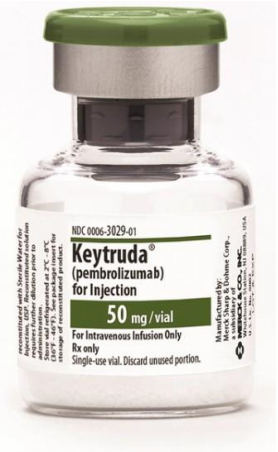
Oregon Prescription Drug
Affordability Board

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

Keytruda®
(*pembrolizumab*)[1]

Version 1.0



[1] Image source: https://www.belgraviacentre.com/download_file/view_inline/20117

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Document version history

Version	Date	Description
v1.0	07/07/2026	Original release

Review summary

Therapeutic alternatives[2,3,4]

Keytruda (*pembrolizumab*) has the following therapeutic alternatives: **Bavencio, Imfinzi, Jemperli, Libtayo, Opdivo**, and **Tecentriq**.

Table 1 Subject drug and therapeutic alternative information

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
Keytruda[5]	*pembrolizumab*	Merck	2014	-	-	-	No
Bavencio[6]	*avelumab*	EMD Serono, Inc.	2017	-	-	-	No
Imfinzi[7]	*durvalumab*	AstraZeneca	2017	-	-	-	No
Jemperli[8]	*dostarlimab-gxly*	Glaxo Smith Kline (GSK)	2021	-	-	-	No

[2]Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book. U.S. Food & Drug Administration. 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. 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 Keytruda. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.

[6] No patent or exclusivity information was listed for Bavencio. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.

[7] No patent or exclusivity information was listed for Imfinzi. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.

[8] No patent or exclusivity information was listed for Jemperli. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.

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
Libtayo[9]	*cempilmab-rwlc*	Regeneron Pharmaceutical, Inc.	2018	-	-	-	No
Opdivo[10]	*nivolumab*	Bristol-Myers Squibb (BMS)	2014	-	-	-	No
Tecentriq[11]	*atezolizumab*	Genetech, Inc.	2016	-	-	-	No

Price history[12,13]

Keytruda® (*pembrolizumab*) WAC per 30-day supply **increased** at an **average annual rate of 3.3 percent** from 2019 to 2025.

- In the same time period, its therapeutic alternatives WAC per 30-day supply increased at these rates:
    - Bavencio: 4.0 percent
    - Imfinzi: 2.5 percent
    - Jemperli: 3.0 percent
    - Libtayo: 3.2 percent
    - Opdivo: 3.0 percent
    - Tecentriq: 3.7 percent

Additionally, the average annual rate of Keytruda exceeded inflation in 2020 to 2022.

[9] No patent or exclusivity information was listed for Libtayo. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.
[10] No patent or exclusivity information was listed for Opdivo. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.
[11] No patent or exclusivity information was listed for Tecentriq. Purple Book Database of Licensed Biological Products. U.S. Food & Drug Administration. https://purplebooksearch.fda.gov/.
[12] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[13] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.

Price concessions [14]

Based on data received from healthcare carriers, Keytruda in 2024 had an expected **gross spend of $20,338 per claim**, while the **average net spend after discount was $20,336 per claim**. Price concession per claim was reported to be **$2**, resulting in **only 0.4 percent** of claims benefiting from some form of price concession, leaving nearly all claims paid at **full gross cost**.

Cost to the payers[15]

Table 2 2024 APAC payer annual total expenditure, claims, and cost per enrollee[16]

Proprietary name	No. of enrollees[17]	No. of claims	Total payer paid	Cost per enrollee, mean	Cost per claim, median
Keytruda	1,591	9,851	$132,020,415	$82,980	$12,015
Bavencio	32	387	$3,085,797	$96,431	$7,798
Imfinzi	294	1,885	$19,636,872	$66,792	$7,923
Jemperli	52	289	$4,051,584	$77,915	$12,236
Libtayo	92	413	$3,881,889	$42,194	$9,694
Opdivo	453	2,824	$30,765,190	$67,914	$7,841
Tecentriq	203	1,281	$12,305,192	$60,617	$10,129

Cost to enrollees[18]

Table 3 2024 gross APAC annual enrollee out-of-pocket (OOP) cost[19]

Proprietary name	Total paid by enrollee	OOP cost per enrollee, median	OOP cost per claim, mean	OOP cost per claim, median
Keytruda	$3,068,403	$264	$311	$0
Bavencio	$78,206	$2,197	$202	$0
Imfinzi	$519,832	$0	$276	$0

[14] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. The data call includes information about the cost of the drug before and after price concessions in the commercial market.

[15] Based on Oregon's 2024 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.

[16] The totals for amounts paid, costs, and claims are from both medical and pharmacy reporting.

[17] 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 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 6, 9, and 10 as compared to other totals indicated in this report.

[18] Based on Oregon's 2024 All Payer All Claims (APAC) data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

[19] Total patient out-of-pocket costs is the sum of reported copayments, coinsurances, and deductibles.

Proprietary name	Total paid by enrollee	OOP cost per enrollee, median	OOP cost per claim, mean	OOP cost per claim, median
Jemperli	$80,860	$0	$280	$0
Libtayo	$166,437	$1,049	$403	$0
Opdivo	$658,636	$0	$233	$0
Tecentriq	$367,023	$0	$287	$0

Rubric considerations

Table 4 Rubric domains and scoring considerations

Domain	Consideration
Number of APAC enrollees	1,591
Price evaluation	Average annual percent chang in WAC of 3.3 percent from 2022-2025
Price concessions	0.0% of claims received rebates or price concessions
System & payer costs	$132,020,415 gross payer paid
Enrollee burden	$1,929 mean of APAC enrollee OOP annual cost
Equity impact	TBD
Access restrictions such as prior authorization, etc.	Yes
Less expensive therapeutic alternative available	Yes
Stakeholder input identify affordability or financial concerns	No (no feedback submitted)
Patent expirations more than 18 months away	Yes (unknown)
Absent from the CMS MFP review list	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) Reporting Program database and the Oregon commercial carrier data call. APAC aggregates claims 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 claims

and cost figures due to broader reporting for more enrollees, while the data call offers insight into actual expenditures from private payers in the commercial market.

In 2023, APAC included data for approximately 3.5 million Oregonians. Approximately 27% of people in APAC had Medicare coverage, 33% of people had Medicaid coverage, and 39% of people had commercial coverage. APAC cannot require submission of claims and enrollment data from entities regulated under the Employee Retirement Income Security Act of 1974 (ERISA), so data for many self-insured plans are not included.[20,21] For these drug reviews, APAC data on people with Medicare coverage are limited to Medicare Advantage and Part D only and do not include claims for Traditional Medicare Part A or Part B.

In this review, cell values with enrollee counts derived from APAC data are suppressed to protect confidentiality when the cell has 30 or fewer individuals. In data tables, this is shown as "<31$^{\alpha}$" with the α (alpha) superscript indicating the exact value of the cell value has been suppressed to protect confidentiality. In some tables, secondary suppression is applied to cell values to prevent backward calculation of other suppressed values. Cells with secondary suppression are shown as a value range with a β (beta) superscript, such as "100-200$^{\beta}$".

The 2026 Oregon commercial carrier data call included data from commercial health plans providing coverage for approximately 800,000 Oregonians based on claims in 2024.[22] The data call is limited to fully-insured plans that are regulated by the state and does not include coverage regulated under ERISA.

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 conducted affordability reviews on prioritized prescription drugs selected under OAR 925-200-**0010**. The board selected ten drugs and two insulin products for affordability review in 2026. The selection process emphasized brand-name products with substantial cost impact and excluded antivirals, toxoids, vaccines, and products with available therapeutic equivalents or biosimilars as of February 2026. The board also removed from consideration products reviewed in 2025 and determined to possibly have potential system- or patient-level cost implications. To ensure broad relevance across Oregon's

[20] Oregon All Payer All Claims Database (APAC) Data User Guide. Version 1.1 updated Nov 19, 2025. APAC-Data-User-Guide.pdf. The number of people represented in 2024 APAC data has not been published as of May 2026.
[21] For 2024, the DCBS Division of Financial Regulation reported that just under one million people in Oregon were enrolled in commercial health plans and slightly more than one million people in Oregon were enrolled in self-insured health plans. *2024 Quarterly enrollment report*, https://dfr.oregon.gov/business/reg/reports-data/annual-health-insurance-report/Pages/health-ins-enrollment.aspx, accessed June 1, 2026.
[22] The number of people covered by plans reporting to the commercial carrier data call was estimated using 2024 insurer data reported in 2025 to the Oregon Drug Price Transparency Program which receives reports on state-regulated health insurance plans.

insured population, the board prioritized drugs reported by seven or more commercial health carriers.

