Oregon Prescription Drug
Affordability Board

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Trulicity®
(*dulaglutide*)[1]

Version 3.1

[1] Image source: https://www.adces.org/education/danatech/insulin-medicine-delivery/find-compare-delivery-devices/product-detail/trulicity

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Document version history

Version	Date	Description
v1.0	08/13/2025	Original Release
v1.1	09/15/2025	Added new public comment to the appendix table. Updated table numbers and table references.
v1.2	09/23/2025	Added new public comment to the appendix table
v2.0	10/09/2025	Added new survey information
v3.0	10/30/2025	Updated table formats and footnotes.
v3.1	12/05/2025	Exclusivity information updated.

Review summary

Therapeutic alternatives[2,3,4]

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

Proprietary name	Non-proprietary name	Manufacturer	Year approved	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
Trulicity[5]	*dulaglutide*	Eli Lilly and Co.	2014				No
Byetta[6]	*Exenatide synthetic*	Astrazeneca Ab	2005				No
Ozempic	*semaglutide*	Novo Nordisk Inc.	2017	19	2025-2028	2028	Yes (2027[7])
Rybelsus[8]	*semaglutide*	Novo Nordisk Inc.	2017	13	2026-2039	2028	Yes (2027[7])
Victoza[9]	*liraglutide*	Novo Nordisk Inc.	2010	4	2025-2037		No

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

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

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

[5] No patent or exclusivity information was listed for Trulicity in the U.S. Food & Drug Administration Purple Book Database. https://purplebooksearch.fda.gov/.

[6] Byetta was discontinued in 2025. Drug Approvals and Databases. U.S. Food & Drug Administration, Aug. 8, 2022. https://www.fda.gov/drugs/development-approval-process-drugs/drug-approvals-and-databases.

[7] The year the Maximum Fair Price (MFP) becomes effective.

[8] New exclusivity date found on Dec. 5, 2025. 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.

[9] No exclusivity was listed for Victoza in the U.S. Food & Drug Administration Orange Book Database.

Price history[10,11]

Trulicity rose at an **average annual rate of 5.0 percent** from 2018-2024.

- In the same time period, its therapeutic alternatives rose at these rates:
    - Byetta: **3.1** percent
    - Ozempic: **4.8** percent
    - Rybelsus: **4.4** percent
    - Victoza: **-2.3** percent

Additionally, the average annual rate of Trulicity exceeded inflation **in 2019, 2021, 2023, and 2024.** Pharmacy acquisition costs for **Medicaid also increased by 25.6 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions [12]

Based on data received from healthcare carriers, Trulicity in 2023 had a **gross spend of $1,236 per claim**, while the **spend net of discount was $689 per claim**. Price concession per claim was reported to be **$547.**

Cost to the payers[13]

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

Proprietary name	Total expenditure	Utilization	Cost per enrollee	Cost per enrollee, median
Trulicity	$152,767,272	142,338	$8,187	$908
Byetta	$418,695	375	$5,234	$826
Ozempic	$81,017,647	78,032	$4,427	$902
Rybelsus	$15,574,551	11,524	$6,023	$973
Victoza	$26,835,206	20,794	$6,963	$1,089

[10] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[11] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[12] 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.
[13] Based on Oregon's 2023 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

Cost to enrollees[14]

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
Trulicity	$528	$30	$79	$10
Byetta	$297	$35	$76	$4
Ozempic	$360	$40	$89	$30
Rybelsus	$530	$47	$121	$40
Victoza	$367	$10	$78	$4

Rubric considerations

Domain	Consideration
Utilization	142,338
Price evaluation	Avg percent change in WAC of 5%, outpaced inflation for four years
Price concessions	25-50% of claims discounted
System & payer costs	Total gross spend >$50M, total net spend >$10M
Enrollee burden	Total APAC OOP $200-$700
Equity impact	Yes
Access restrictions	Yes
Therapeutic alternative fail to reduce system spending	Yes
Stakeholder input identify access or financial hardship?	Yes
Patent expirations more than 18 months from time of review?	Yes
Excluded from CMS Maximum Fair Price List (MFP)	Yes

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

Review background

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

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

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

In accordance with OAR 925-200-0020, PDAB conducts affordability reviews on prioritized prescription drugs selected under OAR 925-200-0010. 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[15]

Drug proprietary name(s)	Trulicity®
Non-proprietary name	*dulaglutide*
Manufacturer	Eli Lilly and Co.
Treatment: Trulicity is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:	• As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus (T2DM). • To reduce the risk of major adverse cardiovascular events in adults with T2DM have established cardiovascular disease or multiple cardiovascular risk factors.
Dosage and strength	• 0.75 mg/0.5 mL solution in a single-dose pen • 1.5 mg/0.5 mL solution in a single-dose pen • 3 mg/0.5 mL solution in a single-dose pen • 4.5 mg/0.5 mL solution in a single-dose pen
Form/Route	Injection

FDA approval

Trulicity was first approved by the FDA on **Sept. 18, 2014**.[16]

The drug qualified for the following expedited forms of approval: **None.**

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.

Weekly autoinjector simplifies dosing frequency, but device handling and cold-chain storage needs can be harder for patients with visual impairment, neuropathy and dexterity limitations, or limited refrigeration access.[17,18] Intermittent U.S. supply constraints have persisted into 2025, which can exacerbate inequities when substitution isn't feasible or formularies restrict

[15] U.S. Food & Drug Administration. Trulicity *(dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.
[16] 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.
[17] U.S. Food & Drug Administration. Trulicity *(dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.
[18] National Diabetes Statistics Report. U.S. Centers for Disease Control and Prevention, May 15, 2024. https://www.cdc.gov/diabetes/php/data-research/index.html.

alternatives.[19,20] Disparities in GLP-1 use across different ethnic groups and income remain documented.[21,22]

Residents prescribed

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

Based on APAC claims, **142,338** Oregonians filled a prescription for Trulicity in 2023.[23]

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.

Price history

This section examines the pricing dynamics of Trulicity, 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 Trulicity's list price trajectory and pharmacy acquisition costs, and the degree to which the list price impacts costs.

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.

