeutic alternatives. The second highest is Ozempic with \$81.0 million. Notably, Trulicity has the most utilization among the drugs, at 104,682 claims, compared to the third highest utilization of Mounjaro, at 22,658 claims. Rybelsus has a higher payer paid per claim compared to Mounjaro, which are \$1,351 and \$1,076 respectively.**

**Ozempic also has the highest total enrollee paid at \$6.2 million and Trulicity follows behind with \$6.0 million.** Rybelsus has the highest patient paid per claim of \$111 and Mounjaro is the **second highest patient paid per claim of \$93.** The drug with the lowest patient paid per claim is Trulicity, which is \$57.

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<sup>30</sup> Therapeutic alternative to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. [ORS 925-200-0020\(2\)\(c\)](#).

Ozempic and Rybelsus have been designated by the FDA as being in shortage from March 31, 2022, to February 21, 2025. Victoza is currently experiencing a drug shortage that began on July 19, 2023. These shortages affect the availability of these medications for patients.

*Table 9 Average healthcare and average patient OOP costs for Mounjaro vs therapeutic alternatives<sup>31</sup>*

Proprietary name	No. of enrollees <sup>32</sup>	No. of claims	Total payer paid	Total enrollees paid <sup>33</sup>	Payer paid/claim	Patient paid/claim <sup>34</sup>
<i>Subject Drug</i> <b>Mounjaro (Data call)<sup>35</sup></b>	<b>3,696</b>	<b>8,019</b>	<b>\$7,805,072</b>	<b>\$827,650</b>	<b>\$973</b>	<b>\$103</b>
<i>Subject Drug</i> <b>Mounjaro (APAC)</b>	<b>4,299</b>	<b>22,658</b>	<b>\$24,384,519</b>	<b>\$2,107,423</b>	<b>\$1,076</b>	<b>\$93</b>
<b>Ozempic</b>	18,301	78,032	\$81,017,647	\$6,223,820	\$1,038	\$80
<b>Rybelsus</b>	2,586	11,524	\$15,574,551	\$1,282,285	\$1,351	\$111
<b>Trulicity</b>	13,794	104,682	\$114,173,339	\$6,011,513	\$1,091	\$57
<b>Victoza</b>	3,854	20,794	\$26,835,206	\$1,213,145	\$1,291	\$58

## 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 Mounjaro, as compared to the subject drug itself. At

<sup>31</sup> The therapeutic alternative information is based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>32</sup> The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 9, as compared to other totals indicated in this report.

<sup>33</sup> The cost includes all lines of business.

<sup>34</sup> Ibid.

<sup>35</sup> Information from the data call with the cost information after price concessions.

the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

## Estimated costs to health insurance plans

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

This section quantifies the financial impact of Mounjaro 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 **22,658 total claims for Mounjaro among 4,393 total enrollees**, corresponding to a **total payer expenditure of \$24.4 million**.

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

- **Medicare** accounted for the largest share of utilization, with **10,614** claims from **1,978** enrollees and a total spend of **\$12.5 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **\$10.5 million** and **\$1.5 million**, respectively.

*Table 10 Estimated 2023 APAC total annual gross payers expenditure for total enrollees and total claims<sup>36</sup>*

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	2,111	10,464	\$10,473,836	\$4,962	\$1,001
Medicaid	304	1,580	\$1,454,528	\$4,785	\$921
Medicare	1,978	10,614	\$12,456,155	\$6,297	\$1,174
<b>Totals<sup>37</sup></b>	<b>4,393</b>	<b>22,658</b>	<b>\$24,384,519</b>		

<sup>36</sup> Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>37</sup> The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

Table 11 provides utilization for the healthcare system for Mounjaro and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the most utilization among the drugs, with 104,682 claims.** In all lines of business, Trulicity is the most utilized, aside from Ozempic in the commercial sector. **Ozempic is the second most utilized at 78,032 claims.**

*Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives<sup>38</sup>*

Proprietary name	Commercial utilization	Medicaid utilization	Medicare utilization	Total claims <sup>39</sup>
<b>Mounjaro</b>	10,464	1,580	10,614	22,658
<b>Ozempic</b>	37,201	8,338	32,493	78,032
<b>Rybelsus</b>	4,571	962	5,991	11,524
<b>Trulicity</b>	35,415	25,337	43,930	104,682
<b>Victoza</b>	6,379	5,180	9,235	20,794