For insulin products, the board focused on products with the highest end-of-year unit prices while excluding those with fewer than 100 covered enrollees. Insulin glargine products reviewed by the board in 2025 were also removed to maintain focus on products not yet evaluated. This approach ensured that the final selection aligned with statutory intent, reflected consistent application of rule-based selection factors, and supported a comprehensive assessment of products with meaningful affordability implications for Oregon's health care system and patients.

Visit the PDAB webpage for more information about purpose and statutory authority of the Oregon Prescription Drug Affordability Board (PDAB).

Drug information

Table 5 Drug and FDA information

Drug proprietary name(s)	Keytruda®
Non-proprietary name (active ingredients)	*pembrolizumab*
Manufacturer	Merck
Pharmacologic category	Antineoplastics and adjunctive therapies
Treatment	Treats many types of cancers: Skin, lung, blood, bladder, gastrointestinal, gynecologic, and breast.
Dosage strength	100 mg/4 mL (25 mg/mL) solution in a single-dose vial
Form/Route	Injection
Physician administered	Yes
NDCs reviewed	00006302601 00006302602 00006302604
First approved by the FDA	9/4/2014
Expedited forms of approval by the FDA	None listed
Designations under the Orphan Drug Act	Yes. See Appendix A for more information. Orphan conditions: Treats rare melanoma, classic Hodgkin Lymphoma; primary mediastinal large B-cell lymphoma; small cell lung cancer.

Health equity considerations

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.

Claims data from APAC was evaluated for health equity considerations related to utilization in Oregon. The analysis included line of business (payer type), race, ethnicity, and gender where available and evaluated member counts, claims numbers, insurer paid amounts, and enrollee out-of-pocket costs.

Keytruda claims were primarily **observed among Medicare enrollees**. Median and average claim costs were reviewed to understand typical and overall impacts. Median enrollee costs were generally similar across coverage categories, while average costs were higher in some groups, indicating a smaller number of higher-cost claims. Race, ethnicity, and gender information was included in the review; however, a substantial proportion of records were categorized as unknown, limiting interpretation of demographic differences.

Table 6 2024 APAC claim and enrollee count by line of business

Line of business	Claim count	Enrollee count[23]	Claims per enrollee
Commercial	2,079	363	5.7
Medicaid	2,940	559	5.3
Medicare	4,832	831	5.8
Total	9,851	1,591	6.2

Table 7 2024 APAC cost by line of business

Line of business	Total payer paid	Mean payer paid/claim	Median payer paid/claim	Total enrollee OOP[24]	Mean enrollee OOP/claim	Median enrollee OOP/claim
Commercial	$40,638,860	$19,547	$15,540	$413,600	$199	$0
Medicaid	$22,657,042	$7,706	$8,910	$0	$0	$0
Medicare	$66,218,182	$13,704	$11,764	$2,545,324	$527	$0

Table 8 2024 APAC mean and median insurer and enrollee out-of-pocket costs per claim, by race

Race	Claims	Mean payer paid	Median payer paid	Mean enrollee OOP[25]	Median enrollee OOP
White	3,879	$11,051	$11,150	$268	$0

[23] 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, meaning that an enrollee can be counted for each claim line of business. As a result, the difference in enrollment numbers may be different as compared to other totals indicated in this report.

[24] Total patient out-of-pocket costs is the sum of reported copayments, coinsurances, and deductibles for all enrollees in a line of business.

[25] The mean only includes claims paid from commercial and Medicare enrollees. Medicaid enrollees had [$]0 out-of-pocket costs.

Race	Claims	Mean payer paid	Median payer paid	Mean enrollee OOP[25]	Median enrollee OOP
Black/African American	179	$8,527	$9,119	$129	$0
American Indian/Alaska Native	79	$8,150	$2,657	$137	$0
Asian	241	$9,781	$9,342	$195	$0
Native Hawaiian/Pacific Islander	48	$11,364	$9,745	$120	$0
Mix race	272	$11,961	$12,015	$476	$0
Other	379	$12,104	$10,193	$174	$0
Refused to answer	51	$12,357	$11,282	$0	$0
Unknown	4,723	$15,478	$11,981	$347	$0

Table 9 2024 APAC claim counts and enrollee counts, by ethnicity

Ethnicity	Claim count	Enrollee count
Hispanic	337	66
Non-Hispanic	4,540	703
Unknown	4,974	822

Table 10 2024 APAC claim counts and enrollee counts, by gender

Gender	Claim count	Enrollee count
Female	5,889	960
Male	3,953	600-700[β]
Unknown	9	<31[α]

Residents prescribed

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

Based on APAC, **1,591 enrollees filled prescriptions** for Keytruda with **9,851 claims paid by payers** in 2024.[26]

[26] Number of 2024 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data: 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 Keytruda, 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), compared to its therapeutic alternatives. Keytruda does not appear on the Oregon AAAC list; therefore, AAAC acquisition cost data are not available. This section's data provides a comprehensive view of Keytruda's list price trajectory, and the degree to which the list price impacts costs.

Price history

WAC per 30-day supply was calculated with package and unit WAC from Medi-Span based on the most utilized NDC in APAC in 2024 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 11 30-day supply for review drug and its therapeutic alternatives

	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
30-day supply	4 vials (16 mL)	8 vials (80 mL)	30 mL	10 mL	1 vial (7 mL)	2 vials (48 mL)	1 vial (20 mL)
Reference NDC	00006302601	44087353501	00310461150	00173089803	61755000801	00003373413	50242091701
Strength	100 MG/ 4 ML (25 MG/ML)	200 MG/ 10 ML (20 MG/ML)	500 MG/ 10 ML (50 MG/ML)	500 MG/ 10 ML (50 MG/ML)	350 MG/ 7 ML (50 MG/ML)	240 MG/ 24 ML (10 MG/ML)	1,200 MG/ 20 ML (60 MG/ML)

Table 12 Drug vs therapeutic alternatives for 2019-2025 WAC per 30-day supply[27]

Year	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
2019	$19,161	$12,770	$10,833	-	$9,100	$13,237	$9,014
2020	$19,740	$13,156	$11,160	-	$9,100	$13,435	$9,194
2021	$20,537	$13,621	$11,160	$10,369	$9,421	$13,841	$9,470
2022	$21,367	$14,032	$11,497	$10,788	$9,610	$14,400	$9,849
2023	$22,230	$14,599	$11,845	$11,114	$9,998	$14,982	$10,347
2024	$23,128	$15,488	$12,384	$11,562	$10,607	$15,587	$10,924
2025	$24,063	$16,752	$12,884	$12,030	$11,335	$16,217	$11,589

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

Year	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
Avg. Annual % Change	3.3%	4.0%	2.5%	3.0%	3.2%	3.0%	3.7%
% change 2019 between 2025	25.6%	31.2%	18.9%	-	24.6%	22.5%	28.6%

The WAC of Keytruda was approximately **$1,503.92 per unit** at the end of 2025.[28] Between 2019-2025, the unit WAC increased at an average annual rate of **3.3 percent**, exceeding the general consumer price index (CPI-U) inflation rate in **2019-2020, 2022-2023, 2023-2024 and 2024-2025** (See Figure 1 and Table 13).[29]

