

Medicaid Evidence Review and Cost Initiative (MERCI) April 2025

APPENDICES Pembrolizumab (Keytruda) for Cancer

TABLE OF CONTENTS

Appendix A	Methods	2
Appendix B	Pembrolizumab Claims, 2021	10
Appendix C	Demographic Information	12
Appendix D	Pembrolizumab Costs	13
References.		15

The Medicaid Evidence and Review of Cost Initiative (MERCI) describes policy considerations for drugs approved by the US Food and Drug Administration through the accelerated approval pathway. This document is the appendix of a brief titled *Pembrolizumab (Keytruda) for Cancer*. The brief and this associated appendix provide information on the estimated prevalence of target diagnoses (the accelerated approval drug's indication[s]) among Medicaid members; Medicaid members who receive this treatment; and the estimated drug costs for state Medicaid programs, including a breakdown of state and federal funds using the Federal Medical Assistance Percentage.

APPENDIX A METHODS

Data Sources

Researchers from the Center for Evidence-based Policy (Center) used the Centers for Medicare & Medicaid Services (CMS) Transformed Medicaid Statistical Information System (T-MSIS) Analytic Files (TAF) as the primary data source for drug indication cohort identification, prevalence estimates, and medication uptake. The TAF are a research-optimized version of state-submitted T-MSIS data, which include information on Medicaid and Children's Health Insurance Program (CHIP) enrollment, demographics, health care service use, and payments, anchored in enrollment and claims records. State-submitted T-MSIS data are processed by the University of Minnesota Research Data Center and then compiled for use as national data files.

We obtained TAF demographic and enrollment data, along with inpatient, other service, and pharmacy claims data for years 2019 through 2021 for all Medicaid and CHIP members aged 0 to 64 years, excluding those with any months of dual enrollment in both Medicaid and Medicare. Using these criteria, we were not able to obtain data from Alabama or Utah, which do not submit claim information related to dual-enrollment status using this method. Sources used to inform cohort definitions, drug indication, and drug identification included peer-reviewed literature, grey literature, and publicly available databases.

The TAF data are subject to quality concerns. To identify data quality or usability issues affecting internal analytical validity, we used the Medicaid Data Quality (DQ) Atlas as a reference.¹ In general, a state was eliminated from analysis if the DQ Atlas identified a state's data as "unusable" for a topic, variable, or year. If a state's data were of "high concern," we investigated to determine the reason behind the rating and made a topic-specific or variable-specific judgment about inclusion or exclusion for analysis; we made decisions on whether to include, with a bias toward underreporting (as opposed to overreporting). We used 3 distinct methods to address large-scale data quality issues during initial data processing, as described below.

Member Demographic Identification and State Assignment

Members have 2 identifiers in the TAF: a primary identifier assigned during processing at the University of Minnesota Research Data Center that compiles claims across states for individual members, and a member-specific identifier (MSIS ID) assigned by the state (plus the identifying state). Ninety-seven percent of members had primary identifiers. For the remaining 3%, we used the combination of MSIS ID and state code. A very small proportion of members with primary identifiers had multiple enrollment records, sometimes with differing state codes and demographic information. Those members were assigned a state code based on the highest frequency and consistency of the following attributes, in order: state of residence, state with the highest proportion of claims, and state with the longest period of enrollment. If there were ties among states for a member, we randomly assigned them to 1 of the states in which they had claims.

Differences in demographic information for members with multiple enrollment records were similarly reconciled. For cases of multiple records with missing demographic information, missing values were imputed from records assigned to the member in other states, or the most frequently reported characteristic was assigned. Race and ethnicity were the most commonly missing characteristics; age and sex were rarely missing in this dataset.

Mississippi Member Identification and Claims

Data linking of Mississippi claims records to member enrollment records was considered unusable by the DQ Atlas for 2019 to 2021.¹ Any members with claims submitted in Mississippi were assigned to that state for drug indication prevalence reporting. Further, the only demographic information that we could identify for members from Mississippi was birth date from submitted claims. We could not use sex or race and ethnicity information in the enrollment files for these members. Only the following data were included from Mississippi:

- The number of people with drug indication, if no demographic information other than age was required for cohort inclusion
- A breakdown of members with a particular drug indication by age (sample size permitting)
- Comorbidities and health care service use for members with the drug indication, and matched comparisons when matching was based only on age
- Drug uptake, if applicable

If additional demographic characteristics were required for cohort inclusion (e.g., sex), members from Mississippi were not included.