Table 12 shows the overall payer expenditure of Mounjaro and its therapeutic alternatives, distinguished by lines of business. Mounjaro has a **total expenditure of \$24.4 million** with **Medicare being the biggest portion at \$12.5 million.** The therapeutic alternative with the **least expenditure is Rybelsus, at \$15.6 million.**

*Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business<sup>40</sup>*

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total <sup>41</sup>
<b>Mounjaro</b>	\$10,473,836	\$1,454,528	\$12,456,155	\$24,384,519
<b>Ozempic</b>	\$36,494,230	\$7,438,499	\$37,084,917	\$81,017,647
<b>Rybelsus</b>	\$5,975,209	\$1,099,301	\$8,500,041	\$15,574,551
<b>Trulicity</b>	\$35,871,104	\$22,574,441	\$55,727,793	\$114,173,339
<b>Victoza</b>	\$7,708,332	\$5,519,972	\$13,606,902	\$26,835,206

<sup>38</sup> Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>39</sup> Total is the sum of all utilization for the drug across all lines of business.

<sup>40</sup> Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

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

Table 13 compares the overall payer cost per enrollee of Mounjaro and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the highest total cost per enrollee at \$8,277.** Trulicity has **highest cost per enrollee in all lines of business** The median cost per enrollee for Mounjaro is **\$974**, which is the second highest median of cost per enrollee.

*Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives<sup>42</sup>*

Proprietary name	Commercial cost/enrollee	Medicaid cost/enrollee	Medicare cost/enrollee	Total <sup>43</sup> cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee 75 <sup>th</sup> percentile	Cost per enrollee, 95 <sup>th</sup> percentile
<b>Mounjaro</b>	\$4,962	\$4,785	\$6,297	\$5,672	\$974	\$239	\$1,085	\$2,932
<b>Ozempic</b>	\$4,117	\$3,736	\$4,288	\$4,427	\$902	\$952	\$1,719	\$2,782
<b>Rybelsus</b>	\$6,036	\$5,336	\$5,870	\$6,023	\$973	\$1,650	\$2,502	\$2,925
<b>Trulicity</b>	\$6,873	\$6,673	\$7,936	\$8,277	\$909	\$1,507	\$2,356	\$2,932
<b>Victoza</b>	\$5,542	\$5,349	\$6,876	\$6,963	\$1,089	\$1,209	\$2,182	\$3,514

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. The collected **total net cost to the healthcare system was around \$8.6 million**, with payer paying \$7.8 million, and enrollees out-of-pocket estimating to be **\$827,650**. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **\$2,360 (large group)** to **\$2,223 (individual)** annually.

*Table 14.a Estimated 2023 annual total net costs to the healthcare system, payers and OOP/enrollee<sup>44</sup>*

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of-pocket cost
<b>Individual</b>	750	393	\$873,750	\$623,139	\$250,611
<b>Large Group</b>	5,631	2,518	\$5,942,646	\$5,559,522	\$383,124
<b>Small Group</b>	1,638	785	\$1,816,327	\$1,622,412	\$193,915
<b>Total</b>	<b>8,019</b>	<b>3,696</b>	<b>\$8,632,723</b>	<b>\$7,805,072</b>	<b>\$827,650</b>

<sup>42</sup> Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>43</sup> The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.

<sup>44</sup> Cost information from the data call is the cost of the drug after price concessions.

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

Market	Avg. plan spend/claim	Avg. payer paid/claim	Avg. enrollee paid/claim	Avg. plan spend/enrollee	Avg. payer paid/enrollee	Avg. OOP/enrollee
Individual	\$1,165	\$831	\$334	\$2,223	\$1,586	\$638
Large Group	\$1,055	\$987	\$68	\$2,360	\$2,208	\$152
Small Group	\$1,109	\$990	\$118	\$2,314	\$2,067	\$247

As shown in Figure 5, the large group represented the majority of commercial spending (69% of total), followed by small group and individual markets.