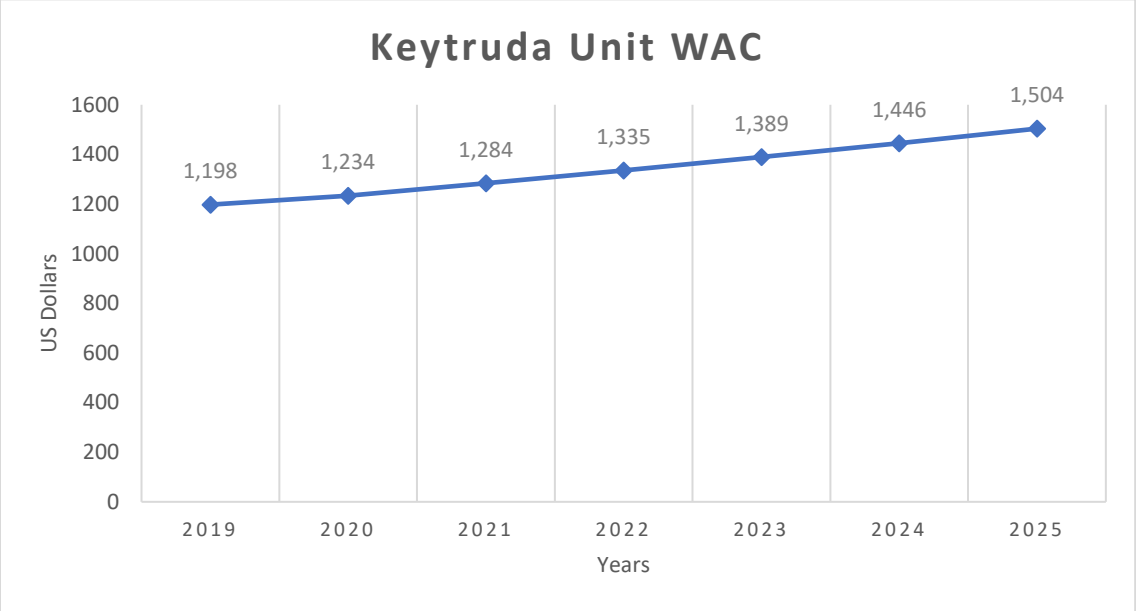

Figure 1 Unit WAC of most utilized NDC from 2019-2025

Table 13 Percent change of unit WAC of drug and therapeutic alternatives with CPI comparison[30]

[28] Medi-Span. Wolters Kluwer, 2025. https://www.wolterskluwer.com/en/solutions/medi-span/medi-span.
[29] Consumer Price Index. U.S. Bureau of Labor Statistics. https://www.bls.gov/cpi/tables/supplemental-files/.
[30] Percentages might differ from Table 12 as Table 13 percentages are based on unit WAC only.

Years	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq	CPI-U
2019-2020	3.0%	3.0%	3.0%	0.0%	0.0%	1.5%	2.0%	0.7%
2020-2021	4.0%	3.5%	0.0%	0.0%	3.5%	3.0%	3.0%	5.3%
2021-2022	4.0%	3.0%	3.0%	4.0%	2.0%	4.0%	4.0%	9.0%
2022-2023	4.0%	4.0%	3.0%	3.0%	4.0%	4.0%	5.1%	3.1%
2023-2024	4.0%	6.1%	4.6%	4.0%	6.1%	4.0%	5.6%	3.0%
2024-2025	4.0%	8.2%	4.0%	4.0%	6.9%	4.0%	6.1%	2.7%

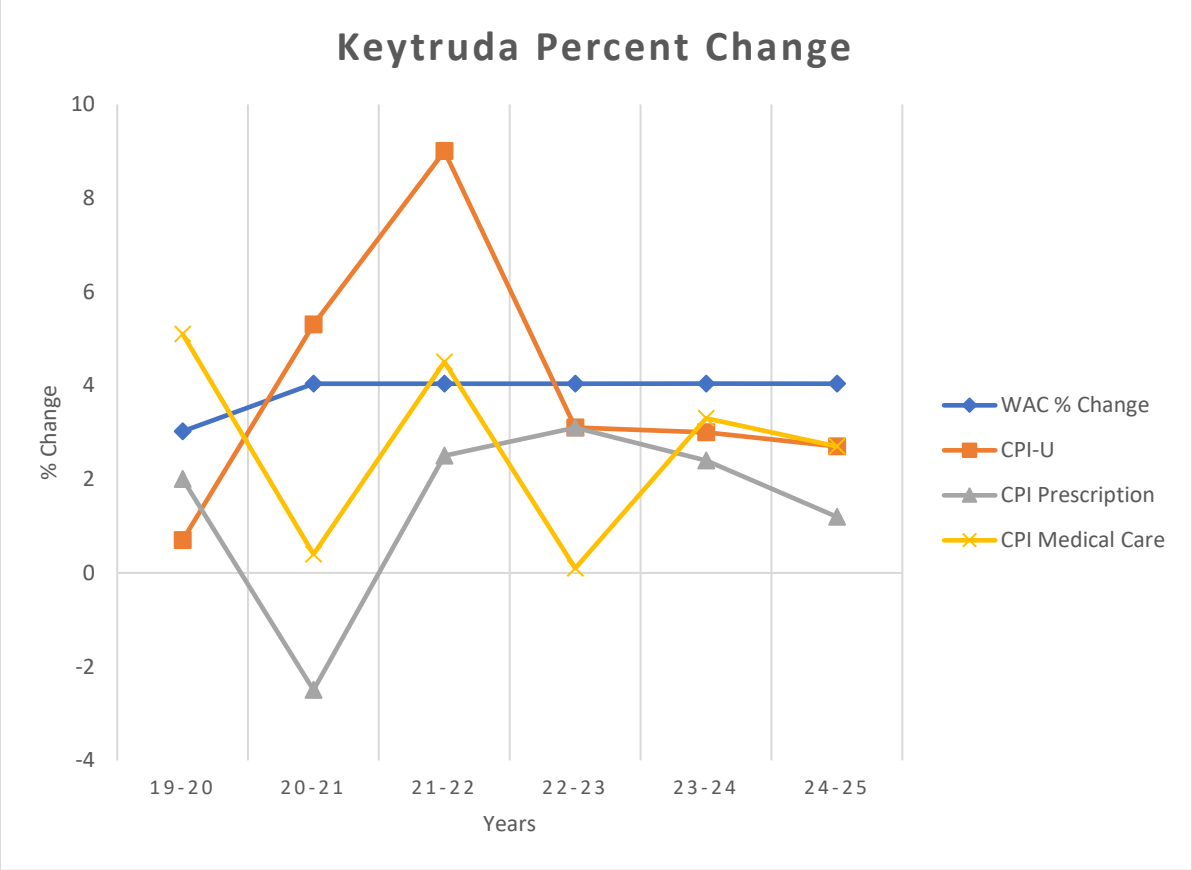

Figure 2 Year over year change in WAC compared to inflation rates[31]

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

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 Keytruda claims in the commercial market. Drawing on 2024 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 2024, the **average gross annual cost of Keytruda per enrollee** in the commercial market was approximately **$115,062**. After accounting for manufacturer rebates, pharmacy benefit manager (PBM) discounts, and other price concessions, the **mean net cost per enrollee** decreased to approximately **$115,052**, reflecting a **mean discount of zero percent** relative to gross costs.

Across all reporting carriers and market segments, the **total gross cost** of Keytruda before concessions was **$46.0 million**, with **total reported price concessions** amounting to approximately **$3,737**, as detailed in Table 15. Notably, **only 0.4% percent** of claims benefited from some form of price concession, leaving nearly all claims paid at **full gross cost**.

Table 14 Net cost price concessions estimate based on carrier submitted 2024 data

Total number of enrollees	360
Total number of claims	2,058
Total number of claims with price concessions applied	8

Percentage of claims with price concessions applied	0.4%
Percentage of cost remaining after concessions	100%
Percentage of discount	0.0%

Manufacturer price concessions for all market types	$3,737
PBM price concessions for all market types	$0
Other price reductions for all market types	$0

Cost before price concessions across all market types	$46,024,660
Total price concessions across all market types	$3,737
Cost after price concessions across all market types	$46,020,923

Mean cost per enrollee without price concessions	$115,062
Mean cost per enrollee with price concessions	$115,052

Including all market segments, the **gross average spend** of Keytruda **per claim for commercial carriers was $20,338 before any discounts, rebates, or other price concessions**. The **net cost per claim after** discounts, rebates, and other price concessions was **$20,336**, meaning that insurers reported a **price concession of $2 per claim** on the initial drug cost as shown in Table 16.