[19] Current drug shortages: Dulaglutide injection. American Society of Health-System Pharmacists (ASHP), July 17, 2025. https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=862&loginreturnUrl=SSOCheckOnly.

[20] Rozner, Lisa. "Diabetes patients frustrated as popularity of Ozempic and Trulicity limits supply." CBS News, Jan. 23, 2024. https://www.cbsnews.com/newyork/news/diabetes-patients-frustrated-as-popularity-of-ozempic-and-trulicity-limits-supply/.

[21] 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.

[22] Rodriguez PJ, Zhang V, Gratzl S, et al. Discontinuation and Reinitiation of Dual-Labeled GLP-1 Receptor Agonists Among US Adults With Overweight or Obesity. *JAMA Netw Open.* 2025;8(1):e2457349. doi:10.1001/jamanetworkopen.2024.57349.

[23] 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.

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

	Trulicity	Byetta	Ozempic	Rybelsus	Victoza
30-day supply	1 package (4 pens of 0.5ml)	1 package (1 pen of 2.4ml)	1 package (1 syringe of 3ml)	30 units (30 pills)	1 package (3 pens of 9ml)

Table 4 Drug vs therapeutic alternatives for 2018-2024 WAC per 30-day supply[24]

Year	Trulicity	Byetta	Ozempic	Rybelsus	Victoza
2018	$730	$708	$729		$870
2019	$759	$730	$772		$922
2020	$797	$752	$811		$968
2021	$844	$778	$852	$852	$1,016
2022	$887	$801	$892	$892	$1,065
2023	$931	$825	$936	$936	$1,117
2024	$977	$850	$969	$969	$677
Avg. Annual % Change	5.0%	3.1%	4.8%	4.4%	-2.3%
% change 2018 between 2024	33.9%	20.0%	32.8%		-22.2%

The WAC of Trulicity, averaged across six NDCs reported, was approximately **$489 per unit** at the end of 2024.[25] Between 2018-2024, the unit WAC increased at an average annual rate of **5.0 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2018-2019, 2020-2021, 2022-2023, and 2023-2024**.[26]