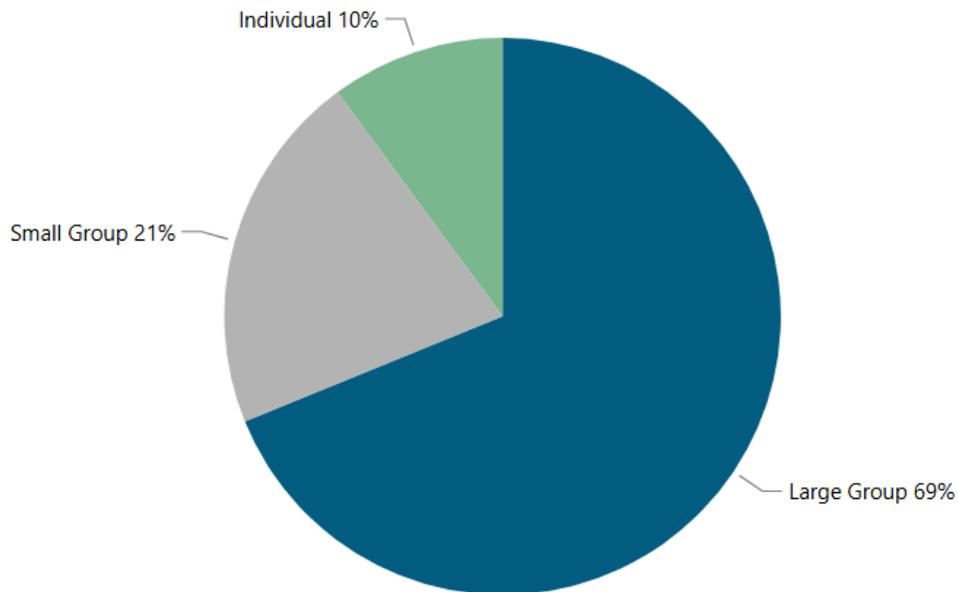


Figure 5 Data call total annual percent spend (payer paid) by market

Table 15 indicates CCOs reported Mounjaro as having an annual greatest increase from 2022-2023 (rebates not included) with a **\$1.3 million year-over-year increased cost growth**.

Table 15 Medicaid CCOs greatest increase in share to total cost from 2022-2023 (rebates not included)<sup>45</sup>

Medicaid CCOs			
2022	2023	YoY change in spending	Percent of total CCO cost 2023
\$52,441	\$1,336,276	\$1,283,835	0.1%

## 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 Mounjaro, 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 Mounjaro. In 2023, approximately **64.2 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **35.4 percent of plans required step therapy** before approving its use.

For formulary placement, **61.7 percent of plans categorized Mounjaro as a non-preferred drug**, and **1.5 percent of plans excluded it entirely from the formulary**.

Table 16 Plan design analysis from 2023

Percentage of plans	
Required prior authorization	64.2%
Required step therapy	35.4%
On a non-preferred formulary	61.7%
Not covered	1.5%

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.

<sup>45</sup> CCO pharmacy spend provided by: Oregon State University Drug Use and Research Management DUR utilization reports 2023. College of Pharmacy, Oregon State University. <https://pharmacy.oregonstate.edu/research/pharmacy-practice/drug-use-research-management/dur-reports>.

## Relative financial impacts to health, medical or social services costs

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

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

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

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

## Estimated average 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 Mounjaro in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC). These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Tables 17 and 18 presents the average annual enrollee cost-sharing amounts derived from APAC. The APAC data, which includes claims from commercial, and Medicare enrollees, showed average per-claim and per-enrollee OOP gross costs. For example, **Medicare enrollees recorded higher average annual OOP costs**. Due to the absence of Medicaid OOP costs, the insurance type has been omitted entirely from the following tables.

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

Proprietary name	Annual Medicare OOP cost/enrollee	Annual Commercial OOP cost/enrollee	Total <sup>46</sup>	Median	IQR	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
<b>Mounjaro</b>	\$453	\$573	\$520	\$35	\$114	\$114	\$940
<b>Ozempic</b>	\$399	\$313	\$360	\$40	\$115	\$115	\$673
<b>Rybelsus</b>	\$560	\$476	\$530	\$47	\$161	\$165	\$828
<b>Trulicity</b>	\$552	\$409	\$499	\$25	\$114	\$114	\$763
<b>Victoza</b>	\$432	\$257	\$367	\$10	\$120	\$120	\$750

Table 18 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim<sup>48</sup>

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total <sup>49</sup>	Median	IQR	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
<b>Mounjaro</b>	\$85	\$116	\$100	\$30	\$85	\$85	\$496
<b>Ozempic</b>	\$106	\$75	\$89	\$30	\$75	\$75	\$454
<b>Rybelsus</b>	\$135	\$103	\$121	\$40	\$101	\$105	\$606
<b>Trulicity</b>	\$88	\$60	\$76	\$10	\$50	\$50	\$396
<b>Victoza</b>	\$93	\$56	\$78	\$4	\$60	\$60	\$400

## Clinical information based on manufacturer material<sup>50</sup>

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

### Drug indications

- FDA Approved:
  - Tirzepatide MOUNJARO<sup>®</sup> is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.