Table 15 Mean price concessions across market types from data call[32]

	Mean	Individual market	Large group	Small group
Spend per claim, gross	$20,338	$21,468	$19,517	$21,982
Spend per claim, net	$20,336	$21,467	$19,515	$21,982
Price concessions per claim	$2	$1	$2	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

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

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

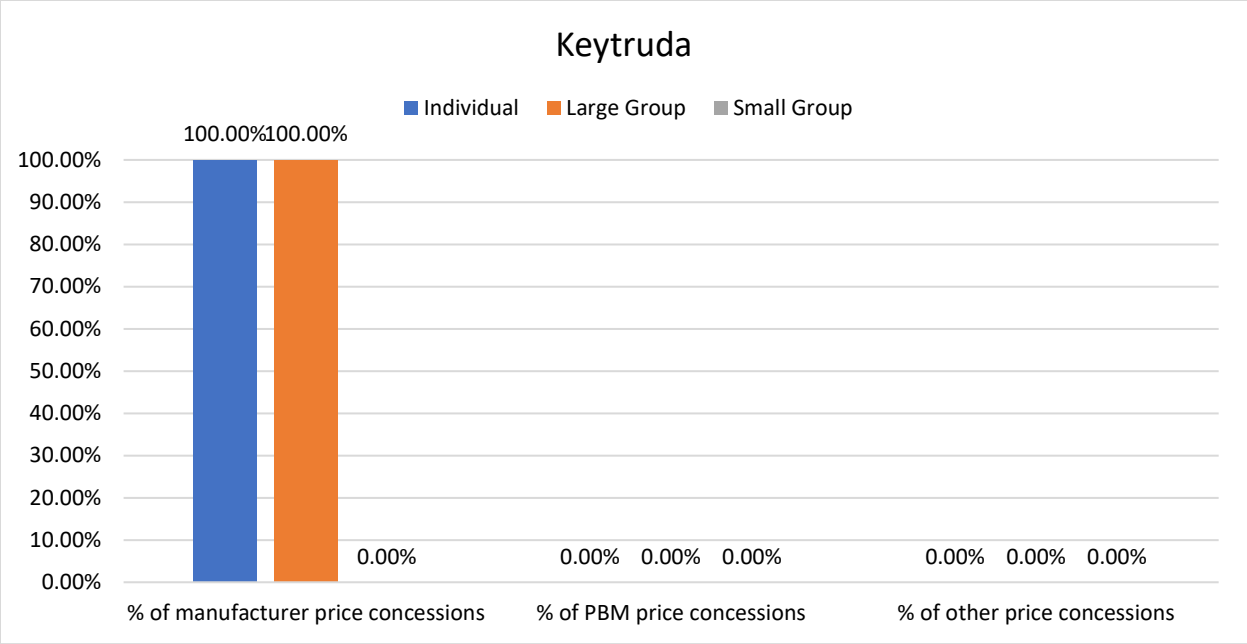

Figure 3 Percent of price concession in each market type[33, 34]

Estimated total amount of the price concession to PBMs

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

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

[33] 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.

[34] 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 price for therapeutic alternatives[35]

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 Keytruda and its therapeutic alternatives using 2024 data from APAC. APAC data reflects gross spending across Medicare, Medicaid, and commercial health plans in Oregon. The therapeutic alternatives are represented using APAC data, which does not reflect price concession or rebates.

Keytruda's **gross total payer spend**, based on APAC data, was nearly **$132.0 million**. Among its therapeutic alternatives, **Opdivo** had the **highest gross total payer spend** at approximately **$30.8 million** and recorded the **largest number of claims** at **2,824**, **compared with 9,851 claims** for Keytruda. **Bavencio** had the **lowest payer-paid amount per claim** at $7,974, while **Jemperli** had the **highest** at **$14,019**.

Although Keytruda had the **highest total enrollee spend overall**, within its therapeutic class **Opdivo** had the **highest total enrollee-paid amount** at **$658,636**. **Libtayo** has the **highest enrollee-paid amount per claim** at **$403**, while **Bavencio** had the **lowest** at **$202**.

Neither the drug nor its therapeutic alternatives are listed by the FDA as being in shortage, so availability is assumed to be unaffected.

Table 16 APAC average healthcare and average enrollee OOP costs for Keytruda vs therapeutic alternatives[36]

Proprietary name	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid[37]	Payer paid/ claim	Enrollee paid/ claim[38]
Keytruda	**1,591**	**9,851**	**$132,020,415**	**$3,068,403**	**$13,402**	**$311**
Bavencio	32	387	$3,085,797	$78,206	$7,974	$202
Imfinzi	294	1,885	$19,636,872	$519,832	$10,417	$276
Jemperli	52	289	$4,051,584	$80,860	$14,019	$280

[35] The definition of therapeutic alternative is 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).

[36] The therapeutic alternative information is based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons. https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.asp.

[37] The cost includes all lines of business.

[38] Ibid.

Proprietary name	No. of enrollees	No. of claims	Total payer paid	Total enrollees paid[37]	Payer paid/ claim	Enrollee paid/ claim[38]
Libtayo	92	413	$3,881,889	$166,437	$9,399	$403
Opdivo	453	2,824	$30,765,190	$658,636	$10,894	$233
Tecentriq	203	1,281	$12,305,192	$367,023	$9,606	$287

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 provides an analysis of the average monetary discounts, rebates, and other price concessions applied to the therapeutic alternatives identified for Keytruda. Based on 2024 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.

Table 18 shows the average **gross cost per enrollee** for therapeutic alternatives in the commercial market ranged broadly, with **Jemperli** having the **highest cost at $29,244,** and **Opdivo the lowest with $12,713**. None of the therapeutic alternatives had manufacturer rebates, pharmacy benefit manager (PBM) discounts, or other price concessions applied, meaning payers provided the **full gross price** for the drugs.

Across all reporting carriers and market segments, **Opdivo** accounted for the **highest total gross spend** at approximately **$13.0 million** for **1025 claims.**

Table 17 Table Net cost estimate for therapeutic alternatives based on carrier submitted 2024 data

	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
Total number of enrollees	9	46	12	9	129	38
Total number of claims	58	230	77	48	1025	211
Total number of claims with price concessions applied	0	0	0	0	3	0

	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
Percentage of claims with price concessions applied	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of cost remaining after concessions	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Percentage of discount	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Manufacturer price concessions for all market types	$0	$0	$0	$0	$0	$0
PBM price concessions for all market types	$0	$0	$0	$0	$0	$0
Other price reductions for all market types	$0	$0	$0	$0	$0	$0
Cost before price concessions across all market types	$755,688	$4,790,728	$2,251,794	$735,375	$13,030,402	$3,783,293
Total price concessions across all market types	$0	$0	$0	$0	$0	$0
Cost after price concessions across all market types	$755,688	$4,790,728	$2,251,794	$735,375	$13,030,402	$3,783,293
Avg. payer spend per enrollee without price concessions	$13,029	$20,829	$29,244	$15,320	$12,713	$17,930
Avg. payer spend per enrollee with price concessions	$13,029	$20,829	$29,244	$15,320	$12,713	$17,930

Across all market segments, **Jemperli** had the **highest gross average spend per claim** at **$29,244**, before any discounts, rebates, or other price concessions. **No discounts, rebates, and other price concessions were applied**, meaning payers paid the **full market price** for the drugs.

