Oregon Prescription Drug
Affordability Board

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Trelegy Ellipta®

(*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*)[1]

Version 2.1

[1] Image source: https://www.drugs.com/trelegy-ellipta.html

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Document version history

Version	Date	Description
v1.0	8/13/2025	Original release
v1.5	8/28/2025	Added new public comment to the appendix table
v1.6	9/24/2025	Updated table numbers and references
v2.0	10/28/2025	30 day supply data added. 75th and 95th percentile data for cost per enrollee, and out of pocket costs added. Formatting changes.
V2.1	12/17/2025	Medicaid expenditure added.

Review summary

Therapeutic alternatives[2,3,4]

Trelegy Ellipta® (*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*) has the following therapeutic alternative: **Breztri Aerosphere,**

Proprietary name	Non-proprietary name	Manufacturer	Number of patents	Patent date range	Exclusivity expiration	On the CMS drug Maximum Fair Price (MFP) list
Trelegy Ellipta[5]	*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*	GlaxoSmithKline Research & Development	13	2025-2031		Yes
Breztri Aerosphere[6]	*budesonide, glycopyrrolate, and formoterol fumarate*	AstraZeneca	9	2030-2038		No

Price history[7,8]

Trelegy rose at an **average annual rate of 3.7 percent** from 2018-2024.

- In the same time period, its therapeutic alternative rose at the rate:
    - Breztri Areosphere: 2.2 percent

[2] Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations
[3] Definitions of patents and exclusivity based on the U.S. Food & Drug Administration. https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a
[4] https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[5] No exclusivity information was listed for Trelegy Ellipta in the U.S. Food & Drug Administration Orange Book Database
[6] No exclusivity information was listed for Breztri Aerosphere in the U.S. Food & Drug Administration Orange Book Database
[7] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[8] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.

Additionally, the average annual rate of Trelegy Ellipta exceeded inflation **in 2020, 2023, and 2024**. Pharmacy acquisition costs (AAAC) for **Medicaid also increased by 14.7 percent** over the same period, reflecting broader trends in pricing escalation.

Price concessions [9]

Based on data received from healthcare carriers, Trelegy Ellipta in 2023 had a **gross spend of $732 per claim**, while the **spend net of discount was $374 per claim**. Price concession per claim was reported to be **$357**.

Cost to the payer[10]

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

Proprietary name	Total Expenditure	Utilization	Cost per Enrollee	Cost per Enrollee, median
Trelegy Ellipta	$49,562,009	70,646	$4,684	$625
Breztri Aerophere	$4,627,756	7,218	$4,146	$609

Cost to enrollees[11]

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

Proprietary name	OOP cost per enrollee	OOP cost per enrollee median	OOP cost per claim	OOP cost per claim median
Trelegy Ellipta	$391	$30	$64	$10
Breztri Aerophere	$327	$35	$71	$10

[9] 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.
[10] 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.
[11] Ibid.

Rubric considerations

Domain	Consideration
Utilization	70,646
Price evaluation	Avg percent change in WAC between 0%-3.99%, outpaced inflation for three years
Price concessions	25-50% of claims discounted
System & payer costs	Total gross spend $15M-$50M, total net spend $3M-$10M
Enrollee burden	Total APAC OOP $200-$700
Equity impact	Yes
Access restrictions	No
Therapeutic alternative fail to reduce system spending	Yes
Stakeholder input identify access or financial hardship?	No
Patent expirations more than 18 months from time of review?	Yes
Excluded from CMS Maximum Fair Price List (MFP)	No

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[12]

Drug proprietary name(s)	Trelegy Ellipta®
Non-proprietary name	*fluticasone/umeclidinium/vilanterol*
Manufacturer	Glaxosmithkline (GSK)
Treatment: Trelegy Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long-acting beta2-adrenergic agonist (LABA), indicated for:	• the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
	• the maintenance treatment of asthma in patients aged 18 years and older.
Dosage and Strengths	• 100 mcg fluticasone furoate, 62.5 mcg umeclidinium, and 25 mcg vilanterol (100/62.5/25 mcg) per actuation.
	• 200 mcg fluticasone furoate, 62.5 mcg umeclidinium, and 25 mcg vilanterol (200/62.5/25 mcg) per actuation.
Form/Route	Powder/Inhalation

FDA approval

Trelegy was first approved by the FDA on September 18, 2017.[13]

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

[12] U.S. Food & Drug Administration. *Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) Prescribing Information*. GSK, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209482s013lbl.pdf.

[13] 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.

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

Health inequities

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

Black individuals with chronic obstructive pulmonary disease (COPD) are more likely than non-Hispanic whites to remain undiagnosed even at similar levels of airflow obstruction, resulting in delayed initiation of advanced therapies.[14] Even after diagnosis, minority patients are less likely to be referred for specialist care or preventive services such as smoking cessation, which contributes to underuse of combination therapies like Trelegy Ellipta (*fluticasone/umeclidinium/vilanterol*).[15]

Race adjusted spirometry equations decrease sensitivity for detecting COPD in Black patients, leading to underdiagnosis and treatment underutilization, including delayed access to newer respiratory therapies.[16] Cost also remains a major barrier as Trelegy is a branded therapy and often subject to higher out-of-pocket requirements under Medicare Part D or limited access with Medicaid and private plans, disproportionately affecting low-income populations.[17] Additionally, underrepresentation of minority patients in clinical trials may reduce clinician familiarity with Trelegy's effectiveness, further limiting equitable prescribing.[18]

Residents prescribed

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

Based on APAC claims, **70,646** Oregonians filled a prescription for Trelegy Ellipta in 2023.[19]

[14] Day, N. C., et al. (2020). Single-inhaler triple therapy fluticasone furoate/umeclidinium/vilanterol versus fluticasone furoate/vilanterol and umeclidinium/vilanterol in patients with COPD: results on cardiovascular safety from the IMPACT trial. *Respiratory research*, *21*(1), 139. https://doi.org/10.1186/s12931-020-01398-w.

[15] Grossi, Giuliana, "ATS 2024 Data Support Triple Therapy FF/UMEC/VI as Preferred Option for COPD." AJMC, Center on Health Equity & Access, The Center for Biosimilars, May 21, 2024. https://www.ajmc.com/view/ats-2024-data-support-triple-therapy-ff-umec-vi-as-preferred-option-for-copd.