Illinois Claims

Illinois claims data are known to be reported with multiple records per care episode, or "claim families," which in other states would be aggregated into a single claim record. Methods for including Illinois claims were applied according to TAF technical guidance resources and recommendations.²

Reporting of Data

Adhering to CMS reporting rules, we reported member counts in any subgroup only when the group size was at least 11. We reported rates and percentages when the group size on the numerator was at least 11 and the denominator group size was at least 50. If there were any race or ethnicity groups with 10 or fewer people, then the largest group was only reported when total of the unreported group sizes was greater than 10.

Identification of Pembrolizumab Claims

We identified members receiving pembrolizumab based on the procedure code J9271 in outpatient claims and the National Drug Codes (NDCs) listed below in outpatient and pharmacy claims: 00006-3026-01, 00006-3026-02, 00006-3026-04, 00006-3029-01, 00006-3029-02.

We searched for any claim with these codes in records for 2019 through 2021 for all non-dually enrolled members who were enrolled to Medicaid at any point in these 3 years.

Cancer Prevalence Among Members With Pembrolizumab Claims

As a primary validation method, all inpatient and outpatient claims for members receiving pembrolizumab in 2021 were searched for any occurrence of an ICD-10 code from the 2020 and 2021 Surveillance, Epidemiology, and End Results Program (SEER) reportable lists.³ Claims files were then searched for all cancers indicated for pembrolizumab. Pembrolizumab-indicated cancers were identified via hand-search of publicly available label and prescribing information and in consultation with clinical experts. We then identified the ICD-10 codes for each indication and aggregated them into clinically meaningful categories using publicly available value sets from the Healthcare Cost and <u>Utilization Project</u>, a federal-state-industry partnership with input from clinical experts sponsored by the Agency for Healthcare Research and Quality.⁴ Pembrolizumab-indicated cancers were identified in the year 2021 by the presence of either 1 inpatient or 2 outpatient claims over a 2-year look-back period (see Exhibit A1). Categories are reported at the member-level and are mutually exclusive; each category includes members both with and without secondary malignancies. Some pembrolizumab indications were reliant upon tumor characteristics not identifiable in administrative claims; those indications are not included here. Forty-two members were not found to have inpatient or outpatient claims for either SEER-reportable or pembrolizumab-indicated cancers. It is possible that those members were either identified via prescription drug claims alone, received care that was not billed to Medicaid, or had other indications for pembrolizumab that were not identifiable in administrative claims.

EXHIBIT A1

Prevalence of pembrolizumab-indicated cancers in Medicaid members with pembrolizumab claims, 2021

Indication category/primary cancer site	n	%
Total members ^a	13,351	
Respiratory cancers	5,102	38.21
Multiple primary sites ^b	2,825	21.16
Breast cancer ^c	1,126	8.43
Female reproductive system cancers - cervix	612	4.58
Urinary system cancers - kidney	560	4.19
Gastrointestinal cancers - colorectal	437	3.27
Skin cancers - melanoma	426	3.19
Female reproductive system cancers - endometrium	409	3.06
Secondary malignancies only ^d	388	2.91
Urinary system cancers - bladder	246	1.84
Gastrointestinal cancers - esophagus	179	1.34
Head and neck cancers - lip and oral cavity	164	1.23
Gastrointestinal cancers - stomach	140	1.05
Other Cancer - not indicated ^e	99	<1
Head and neck cancers - laryngeal	95	<1
Hodgkin lymphoma	79	<1
Skin cancers- squamous cell carcinoma	70	<1
Gastrointestinal cancers - liver	65	<1
Head and neck cancers - nasopharyngeal	57	<1
Head and neck cancers - tonsils	51	<1
No identified cancer claims ^e	50	<1
Non-Hodgkin lymphoma	39	<1
Skin cancers - all other types	27	<1
Head and neck cancers – throat	25	<1
Head and neck cancers – salivary glad	21	<1
Gastrointestinal cancers - all other types	20	<1
Head and neck cancers - hypopharyngeal	11	<1
Gastrointestinal cancers - bile duct	^f	f
Mesothelioma	^f	f
Urinary system cancers - ureter and renal pelvis	^f	f
Gastrointestinal cancers - gallbladder	f	f
Urinary system cancers - urethra	f	f

Notes. ^a Excludes dually eligible members and members in Alabama, Illinois, New York, and Utah. ^b Includes members with multiple cancer types identified in outpatient, inpatient, or a combination of inpatient and outpatient claims; secondary malignancies were not calculated as a cancer type for this category. ^c Excludes ductal carcinoma in situ. ^d Includes members who only had claims for secondary malignancy categories. ^e Includes those members who did not have claims for pembrolizumab-indicated cancers or Surveillance, Epidemiology, and End Results Program (SEER)-reportable cancers. ^f Suppressed (n < 11).