Table 18 The average price concessions per claim across market types from data call for identified therapeutic alternatives[39]

Bavencio	Mean	Individual market	Large group	Small group
Spend per claim, gross	$13,029	$28,280	$12,147	$16,867
Spend per claim, net	$13,029	$28,280	$12,147	$16,867
Price concessions per claim	$0	$0	$0	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

Imfinzi	Mean	Individual market	Large group	Small group
Spend per claim, gross	$20,829	$22,151	$21,968	$15,411
Spend per claim, net	$20,829	$22,151	$21,968	$15,411
Price concessions per claim	$0	$0	$0	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

Jemperli	Mean	Individual market	Large group	Small group
Spend per claim, gross	$29,244	$ 23,370	$ 31,746	$0
Spend per claim, net	$29,244	$ 23,370	$ 31,746	$0
Price concessions per claim	$0	$0	$0	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

Libtayo	Average	Individual market	Large group	Small group
Spend per claim, gross	$15,320	$ 15,400	$15,129	$17,644
Spend per claim, net	$15,320	$15,400	$15,129	$17,644
Price concessions per claim	$0	$0	$0	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

Opdivo	Average	Individual market	Large group	Small group
Spend per claim, gross	$12,713	$13,128	$11,851	$16,931
Spend per claim, net	$12,713	$13,128	$11,851	$16,931
Price concessions per claim	$0	$0	$0	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

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

Tecentriq	Average	Individual market	Large group	Small group
Spend per claim, gross	$17,930	$17,562	$16,388	$20,861
Spend per claim, net	$17,930	$17,562	$16,388	$20,861
Price concessions per claim	$0	$0	$0	$0
Percent discount	0.0%	0.0%	0.0%	0.0%

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 aggregate financial impact of Keytruda on health insurance plans in Oregon, based on claims and expenditure data from APAC and the 2024 carrier data call. Costs are delineated by payer type—including commercial plans, Medicaid, and Medicare—as well as by market segment within the commercial plans. These estimates highlight the distribution of expenditures across different types of health coverage and inform assessments of the drug's budgetary implications for public and private payers.

In 2024, the Oregon APAC database recorded **9,851 total claims** for Keytruda among **1,591 enrollees**, corresponding to a **total payer expenditure of nearly $132.0 million.**

Table 20 provides gross cost estimates on total APAC payer spending across all lines of business:

- **Medicare** accounted for the largest share of claims, with **4,832 claims** and a total spend of approximately **$67.6 million**.
- **Commercial** had the **fewest enrollees** at **365,** with the **second highest expenditures**, totaling approximately **$41.4 million**.

Table 19 Estimated 2024 APAC total annual gross payment, total enrollees and total claims [40]

Payer line of business	Total enrollees	Total claims	Total payer paid	Percent of total payer spend by LOB
Commercial	363	2,079	$41,400,421	31.4%
Medicaid	559	2,940	$23,066,881	17.5%
Medicare	831	4,832	$67,553,113	51.2%
Totals[41]	**1,591**	**9,851**	**$132,020,415**	

[40] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.

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

Table 21 provides claims information for the healthcare system for Keytruda's therapeutic alternatives, distinguished by lines of business. Among its therapeutic alternatives, **Opdivo** has the most claims at **2,824**, with **Medicare** accounting for the largest share at **1,466 claims**.

Table 20 Estimated APAC payer 2024 claims of review drug's therapeutic alternatives[42]

Proprietary name	Commercial claims	Medicaid claims	Medicare claims	Total claims[43]
Bavencio	19	38	330	387
Imfinzi	226	716	943	1,885
Jemperli	67	102	120	289
Libtayo	49	121	243	413
Opdivo	550	808	1,466	2,824
Tecentriq	182	429	670	1,281

Table 22 shows the overall payer expenditure of the therapeutic alternative, with **Opdivo** having the **highest total expenditure** at approximately **$30.8 million.** Within that amount, **Medicare** accounts for the largest share with expenditure totaling **$16.7 million.**

[42] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[43] Total is the sum of all claims for the drug across all lines of business.

Table 21 Estimated 2024 APAC payer annual gross expenditures of the review drug's therapeutic alternatives from all lines of business[44]

Proprietary name	Commercial expenditure	Medicaid expenditure	Medicare expenditure	Total[45]
Bavencio	$356,342	$46,640	$2,682,815	$3,085,797
Imfinzi	$4,666,116	$4,792,369	$10,178,387	$19,636,872
Jemperli	$1,362,870	$991,101	$1,697,614	$4,051,584
Libtayo	$777,659	$549,319	$2,554,911	$3,881,889
Opdivo	$8,877,683	$5,156,168	$16,731,339	$30,765,190
Tecentriq	$2,843,663	$2,007,146	$7,454,383	$12,305,192

Table 23 compares the overall payer cost per enrollee of Keytruda and its therapeutic alternatives, distinguished by lines of business. Among the therapeutic alternatives, **Bavencio** has the **highest mean cost per enrollee** at **$96,431,** compared to **Keytruda's** mean cost per enrollee at **$82,522.**

Table 22 Estimated 2024 APAC payer annual gross cost per enrollee of the review drug and its therapeutic alternatives[46]

Proprietary name	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
Commercial cost/enrollee	$114,051	$71,268	$103,691	$123,897	$64,805	$90,589	$91,731
Medicaid cost/ enrollee	$41,265	$7,773	$37,440	$45,050	$22,888	$34,374	$23,613
Medicare cost/ enrollee	$81,291	$116,644	$63,220	$77,164	$42,582	$68,853	$67,767
Mean[47] cost/enrollee	$82,980	$96,431	$66,792	$77,915	$42,194	$67,914	$60,617
Median, Cost/enrollee	$62,522	$93,691	$49,486	$58,247	$27,331	$42,642	$43,811
Inter-quartile range (IQR)	$103,526	$139,713	$74,241	$101,092	$46,024	$80,581	$71,845

[44] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[45] Total is the sum of all expenditure for the drug across all lines of business.
[46] Based on 2024 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[47] The overall mean cost per enrollee across commercial insurers, Medicaid, and Medicare.

Proprietary name	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
Cost per enrollee, 75th percentile	$126,506	$151,568	$96,315	$125,076	$60,049	$95,738	$86,961
Cost per enrollee, 95th percentile	$214,869	$214,032	$172,180	$201,082	$137,880	$203,418	$161,107

Table 24 compares the overall payer cost per claim of Keytruda and its therapeutic alternatives, distinguished by lines of business. Among the therapeutic alternatives, **Jemperli** has the **highest mean cost per claim** at **$14,019,** compared to **Keytruda's** mean cost per enrollee at **$13,402.**

Table 23 Estimated 2024 APAC payer annual gross cost per claim of the review drugs

Proprietary name	Keytruda	Bavencio	Imfinzi	Jemperli	Libtayo	Opdivo	Tecentriq
Commercial cost/claim	$19,914	$18,755	$20,647	$20,341	$15,871	$16,141	$15,625
Medicaid cost/claim	$7,846	$8,130	$10,794	$14,147	$10,514	$11,413	$11,126
Medicare cost/claim	$13,980	$1,227	$6,693	$9,717	$4,540	$6,381	$4,679
Cost per claim, mean	$13,402	$7,974	$10,417	$14,019	$9,399	$10,894	$9,606
Cost per claim, median	$12,015	$7,798	$7,923	$12,236	$9,694	$7,841	$10,129
IQR	$8,092	$870	$9,967	$8,976	$3,212	$8,845	$4,713
Cost per claim, 75th percentile	$17,473	$8,125	$12,397	$18,661	$10,901	$13,459	$12,559
Cost per claim, 95th percentile	$26,640	$11,840	$20,306	$27,025	$19,223	$18,924	$16,320

Data for plan year 2024 submitted through the carrier data call further stratifies commercial expenditures by market segment. The total **net cost** reported across all market types was approximately **$41.2 million**, with payers paying **$40.7 million** and **enrollees out-of-pocket estimated** to be **$487,398**.

Table 24 Estimated 2024 annual total net costs to the healthcare system, payers and OOP/enrollee[48]

Market	Number of claims	Number of enrollees	Total net annual spending	Total annual payer paid	Total annual enrollee out-of- pocket cost
Individual	490	94	$10,315,813	$10,141,450	$174,363
Large Group	1294	220	$24,889,245	$24,662,518	$226,727
Small Group	274	46	$6,029,343	$5,943,035	$86,308
Total	**2058**	**360**	**$41,234,401**	**$40,747,003**	**$487,398**

Table 26 shows the average payer costs **per enrollee** in the commercial market, ranging from **$21,690 (small group) to $19,059 (large group)** annually.