[16] Davidson, Sean Richard, et al., "Race Adjustment of Pulmonary Function Tests in the Diagnosis and Management of COPD: A Scoping Review." International Journal of Chronic Obstructive Pulmonary Disease, April 29, 2024. https://pubmed.ncbi.nlm.nih.gov/38708410/.

[17] Ndugga, Nambi, et al. "Racial and Ethnic Disparities in Access to Medical Advancements and Technologies." KFF, Feb. 22, 2024. https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-and-ethnic-disparities-in-access-to-medical-advancements-and-technologies/.

[18] Ibid.

[19] 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 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 Trelegy Ellipta, drawing on multiple data sources to characterize its historical cost trends and implications for affordability. It includes an analysis of WAC and the Oregon Actual Average Acquisition Cost (AAAC), as well as the impact of negotiated price concessions which include discounts, rebates, and other price reduction negotiations. Together, the data provides a comprehensive view of Trelegy Ellipta's list price trajectory, pharmacy acquisition costs, and the degree to which price reductions are realized in practice by payers in Oregon.

Price history

WAC per 30-day summary 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

	Trelegy Ellipta	Breztri Aerosphere
30-day supply	1 inhaler (1 package)	1 inhaler (1 package)

Table 4 Drug vs therapeutic alternatives and 2018-2024 WAC per 30-day supply[20]

Year	Trelegy Ellipta	Breztri Aerosphere
2018	$512	
2019	$527	
2020	$560	$590
2021	$588	$590
2022	$606	$608
2023	$624	$626
2024	$643	$645
Avg. Annual % Change	3.9%	2.2%
% change 2018 and 2024	25.5%	

The WAC of Trelegy Ellipta, averaged across three NDCs reported, was approximately **$10.96 per unit** at the end of 2024.[21] Between 2018-2024, the unit WAC increased at an average

[20] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[21] Ibid.

annual rate of **3.7 percent**, exceeding the general consumer price index (CPI-U) inflation rate in 2018-2019 and 2019-2020.[22]

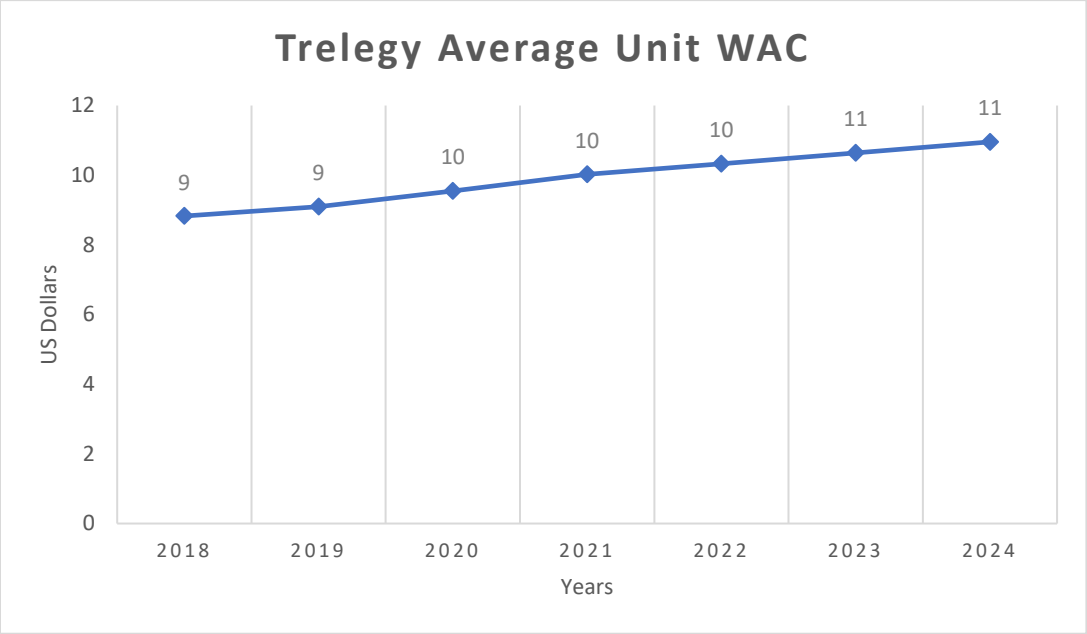

Figure 1 Trelegy Ellipta average unit WAC from 2018-2024

Table 5 Percent change of WAC of drug and therapeutic alternatives with CPI comparison[23]

Year	Trelegy Ellipta	Breztri Aerosphere	CPI-U
2018-2019	3.0%		1.7%
2019-2020	5.0%		0.7%
2020-2021	5.0%		5.3%
2021-2022	3.0%	3.0%	9.0%
2022-2023	3.0%	3.0%	3.1%
2023-2024	3.0%	3.0%	3.0%