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

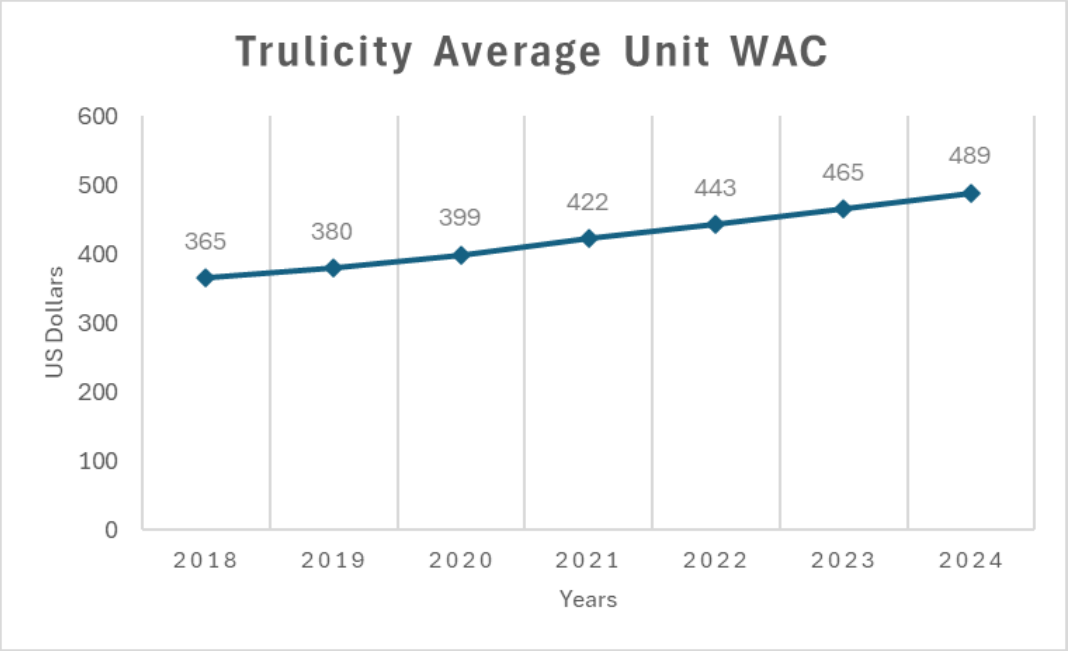

Figure 1 Trulicity average unit WAC from 2018-2024

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

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

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

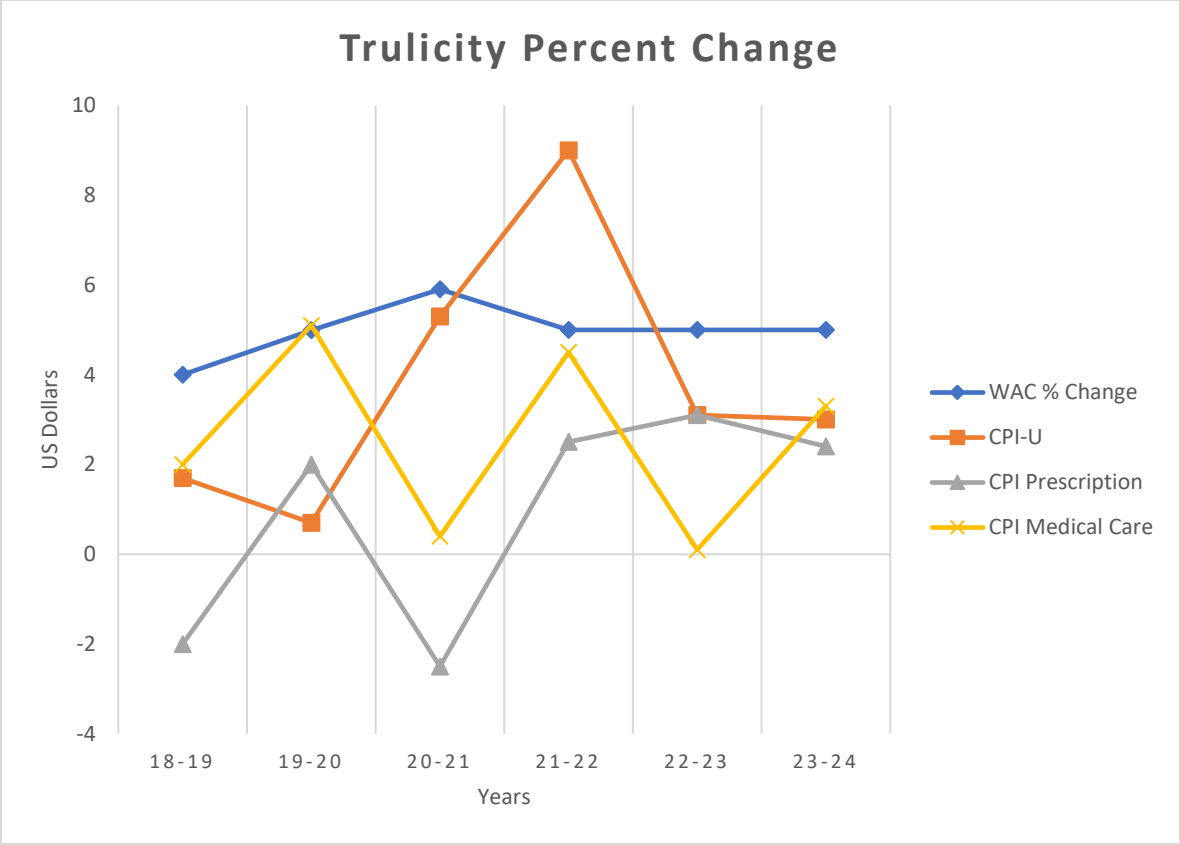

Figure 2 Year over year change in WAC compared to inflation rates[28]

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$374.76 per unit in Quarter 1 of 2020 to $470.88 per unit in Quarter 4 of 2024**, an approximate **25.6 percent increase** over the period (see Table 6).[29] Relative to the **$488.71** WAC in end-of-year 2024 an **AAAC discount of 3.6 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 Trulicity's price trajectory relative to inflation and affordability for public and private payers.

[28] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[29] 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/.

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

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual AAAC Average	Average Unit WAC
2020	$375	$382	$382	$382	$380	$399
2021	$403	$405	$405	$405	$405	$422
2022	$424	$427	$427	$426	$426	$443
2023	$446	$447	$447	$449	$447	$465
2024	$471	$470	$471	$471	$471	$489

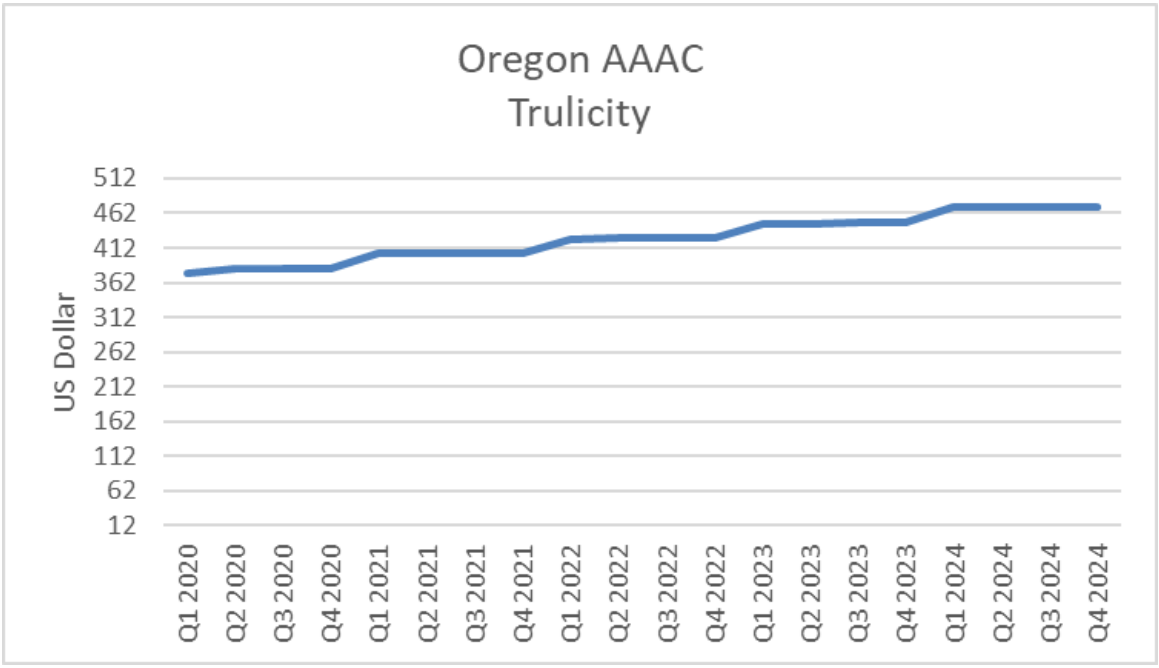

Figure 3 AAAC For Trulicity from Q1 2020 to Q4 2024

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 Trulicity 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 Trulicity per enrollee in the commercial market was approximately $4,384**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $2,445**, reflecting an **estimated mean discount of 44.2 percent** relative to gross costs.