For members identified with multiple cancer sites that did not include a primary site combined with a secondary malignancy, there were over 60 different primary site combinations between inpatient and outpatient claims; the 20 most common identified from outpatient claims are listed in Exhibit A2. Outpatient primary site combinations are those where the member had at least 2 instances of an ICD-10 code within each classification category. Primary site combinations below are listed in order of commonality; however, the order of sites across columns is not representative of severity or diagnosis position on an individual claim. Importantly, although these combinations represent members who did not have claims for secondary malignancies, we were not able to determine definitively whether these members had two primary cancer sites, or a primary site paired with a secondary malignancy that is not coded as such.

EXHIBIT A2

Site 1	Site 2	Site 3	Members	%
Gastrointestinal cancers - esophagus	Gastrointestinal cancers - stomach	-	118	4.6
Respiratory cancers	Breast cancers - all other types	-	99	3.9
Hodgkin lymphoma	Non-Hodgkin lymphoma	-	84	3.3
Respiratory cancers	Head and neck cancers - laryngeal	-	82	3.2
Respiratory cancers	Urinary system cancers - kidney	-	80	3.1
Female reproductive system cancers - cervix	Female reproductive system cancers - endometrium	-	75	2.9
Head and neck cancers - lip and oral cavity	Skin cancers- squamous cell carcinoma	-	62	2.4
Respiratory cancers	Gastrointestinal cancers- colorectal	-	56	2.2
Head and neck cancers - lip and oral cavity	Head and neck cancers - throat	-	54	2.1
Respiratory cancers	Female reproductive system cancers - cervix	-	52	2.0
Respiratory cancers	Head and neck cancers - lip and oral cavity	-	45	1.8
Respiratory cancers	Non-Hodgkin lymphoma	-	44	1.7
Head and neck cancers - throat	Head and neck cancers - tonsils	-	41	1.6
Respiratory cancers	Skin cancers - squamous cell carcinoma	-	41	1.6
Respiratory cancers	Gastrointestinal cancers - esophagus	-	33	1.3
Respiratory cancers	Gastrointestinal cancers - liver	-	33	1.3
Head and neck cancers - lip and oral cavity	Head and neck cancers - throat	Head and neck cancers - tonsils	29	1.1
Respiratory cancers	Urinary system cancers - bladder	-	28	1.1
Respiratory cancers	Skin cancers - melanoma	-	26	1.0
Respiratory cancers	Female reproductive system cancers - endometrium	-	26	1.0

Most common primary site combinations among Medicaid members with pembrolizumab, 2021

Note. Naming conventions are those listed by the Healthcare Cost and Utilization Project.⁴

Health Care Service Use

We summarized health care service use outcomes (hospitalizations and emergency department [ED] visits) for members with pembrolizumab claims between January 1, 2021, and December 31, 2021. We identified hospitalizations in the inpatient files as episodes of care based on unique admission date. Unique discharge dates were used in the case of missing admission dates. We identified ED visits in both inpatient and outpatient files using revenue center codes 450 through 459 and 981, and service date. The ED visits we report include visits that resulted in an admission.

Cost Estimates

We first identified pembrolizumab claims in outpatient and pharmacy files for years 2019 through 2021. We assumed that each claim represented a patient receiving one of the 2 recommended dosages: 200 mg every 3 weeks, or 400 mg every 6 weeks. While the 2 dosages have the same annual cost, the cost of a single claim depends on which dosage is administered. Because of the unreliable or missing dose information in the claims, we determined the dosage administered based on the number of days between outpatient claims for the same patient when possible, and on the days' supply information in the pharmacy claims when available. The percentage of claims for each dosage identified using this method was assumed to apply all pembrolizumab claims.

Because the treatment dosage is dependent on patient body weight for pediatric members, we first identified the number of claims for this group, as well as the sex and age composition of the pediatric members receiving this treatment. We calculated the dosage needed for a member with a median body weight in this group using age- and sex-specific body weight data from the Centers for Disease Control and Prevention.⁵ We assumed that each pembrolizumab claim for a member under the age of 18 was for 100 mg every 3 weeks, which corresponds to the recommended dose for a pediatric patient with 110 pounds (50 kg) body weight.

