APPENDICES

Sotorasib (Lumakras) for Non–Small Cell Lung Cancer

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The Medicaid Evidence and Review of Cost Initiative (MERCI) describes policy considerations for drugs approved by the US Food and Drug Administration (FDA) through the accelerated approval pathway. This document is the appendix of a brief titled *Sotorasib (Lumakras) for Non–Small Cell Lung Cancer*. The brief and the associated appendix provide information on: the estimated prevalence of target diagnoses (the accelerated approval drug's indication[s]) among Medicaid members; the clinical trial population used to support FDA approval, and how similar it is to Medicaid members overall; and projected drug costs for state Medicaid programs, including a breakdown of state and federal funds using the Federal Medical Assistance Percentage (FMAP).

APPENDIX A

METHODS

Data Sources

Researchers from the Center for Evidence-based Policy (Center) used the 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, based on enrollment and claims records. State-submitted T-MSIS data are processed by the University of Minnesota Research Data Center, and compiled for use as national data files.

We obtained TAF demographic and enrollment data, with inpatient, other service, and pharmacy claims data for years 2019 through 2021 for all Medicaid and CHIP members aged 0 to 64, excluding those with any months of dual enrollment in Medicaid and Medicare. Using these criteria, we were not able to obtain data from Utah or Alabama, as these states do not submit claim information related to dual enrollment status using this method. Cohorts for analysis were anchored in the most recent year of data available (2021), with preceding years used to maintain internal validity for diagnosis and service-use identification, based on established methods specific to the indication of interest. Other sources that informed cohort definitions, drug indication, and drug identification included peer-reviewed literature, grey literature sources, and publicly available databases.

The TAF data are subject to quality concerns. To identify data quality or usability issues affecting internal analytical validity, the Medicaid Data Quality (DQ) Atlas was used as a reference.[1] In general, if the DQ Atlas identified a state's data as "unusable" for a topic, variable, or year, that state was eliminated from analysis. If a state's data were of "high concern," we investigated further 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 to include with a bias towards 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 this 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 one of the states within which they had claims.

Differences in demographic information for members with multiple enrollment records were similarly reconciled. In the case 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 common 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. Any members with claims submitted in Mississippi were assigned to that state for drug indication prevalence reporting. Further, the only demographic information from submitted claims that we could identify for members from Mississippi was birth date. We could not use sex or race or ethnicity information in the enrollment files for these members. In the brief, only the following data are included from Mississippi:

- Number of people with drug indication, if no demographic information other than age is 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 where matching is based only on age
- Drug uptake, if applicable

If other demographic characteristics are 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 would otherwise be aggregated into a single claim record in other states. 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 only the largest group was reported when the total of the unreported group sizes was greater than 10.

Prevalence Estimates

We identified members with lung cancer based on having at least 1 claim with an ICD-10 (International Classification of Diseases, 10th revision) diagnosis code C34 in their inpatient and other outpatient service claims in the past 3 years. A member was classified as having metastatic lung cancer if they also had at least 1 claim with the metastasis code (ICD-10 C77-C79) in addition to the lung cancer diagnosis any time in the past 3 years.

Matched Comparison Group

We used a matched-comparison method to analyze health care service use and health states between members with metastatic lung cancer and the Medicaid population at large. We performed 1-to-3 exact matching between members with metastatic lung cancer and members without any lung cancer diagnosis, based on member state of residence, sex, age in years, and race and ethnicity groups, when available. If we identified more than 3 matched members for someone with metastatic lung cancer, we selected the 3 members into our matched cohort at random.

Comorbid Conditions

We used the Chronic Disability Payment System (CDPS) algorithm to identify the prevalence of affected body systems and relevant comorbidities in the metastatic lung cancer cohort and matched comparisons.[3] The CDPS has a hierarchical method to classify members into risk groups by body system using ICD-10 diagnosis codes in medical claims. There are multiple risk groups per body system, and a member may belong only to 1 risk group per body system. Once categorized, we aggregated risk groups into whole-system categories (e.g., cardiovascular, pulmonary).