Table 25 Estimated 2024 annual total net costs to the healthcare system, payers and OOP/enrollee

Market	Avg. total paid/ claim	Avg. payer paid/ claim	Avg. enrollee paid/ claim	Avg. total paid/ enrollee	Avg. payer paid/ enrollee	Avg. enrollee OOP/ enrollee
Individual	$21,053	$20,697	$356	$109,743	$107,888	$1,855
Large Group	$19,234	$19,059	$175	$113,133	$112,102	$1,031
Small Group	$22,005	$21,690	$315	$131,073	$129,196	$1,876

As shown in Figure 5, the **large group market segment** represented the majority of commercial spending (59% of total), followed by individual and small group.

[48] Cost information from the data call is the cost of the drug after price concessions.

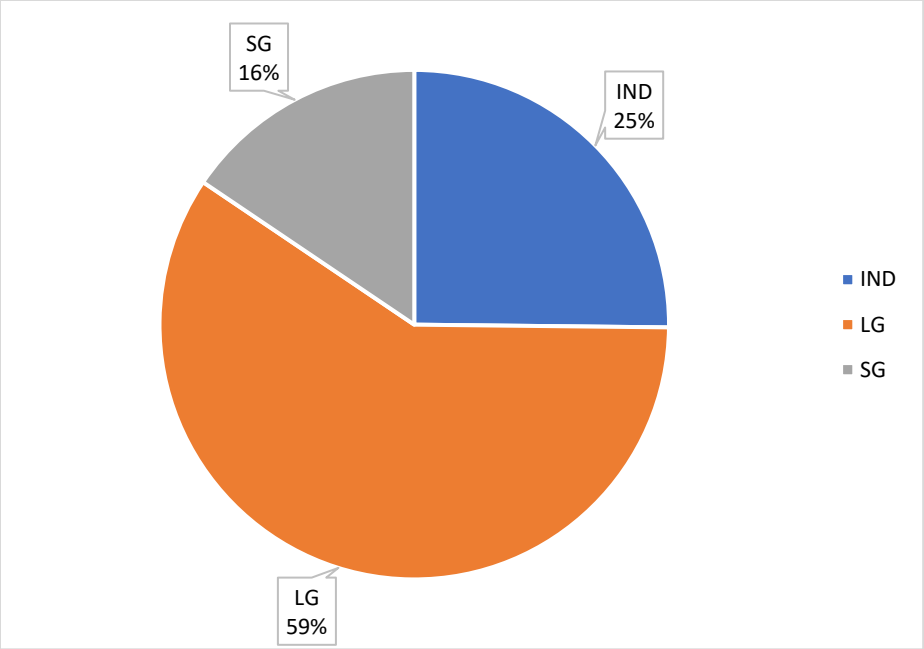

Figure 4 Data call total annual percent spend (payer paid) for Keytruda by market

Impact on enrollee access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

This section summarizes information reported by carriers regarding plan design features that relate to coverage of Keytruda, 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 Keytruda. In 2024, **all reporting plans (100 percent)** required prior authorization (PA) for coverage of the drug, and **no plans required step therapy** before approving its use.

For formulary placement, **54.2 percent** of plan types categorized Keytruda as a **non-preferred drug**, while **12.5 percent did not cover it**.

Table 26 Plan design analysis from 2024

Percentage of plans	
Required prior authorization	100%
Required step therapy	0.0%
On a non-preferred formulary	54.2%
Not covered	12.5%

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

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

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

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

Estimated average patient 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 Keytruda in Oregon, as reported in 2024 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 lines of business of Medicare and commercial heath care carriers.

Tables 29 and 30 presents the average annual enrollee OOP costs derived from APAC. The APAC data, which includes claims from commercial, and Medicare enrollees, showed average per-enrollee and per-claim and OOP gross costs. For example, **Medicare enrollees recorded higher average annual OOP costs**.

[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 27 Review drug vs. therapeutic alternatives: Annual out-of-pocket cost per enrollee by line of business (light green table header) and descriptive statistics for total market (dark green table header) [50]

Proprietary name	Commercial	Medicare	Medicaid	Mean[51]	Median[52]	IQR	75th percentile	95th percentile
Keytruda	$1,139	$3,195	$0	$1,929	$264	$3,286	$3,286	$7,318
Bavencio	$1,341	$3,109	$0	$2,444	$2,197	$4,289	$4,289	$6,058
Imfinzi	$1,213	$2,890	$0	$1,768	$0	$3,165	$3,165	$5,716
Jemperli	$468	$3,441	$0	$1,555	$0	$3,377	$3,377	$4,878
Libtayo	$965	$2,581	$0	$1,809	$1,049	$3,307	$3,307	$5,302
Opdivo	$1,233	$2,213	$0	$1,454	$0	$2,459	$2,459	$5,863
Tecentriq	$2,051	$2,759	$0	$1,808	$0	$3,095	$3,095	$6,663

Table 28 Review drug vs. therapeutic alternatives: Annual out-of-pocket cost per claim by line of business (light green table header) and descriptive statistics for total market (dark green table header) [53]

Proprietary name	Commercial	Medicare	Medicaid	Mean[54]	Median	IQR	75th percentile	95th percentile
Keytruda	$199	$549	$0	$311	$0	$0	$0	$2,452
Bavencio	$353	$217	$0	$202	$0	$0	$0	$1,481
Imfinzi	$241	$493	$0	$276	$0	$0	$0	$2,302
Jemperli	$77	$631	$0	$280	$0	$0	$0	$2,386
Libtayo	$236	$637	$0	$403	$0	$0	$0	$2,115
Opdivo	$220	$367	$0	$233	$0	$0	$0	$1,527
Tecentriq	$349	$453	$0	$287	$0	$0	$0	$2,244

[50] Based on 2024 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[51] Includes summation of copay, coinsurance, and deductible across all from all markets across all claims.
[52] Median represents the middle value of the data set when arranged in ascending order.
[53] Based on 2024 Oregon APAC data across commercial insurers and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[54] Includes summation of copay, coinsurance, and deductible across all from all markets across all claims.

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 (Non-Orphan)

- FDA Approved:
    - Keytruda is a programmed death receptor-1 (PD-1)-blocking antibody indicated:
        - **Non-Small Cell Lung Cancer:**
            - In combination with pemetrexed and platinum chemotherapy, as first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations.
            - In combination with carboplatin and either paclitaxel or paclitaxel protein-bound, as first-line treatment of patients with metastatic squamous NSCLC.
            - As a single agent for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-authorized test, with no EGFR or ALK genomic tumor aberrations, and is:
                - Stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
                - Metastatic.
            - As a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-authorized test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
            - For the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
            - As a single agent, for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥4 cm), II, or IIIA NSCLC.

- **Malignant Pleural Mesothelioma (MPM):**
    - In combination with pemetrexed and platinum chemotherapy, as first-line treatment of adult patients with unresectable advanced or metastatic MPM.
- **Urothelial Cancer:**
    - In combination with enfortumab vedotin, for the treatment of adult patients with locally advanced or metastatic urothelial cancer.
    - As a single agent for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:
        - Are not eligible for any platinum-containing chemotherapy, or
        - Who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
    - In combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.
    - As a single agent for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
- **Microsatellite Instability-High or Mismatch Repair Deficient Cancer:**
    - For the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-authorized test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.
- **Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer (CRC):**

- For the treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-authorized test.

- **Cervical Cancer:**
  - In combination with chemoradiotherapy, for the treatment of patients with locally advanced cervical cancer involving the lower third of the vagina, with or without extension to pelvic sidewall, or hydronephrosis/non-functioning kidney, or spread to adjacent pelvic organs (FIGO 2014 Stage III-IVA).
  - In combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
  - As a single agent for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- **Renal Cell Carcinoma:**
  - In combination with axitinib, for the first-line treatment of adult patients with advanced RCC.
  - In combination with lenvatinib, for the first-line treatment of adult patients with advanced RCC.
  - For the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
- **Endometrial Carcinoma:**
  - In combination with carboplatin and paclitaxel, followed by Keytruda as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.
  - In combination with lenvatinib, for the treatment of adult patients with advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not MSI-H as determined by an FDA-authorized test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

- As a single agent, for the treatment of adult patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-authorized test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

- **Tumor Mutational Burden-High (TMB-H) Cancer:**
  - For the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-authorized test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.
    - This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- **Cutaneous Squamous Cell Carcinoma (cSCC):**
  - For the treatment of patients with recurrent or metastatic cSCC or locally advanced cSCC that is not curable by surgery or radiation.
- **Triple-Negative Breast Cancer (TNBC):**
  - For the treatment of patients with high-risk early-stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
  - In combination with chemotherapy, for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.
- **Ovarian Cancer:**
  - In combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.