Across all reporting carriers and market segments, the **total cost of Trulicity before concessions was $26,245,521**, with total reported **price concessions amounting to approximately $11,612,175**, as detailed in Table 7. Notably, **91.7 percent of claims benefited from some form of price concession,** leaving **8.2 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	5,986
Total number of claims	21,238
Total number of claims with price concessions applied	19,465
Percentage of claims with price concessions applied	91.7%
Percentage of cost remaining after concessions	55.8%
Percentage of discount	44.2%
Manufacturer price concessions for all market types	$9,829,548
PBM price concessions for all market types	$1,782,049
Other price reductions for all market types	$578
Cost before price concessions across all market types	$26,245,521
Total price concessions across all market types	$11,612,175
Cost of after price concessions across all market types	$14,633,347
Avg. payer spend per enrollee without price concessions	$4,384
Avg. payer spend per enrollee with price concessions	$2,445

Including all market segments, the **gross spend of Trulicity per claim for commercial carriers was $1,236** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$689**, meaning that insurers reported a price concession of **$547** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types from data call[30]

	Average	Individual market	Large market	Small market
Spend per claim, gross	$1,236	$1,192	$1,248	$1,232
Spend per claim, net	$689	$627	$717	$637
Price concessions per claim	$547	$565	$530	$594

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

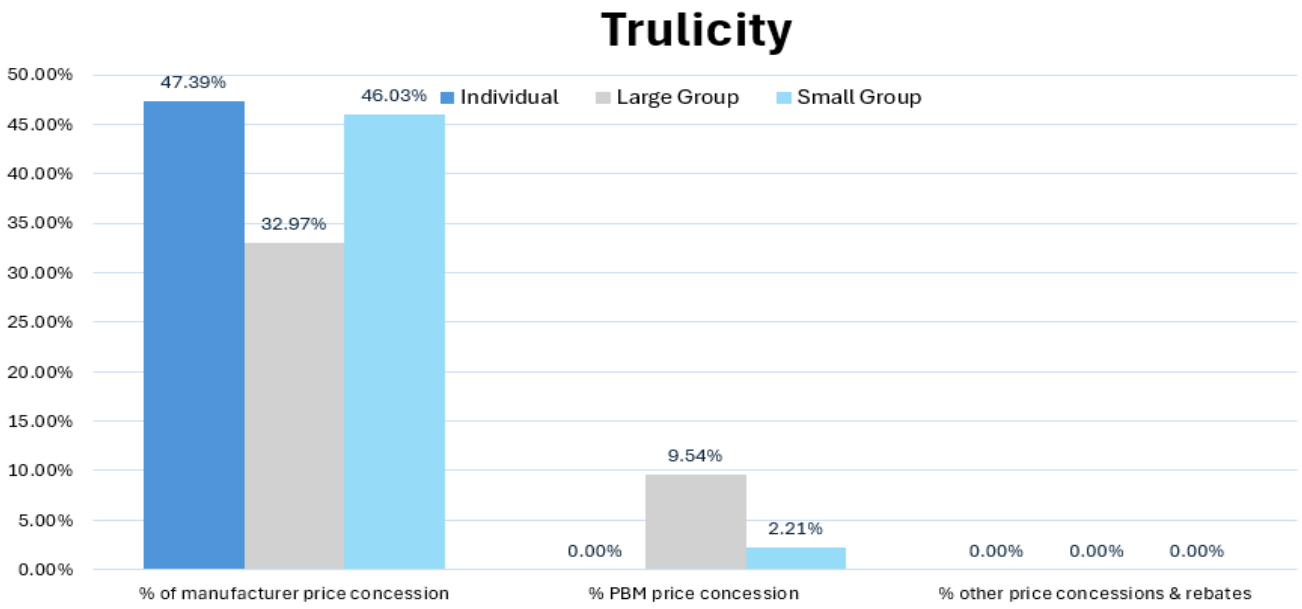

Figure 4 Percent of price concession in each market type[31, 32]

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

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

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

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

Estimated price for therapeutic alternatives[33]

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

This section presents information on the estimated spending associated with Trulicity 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.

Trulicity' gross total payer paid, based on APAC data, **was $152.8 million**, while total net payer paid received from the **carriers indicated a cost of $23.1 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 142,338 claims**, as compared to the second highest utilization of Ozempic, at 78,032 claims. Only Ozempic has a lower payer paid per claim than Trulicity, which are $1,038 and $1,073 respectively.

Trulicity also has the highest total enrollee paid at $8.3 million and Ozempic follows behind with $6.2 million. Rybelsus has the highest patient paid per claim of $111, which is higher than both Trulicity at $60 and Ozempic at $80. The drug with the lowest patient paid per claim is Byetta, which is $49.

Ozempic and Rybelsus have been designated by the FDA as being in a 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.

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

Table 9 Average healthcare and average patient OOP costs for Trulicity vs therapeutic alternatives[34]

Proprietary name	No. of enrollees[35]	No. of claims	Total payer paid	Total enrollees paid[36]	Payer paid/ claim	Patient paid/ claim[37]
Subject Drug **Trulicity (Data call)[38]**	**5,986**	**21,238**	**$23,128,584**	**$2,186,726**	**$1,089**	**$103**
Subject Drug **Trulicity (APAC)**	**18,659**	**142,338**	**$152,767,272**	**$8,337,684**	**$1,073**	**$60**
Byetta	80	675	$418,695	$18,421	$1,117	$49
Ozempic	18,301	78,032	$81,017,647	$6,223,820	$1,038	$80
Rybelsus	2,586	11,524	$15,574,551	$1,282,285	$1,351	$111
Victoza	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 Trulicity, 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.

[34] The therapeutic alternative information is based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[35] The number of enrollees is derived from unique individuals collected from APAC at the drug level. A single unique individual may occur across multiple lines of business indicating, meaning that an enrollee can be counted for each claim line of business. As a result, this leads to the elevated enrollment numbers presented in Table 9, as compared to other totals indicated in this report.
[36] The cost includes all lines of business.
[37] Ibid.
[38] Information from the data call with the cost information after price concessions.

The statutory and regulatory criteria call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through 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 Trulicity 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 **142,338 total claims for Trulicity among 21,058 total enrollees**, corresponding to a **total payer expenditure of $152.8 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 **61,023** claims from **9,623** enrollees and a total spend of **$75.6 million**.
- **Commercial** and **Medicaid** payers reported smaller but notable expenditures of approximately **$46.9 million** and **$30.3 million**, respectively.

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

Payer line of business	Total enrollees	Total claims	Total payer paid	Average cost amount per enrollee	Average cost amount per claim
Commercial	6,837	47,256	$46,916,082	$6,862	$993
Medicaid	4,598	34,059	$30,280,945	$6,586	$889
Medicare	9,623	61,023	$75,570,255	$7,853	$1,238
Totals[40]	**21,058**	**142,338**	**$152,767,272**		

Table 11 provides utilization for the healthcare system for Trulicity and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the most utilization** among the

[39] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

[40] The total number of enrollees is the summation of enrollees across all markets which differs from the unique enrollees at the drug level.

drugs, with **142,338 claims**. In all lines of business, Trulicity is the most utilized. **Ozempic is the second most utilized at 78,032 claims**.