Health Care Service Use

We compared health care service use (hospitalizations and emergency department [ED] visits), measured in both metastatic lung cancer and matched comparison groups, 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, revenue center code 981, and service date. Accordingly, the ED visits we report include those resulting in an admission.

Medication Uptake

Medication uptake was calculated as the proportion of estimated number of members with metastatic and locally advanced lung cancer with any identified claim for sotorasib with the following National Drug Code (NDC) directory codes:

- 55513-488-01
- 55513-488-02
- 55513-488-24
- 55513-488-40
- 55513-488-96
- 55513-504-50

Cost Estimates

The cost estimates represent the projected annual total national costs associated with covering sotorasib for treatment of Medicaid members with metastatic or locally advanced NSCLC. There is no diagnosis code specific to NSCLC, and the stage or the genetic variant of the cancer cannot be determined in the claims. To identify the number of members with locally advanced lung cancer, we applied the percentage of locally advanced (or stage III) patients reported elsewhere[4] to the total number with lung cancer. We then assumed that 84% of these metastatic or locally advanced lung cancer patients are NSCLC patients[5] and that 12.5% of those (1 in 8) have the KRAS G12C variant[6] for which sotorasib is indicated. The estimated number of members eligible for sotorasib was 8% of all members with lung cancer. We assumed the number of eligible patients stay constant within a 1-year period based on the similar reported rates for annual incidence and mortality for stage III and stage IV lung cancer.[7]

Sotorasib was approved in May 2021, and we identified Medicaid pharmacy claims for this drug in the second half of 2021. To calculate sotorasib uptake in Medicaid in 2021, we first estimated the total number of Medicaid members eligible for this treatment in 2021 as described above. We estimated there were 5,732 Medicaid members who had metastatic or locally advanced NSCLC with the KRAS G12C mutation. The uptake of this drug would be 2.9% in 2021, assuming all these patients were eligible for sotorasib. The approved label indicates patients who received prior treatment are eligible for sotorasib. We identified that about 62.8% of the metastatic lung cancer patients had prior treatment listed as a first-line lung cancer treatment in the literature.[8] If the same percentage is applied to the locally advanced lung cancer patients and NSCLC patients with KRAS G12C mutation, there would be 3,603 patients eligible for sotorasib. The sotorasib uptake would then be 4.6% in 2021. This is likely an underestimate considering we have limited ability to identify prior treatments in the claims data.

We modified the uptake rates observed in 2021, assuming the uptake increased by 40% since then based on the trends reported in the Medicaid Drug Rebate Program State Drug Utilization Data.[9] We combined prevalence and drug uptake rates with current wholesale acquisition cost for the drug and statutorily required rebate percentages to calculate total annual costs. All model inputs and justifications are summarized in Exhibit A1.

EXHIBIT A1

Cost modeling inputs for all metastatic and locally advanced NSCLC patients

Input name	Input	Source	Sensitivity analysis bounds
Prevalence and uptake[a]			
Prevalence of lung cancer (# members)	72,034	Data	69,243 to 73,137
Prevalence metastatic lung cancer (# members)	39,423	Data	23,841 to 40,062
Percentage of eligible locally advanced lung cancer patients	22.4%	SEER[4]	± 20%
Percentage of lung cancer patients with NSCLC	84%	ACS[5]	± 10%
Percentage of NSCLC patients with KRAS G12C mutation	12.5%	ACS[6]	± 20%
Uptake (% eligible patients using the drug)	4%	Data, SDUD[9]	1% to 8%
Drug cost			
Annual drug cost (WAC)	$256,912	IPD Analytics	--
Federal rebates[b]	23.1%	SSA §1927(c)(1)(B)(i)[10]	--
Treatment duration			
Average treatment duration (months)	6	Skoulidis et al. 2021[11]	3 to 9

Notes. [a] Includes estimated patient populations in Alabama and Utah at the national prevalence rate [b] Does not include state-negotiated supplemental rebates.