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

<sup>47</sup> Based on 2023 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

<sup>48</sup> Ibid

<sup>49</sup> The total is the overall cost per claim across commercial insurers and Medicare.

<sup>50</sup> <sup>50</sup> U.S. Food & Drug Administration. *Mounjaro (tirzepatide)* Prescribing information, May 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/215866s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf).

- Limitations of Use:
  - Has not been studied in patients with a history of pancreatitis
  - Is not indicated for use in patients with type 1 diabetes mellitus
- Off Label Uses:
  - Chronic weight management.

## Clinical efficacy

Approval of tirzepatide was based on five phase 3 trials (SURPASS trials). Tirzepatide was compared to placebo in 2 trials and active treatment in 3 trials, including insulin glargine, insulin degludec and semaglutide 1 mg. Tirzepatide was studied with background therapy of insulin glargine (with or without metformin), metformin alone, or combination treatment with metformin, sulfonylurea and SGLT2inhibitors. Once-weekly tirzepatide demonstrated improved efficacy overall comparators, with HbA1c changes from baseline ranging from -1.87% to -2.58%. Patients receiving tirzepatide achieved HbA1c less than 7% more than comparators ranging from 75.1% to 89.6% of the population studied (P<0.05 for all comparisons). Weight loss was more significant in the tirzepatide groups versus comparators, including semaglutide, with losses of -5.3 kg to -11.3 kg. Additional details are included in the trail information below.

*Table 19 Trial: SURPASS-1 (Monotherapy vs placebo) – Week 40*

Endpoint	Placebo	Tirzepatide		
		5 mg	10 mg	15 mg
<b>A1C change (% from BL)</b>	0.04	-1.87	-1.89	-2.07
<b>Diff vs placebo (95% CI)</b>	—	-1.9 (-2.2, -1.4)	-1.6 (-1.9, -1.3)	-1.6 (-1.9, -1.3)
<b>A1C &lt; 7% (% pts)</b>	23%	82%	85%	78%
<b>OR (95% CI)</b>	—	49.0 (21.1, 113.7)	80.4 (31.8, 203.2)	52.9 (22.3, 125.7)
<b>Weight change (kg)</b>	-1.0	-7.0	-7.8	-9.5
<b>Diff vs. placebo (95% CI)</b>	—	-6.3 (-7.8 to -4.7)	-7.1 (-8.6 to -5.5)	-8.8 (-10.3 to -7.2)

Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c

Table 20 Trial: SURPASS-2 (Add-on to metformin; vs semaglutide 1 mg) – Week 40

Endpoint	Semaglutide	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-1.9	-2.0	-2.2	-2.3
Diff vs sema (95% CI)	—	-0.2 (-0.3, -0.0)	-0.4 (-0.5, -0.3)	-0.5 (-0.6, -0.3)
A1C < 7% (% pts)	79%	82%	86%	86%
Weight change (kg)	-5.7	-7.6	-9.3	-11.2
Diff vs. sema (95% CI)	—	-1.9 (-0.28, -1.0)	-3.6 (-4.5, -2.7)	-5.5 (-6.4, -4.6);

Term: BL=baseline; CI: confidence interval; kg: kilogram; A1c: hemoglobin A1c; sema: semaglutide

Table 21 Trial: SURPASS-3 (Add-on to metformin ± SGLT2i; vs insulin degludec) – Week 52

Endpoint	Insulin degludec	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-1.3	-1.9	-2.0	-2.4
Diff vs insulin (95% CI)	—	-0.6 (-0.7, -0.5)	-0.9 (-1.0, -0.7)	-1.0 (-1.2, -0.9)
A1C < 7% (% pts)	61%	82%	90%	93%
OR (95% CI)	—	3.45 (2.38, 5.01)	7.02 (4.55, 10.84)	10.79 (6.65, 17.48)
Weight change (kg)	2.3	-7.5	-10.7	-12.9
Diff vs. insulin (95% CI)	—	-9.8 (-10.8, -8.8)	-13.0 (-14.0, -11.9)	-15.2 (-16.2, -14.2)

Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c; sema: semaglutide

Table 22 Trial: SURPASS-4 (Add-on to 1–3 orals; vs insulin glargine) – Week 52

Endpoint	Insulin glargine	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-1.4	-2.2	-2.4	-2.6
Diff vs insulin (95% CI)	—	-0.8 (-0.9, -0.7)	-1.0(-1.1, -0.9)	-1.1 (-1.3, -1.0)
A1C < 7% (% pts)	51%	81%	88%	91%
OR (95% CI)	—	4.78 (3.47, 6.58)	9.23 (6.31, 13.49)	11.87 (7.88, 17.89)
Weight change (kg)	1.9	-7.1	-9.5	-11.7
Diff vs. insulin (95% CI)	—	-9.0 (-9.8, -8.3)	-11.4(-12.1, -10.6)	-13.5(-14.3, -12.8)

Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c; sema: semaglutide

Table 23 Trial: SURPASS-5 (Add-on to insulin glargine ± metformin; vs placebo) – Week 40

Endpoint	Placebo	Tirzepatide		
		5 mg	10 mg	15 mg
A1C change (% from BL)	-0.9	-2.1	-2.4	-2.3
Diff vs placebo (95% CI)	—	-1.2 (-1.5, -1.0)	-1.5 (-1.8, -1.3)	-1.5 (-1.7, -1.2)
A1C < 7% (% pts)	35%	87%	90%	85%
OR (95% CI)	—	14.7 (7.0, 30.6);	19.5 (9.2, 41.3)	11.5 (5.6, 23.3)
Weight change (kg)	1.6	-5.4	-7.5	-8.8
Diff vs. placebo (95% CI)	—	-7.1 (-8.7, -5.4)	-9.1 (-10.7, -7.5)	-10.5 (-12.1, -8.8)

Term: BL=baseline; CI: confidence interval; kg: kilogram; OR: odds ratio; A1c: hemoglobin A1c

## Clinical safety

- FDA safety warnings and precautions:
  - Risk of Thyroid C-Cell Tumors
  - Pancreatitis
  - Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin
  - Hypersensitivity Reactions
  - Acute Kidney Injury
  - Severe Gastrointestinal Reactions
  - Diabetic Retinopathy Complications

- Acute Gallbladder Disease
- Contraindications:
  - Personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
  - Known serious hypersensitivity to tirzepatide
- Common side effects:
  - Gastrointestinal: constipation (6-17%), decreased appetite (5-11%), diarrhea (12-23%), nausea (12-29%), vomiting (5-13%)
  - Immunologic: antibody development (51-65%)

## Therapeutic alternatives

Table 24 FDA-approved indications<sup>51,52,53,54,55</sup>

Drug	Formulation	Dosing Frequency	Indications (per label)		
			T2DM	CV Risk Reduction	CKD
<b>Tirzepatide (Mounjaro)</b>	SubQ	Weekly	Yes		
<b>semaglutide (Ozempic)</b>	SubQ	Weekly	Yes	Yes	Yes
<b>semaglutide (Rybelsus)</b>	Oral	Daily	Yes		
<b>Dulaglutide (Trulicity)</b>	SubQ	Weekly	Yes	Yes	
<b>Liraglutide (Victoza)</b>	SubQ	Daily	Yes	Yes	
<b>Exenatide (Byetta)</b>	SubQ	Twice Daily	Yes		

Abbreviations: CKD: chronic kidney disease; CV: cardiovascular; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus

<sup>51</sup> U.S. Food & Drug Administration. *Mounjaro (tirzepatide)* Prescribing information, May 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/215866s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf).

<sup>52</sup> U.S. Food & Drug Administration. *Ozempic (semaglutide)* Prescribing information, May 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/209637s020s021lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf).

<sup>53</sup> U.S. Food & Drug Administration. *Rybelsus (semaglutide)* Prescribing information, May 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/213051s012lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf).

<sup>54</sup> U.S. Food & Drug Administration. *Trulicity (dulaglutide)* Prescribing information, May 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/125469s051lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf).

<sup>55</sup> U.S. Food & Drug Administration. *Victoza (liraglutide)* Prescribing information, May 2022. [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/022341s037s038lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf).