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives[41]

Proprietary name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total claims[42]
Trulicity	47,256	34,059	61,023	142,338
Byetta	56	132	187	375
Ozempic	37,201	8,338	32,493	78,032
Rybelsus	4,571	962	5,991	11,524
Victoza	6,379	5,180	9,235	20,794

Table 12 shows the overall payer expenditure of Trulicity and its therapeutic alternatives, distinguished by lines of business. Trulicity has a **total expenditure of $161.1 million** with **Medicare being the biggest portion at $80.8 million**. The therapeutic alternative with the **least expenditure is Byetta, at $418,695.**

Table 12 Estimated APAC payer 2023 annual gross expenditure of the review drug and its therapeutic alternatives from all lines of business[43]

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total[44]
Trulicity	$46,916,082	$30,280,945	$75,570,255	$152,767,272
Byetta	$61,211	$105,425	$252,059	$418,695
Ozempic	$36,494,230	$7,438,499	$37,084,917	$81,017,647
Rybelsus	$5,975,209	$1,099,301	$8,500,041	$15,574,551
Victoza	$7,708,332	$5,519,972	$13,606,902	$26,835,206

Table 13 compares the overall payer cost per enrollee of Trulicity and its therapeutic alternatives, distinguished by lines of business. **Trulicity has the highest total cost per enrollee at $8,187.** Trulicity has **highest cost per enrollee in all lines of business. The median cost per enrollee for Trulicity is $908**, which is comparable to the median cost per enrollee for Ozempic

[41] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[42] Total is the sum of all utilization for the drug across all lines of business.
[43] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[44] Total is the sum of all expenditure for the drug across all lines of business.

at $902. **Rybelsus and Victoza have higher median costs per enrollee as compared to Trulicity**, at $973 and $1,089 respectively.

Table 13 Estimated 2023 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives[45]

Proprietary name	Commercial cost/ enrollee	Medicaid cost/ enrollee	Medicare cost/ enrollee	Total[46] cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee, 75th percentile	Cost per enrollee, 95th percentile
Trulicity	$6,862	$6,586	$7,853	$8,187	$908	$1,359	$2,200	$2,910
Byetta	$4,372	$3,905	$5,251	$5,234	$826	$1,453	$2,241	$2,673
Ozempic	$4,117	$3,736	$4,288	$4,427	$902	$952	$1,719	$2,782
Rybelsus	$6,036	$5,336	$5,870	$6,023	$973	$1,650	$2,502	$2,925
Victoza	$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 $25.3 million**, with payer paying **$23.1 million**, and enrollees out-of-pocket estimating to be **$2.2 million**. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **$4,305 (individual)** to **$3,929 (small group)** annually.

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

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	3,567	988	$4,252,909	$3,599,306	$653,602
Large group	14,172	4,003	$17,152,829	$15,975,770	$1,177,059
Small group	3,499	995	$3,909,573	$3,553,508	$356,065
Total	**5,986**	**21,238**	**$25,315,310**	**$23,128,584**	**$2,186,726**

[45] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[46] The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.
[47] Cost information from the data call is the 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. plans spend/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. plans spend/ enrollee	Avg. payer paid/ enrollee	Avg. OOP/ enrollee
Individual	$1,192	$1,009	$183	$4,305	$3,643	$662
Large group	$1,210	$1,127	$83	$4,285	$3,991	$294
Small group	$1,117	$1,016	$102	$3,929	$3,571	$358

As shown in Figure 5, the large group represented the majority of commercial spending (68% of total), followed by individual and small group markets.

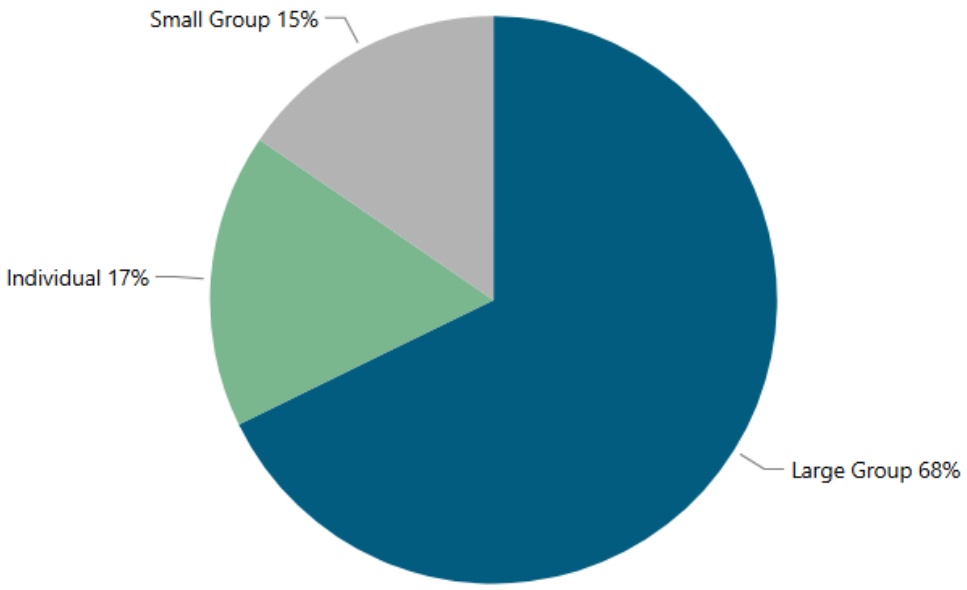

Figure 5 Data call total annual percent spend (payer paid) by market

Table 15 indicates CCOs reported Trulicity as having an annual greatest increase from 2022-2023 (rebates not included) with a **$5.3 million year-over-year increased cost growth**.

Table 15 Medicaid CCOs greatest increase in share to total cost from 2022-2023 (rebates not included)[48]

Medicaid CCOs			
2022	**2023**	**YoY change in spending**	**Percent of total CCO cost 2023**
$22,160,030	$27,421,046	$5,261,016	0.4%

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 Trulicity, 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 Trulicity. In 2023, approximately **76.5 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **11.9 percent of plans required step therapy** before approving its use.