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

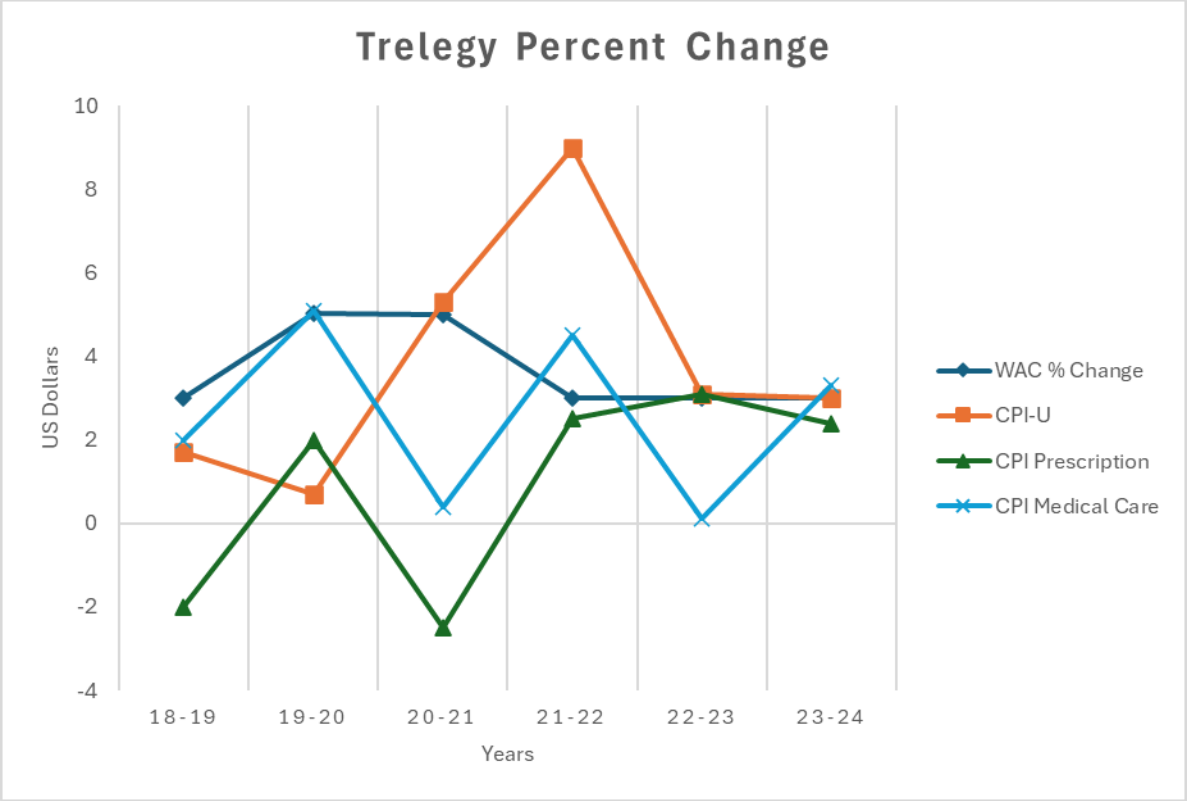

Figure 2 Year over year change in unit WAC compared to inflation rates[24]

Pharmacy acquisition costs

The AAAC, which reflects pharmacies' actual purchase prices for Medicaid fee-for-service claims, rose from **$9.16 per unit in Quarter 1 of 2020 to $10.51 per unit in Quarter 4 of 2024**, an approximate **14.7 percent increase** over the period (Table 6).[25] Relative to the **$10.97** WAC in end-of-year 2024 a **AAAC discount of 4.2 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 Trelegy Ellipta's price trajectory relative to inflation and affordability for public and private payers.

[24] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[25] Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs. Pharmacy Prescription Volume Survey, January 2020 to December 2023. AAAC Rate Review. Myers and Stauffer and Oregon Health Authority. https://myersandstauffer.com/client-portal/oregon/.

Table 6 2020-2024 AAAC Medicaid FFS quarterly purchase prices

Year	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Average AAAC	Average WAC
2020	$9	$9	$9	$9	$9	$10
2021	$10	$10	$10	$10	$10	$10
2022	$10	$10	$10	$10	$10	$10
2023	$10	$10	$10	$10	$10	$11
2024	$10	$11	$11	$11	$11	$11

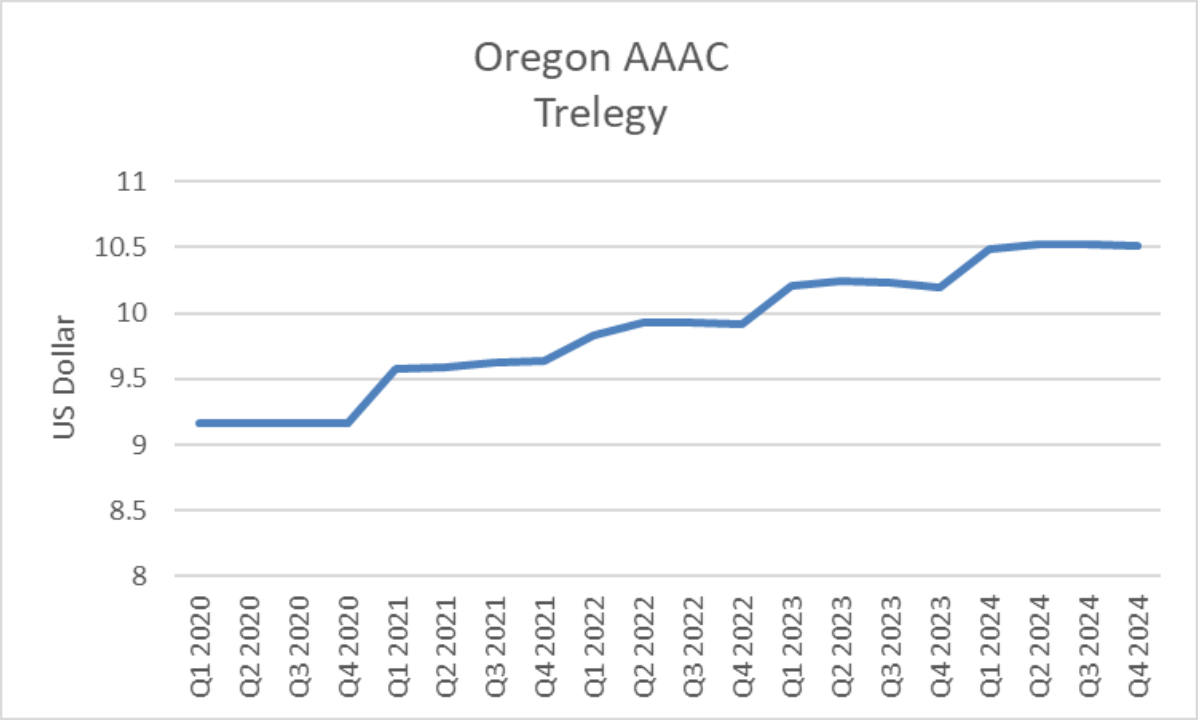

Figure 3 AAAC for Trelegy Ellipta from Q1 2020 to Q4 2024

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 Trelegy Ellipta claims in the commercial market. Drawing on data submitted through the 2023 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 Trelegy Ellipta per enrollee in the commercial market was approximately $3,289**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **average net cost per enrollee declined to approximately $1,683**, reflecting an **estimated mean discount of 48.8 percent** relative to gross costs.