Table 25 Comparative clinical efficacy (selected label trials)

Drug	~A1C Decrease	Short term weight loss	Rates of nausea	Cardiovascular Benefits
<b>Tirzepatide (Mounjaro)</b>	1.7%-2.5%	5.0-12.0 kg	12% - 29%	↓ MACE*
<b>Dulaglutide (Trulicity)</b>	1.0% - 1.8 %	2.5 – 4.6 kg	12% - 20%	↓ MACE (NNT 71)
<b>Exenatide (Byetta)</b>	1.0%	2 kg	8% - 11%	_____
<b>Exenatide ER (Bydureon)</b>	1.5%	1.5 - 2.5 kg	8% - 11%	_____
<b>Liraglutide (Victoza)</b>	1.0% - 1.3%	2.5 kg	18% - 20%	↓ MACE (NNT 53)
<b>Semaglutide (Ozempic)</b>	1.0%- 1.7%	4.0 – 6.0 kg	15% - 20%	↓ MACE (NNT 44)
<b>Semaglutide (Rybelsus)</b>	1.0%	2.5 kg	11% - 20%	↓ MACE (NNT 56)

Abbreviations: CV: cardiovascular; ER: extended release; kg: kilogram; MACE: major adverse cardiovascular events; NNT: number needed to treat; SubQ: subcutaneous; T2DM: type 2 diabetes mellitus  
 \*Unpublished data. Pending publication of CV outcomes trial in 2025.

- Clinical guidelines recommend GLP-1 agonists as a first line option for patients with T2DM and compelling indications with evidence of benefit, including atherosclerotic cardiovascular disease (ASCVD) and those at high risk for ASCVD.<sup>56</sup> Agents with proven CV benefits are recommended, including dulaglutide (Trulicity), liraglutide (Victoza), and subcutaneous semaglutide (Ozempic). There are no published studies directly comparing GLP-1 agonists on CV outcomes. A large randomized, double-blind, phase 3 trial comparing tirzepatide to dulaglutide in adults with T2DM and CV disease evaluating CV outcomes is expected to be published in early 2026. Preliminary results suggest tirzepatide decreased major adverse cardiovascular events.
- Within the GLP-1 agonists, semaglutide is considered to have very high efficacy in lowering HgA1c and very high efficacy for weight loss. It is a long acting GLP-1 agonist and is available as weekly dosing which may be preferred by some patients. Tirzepatide is the only GLP-1/GIP agonist and has the highest efficacy for weight loss and similar HgA1c lowering ability to semaglutide.
- Compared to dulaglutide, exenatide and liraglutide, semaglutide SC (Ozempic) was shown to be superior in reduction in HgA1C (-1.5% to -1.8%), and in reduction in body weight (-5.6 kg to -6.5 kg).

<sup>56</sup> American Diabetes Association Professional Practice Committee. “9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024.” Diabetes Care, January 2024, 47 (Supplement\_1): S158–S178. <https://doi.org/10.2337/dc24-S009>.

- Compared to liraglutide, oral semaglutide (Rybelsus) is noninferior in reduction in HgA1C (estimated treatment difference -0.2%; 95% CI -0.3 to -0.1) and superior in reduction in body weight (-4.4 kg vs. -3.1 kg; p=0.003), with no known effects on CV outcomes.<sup>57</sup>
- In addition to the in-class (GLP-1 agonists) therapeutic alternatives included in above table, additional first line drug classes used for the treatment of T2DM include metformin, sodium-glucose cotransporter 2 inhibitors (SGLT2i), and inhibitors of dipeptidyl peptidase 4 (DPP-4).<sup>58</sup>

*Table 26 Safety & therapeutic considerations (from warnings/precautions & highlights)*

Drug	Key Warnings/Precautions	Notable considerations
<b>Tirzepatide (Mounjaro)</b>	Boxed warning: thyroid C-cell tumors; pancreatitis; hypoglycemia with insulin/SU; hypersensitivity; acute kidney injury (often with severe GI AEs); severe GI disease (incl. gastroparesis) — not recommended; retinopathy monitoring if history; acute gallbladder disease.	May reduce efficacy of oral contraceptives around dose-escalation—use non-oral or barrier method for 4 weeks after initiation and each escalation.
<b>Semaglutide (Ozempic)</b>	Boxed warning; pancreatitis; diabetic retinopathy complications signal from semaglutide injection CVOT; AKI; gallbladder disease; hypoglycemia with insulin/SU.	SC once weekly; counsel patients with pre-existing retinopathy.
<b>Semaglutide (Rybelsus)</b>	Same class warnings; retinopathy warning references semaglutide injection CVOT; AKI; gallbladder disease; hypoglycemia with insulin/SU.	Oral administration with strict empty-stomach instructions (≥30 min before first food/drink/other meds, with ≤4 oz water).
<b>Dulaglutide (Trulicity)</b>	Boxed warning; pancreatitis; diabetic retinopathy complications observed in REWIND; acute gallbladder disease; severe GI disease caution.	Once-weekly SC; approved in pediatrics ≥10 y.
<b>Liraglutide (Victoza)</b>	Boxed warning; pancreatitis; acute gallbladder disease; renal impairment/AKI caution; hypoglycemia with insulin/SU.	Once-daily SC dosing (titrate 0.6 to 1.2 to 1.8 mg).