Drug indications (Orphan)

- Melanoma
- Classical Hodgkin Lymphoma
- Primary Mediastinal Large B-Cell Lymphoma
- Gastric Cancer
- Esophageal Cancer
- Hepatocellular Carcinoma
- Biliary Tract Cancer
- Merkel Cell Carcinoma

- Limitations of Use:
  - KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.
  - The safety and effectiveness of Keytruda in pediatric patients with TMB-H central nervous system cancers have not been established.
- Off Label Uses:
  - Other cancers

Clinical efficacy

Efficacy in Non-Small Cell Lung Cancer

The KEYNOTE-189 study was a randomized, multicenter, double-blind, active-controlled trial conducted in 616 patients with metastatic nonsquamous NSCLC, regardless of PD-L1 tumor expression status, who had not previously received systemic therapy for metastatic disease and in whom there were no EGFR or ALK genomic tumor aberrations. Patients were randomized to receive either Keytruda 200 mg or placebo, along with pemetrexed, and investigator's choice of cisplatin or carboplatin for 4 cycles, followed by Keytruda or placebo and pemetrexed every 3 weeks. The trial demonstrated a statistically significant improvement in overall survival (OS) and progression-free survival (PFS) for patients receiving Keytruda.

Table 29 Clinical Efficacy in Metastatic Nonsquamous NSCLC

Endpoint	Keytruda 200 mg every 3 weeks Pemetrexed Platinum Chemotherapy	Placebo Pemetrexed Platinum Chemotherapy
Progression-Free Survival	**N=410**	**N=206**

Endpoint	Keytruda 200 mg every 3 weeks Pemetrexed Platinum Chemotherapy	Placebo Pemetrexed Platinum Chemotherapy
Median in months (95% CI)	8.8 (7.6, 9.2)	4.9 (4.7, 5.5)

Efficacy in Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer

The efficacy of Keytruda was investigated in KEYNOTE-177, a multicenter, randomized, open-label, active-controlled trial of patients with previously untreated unresectable or metastatic MSI-H or dMMR CRC. Patients were randomized to receive Keytruda 200 mg every 3 weeks or investigator's choice of mFOLFOX6 or FOLFIRI alone or in combination with either bevacizumab or cetuximab every 2 weeks. The trial demonstrated a statistically significant improvement in PFS for patients randomized to Keytruda compared with chemotherapy. There was no statistically significant difference between Keytruda and chemotherapy in the final OS analysis.

Table 30 Clinical Efficacy in MSI-H or dMMR CRC

Endpoint	Keytruda 200 mg every 3 weeks	Chemotherapy
Progression-Free Survival	**N=153**	**N=154**
Median in months (95% CI)	16.5 (5.4, 32.4)	8.2 (6.1, 10.2)

Efficacy in Endometrial Cancer

The efficacy of KEYTRUDA in combination with paclitaxel and carboplatin was investigated in KEYNOTE-868, a multicenter, randomized, double-blind, placebo-controlled trial patients with advanced or recurrent endometrial carcinoma. Patients were separated into mismatch repair deficient (dMMR) and mismatch repair proficient (pMMR) cohorts and were randomized to receive Keytruda 200 mg or placebo plus paclitaxel and carboplatin for 6 cycles, followed by Keytruda 400 mg or placebo every 6 weeks for up to 14 cycles. The trial demonstrated statistically significant improvements in PFS for patients randomized to the Keytruda treatment group in both the dMMR and pMMR populations.

Table 31 Clinical Efficacy in Stage III-IV or Recurrent Endometrial Cancer

Endpoint	dMMR Population		pMMR Population	
	Keytruda with paclitaxel and carboplatin	Placebo with paclitaxel and carboplatin	Keytruda with paclitaxel and carboplatin	Placebo with paclitaxel and carboplatin
Progression-Free Survival	**N=110**	**N=112**	**N=294**	**N=294**
Median in months (95% CI)	NR (30.7, NR)	6.5 (6.4, 8.7)	11.1 (8.7, 13.5)	8.5 (7.2, 8.8)
NR = not reached				

Clinical safety

- FDA safety warnings and precautions:
    - Immune-Mediated Adverse Reactions
    - Infusion-related reactions
    - Complications of allogeneic HSCT: Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody
    - Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials
    - Embryo-Fetal toxicity
- Common side effects:
    - Keytruda as a single agent: fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism
    - Keytruda in combination with chemotherapy or chemoradiotherapy: fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, pyrexia, alopecia, peripheral neuropathy, mucosal inflammation, stomatitis, headache, weight loss, abdominal pain, arthralgia, myalgia, insomnia, palmar-plantar erythrodysesthesia, urinary tract infection, hypothyroidism, radiation skin injury, dysphagia, dry mouth, and musculoskeletal pain.
    - Keytruda in combination with chemotherapy and bevacizumab: peripheral neuropathy, alopecia, anemia, fatigue/asthenia, nausea, neutropenia, diarrhea,

hypertension, thrombocytopenia, constipation, arthralgia, vomiting, urinary tract infection, rash, leukopenia, hypothyroidism, decreased appetite, pyrexia, epistaxis, decreased white blood cell count, and stomatitis.

- Keytruda in combination with axitinib: diarrhea, fatigue/asthenia, hypertension, hepatotoxicity, hypothyroidism, decreased appetite, palmar-plantar erythrodysesthesia, nausea, stomatitis/mucosal inflammation, dysphonia, rash, cough, and constipation.
- Keytruda in combination with lenvatinib: hypothyroidism, hypertension, fatigue, diarrhea, musculoskeletal disorders, nausea, decreased appetite, vomiting, stomatitis, weight loss, abdominal pain, urinary tract infection, proteinuria, constipation, headache, hemorrhagic events, palmar-plantar erythrodysesthesia, dysphonia, rash, hepatotoxicity, and acute kidney injury.
- Keytruda in combination with enfortumab vedotin: rash, peripheral neuropathy, fatigue, pruritus, diarrhea, alopecia, weight loss, decreased appetite, dry eye, nausea, constipation, dysgeusia, and urinary tract infection.

Therapeutic alternatives[55, 56, 57, 58, 59, 60, 61]

Table 32 Selected FDA-approved indications

Drug	NSCLC	MPM	Urothelial/ Bladder Cancer	MSI-H or dMMR Cancer	Renal Cell Carcinoma	Endometrial Carcinoma	SCC
Keytruda (pembrolizumab)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bavencio (avelumab)	-	-	Yes	-	Yes	-	-

[55] U.S. Food & Drug Administration. *Keytruda (pembrolizumab) Prescribing Information*. Merck Sharp & Dohme, Revised 05/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/125514s190lbl.pdf
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[57] U.S. Food & Drug Administration. *Imfinzi (durvalumab) Prescribing Information*. AstraZeneca UK Limited, Revised 05/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761069s053lbl.pdf
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[60] U.S. Food & Drug Administration. *Opdivo (nivolumab) Prescribing Information*. Bristol-Myers Squibb Company, Revised 05/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/125554s136lbl.pdf
[61] U.S. Food & Drug Administration. *Tecentriq (atezolizumab) Prescribing Information*. Genentech Inc., Revised 05/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761034s061lbl.pdf

Drug	NSCLC	MPM	Urothelial/ Bladder Cancer	MSI-H or dMMR Cancer	Renal Cell Carcinoma	Endometrial Carcinoma	SCC
Imfinzi (durvalumab)	Yes	-	Yes	-	-	Yes	-
Jemperli (dostarlimab-gxly)	-	-	-	Yes	-	Yes	-
Libtayo (cemiplmab-rwlc)	Yes	-	-	-	-	-	Yes
Opdivo (nivolumab)	Yes	Yes	Yes	Yes	Yes	-	Yes
Tecentriq (atezolizumab)	Yes	-	Yes	-	-	-	-