Abbreviations. ACS: American Cancer Society; NSCLC: non–small cell lung cancer; SDUD: State Drug Utilization Data; SEER: National Cancer Institute Surveillance, Epidemiology, and End Results Program; SSA: Social Security Administration; WAC: wholesale acquisition cost.

Sotorasib is indicated as a second-line therapy for patients who have received at least 1 prior systematic therapy. We performed an additional cost analysis for the patient group with previous treatment. We further restricted the eligible members to those who have had at least 1 claim for a systematic therapy using the J-codes and NDC codes listed in the literature for lung cancer patients[8] and calculated the total annual costs with that base patient population. We identified that 62.8% of metastatic lung cancer patients in 2021 had a prior therapy in the last year. This is likely an underestimate as we cannot accurately identify all patients with a prior therapy due to our inability to observe the entire history of treatments for all members and the issues around completeness and accuracy of the pharmacy claims. We assumed the same percentage applies to the patients with locally advanced lung cancer. All model inputs and justifications for the cost analysis of this patient group are summarized in Exhibit A2.

EXHIBIT A2

Cost modeling inputs for metastatic and locally advanced NSCLC patients with prior treatment

Input name	Input	Source	Sensitivity analysis bounds
Prevalence and uptake[a]			
Prevalence of lung cancer (# members)	72,034	Data	69,243 to 73,137
Prevalence metastatic lung cancer (# members)	24,763	Data	23,841 to 40,062
Percentage of locally advanced lung cancer patients	22.4%	SEER[4]	± 20%
Percentage of locally advanced lung cancer patients with previous treatment	63%	Data	± 20%
Percentage of NSCLC patients	84%	ACS[5]	± 10%
Percentage of NSCLC patients with KRAS G12C mutation	12.5%	ACS[6]	± 20%
Uptake (eligible patients using the drug)	5.5%	Data, SDUD[9]	1% to 10%
Drug cost			
Annual drug cost (WAC)	$256,912	IPD Analytics	--
Federal rebates[b]	23.1%	SSA §1927(c)(1)(B)(i)[10]	--
Treatment duration			
Average treatment duration (months)	6	Skoulidis et al. 2021[11]	3 to 9

Notes. [a] Includes estimated patient populations in Alabama and Utah at the national prevalence rate [b] Does not include state-negotiated supplemental rebates.

Abbreviations. ACS: American Cancer Society; NSCLC: non–small cell lung cancer; SDUD: State Drug Utilization Data; SEER: National Cancer Institute Surveillance, Epidemiology, and End Results Program; SSA: Social Security Administration; WAC: wholesale acquisition cost.

As our focus is direct drug costs, we did not include the costs of drug dispensing and monitoring. Due to lack of published data, we also did not include cost offsets associated with replacement of treatment-as-usual. Similarly, we did not include cost implications of treatment effectiveness in terms of recovery, reduced health care service use, or mortality.

We performed sensitivity analyses using Monte Carlo simulations, taking into consideration uncertainty in the model inputs, and reporting the range that contained 95% of the simulated cost values as the confidence bounds for our cost estimate. The lower and upper bounds considered for prevalence corrects for known data quality issues in some states (i.e., overreporting in Massachusetts and New Jersey, and underreporting in Rhode Island) and assumes the lowest and highest prevalence observed in other states for Alabama and Utah, rather than the national average rate. The prevalence bounds also reflect the possibility of treatment being offered only to those with previous treatment in

the first cost model and the possibility of treatment being offered to those without previous treatment in the second cost model.

For our per-member per-month (PMPM) cost estimates, we used the member month counts we observed in the 2021 data, excluding any dually enrolled members. For the state and federal breakdown of the costs, we first calculated the percentage of the members with lung cancer in CHIP and adult Medicaid expansion enrollment categories. We then calculated the average Federal Medical Assistance Percentage (FMAP) rates across states weighted by the number of lung cancer patients in each enrollment category, and applied the corresponding matching rates to the relevant portion of the total costs for Medicaid and CHIP members. We applied the 90% FMAP exception for the portion of the costs by the members with adult Medicaid expansion enrollment.