We then estimated the projected annual total national costs associated with covering pembrolizumab in Medicaid based on the number of claims we observed in outpatient and pharmacy claims from 2019 through 2021 projected out using a quadratic time series trend analysis of state-level quarterly data on the number of pembrolizumab prescriptions reimbursed by Medicaid from the State Drug Utilization Data from 2015 (when this treatment was approved) through 2023.⁶ We assume a 17.6% increase in number of Medicaid pembrolizumab claims from the number of claims observed in 2021.

We converted the total estimated quantity represented in claims into a dollar cost using the wholesale acquisition cost and applying the statutorily required 23.1% rebate to these prices.⁷ The model inputs and sources are summarized in Exhibit A3.

EXHIBIT A3 Cost modeling inputs

Input name	Input	Source	Sensitivity analysis bounds
Pembrolizumab claims			
Number of claims in 2021 ^a	80,764	Data	68,557 to 94,215
Increase in number of claims compared to 2021	17.6%	Data, SDUD ⁶	0% to 50%
Share of claims			
For 200 mg every 3 weeks ^b	85%	Data	60% to 100%
For pediatric patients	0.5%	Data	0.2% to 1%
Price			
Current annual drug cost (WAC), \$	196,591	IPD Analytics	
Federal rebates ^c	23.1%	SSA §1927(c)(1)(B)(i) ⁷	

Notes. ^a Includes estimated claims volume in Alabama, Illinois, New York, and Utah. ^b The remaining claims are assumed to be for 400 mg every 6 weeks. ^c Do not include state-negotiated supplemental rebates.

Abbreviations. SDUD: State Drug Utilization Data; SSA: Social Security Administration; WAC: wholesale acquisition cost.

The 4 states excluded from the analyses due to limited data availability (Alabama, Illinois, New York and Utah) were included in the national cost estimates, using the estimated pembrolizumab usage rate and use patterns set at the average rates observed in other states. For state level forecasted costs, we distributed the national estimate proportionally based on the percentage of members with pembrolizumab claims in each state in 2021.

As our focus was on direct drug costs, we did not include the costs of drug dispensing, administration, and monitoring. We also did not include any cost offsets associated with replacement of treatmentas-usual, costs associated with adverse events, or cost implications of treatment effectiveness in terms of reduced health care service use or mortality.

We performed sensitivity analyses using Monte Carlo simulations that considered uncertainty in the model inputs, then we reported the range that contained 95% of the simulated cost values as the confidence bounds for our cost estimate. We considered uncertainty in the number of pembrolizumab claims by accounting for errors in estimating the number of claims in states with missing data, using the lowest and highest prevalence rates observed in other states, and allowing for up to 25% error in the number of claims identified in other states from 2019 through 2021. We consider wide confidence bounds around the percentage of pediatric claims, the share of the 2 possible dosages, and the estimated increase in uptake.

For the state and federal breakdown of the forecasted costs in each state, we first calculated the percentage of the members with pembrolizumab claims in CHIP and adult Medicaid Expansion

enrollment categories. We then applied the corresponding federal matching rates in each state to the relevant portion of the total costs using the current Federal Medical Assistance Percentage (FMAP) rates for Medicaid and CHIP members.⁸ Additionally, we applied the 90% FMAP exception to the portion of the costs associated with members enrolled in adult Medicaid Expansion.⁹ For states with unusable data quality for identifying enrollment eligibility category, we used the average rates of other states. Similarly, for expansion states with unusable data quality for identifying Medicaid adult expansion enrollment, we used the average adult expansion enrollment share from other expansion states. For the state and federal breakdown of the costs nationally, we calculated the weighted national average federal matching rates for each year based on the state FMAP rates, weighted by the percentage of members with pembrolizumab claims in each corresponding enrollment category in each state each year.

For our per-member per-month cost estimates in each state, we used the member-month counts reported in 2023,¹⁰ excluding any dually enrolled members.¹¹

Limitations

Our cost estimates are based on the pembrolizumab claims we identified using the aforementioned procedure code and NDCs. The accuracy of our analysis depends on the completeness and reliability of the claims and treatment codes recorded, as well as the enrollment and demographic information (e.g., dual-enrollment, age) provided for each member.