Across all reporting carriers and market segments, the total cost of Trelegy Ellipta before concessions was **$3,532,805**, with total reported price concessions amounting to approximately **$1,725,195**, as detailed in Table 7. Notably, **95.2 percent of claims benefited from some form of price concession**, leaving **4.8 percent at full gross cost**.

Table 7 Net cost estimate based on carrier submitted 2023 data

Total number of enrollees	1,074
Total number of claims	4,827
Total number of claims with price concessions applied	4,595
Percentage of claims with price concessions applied	95.2%
Percentage of cost remaining after concessions	51.2%
Percentage of discount	48.8%
Manufacturer price concessions for all market types	$1,364,864
PBM price concessions for all market types	$359,231
Other price reductions for all market types	$1,100
Cost before price concessions across all market types	$3,532,805
Total price concessions across all market types	$1,725,195
Cost of after price concessions across all market types	$1,807,610
Avg. payer spend per enrollee without price concessions	$3,289
Avg. payer spend per enrollee with price concessions	$1,683

Including all market segments, the **gross spend of Trelegy per claim for commercial carriers was $732** before any discounts, rebates, or other price concessions. The net cost per enrollee discounts, rebates, and other price concessions was **$374**, meaning that insurers reported a price concession of **$357** per claim on the initial drug cost as shown in Table 8.

Table 8 The average price concessions across market types from data call[26]

	Average	Individual market	Large market	Small market
Spend per claim, gross	$732	$742	$724	$754
Spend per claim, net	$374	$384	$371	$378
Price concession per claim	$357	$359	$353	$376

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

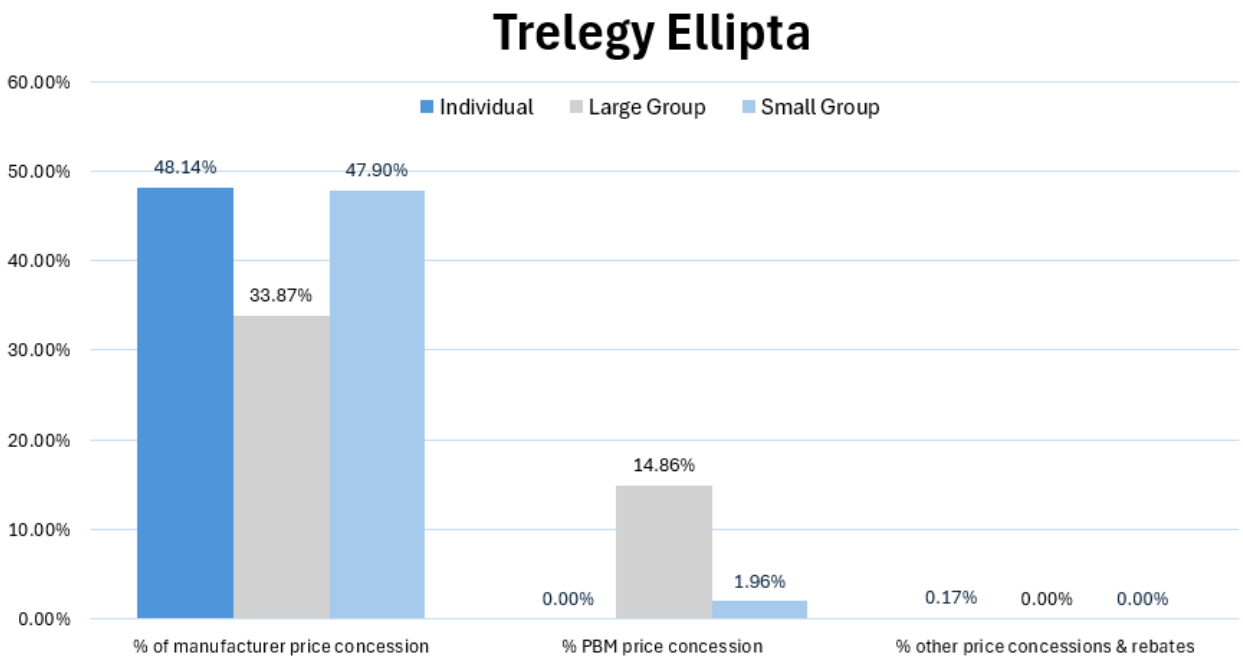

Figure 4 Percent of price concession in each market type[27, 28]

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

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

[28] Rebate refers to a discount that occurs after drugs are purchased from a pharmaceutical manufacturer and involves the manufacturer returning some of the purchase price of the purchaser. When drugs are purchased by a managed care organization, a rebate is based on volume, market share, and other factors. Academy of Managed Care Pharmacy. Managed Care Glossary | AMCP.org.

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

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

Estimated price for therapeutic alternatives[29]

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 Trelegy and its therapeutic alternatives using data from APAC and data call collection for 2023 information. APAC data reflects gross spending across Medicare, Medicaid, and commercial health plans in Oregon, while the data call includes net spending submitted by 11 commercial health insurers. All therapeutic alternatives are represented using APAC data, which does not reflect price concessions or rebates.

Trelegy Ellipta's gross total payer paid, based on APAC data, was $49.6 million, **while total net payer paid received from the carriers indicated a cost of $3.1 million. Trelegy Ellipta has the highest gross total pay in consideration with its therapeutic alternative,** which has the total gross payer paid of $4.6 million. **Notably, Trelegy has more utilization than its therapeutic alternative, at 70,646 claims**, as compared to Breztri Aerosphere, at 7,218 claims**. Trelegy Ellipta also has a higher payer paid per claim as compared to Breztri Aerosphere, $702 and $641 respectively.**

Trelegy also has the highest total enrollee paid at $3.8 million and Breztri Aerosphere follows behind with $462,080. Breztri Aerosphere has a patient paid per claim at $71, which is higher than **Trelegy's patient paid per claim at $55.**

[29] 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).