<sup>57</sup> Pratley R, Amod A, Hoff ST, Kadowaki T, et al. Oral semaglutide versus subcutaneous liraglutide and placebo in type 2 diabetes (PIONEER 4): a randomised, double-blind, phase 3a trial. *Lancet*. 2019 Jul 6;394(10192):39-50.

<sup>58</sup> American Diabetes Association Professional Practice Committee. “9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024.” *Diabetes Care*, January 2024, 47 (Supplement\_1): S158–S178. <https://doi.org/10.2337/dc24-S009>.

# Input from specified stakeholders

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

## See appendix 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 collected from 18 individuals taking or having an association with Mounjaro. According to the survey results, 39 percent of respondents had insurance covered for Mounjaro.

Zero patients were on Medicaid, 10 patients were on Medicare, and eight patients had private health insurance. Six patients with private health insurance reported their prescription was not covered. Two patients reported being on patient assistance programs.

Below is a letter submitted by a retired patient who planned to speak at the May 21 board meeting but was unable to because of a scheduling conflict. This patient also submitted a letter to the board, which is included in the appendix.



## Mounjaro



✚ I've been overweight for 40 years and on many diets and programs for weight loss. None have worked for me until Ozempic. I took Ozempic for one year and lost 30 pounds. My doctor prescribed Mounjaro to help me continue to lose weight. Then my insurance decided not to cover it. I couldn't afford it without insurance as it was between \$300-\$349 per month. Since I could not afford that, and have had no meds since, I've gained 20 pounds back. This has caused me extreme anguish and depression. I think about my extra weight every day. I need these medications as they are the only thing that has worked for me. Please consider reducing the cost of these medications. I was prediabetic before the weight loss meds and Ozempic helped me to go off these meds. However, I just had a blood test recently and it appears my prediabetes has returned. Weight loss drugs are key to my health, but I need to be able to afford them.

## Individuals with scientific or medical training

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

## Safety net providers

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

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

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

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

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

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

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

These results suggest that while Mounjaro 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 27 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	8
Reported having an internal pharmacy they use to dispense 340B eligible prescriptions.	91%
Reported having one or more contract pharmacies from which 340b eligible prescriptions are dispensed.	64%
Reported having a prescription savings program to improve patient access to prescription medications	82%
Reported having a staff person dedicated to 340B compliance requirements	100%
Reported total amount paid for drug under 340B was between \$0-\$100,000	27%
Reported total amount paid for drug under 340B was between \$100,001-\$300,000	18%
Reported total amount paid for drug under 340B was between this was trade secret and did not provide an amount	55%
Reported total reimbursement for drugs dispensed under 340B was between \$0-\$100,000	18%
Reported total reimbursement for drugs dispensed under 340B was between \$100,001-\$500,000	9%
Reported total reimbursement for drugs dispensed under 340B was between \$500,000-\$10,000,000	18%