For the 4 states excluded due to limited data availability, our cost estimates assume that pembrolizumab use rates and patterns are similar to those observed in other states. The cost associated with each claim depends on the dosage administered, and the dosage information cannot be accurately identified in all claims. Our cost estimates do not include supplemental rebates, and the estimated total cost is broken down by state and federal share without any consideration for third-party liability or other insurance payments.

APPENDIX B PEMBROLIZUMAB CLAIMS, 2021

EXHIBIT B

Medicaid members aged 0 to 64 years with at least 1 claim for pembrolizumab, 2021

State	Total members aged 0 to 64 years	Members with at least 1 pembrolizumab claim	Pembrolizumab use rate (per 10,000 members)
United States	72,692,096	13,351	(per 10,000 members) 1.8
Alabamaª			
Alaska	231,443	43	1.9
Arizona	2,066,692	270	1.3
Arkansas	975,513	156	1.6
California	14,068,017	1,698	1.0
Colorado	1,496,616	242	1.2
Connecticut	964,247	198	2.1
Delaware	264,072	57	2.1
		45	1.9
District of Columbia Florida	242,774	695	1.7
	3,977,142		
Georgia	2,258,438	423	1.9
Hawaii	391,262	62	1.6
Idaho	402,324	86	2.1
Illinois ^a			
Indiana	1,748,833	532	3.0
lowa	753,353	188	2.5
Kansas	426,693	102	2.4
Kentucky	1,613,911	402	2.5
Louisiana	1,693,162	373	2.2
Maine	328,623	118	3.6
Maryland	1,506,988	215	1.4
Massachusetts	1,798,991	331	1.8
Michigan	2,687,982	597	2.2
Minnesota	1,197,056	252	2.1
Mississippi	701,642	146	2.1
Missouri	1,093,093	369	3.4
Montana	280,337	60	2.1
Nebraska	323,274	64	2.0
Nevada	792,179	103	1.3
New Hampshire	227,212	55	2.4
New Jersey	1,886,202	299	1.6
New Mexico	857,354	88	1.0
New York ^a			

State	Total members aged 0 to 64 years	Members with at least 1 pembrolizumab claim	Pembrolizumab use rate (per 10,000 members)
North Carolina	2,396,142	578	2.4
North Dakota	109,481	18	1.6
Ohio	2,926,428	876	3.0
Oklahoma	1,052,565	151	1.4
Oregon	1,250,950	232	1.9
Pennsylvania	3,183,117	777	2.4
Rhode Island	319,305	69	2.2
South Carolina	1,255,923	228	1.8
South Dakota ^b	123,851		
Tennessee	1,564,046	304	1.9
Texas	5,516,394	567	1.0
Utahª			
Vermont ^b	160,890		
Virginia	1,746,298	433	2.5
Washington	1,955,277	375	1.9
West Virginia	567,561	174	3.1
Wisconsin	1,241,483	278	2.2
Wyoming ^b	66,958		

Notes. ^a Data not available. ^b Data suppressed (N < 11).

APPENDIX C DEMOGRAPHIC INFORMATION

EXHIBIT C

Availability of demographic information for Medicaid members included in analyses, 2021

	Members with at least 1 pembrolizumab claim	%	Members without pembrolizumab claim	%	Members without pembrolizumab- indicated cancer	%
Total	13,351	-	438,529	-	72,240,213	-
Sex available	13,205	98.9	436,010	99.4	71,540,336	99.0
Sex not reported ^a	146	1.1	3	< 1	698,989	1.0
Sex missing ^b	0	< 1	12	< 1	888	< 1
Race or ethnicity available	9,668	72.4	322,747	73.6	53,216,060	73.7
Race or ethnicity not reported ^a	2,309	17.3	82,766	18.9	12,984,083	18.0
Race or ethnicity missing ^b	1,374	10.3	33,016	7.5	6,040,070	8.4

Notes. ^a We did not report sex and race/ethnicity data for Mississippi, which had unusable data quality for linking of claims to Medicaid members in the demographic data file. Age information for Mississippi members with pembrolizumab claims was obtained from the birth date on the claims. We also did not report race/ethnicity data from states with unusable or high-concern data quality for race/ethnicity information, including Arizona, Connecticut, District of Columbia, Iowa, Louisiana, Massachusetts, New York, Oregon, Rhode Island, South Carolina, Tennessee, and Wyoming. ^b Missing in states for which sex or race and ethnicity data is reported.