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

Table 9 Average healthcare and average patient OOP costs vs therapeutic alternatives[30]

Proprietary name	No. of enrollees [31]	No. of claims	Total payer paid	Total enrollees paid[32]	Payer paid/ claim	Patient paid/ claim[33]
Subject Drug **Trelegy (Data call)**[34]	**1,074**	**4,827**	**$3,086,878**	**$318,465**	**$640**	**$66**
Subject Drug **Trelegy (APAC)**	**10,582**	**70,646**	**$49,562,009**	**$3,750,276**	**$702**	**$55**
Breztri Aerosphere	1,471	7,218	$4,627,756	$462,080	$641	$71

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 Trelegy, as compared to the subject drug itself. At the time of this review, there was no quantifiable data available to PDAB to assess the average price concessions for the identified therapeutic alternatives in the Oregon market.

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

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

Estimated costs to health insurance plans

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

This section quantifies the financial impact of Trelegy 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 **70,646 total claims for Trelegy among 10,582 total enrollees**, corresponding to a **total payer expenditure of $49.6 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 46,375 claims from 7,722 enrollees and a total spend of **$34.9 million**.
- **Medicaid** and **commercial** payers reported smaller but notable expenditures of approximately **$7.5 million** and **$7.2 million**, respectively.

Table 10 Estimated 2023 APAC total annual gross payers' expenditure for total enrollees and total claims [35]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial	1,960	11,859	$7,157,460	$3,652	$604
Medicaid	1,909	12,412	$7,486,718	$3,922	$603
Medicare	7,722	46,375	$34,917,832	$4,522	$753
Total[36]	**10,582**	**70,646**	**$49,562,009**		

Table 11 provides utilization for the healthcare system for Trelegy and its therapeutic alternatives, distinguished by lines of business. **Trelegy had the most utilization** with **70,646 claims**. In all lines of business, Trelegy is the most utilized. **Breztri Aerosphere is the second most utilized at 7,218 claims**.

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

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

Table 11 Estimated APAC payer 2023 utilization of review drug and its therapeutic alternatives [37]

Proprietary name	Commercial Utilization	Medicaid Utilization	Medicare Utilization	Total claims[38]
Trelegy Ellipta	11,859	12,412	46,375	70,646
Breztri Aerosphere	981	711	5,526	7,218

Table 12 shows the overall payer expenditure of Trelegy Ellipta and its therapeutic alternatives, distinguished by lines of business. Trelegy Ellipta has a **total expenditure of $49.6 million** with **Medicare being the biggest portion at $34.9 million**. The therapeutic alternative, Breztri Aerosphere, has less expenditure at $4.6 million.

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

Proprietary name	Commercial Expenditure	Medicaid Expenditure	Medicare Expenditure	Total[40]
Trelegy Ellipta	$7,157,460	$7,486,718	$34,917,832	$49,562,009
Breztri Aerosphere	$502,890	$421,270	$3,703,586	$4,627,756

Table 13 compares the overall payer cost per enrollee of Trelegy Ellipta and its therapeutic alternatives, distinguished by lines of business. **Trelegy Ellipta has the highest total cost per enrollee at $4,684**. Trelegy Ellipta has higher costs per enrollee in every line of business compared to Breztri Aerosphere. **The median cost per enrollee for Trelegy is $625**, which is higher than the median for the therapeutic alternative.

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

Table 13 Estimated 2023 APAC payer cost per enrollee of drug and its therapeutic alternatives[41]

Proprietary name	Commercial Cost/ Enrollee	Medicaid Cost/ Enrollee	Medicare Cost/ Enrollee	Total[42] cost per enrollee	Cost per enrollee, median	IQR	Cost per enrollee, 75th percentile	Cost per enrollee, 95th percentile
Trelegy Ellipta	$3,652	$3,922	$4,522	$4,684	$625	$141	$700	$2,025
Breztri Aerosphere	$2,255	$2,790	$3,066	$3,146	$609	$164	$667	$1,902

Data submitted via the carrier data call further stratifies commercial expenditures by market segment. The collected **total net cost to the healthcare system was around $3.4 million**, with payer paying $3.1 million, and enrollees out-of-pocket estimating to be $318,465. Table 14 includes the average plan costs per enrollee in the commercial market, ranging from **$3,309 (individual)** to **$2,983 (small group)** annually.

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

Market	Number of claims	Number of enrollees	Total annual spending	Payer paid	Enrollee out-of- pocket cost
Individual	858	192	$635,234	$542,183	$93,051
Large Group	3,238	711	$2,260,013	$2,071,688	$188,325
Small Group	731	171	$510,095	$473,006	$37,088
Total	**4,827**	**1,074**	**$3,405,342**	**$3,086,878**	**$318,465**

[41] Based on 2023 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[42] The total is the overall cost per enrollee across commercial insurers, Medicaid, and Medicare.
[43] Cost information from the data call is the cost of the drug after price concessions.

Table 1415.b Estimated 2023 data 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	$740	$632	$108	$3,309	$2,824	$485
Large Group	$698	$640	$58	$3,179	$2,914	$265
Small Group	$698	$647	$51	$2,983	$2,766	$217

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (66% of total), followed by individual and small group markets.