Table 33 Summary of Key Clinical Trials – First-Line Treatment of Renal Cell Carcinoma with[62]

Endpoint	Keytruda plus Axitinib (KEYNOTE-426)	Bavencio plus Axitinib (JAVELIN Renal 101)
Progression-Free Survival	**N=432**	**N=442**
Median in months (95% CI)	15.1 (12.6, 17.7)	13.8 (11.1, NE)
NE = not estimable		

Table 34 Summary of Key Clinical Trials – Advanced or Recurrent Endometrial Carcinoma[9]

Endpoint	Keytruda plus Carboplatin and Paclitaxel* (KEYNOTE-868)	Jemperli plus Carboplatin and Paclitaxel (RUBY)
Progression-Free Survival	**N=294**	**N=245**
Median in months (95% CI)	11.1 (8.7, 13.5)	11.8 (9.6, 17.1)
*dMMR cohort		

[62] Data are presented from separate pivotal trials for each agent. Trials are not direct head-to-head comparative trials; differences in trial design, patient population, and follow-up duration preclude direct statistical comparison of the results shown.

Table 35 Summary of Key Clinical Trials – Advanced Cutaneous Squamous Cell Carcinoma [9]

Endpoint	KEYNOTE-629		Study 1540	
	Keytruda Recurrent or Metastatic cSCC	Keytruda Locally Advanced cSCC	Libtayo Metastatic cSCC	Libtayo Locally Advanced cSCC
Objective Response Rate	**N=105**	**N=54**	**N=59**	**N=78**
ORR (95% CI)	35% (26, 45)	52% (38, 66)	51% (37, 64)	45% (34, 57)

Keytruda and its comparators have similar notable warnings and precautions, including:

- Immune-Mediated Adverse Reactions
- Infusion-related reactions
- Complications of allogeneic HSCT:
- Embryo-Fetal toxicity

In addition to the warnings above, Bavencio (avelumab) in combination with axitinib can cause severe and fatal cardiovascular events.

Table 36 Strengths, Dosing & Route

Proprietary name	Non-proprietary name	Formulation	Dosing Frequency*
Keytruda	*pembrolizumab*	IV infusion	200 mg every 3 weeks or 400 mg every 6 weeks
Bavencio	*avelumab*	IV infusion	800 mg every 2 weeks
Imfinzi	*durvalumab*	IV infusion	1,500 mg every 3 to 4 weeks
Jemperli	*dostarlimab-gxly*	IV infusion	EC: 500 mg every 3 weeks for 6 cycles, followed by 1,000 mg every 6 weeks dMMR: 500 mg every 3 weeks for 4 cycles, followed by 1,000 mg every 6 weeks
Libtayo	*cempilmab-rwlc*	IV infusion	350 mg every 3 weeks
Opdivo	*nivolumab*	IV Infusion	NSCLC, MPM: 360 mg every 3 weeks Renal cell carcinoma, SCC, MSI-H or dMMR CRC: 240 mg every 2 weeks or 480 mg every 4 weeks

Proprietary name	Non-proprietary name	Formulation	Dosing Frequency*
Tecentriq	*atezolizumab*	IV Infusion	840 mg every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks
*See each drug's prescribing information for complete dosing recommendations by indication.			

Input from specified stakeholders

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

See Appendix B for all stakeholder comment letters.

Survey-style feedback forms were posted on the PDAB website from April to August 2026 to collect voluntary input about drugs under review from a broad range of stakeholders, including patients, caregivers, and advocacy groups; individuals with scientific or medical training; safety-net providers; pharmaceutical manufacturers; pharmacy benefit managers; and health insurers. This section summarizes the drug-specific input received. Additional general feedback on drug prices and patient experiences is presented in the 2026 community outreach report.

Note: The information summarized here is based on self-reported survey responses from individuals prescribed certain medications. Participation was voluntary, and responses reflect each individual's personal understanding and interpretation of the questions. As a result, the information may include inconsistencies or inaccuracies related to varying levels of comprehension, recall bias, or misinterpretation of question intent. These limitations should be considered when interpreting the findings.

Patients and caregivers:

No survey information has been received from safety net providers about this drug as of the last update of this document

Individuals with scientific or medical training

No survey information has been received from safety net providers about this drug as of the last update of this document

Safety net providers

No survey information has been received from safety net providers about this drug as of the last update of this document.

Manufacturers

No survey information has been received from manufacturers about this drug as of the last update of this document.

Pharmacy benefit managers

No survey information has been received from PBMs about this drug as of the last update of this document.

Health insurers

No survey information has been received from health insurers about this drug as of the last update of this document.

Appendix A: Orphan review methodology

Under the orphan review methodology, claims associated with orphan designated indications were removed from the review dataset when feasible. The purpose of the methodology is to focus affordability analyses on non-orphan utilization while maintaining transparency regarding excluded claims. The methodology was developed using available data elements withing Oregon's All Payer All Claims (APAC) database, including ICD-10 diagnosis codes, birth year, National Drug Codes (NDCs), and unique enrollee identifiers. APAC limitations include incomplete NDC reporting for some physician administered drugs and the absence of diagnosis codes on pharmacy claims.

Methodology

Keytruda is primarily a physician administered oncology medication billed through the medical benefit. Because most Keytruda medical claims contain ICD-10 diagnosis codes, orphan designated utilization was identified through diagnosis based analysis. FDA orphan designated indications were mapped to corresponding ICD-10 diagnosis codes and claims associated with those conditions were removed from the review dataset. Examples of orphan designated conditions included malignant melanoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, gastric cancer, esophageal cancer, hepatocellular carcinoma, Merkel cell carcinoma, and selected head and neck cancers.

For pharmacy claims, any Keytruda claims associated with an enrollee identified through the orphan review methodology were also removed from the review dataset using the APAC unique person identifier.

Data summary

Measure	Count
Total claims identified	11,996
Claims removed due to orphan designated conditions	1,281
Unique patients associated with removed claims	202
Claims remaining for affordability reviews	10,715
Unique patients remaining for affordability review	1,595

Dataset impact

Approximately 10.7 percent of Keytruda claims identified in APAC were removed through application of the orphan review methodology. The remaining claims represent non-orphan Keytruda utilization and form the basis of the affordability review analyses contained within the report.

Orphan condition identification

* Represents all codes containing the characters before the asterisk. Example: C43* includes C43.01, C43.02, C43.03, etc.

- Stage IIB through IV malignant melanoma: C43*
- Head and neck squamous cell cancer: C44.02, C44.12*, C44.22*, C44.32*, C44.42*
- Classical Hodgkin lymphoma: C81*
- Primary mediastinal large b-cell lymphoma: C85.2
- Gastric cancer: C16*
- Esophageal cancer: C15*
- Hepatocellular carcinoma: C22.0
- Merkel cell carcinoma: C4A*

Appendix B: Stakeholder feedback

Table 37 Feedback

Name	Association to drug under review	Drug	Format	Date	Exhibit website link
Terri Lee and Christin O'Neill	Merck	Keytruda	Letter	7/1/2026	Click here to view letter
Terri Lee and Christin O'Neill	Merck	Keytruda	Letter	7/1/2026	Click here to view letter
Terri Lee	Merck	Keytruda	Speaker	5/20/2026	Click here to view video
Michael Eging	Rare Access Action Project	Keytruda	Letter	5/18/2026	Click here to view letter
Terri Lee and Christin O'Neill	Merck	Keytruda	Letter	5/15/2026	Click here to view letter
Suzanna Masartis	Community Liver Alliance	Keytruda	Letter	4/24/2026	Click here to view letter
Jane Leo	American Cancer Society Cancer Action Network	Keytruda	Letter	4/17/2026	Click here to view letter

Name	Association to drug under review	Drug	Format	Date	Exhibit website link
Terri Lee and Christin O' Neill	Merck	Keytruda	Letter	4/10/2026	Click here to view letter
Terri Lee and Christin O' Neill	Merck	Keytruda	Letter	3/13/2026	Click here to view letter