For formulary placement, **34.7 percent of plans categorized Trulicity as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 16 Plan design analysis from 2023

Percentage of Plans	
Required prior authorization	76.5%
Required step therapy	11.9%
On a non-preferred formulary	34.7%
Not covered	0.0%

Note: percentages can equal over 100 percent as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in

[48] 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.

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 Trulicity 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 call for consideration of such information to the extent practicable. However, due to limitations in available evidence and reporting, this analysis was not performed. Future reviews may incorporate this data as it becomes available through 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 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 Trulicity in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).[49] 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.

[49] 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.

Table 17 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee[50]

Proprietary name	Annual Medicare OOP cost/ enrollee	Annual commercial OOP cost/ enrollee	Total[51]	Median	IQR	75th percentile	95th percentile
Trulicity	$569	$451	$528	$30	$125	$125	$843
Byetta	$362	$75	$297	$35	$146	$146	$455
Ozempic	$399	$313	$360	$40	$115	$115	$673
Rybelsus	$560	$476	$530	$47	$161	$165	$828
Victoza	$432	$257	$367	$10	$120	$120	$750

Table 18 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim[52]

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total[53]	Median	IQR	75th percentile	95th percentile
Trulicity	$90	$65	$79	$10	$50	$50	$446
Byetta	$93	$19	$76	$4	$89	$89	$441
Ozempic	$106	$75	$89	$30	$75	$75	$454
Rybelsus	$135	$103	$121	$40	$101	$105	$606
Victoza	$93	$56	$78	$4	$60	$60	$400

Clinical information based on manufacturer material

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:
  - Trulicity is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:
    - As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with T2DM.

[50] 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.
[51] The total is the overall cost per enrollee across commercial insurers and Medicare.
[52] 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.
[53] The total is the overall cost per claim across commercial insurers and Medicare.

        - To reduce the risk of major adverse cardiovascular events in adults with T2DM who have established cardiovascular disease or multiple cardiovascular risk factors.

- Limitations of Use:
    - Includes warnings of pancreatitis and gallbladder events.
    - Evidence is insufficient to make recommendations in type 1 diabetes (T1DM) and it is currently not recommended in this population.

- Off Label Uses:
    - Type 1 diabetes mellitus (T1DM)
    - Chronic weight management

Clinical efficacy[54]

- Dulaglutide was FDA approved based on three, phase 3, double-blind, randomized controlled trials (RCTs) in patients with T2DM both as monotherapy and as add-on therapy to background metformin with or without additional oral agents. These studies compared dulaglutide to placebo and active comparators including metformin, sitagliptin, and exenatide. The primary outcome in all trials was change in hemoglobin A1c (HbA1C) from baseline to week 26 or 52.[55]

- These initial studies concluded that dulaglutide 0.75 mg and 1.5 mg weekly reduces short term HbA1c from baseline, ranging from -0.71% to -1.51% as monotherapy or as add-on therapy.[56] Dulaglutide resulted in a dose-dependent weight loss of 1 to 3 kg in clinical trials.[57]

- In February 2020, the FDA labeling of dulaglutide was expanded to include the reduction of risk of major adverse CV events.[58] This indication was added based on data from the REWIND study, a double-blind, randomized placebo-controlled trial comparing dulaglutide to placebo in 9,901 adults with T2DM and CV disease on background therapy for glycemic

[54] U.S. Food & Drug Administration. Trulicity *(dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.
[55] FDA Center for Drug Evaluation and Research. Dulaglutide Summary Review. Application Number: 125469Orig1s000. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000MedRedt.pdf.
[56] Pasqua, MR., Tsoukas, M.A., Kobayati, A. etal. Subcutaneous weekly semaglutide with automated insulin delivery in type 1 diabetes: a double blind, randomized, crossover trial. Nat Med 31, 123901245 (2025). http://doi.org/10.1038/s41591-024-03463-z.
[57] Ibid.
[58] U.S. Food & Drug Administration. Trulicity *(dulaglutide*) Prescribing information, May 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.

control.[59] Over a median follow-up of 5.4 years, there was a reduction in the primary composite CV outcome (nonfatal myocardial infarction, nonfatal stroke, CV death) of 1.4% (12% in the dulaglutide group and 13.5% in the placebo group; hazard ratio [HR] 0.99; 95% CI 0.79 to 0.99; p=0.26; number needed to treat [NNT] 71) and an absolute difference of 0.9% in the risk of stroke (HR 0.76; 0.62 to 0.94).

- In September 2020, FDA approved additional, higher doses of dulaglutide (3.0 and 4.5 mg once weekly) based on a randomized, double-blind, parallel-arm study over 52 weeks comparing these higher doses to 1.5 mg weekly in adults with T2DM, BMI ≥ 25 kg/m2, and on metformin therapy.[60] There was a significant difference in HbA1C between the 4.5 mg dose compared to 1.5 mg dose (-0.24%; 95% CI -0..36 to -0.11; p<0.001) but not with the 3.0 mg dose (treatment difference -0.10%; 95% CI -.23 to 0.02). The mean change from baseline in HgA1C in each group was -1.54% with 1.5 mg, -1.64% with 3 mg and -1.77% for 4.5 mg. The higher doses also resulted in more weight loss (3 kg in 1.5 mg group, 3.8 kg in 3 mg group, and 4.6 kg in 4.5 mg group).[61]

Clinical safety[62]

- 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 disease
  - Diabetic Retinopathy complications
  - Acute gallbladder disease
- Contraindications:
  - Patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2.
  - Patients with a serious hypersensitivity reaction to dulaglutide or any of the product components.
- Common side effects:
  - Gastrointestinal effects, including diarrhea (9 to 13%), nausea (12-21%), and vomiting (6 to 13%), abdominal pain (6 to 9%), decreased appetite (5 to 9%), and dyspepsia (4 to 6%).