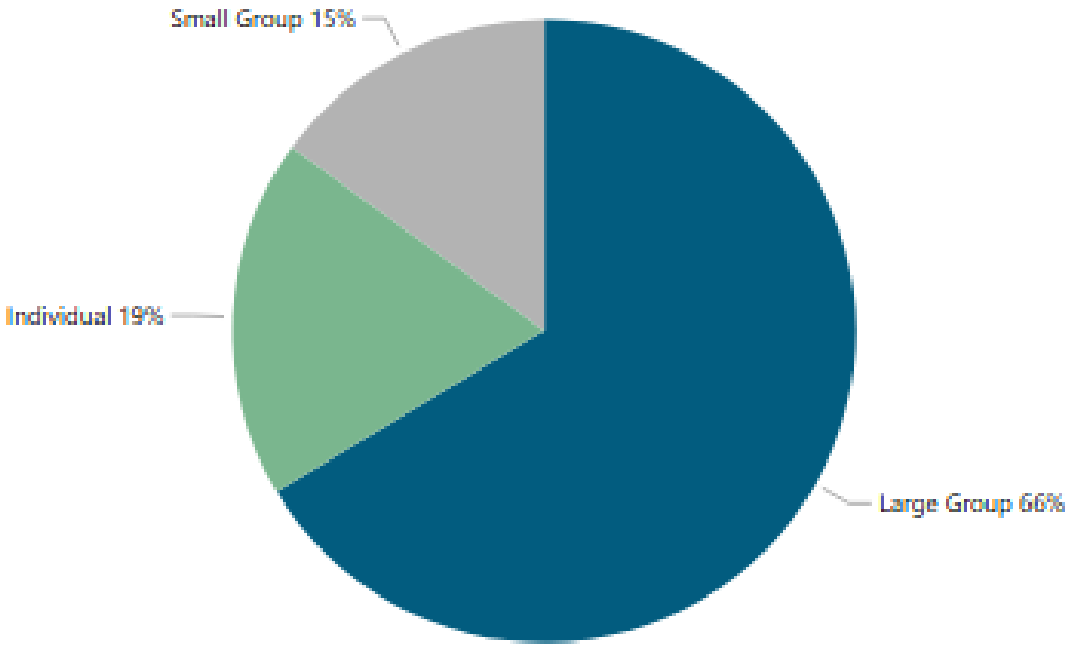

Figure 5 Data call total annual spend (payer paid) for each market type

Table 15 indicates CCOs that reported Trelegy as having an annual greatest increase from 2022-2023 (rebates not included) with about **$1.5 million in year-over-year increased cost growth**.

Table 16 Medicaid CCOs greatest increase in share to total cost from 2022-2023 (rebates not included)[44]

Medicaid CCOs			
2022	**2023**	**YoY change in spending**	**Percent of total CCO cost 2023**
$5,547,915	$7,026,551	$1,478,636	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.

Review of rejected claims and drug benefit designs

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Trelegy, 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 Trelegy. In 2023, approximately **36.1 percent of reporting plans required prior authorization (PA)** for coverage of the drug, and **0.4 percent of plans required step therapy** before approving its use.

For formulary placement, **37.2 percent of plans categorized Trelegy as a non-preferred drug**, and **no plans excluded it entirely from the formulary**.

Table 17 Plan design analysis from 2023

Percentage of plans	
Required prior authorization	36.1%
Required step therapy	0.4%
On a non-preferred formulary	37.2%
Not covered	0.0%

Note: percentages can equal over 100 percent as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in the small group market that require prior authorization but two other plans in the small group market that do not require prior authorization.

[44] CCO Pharmacy spend provided by Oregon State University drug use research and management program. 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)(i)(A-B). Limitations in scope and resources available for this statute requirement.

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

The statutory and regulatory criteria contemplate consideration of such 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 Trelegy in Oregon, as reported in 2023 by the Oregon All Payers All Claims (APAC).[45] These costs include enrollee copayments, coinsurance, and deductible contributions for the drug and are presented by insurance type.

Table 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 insured 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.

[45] 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 18 Review drug vs. therapeutic alternatives and annual out-of-pocket cost per enrollee [46]

Proprietary name	Annual Medicare OOP cost/ enrollee	Annual Commercial OOP cost/ enrollee	Total [47]	Median	IQR	75th percentile	95th percentile
Trelegy Ellipta	$425	$239	$391	$30	$125	$125	$546
Breztri Aerosphere	$328	$296	$327	$35	$146	$125	$563

Table 19 Review drug vs. therapeutic alternatives and out-of-pocket cost per claim[48]

Proprietary name	Medicare OOP cost/claim	Commercial OOP cost/claim	Total[49]	Median	IQR	75th percentile	95th percentile
Trelegy Ellipta	$71	$39	$64	$10	$47	$47	$348
Breztri Aerosphere	$72	$67	$71	$10	$47	$47	$436

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:
  - the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).
  - the maintenance treatment of asthma in patients aged 18 years and older.
- Limitations of Use
  - Not indicated for relief of acute bronchospasm.
- Off Label Uses: none

[46] 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.
[47] The total is the overall cost per enrollee across commercial insurers and Medicare.
[48] 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.
[49] The total is the overall cost per claim across commercial insurers and Medicare.

Clinical efficacy

The clinical efficacy of Trelegy Ellipta *(Fluticasone Furoate/Umeclidinium/Vilanterol; FF/UMEC/VI)*, a once-daily combination inhaler containing fluticasone furoate (FF; an inhaled corticosteroid [ICS]), umeclidinium (UMEC; a long-acting muscarinic antagonist [LAMA]), and vilanterol (VV; a long-acting beta$_2$-agonist [LABA]), was established in multiple randomized, double-blind, controlled clinical trials evaluating both chronic obstructive pulmonary disease (COPD) and asthma. In COPD, two identical 12-week double blind studies compared UMEC + FF/VI to placebo + FF/VI in patients with COPD on change from baseline in FEV1 on day 85.[50] One study found a difference of 125 ml increase in trough FEV1 from baseline in patients receiving UMEC + FF/VI compared to patients receiving placebo + FF/VI and a difference of 122 ml in a second study. A large (n=10,355) randomized controlled trial (IMPACT) confirmed the efficacy of FF/UMEC/VI on moderate to severe exacerbations (Table 1) compared to FF/VI and UMEC/VI.

In 2022, Trelegy Ellipta received an expanded indication for maintenance treatment of asthma in adults and a new dosage form of FF/UMEC/VI 200mcg/62.5mcg/25mcg was approved. Approval was based on a 24-week, double blind, randomized, study comparing FF/UMEC/VI to FF/VI (Table 1). This trial demonstrated statistically significant improvements in trough FEV1with both doses compared to FF/VI. However, there was no significant difference in moderate or severe exacerbations with triple therapy compared to FF/VI.

Table 20 Clinical efficacy results

Trial / Population	Treatment group	Comparator	Endpoint	Treatment effect	p-value
COPD (IMPACT)	FF/UMEC/VI 100/62.5/25	FF/VI 100/25	Annual exacerbation rate	0.91/yr vs. 1.07/yr RR 0.85 (95% CI, 0.80 to 0.90)	<0.001
		UMEC/VI 62.5/25	Annual exacerbation rate	0.91/yr vs. 1.21/yr RR 0.75 (95% CI, 0.70 to 0.81)	<0.001
Asthma (CAPTAIN)	FF/UMEC/VI 100/62.5/25	FF/VI 100/25	Change from baseline in	Difference 110 mL 95% CI 66 to 153)	<0.001

[50] Siler TM, Kerwin E, Sousa AR, Donald A, Ali R, Church A. Efficacy and safety of umeclidinium added to fluticasone furoate/vilanterol in chronic obstructive pulmonary disease: Results of two randomized studies. Respir Med. 2015 Sep;109(9):1155-63. doi: 10.1016/j.rmed.2015.06.006. Epub 2015 Jun 14. Erratum in: Respir Med. 2015 Nov;109(11):1493. PMID: 26117292.