For states with unusable data quality for identifying CHIP enrollment, we used the average percentage of CHIP enrollment in other states. Similarly, for expansion states with unusable data quality for identifying Medicaid adult expansion enrollment, we used the average of adult expansion enrollment share in other expansion states.

Limitations

Our cost estimates are based on the prevalence of lung cancer and metastatic lung cancer as identified in the claims data and the reports of percentage of NSCLC, percentage of stage III and stage IV patients, and prevalence of KRAS G12C variant. The accuracy of our lung cancer prevalence estimates depends on the completeness and reliability of the claims (e.g., diagnosis and procedure codes in the inpatient and outpatient claims) and the information recorded in the data, as well as enrollment and demographic information (e.g., dual enrollment, age) given for each member. Comprehensive and correct identification of patients with previous treatment is unlikely as it requires complete and accurate data on procedure codes in the inpatient and outpatient claims, and the NDC codes in pharmacy and outpatient claims, as well as the entire treatment history for each patient.

For the 2 states for which we have no data on lung cancer prevalence, our cost estimates assume lung cancer prevalence in these states is similar to what is observed in other states. 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

DEMOGRAPHIC INFORMATION

EXHIBIT B1

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

	Members with metastatic lung cancer	%	Members with lung cancer	%	Members without lung cancer	%
Total	*38,733*	-	*70,775*	-	*82,885,834*	-
Sex						
Sex available	38,436	99.2	70,203	99.2	82,010,752	98.9
Sex NR[a]	297	< 1	571	< 1	701,642	< 1
Sex missing[b]	0	0.0	1	< 1	173,440	< 1
Race and ethnicity						
Race or ethnicity available	26,544	68.5	47,859	67.6	56,855,472	68.6
Race or ethnicity NR[a]	8,976	23.2	17,404	24.6	19,471,706	23.5
Race or ethnicity missing[b]	3,213	8.3	5,512	7.8	6,558,656	7.9

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. 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.
Abbreviation. NR: not reported.

APPENDIX C

MEDICAID MEMBERS WITH AND WITHOUT LUNG CANCER, 2021

EXHIBIT C1

Medicaid members with and without lung cancer and metastatic lung cancer included in analyses, 2021

State	Total Medicaid population	Members with metastatic lung cancer			Members with lung cancer			Members without lung cancer
		n	Per 10,000 members	%	n	Per 10,000 members	%	n
United States	*82,254,400*	*38,733*	*4.7*	*0.05*	*70,204*	*8.5*	*0.09*	*82,184,196*
Alabama[a]	--	--	--	--	--	--	--	--
Alaska	233,201	125	5.4	0.05	205	8.8	0.09	232,996
Arizona	2,079,994	683	3.3	0.03	1,283	6.2	0.06	2,078,711
Arkansas	985,310	443	4.5	0.04	742	7.5	0.08	984,568
California	14,309,281	3,851	2.7	0.03	7,082	4.9	0.05	14,302,199
Colorado	1,513,275	482	3.2	0.03	883	5.8	0.06	1,512,392
Connecticut	976,877	564	5.8	0.06	982	10.1	0.10	975,895
Delaware	266,190	143	5.4	0.05	284	10.7	0.11	265,906
District of Columbia	247,013	94	3.8	0.04	195	7.9	0.08	246,818
Florida	3,988,310	2,112	5.3	0.05	3,610	9.1	0.09	3,984,700
Georgia	2,267,465	1,028	4.5	0.05	1,720	7.6	0.08	2,265,745
Hawaii	395,106	142	3.6	0.04	262	6.6	0.07	394,844
Idaho	404,442	141	3.5	0.03	219	5.4	0.05	404,223
Illinois	3,225,492	1,736	5.4	0.05	3,256	10.1	0.10	3,222,236
Indiana	1,761,425	996	5.7	0.06	1,986	11.3	0.11	1,759,439
Iowa	758,080	400	5.3	0.05	717	9.5	0.09	757,363
Kansas	427,717	226	5.3	0.05	356	8.3	0.08	427,361
Kentucky	1,622,220	1,241	7.7	0.08	2,261	13.9	0.14	1,619,959
Louisiana	1,705,484	975	5.7	0.06	1,719	10.1	0.10	1,703,765