[59] Gerstein HC, Colhoun HM, Dagenais GR, et al. Dulaglutide and cardiovascular outcomes in type 2 diabetes (REWIND): a double-blind, randomised placebo-controlled trial. Lancet. 2019 Jul 13;394(10193):121-130. doi: 10.1016/S0140-6736(19)31149-3. Epub 2019 Jun 9. PMID: 31189511.
[60] Frias JP, Bonora E, Nevarez Ruiz L, Li YG, Yu Z, Milicevic Z, Malik R, Bethel MA, Cox DA. Efficacy and Safety of Dulaglutide 3.0 mg and 4.5 mg Versus Dulaglutide 1.5 mg in Metformin-Treated Patients With Type 2 Diabetes in a Randomized Controlled Trial (AWARD-11). Diabetes Care. 2021 Mar;44(3):765-773. doi: 10.2337/dc20-1473. Epub 2021 Jan 4. PMID: 33397768; PMCID: PMC7896253.
[61] Ibid.
[62] Ibid.

- The most common side effects associated with GLP-1 receptor agonists include gastrointestinal side effects. These are dose-related and likely due to delayed gastric emptying or activation of centers involved in appetite regulation, satiety, and nausea. These are most common soon after initiation and during dose escalation. Rapid titration is associated with higher risk of GI symptoms. There is no evidence that one GLP-1 is associated with higher rates of GI symptoms than others.

Therapeutic alternatives[63,64,65,66,67]

Table 19 FDA-approved indications

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

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

Table 20 Efficacy: Responder rates

Drug	~A1C Decrease	Short term weight loss	Rates of nausea	Cardiovascular benefits
Dulaglutide (Trulicity)	1.0% - 1.8 %	2.5 – 4.6 kg	12% - 20%	↓ MACE (NNT 71)

[63] Ozempic https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf.
[64] Byetta https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021773s9s11s18s22s25lbl.pdf.
[65] Rybelsus https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/213051s012lbl.pdf.
[66] Trulicity https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf.
[67] Victoza https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/022341s037s038lbl.pdf.

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

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.

Comparative clinical efficacy (selected labeled trials)

- 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.[68] 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

[68] American Diabetes Association Professional Practice Committee. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S158-S178. https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment.

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).
- 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.[69]
- 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).[70]

Table 21 Safety & therapeutic considerations

Drug	Boxed warning	Notable warnings/precautions (selected)
Dulaglutide (Trulicity)	Thyroid C-cell tumors	Pancreatitis; retinopathy complications (monitor if hx); AKI with severe GI events; severe GI disease caution; gallbladder disease; hypoglycemia with SU/insulin.
Semaglutide (Ozempic)	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI/dehydration; gallbladder disease; hypoglycemia with SU/insulin; delayed gastric emptying affecting oral meds.
Semaglutide (Rybelsus)	Thyroid C-cell tumors	Pancreatitis; diabetic retinopathy complications; AKI; severe GI effects; gallbladder disease; aspiration risk under anesthesia; oral-drug absorption interactions; strict empty-stomach dosing.

[69] 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.
[70] American Diabetes Association Professional Practice Committee. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan 1;47(Suppl 1):S158-S178. https://diabetesjournals.org/care/article/47/Supplement_1/S158/153955/9-Pharmacologic-Approaches-to-Glycemic-Treatment.

Drug	Boxed warning	Notable warnings/precautions (selected)
Liraglutide (Victoza)	Thyroid C-cell tumors	Pancreatitis; renal impairment cautions; hypersensitivity; gallbladder disease; daily injection/titration requirements.
Exenatide (Byetta)	No thyroid C-cell boxed warning on label.	Pancreatitis; avoid in severe renal impairment/ESRD; caution in moderate renal impairment; GI disease caution; immunogenicity; drug-induced thrombocytopenia warning added.

Table 22 Strengths, dosing & route

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
Dulaglutide (Trulicity)	SC, once weekly	Adults: start 0.75 mg to 1.5 mg; may increase in 1.5-mg steps to max 4.5 mg. Peds (≥10 y): start 0.75 mg; max 1.5 mg.	Single-dose pens: 0.75 mg/0.5 mL; 1.5 mg/0.5 mL; 3 mg/0.5 mL; 4.5 mg/0.5 mL.
Semaglutide (Ozempic)	SC, once weekly	Start 0.25 mg weekly ×4 wk to 0.5 mg; may increase to 1 mg then 2 mg (≥4 wk steps).	Pens delivering 0.25/0.5 mg (2 mg/3 mL), 1 mg (4 mg/3 mL), 2 mg (8 mg/3 mL).
Semaglutide (Rybelsus)	Oral, once daily (empty stomach with ≤4 oz water; wait ≥30 min)	R1: 3 mg to 7 mg to 14 mg; R2: 1.5 mg to 4 mg to 9 mg (formulations not mg-for-mg substitutable).	Tablets: R1 3/7/14 mg; R2 1.5/4/9 mg.
Liraglutide (Victoza)	SC, once daily	Start 0.6 mg daily ×≥1 wk to 1.2 mg; may increase to 1.8 mg if needed; same titration in pediatrics (≥10 y).	6 mg/mL pen delivering 0.6, 1.2, or 1.8 mg doses.
Exenatide (Byetta)	SC, twice daily (≤60 min before morning & evening meals)	Start 5 mcg BID ×1 mo to 10 mcg BID as tolerated.	Prefilled pens: 5 mcg/dose (60 doses); 10 mcg/dose (60 doses).

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 three individuals taking or having an association with Trulicity. According to the survey results, 67 percent of respondents had Trulicity covered under the insurance, regardless of the type of insurance used.

Zero patients were on Medicaid, two patients were on Medicare, and one patient had private health insurance. One patient reported that their prescription was not covered, although they were under private health insurance. Two patients reported being on patient assistance programs.

Below is a written answer from an Oregon caregiver who responded to the PDAB survey in May 2025, edited for readability, length and to protect patient privacy.

"Trulicity"

- A caregiver said their patient has had Trulicity 1.5 mg weekly injections for diabetes for the past two years to control blood sugar and help with weight loss. They pay $47 per month with Medicare but in 2024 paid $200 per month after the initial $550 deductible. The patient tried Metformin but it caused gastric pain and did not control blood sugar or weight. They had to change pharmacies twice to be able to get Trulicity during shortages.