Trial / Population	Treatment group	Comparator	Endpoint	Treatment effect	p-value
			trough FEV1 at week 24		
			Annual exacerbation rate	0.68/yr vs. 0.87/year RR 0.78 (95% CI 0.61 to 1.01)	0.06
	FF/UMEC/VI 200/62.5/25	FF/VI 100/25	Change from baseline in trough FEV1 at week 24	Difference 92 mL 95% CI 49 to 135)	<0.001
			Annual exacerbation rate	0.55/yr vs. 0.57/year RR 0.97 (95% CI 0.73 to 1.28)	0.08
Abbreviations: FEV1: Forced Expiratory Volume in one second; FF: fluticasone furoate; RR: rate ratio; UMEC: umeclidinium; VI: vilanterol					

Clinical safety

- FDA safety warnings and precautions:
  - Serious Asthma-Related Events with use of LABA monotherapy (without ICS) for asthma
  - Deterioration of disease and acute episodes if initiated in rapidly deteriorating or life-threatening episodes of COPD or asthma
  - Avoid excess use of Trelegy Ellipta and avoid use with other LABAs
  - Oropharyngeal candidiasis
  - Pneumonia
  - Immunosuppression and risk of infections
  - Hypercorticism and adrenal suppression, especially when transferring patients from systemic corticosteroid therapy
  - Drug interactions with strong cytochrome P450 3A4 inhibitors
  - Paradoxical Bronchospasm
  - Hypersensitivity reactions, including anaphylaxis
  - Cardiovascular effects: beta agonists may cause elevations in blood pressure, heart rate, and arrythmias
  - Reduction in bone mineral density
  - Glaucoma and cataracts, worsening of narrow-angle glaucoma
  - Worsening of urinary retention

    - Hypokalemia and hyperglycemia
    - Effect on growth in children and adolescents
- Contraindications:
    - Primary treatment of status asthmaticus or other acute episodes of COPD or asthma where intensive measures are required.
    - Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients.
- Common side effects:
    - Nasopharyngitis and pharyngitis
    - Constipation, diarrhea, gastroenteritis, dysgeusia
    - Oral candidiasis
    - Headache
    - Voice disorder
    - Bronchitis, cough, respiratory tract infections, sinusitis
    - Back pain and arthralgia

Therapeutic alternatives:[51,52]

Triple therapy with a LABA/LAMA/ICS should be considered for patients with severe or very severe COPD with continued frequent and/or serious exacerbations despite optimized use of LABA and LAMA or LABA/ICS. There are currently two combination ICS/LAMA/LABA products available (Table 15). There are no randomized controlled trials directly comparing these agents or evidence demonstrating differences in efficacy or safety.

Table 21 FDA approved indications

Proprietary name	Non-proprietary name	Manufacturer (year approved)	FDA approved indications
Trelegy Ellipta	*fluticasone furoate, umeclidinium, and vilanterol inhalation powder*	GlaxoSmithKline Research & Development (2017)	Maintenance treatment of COPD and asthma in adults
Breztri Aerosphere	*budesonide, glycopyrrolate, and formoterol fumarate*	AstraZeneca (2020)	Maintenance treatment of COPD only

[51] U.S. Food & Drug Administration. *Trelegy Ellipta (fluticasone furoate, umeclidinium, and vilanterol inhalation powder) Prescribing Information*. GSK, Action yr 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/209482s013lbl.pdf.

[52] U.S. Food & Drug Administration. *Breztri Aerosphere (budesonide, glycopyrrolate, and formoterol fumarate) Prescribing Information*. AstraZeneca, Action yr 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212122s000lbl.pdf.

Table 22 Efficacy (clinical trials & practice)

Measure	Trelegy Ellipta	Breztri Aerosphere
Annual rate of moderate/severe exacerbations	Decreased 15–25% vs. FF/VI and UMEC/VI (p<0.001)	Decreased 15–20% vs. dual therapy (Hazard ratio ~0.85)
Trough FEV1 improvement (mL)	Increased 65–95 mL over dual therapy (p<0.001)	Increased 55–78 mL over dual therapy (p<0.001)
Quality of life (SGRQ score improvement)	Clinically meaningful improvements (≥4-point SGRQ)	Modest improvements; sometimes not clinically meaningful
Abbreviations: SGRQ: St. George's Respiratory Questionnaire		

Table 23 Adverse effects profile

Adverse effect category	Trelegy Ellipta	Breztri Aerosphere
Common adverse effects	Nasopharyngitis, headache, URTI, pneumonia, back pain	URTI, pneumonia, back pain, oral candidiasis, influenza
Notable risks	Increased risk of pneumonia, oral candidiasis, potential cardiovascular effects	Increased risk of pneumonia, oral candidiasis, systemic corticosteroid effects

Table 24 Dosing and route

Product	Trelegy Ellipta	Breztri Aerosphere
Route	Oral inhalation via dry powder inhaler (DPI)	Oral inhalation via pressurized metered dose inhaler (pMDI)
Strength per inhalation	Fluticasone furoate/umeclidinium/vilanterol COPD 100/62.5/25 mcg. Asthma 100/62.5/25 mcg, or 200/62.5/25 mcg	Budesonide 160 mcg, glycopyrrolate 9 mcg, formoterol fumarate 4.8 mcg
Recommended dose	1 inhalation once daily	2 inhalations twice daily

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 13 individuals** taking or having an association with Trelegy. According to the survey results, 10 respondents had insurance coverage for Trelegy.

There were no patients on Medicaid, 12 patients were on Medicare, and one patient had private health insurance but was on a patient assistance program because their prescription was not covered by insurance.

Individuals with scientific or medical training

Surveys were posted on the PDAB website to collect drug information from individuals with scientific and medical training. There were no reports for Trelegy 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 Trelegy, 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 Trelegy 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 Trelegy is incorporated into many safety-net programs, further data would be necessary to understand how reimbursement aligns with acquisition cost and whether 340B discounts adequately mitigate financial exposure for patients and the healthcare system.