APPENDIX D PEMBROLIZUMAB COSTS

EXHIBIT D

Forecasted annual cost of pembrolizumab (in \$millions), by state

State	Forecasted spending, \$	Per member per month ^c ,\$	State contribution ^d ,\$	Federal contribution ^d ,\$
United States	941.1	1.0	268.9	672.2
Alabamaª	12.0	1.1	2.4	9.6
Alaska	2.6	0.9	0.7	2.0
Arizona	16.5	0.7	3.6	12.9
Arkansas	9.6	1.0	2.0	7.6
California	104.0	0.7	28.2	75.8
Colorado	14.8	0.8	3.5	11.4
Connecticut	12.1	1.2	2.3	9.8
Delaware	3.5	1.1	0.6	2.9
District of Columbia	2.8	0.9	0.6	2.1
Florida	42.6	0.9	18.2	24.3
Georgia	25.9	1.1	8.8	17.1
Hawaii	3.8	0.8	0.8	3.0
Idaho	5.3	1.3	1.7	3.6
Illinois ^a	35.8	0.9	11.5	24.3
Indiana	32.6	1.6	7.4	25.2
lowa	11.5	1.4	2.3	9.2
Kansas	6.2	1.3	2.4	3.9
Kentucky	24.6	1.6	5.1	19.5
Louisiana	22.8	1.2	4.5	18.4
Maine	7.2	2.1	1.9	5.3
Maryland	13.2	0.7	3.7	9.5
Massachusetts	20.3	1.0	7.4	12.9
Michigan	36.6	1.2	8.2	28.4
Minnesota	15.4	1.1	3.8	11.7
Mississippi	8.9	1.2	1.6	7.4
Missouri	22.6	1.5	7.6	15.0
Montana	3.7	1.2	0.5	3.2
Nebraska	3.9	1.0	1.0	2.9
Nevada	6.3	0.7	1.1	5.2
New Hampshire	3.4	1.6	0.5	2.9
New Jersey	18.3	0.8	4.3	14.0
New Mexico	5.4	0.6	0.9	4.4
New York ^a	70.4	0.9	23.2	47.3

MERCI Brief	Appendices:	Pembrolizumab	(Keytruda)	for Cancer
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	Forecasted	Per member		Federal
State	spending, \$	per month ^c ,\$	State contribution ^d ,\$	contribution ^d ,\$
North Carolina	35.4	1.5	12.4	23.0
North Dakota	1.1	0.8	0.5	0.6
Ohio	53.7	1.6	11.8	41.8
Oklahoma	9.2	0.7	2.5	6.8
Oregon	14.2	0.9	2.8	11.4
Pennsylvania	47.6	1.3	14.3	33.3
Rhode Island	4.2	1.1	1.1	3.1
South Carolina	14.0	1.1	4.2	9.7
South Dakota [♭]				
Tennessee	18.6	1.0	6.6	12.1
Texas	34.7	0.6	13.9	20.8
Utahª	5.1	1.1	1.3	3.9
Vermont ^b				
Virginia	26.5	1.3	8.6	17.9
Washington	23.0	1.0	6.0	17.0
West Virginia	10.7	1.7	1.8	8.8
Wisconsin	17.0	1.2	6.7	10.3
Wyoming ^b				

Notes. ^a Cost estimates for Alabama, Illinois, New York, and Utah are based on national prevalence rates. ^b Not calculated. (N<11). ^c Excluding dual enrollment. ^d Based on the share of the members with pembrolizumab claims in Medicaid, Medicaid Expansion, and CHIP enrollment categories in each state in 2021. For states with unusable data quality for identifying expansion enrollment (i.e., Idaho, Illinois, and Virginia), the average expansion enrollment percentages in other expansion states were used. For states with unusable data quality for identifying CHIP enrollment (i.e., Arkansas, Kentucky, and North Dakota), the average CHIP enrollment percentages in all states were used.

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Suggested citation

Shaw B, Cil G, Burbank C, Yeddala S, Ryan J, Radley D, Stuard S. *Appendices: pembrolizumab (Keytruda) for cancer.* Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University; 2025.

Conflict of interest disclosure

No authors have conflicts of interest to disclose. All authors have completed and submitted the Oregon Health & Science University form for Disclosure of Potential Conflicts of Interest, and none were reported.

Funding and support

Research reported in this brief was supported by a grant from Arnold Ventures.

About the Center for Evidence-based Policy

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