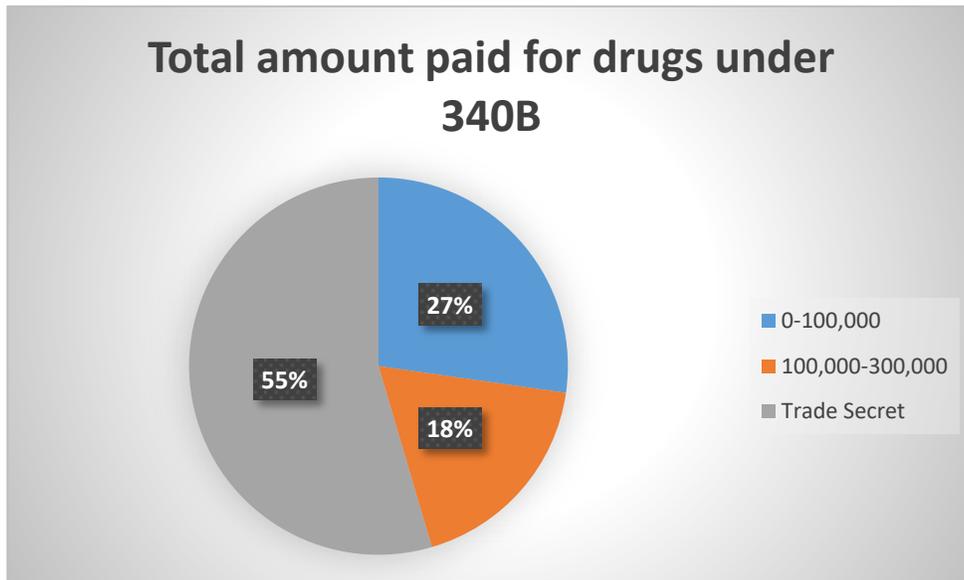


Figure 6 Amounts paid for drug under 340B discount program

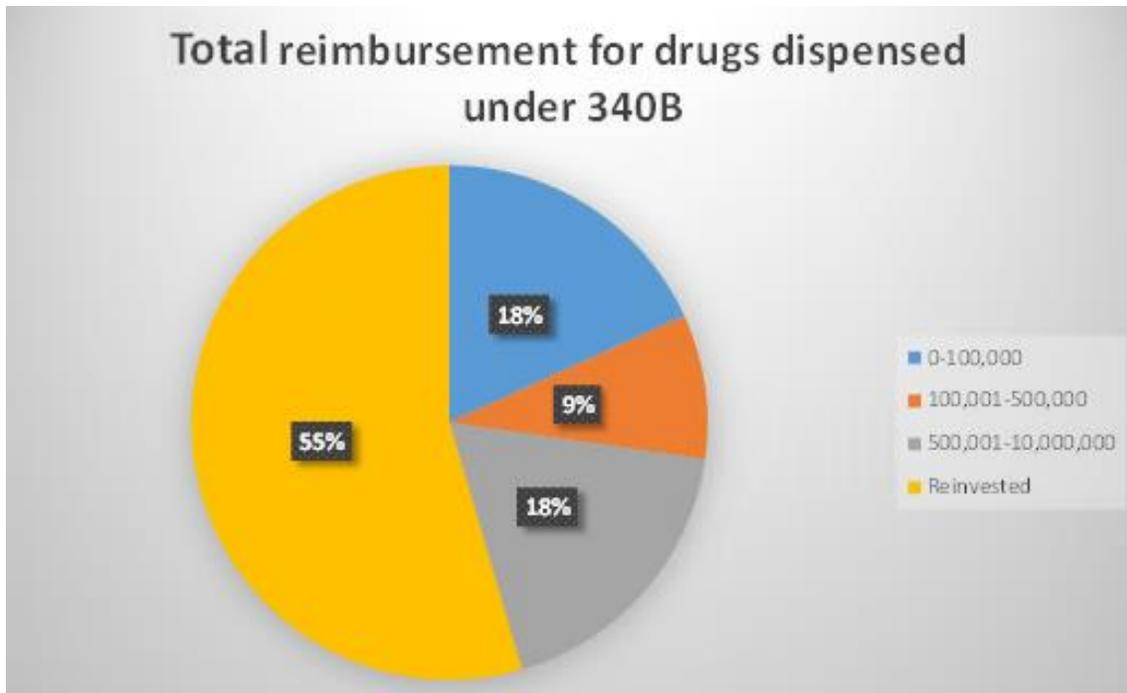


Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

## Payers

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

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

## Appendix

### Stakeholder feedback:

Name of speaker	Association to drug under review	Drug	Format	Date	Exhibit website link
Suzanna Masartis	Community Liver Alliance	Mounjaro	Letter	5/21/2025	<a href="#">Exhibit A</a>
Cynthia Ransom	Eli Lilly	Mounjaro	Letter	5/21/2025	<a href="#">Exhibit B</a>
Carol Elkins	Retired, patient	Mounjaro	Letter	6/18/25	<a href="#">Exhibit C</a>
Dr. Harry Gewanter	Let My Doctors Decide Action Network	Mounjaro	Letter	5/15/2025	<a href="#">Exhibit D</a>
Mary Anne Cooper	Regence BlueCross BlueShield	Mounjaro	Letter	5/12/2025	<a href="#">Exhibit E</a>
Jennifer Hazen	Patient	Mounjaro	Letter	9/15/2025	<a href="#">Exhibit F</a>
Derek Asay	Eli Lilly	Mounjaro	Letter	9/15/2025	<a href="#">Exhibit G</a>