Table 25 Safety net provider survey responses

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

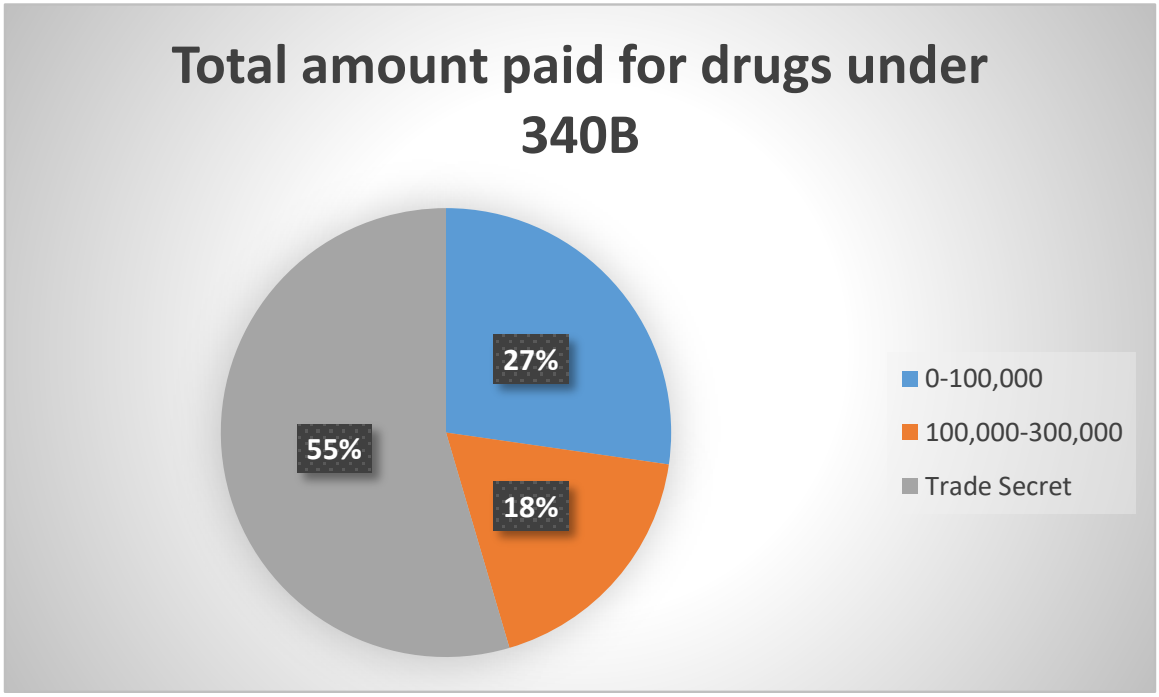

Figure 6 Amounts paid for drug under 340B discount program

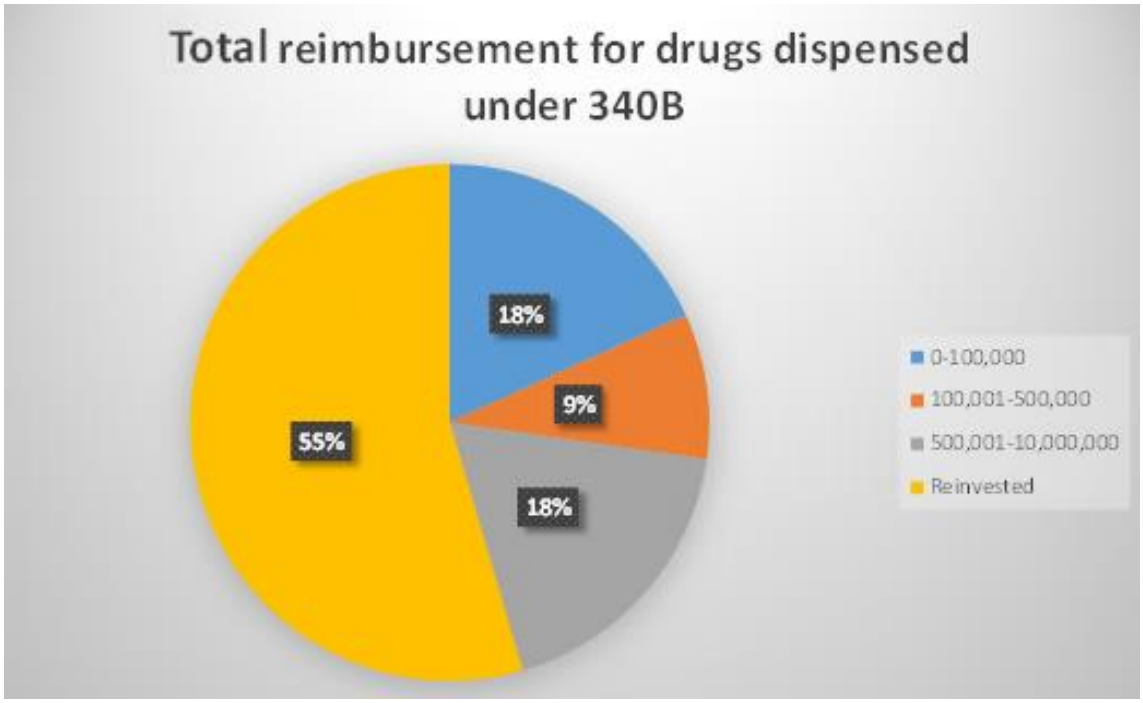

Figure 7 Estimated reimbursement ranges in dollars for potential reimbursement with drugs dispensed under 340B discount program

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
Harmeet Dhillon	GSK	Trelegy	Letter	5/21/2025	Exhibit A
Linda Nelson	Oregon Coalition for Affordability Prescriptions	Trelegy	Letter	5/21/2025	Exhibit B
Molly Burich	GSK	Trelegy	Letter	8/15/2025	Exhibit C
Tom Corbridge	GSK	Trelegy	Speaker	8/20/2025	Exhibit D
Nissa Shaffi	Allergy & Asthma Network	Trelegy	Letter	8/28/2025	Exhibit E