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 Trulicity 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 Trulicity, 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, **ten clinics indicated that Trulicity 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 Trulicity is incorporated into many safety-net programs, further data would be necessary to understand how reimbursement aligns with acquisition cost and whether 340B discounts adequately mitigate financial exposure for patients and the healthcare system.

Table 23 Safety net provider survey responses

Survey information	Response
Clinics responded	11
The drug is covered as a 340B eligible prescription in their program	10
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%

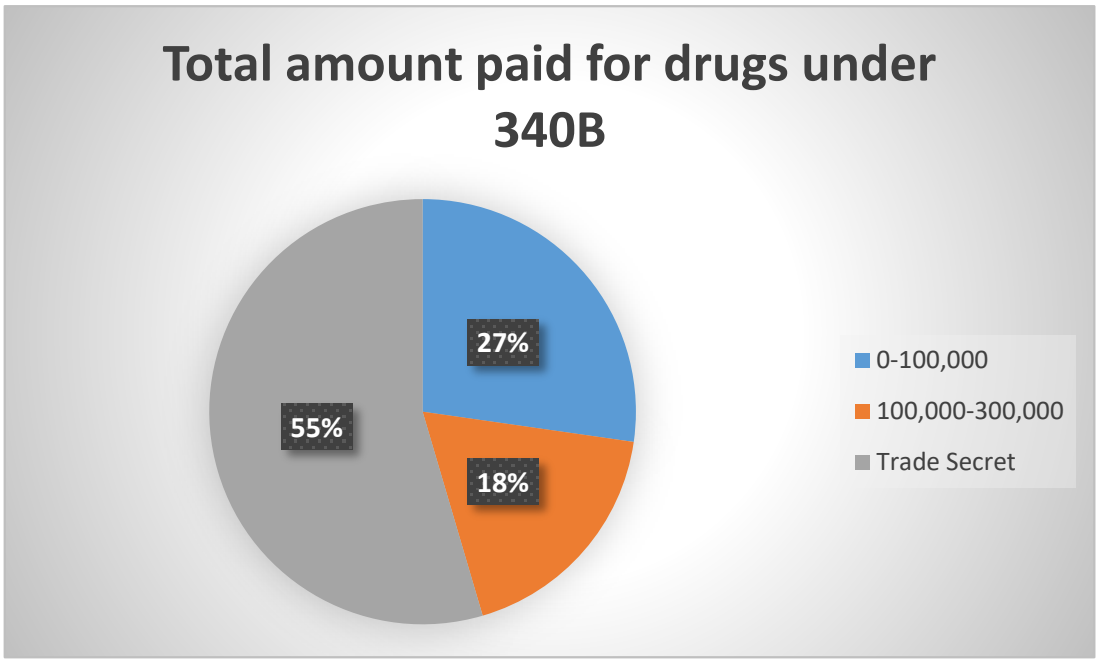

Figure 6 Amounts paid for drug under 340B discount program

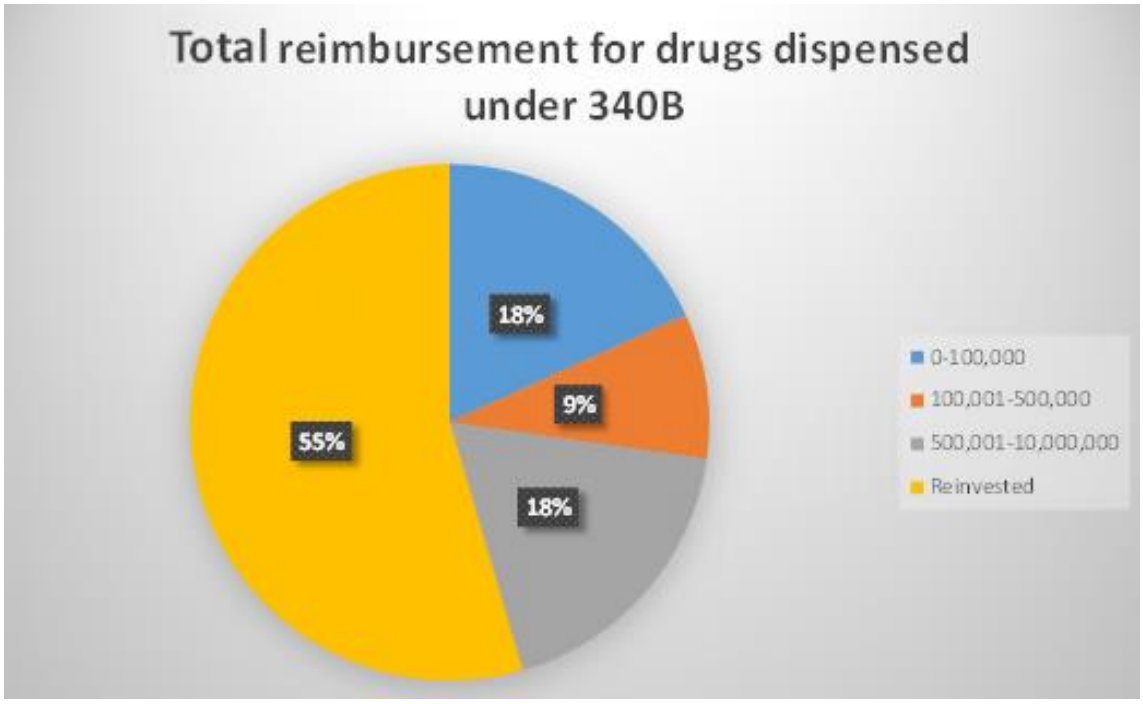

Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B program

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	Trulicity	Letter	5/21/2025	Exhibit A
Cynthia Ransom	Eli Lilly	Trulicity	Letter	5/21/2025	Exhibit B
Dr. Harry Gewanter	Let My Doctors Decide Action Network	Trulicity	Letter	5/15/2025	Exhibit C
Mary Anne Cooper	Regence BlueCross BlueShield	Trulicity	Letter	5/12/2025	Exhibit D
Derek Asay	Eli Lilly	Trulicity	Letter	9/15/2025	Exhibit E