State	Total Medicaid population	Members with metastatic lung cancer			Members with lung cancer			Members without lung cancer
		n	Per 10,000 members	%	n	Per 10,000 members	%	n
Maine	330,861	272	8.2	0.08	459	13.9	0.14	330,402
Maryland	1,519,447	779	5.1	0.05	1,452	9.6	0.10	1,517,995
Massachusetts	1,811,949	837	4.6	0.05	1,656	9.1	0.09	1,810,293
Michigan	2,721,194	1,887	6.9	0.07	3,315	12.2	0.12	2,717,879
Minnesota	1,220,201	615	5.0	0.05	996	8.2	0.08	1,219,205
Mississippi	701,642	297	4.2	0.04	571	8.1	0.08	701,071
Missouri	1,099,753	907	8.2	0.08	1,487	13.5	0.14	1,098,266
Montana	283,264	108	3.8	0.04	205	7.2	0.07	283,059
Nebraska	324,846	149	4.6	0.05	253	7.8	0.08	324,593
Nevada	796,854	280	3.5	0.04	510	6.4	0.06	796,344
New Hampshire	228,781	145	6.3	0.06	261	11.4	0.11	228,520
New Jersey	1,910,085	737	3.9	0.04	1,416	7.4	0.07	1,908,669
New Mexico	866,398	211	2.4	0.02	395	4.6	0.05	866,003
New York	6,327,506	2,947	4.7	0.05	6,290	9.9	0.10	6,321,216
North Carolina	2,410,046	1,468	6.1	0.06	2,375	9.9	0.10	2,407,671
North Dakota	110,561	50	4.5	0.05	86	7.8	0.08	110,475
Ohio	2,963,699	2,604	8.8	0.09	4,839	16.3	0.16	2,958,860
Oklahoma	1,056,873	438	4.1	0.04	753	7.1	0.07	1,056,120
Oregon	1,264,765	514	4.1	0.04	909	7.2	0.07	1,263,856
Pennsylvania	3,233,076	2,254	7.0	0.07	4,204	13.0	0.13	3,228,872
Rhode Island	321,524	142	4.4	0.04	284	8.8	0.09	321,240
South Carolina	1,262,914	608	4.8	0.05	1,063	8.4	0.08	1,261,851
South Dakota	124,100	30	2.4	0.02	44	3.5	0.04	124,056
Tennessee	1,568,562	761	4.9	0.05	1,440	9.2	0.09	1,567,122
Texas	5,539,535	1,296	2.3	0.02	2,270	4.1	0.04	5,537,265
Utah[a]	--	--	--	--	--	--	--	--

State	Total Medicaid population	Members with metastatic lung cancer			Members with lung cancer			Members without lung cancer
		n	Per 10,000 members	%	n	Per 10,000 members	%	n
Vermont	163,325	103	6.3	0.06	200	12.2	0.12	163,125
Virginia	1,764,200	985	5.6	0.06	1,846	10.5	0.10	1,762,354
Washington	1,969,953	800	4.1	0.04	1,375	7.0	0.07	1,968,578
West Virginia	574,139	515	9.0	0.09	940	16.4	0.16	573,199
Wisconsin	1,251,985	600	4.8	0.05	1,086	8.7	0.09	1,250,899
Wyoming	67,122	12	1.8	0.02	33	4.9	0.05	67,089

Notes. [a] Data not available.

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The Center for Evidence-based Policy (Center) is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring that diverse and relevant perspectives are considered and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon.

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