APPENDICES

Deferiprone (Ferriprox) for Transfusional Iron Overload

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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 contains the appendices of MERCI brief *Deferiprone (Ferriprox) for Transfusional Iron Overload*. The brief and the associated appendices 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 drug costs for state Medicaid programs, including a breakdown of state and federal funds using the Federal Medical Assistance Percentage (FMAP).

APPENDIX A

DETAILED PARTICIPANT DEMOGRAPHIC INFORMATION OF THE *FIRST* CONFIRMATORY TRIAL

EXHIBIT A1

Demographic information of the participants in the efficacy and safety of deferiprone (Ferriprox) in patients with sickle cell disease or other anemias (FIRST) trial[1-5]

	Randomized to deferiprone tablets or oral solution	Randomized to deferoxamine infusions	Overall
Participants, n	152	76	228
Age (years), n (%)			
≥ 18	58 (38.1)	28 (36.8)	86 (37.7)
≥ 6 to < 18	84 (55.3)	46 (60.6)	130 (57.0)
≥ 2 to < 6	10 (6.6)	2 (2.6)	12 (5.3)
Sex, n (%)			
Female	69 (45.4)	38 (50.0)	107 (46.9)
Male	83 (54.6)	38 (50.0)	121 (53.1)
Race, n (%)			
Black	23 (15.1)	14 (18.4)	37 (16.2)
Multiracial	9 (5.9)	6 (7.9)	15 (6.6)
White	120 (78.9)	56 (73.7)	176 (77.2)
Ethnicity, n (%)[a]			
African or African American	7 (4.6)	7 (9.2)	14 (6.1)
Arab or Egyptian	18 (11.8)	6 (7.9)	24 (10.5)
Black British, non-Hispanic, or unknown	17 (11.2)	8 (10.5)	25 (11.0)
Caucasian	100 (65.8)	49 (64.5)	149 (65.4)
Hispanic or Latino	10 (6.6)	6 (7.9)	16 (7.0)

Note. [a]The FIRST trial used the ethnicity categories of Caucasian; Black British, non-Hispanic, or unknown; Arab or Egyptian; Hispanic or Latino; African or African American.

EXHIBIT A2

Primary diagnosis of the participants in the efficacy and safety of deferiprone (Ferriprox) in patients with sickle cell disease or other anemias (FIRST) trial[1-5]

	Randomized to deferiprone tablets or oral solution	Randomized to deferoxamine infusions	Overall
Participants, n	152	76	228
Primary diagnosis, n (%)			
Autoimmune hemolytic anemia	1 (0.7)	1 (1.3)	2 (0.9)
Congenital anemia	1 (0.7)	1 (1.3)	2 (0.9)
Congenital dyserythropoietic anemia	4 (2.6)	3 (3.9)	7 (3.1)
Hereditary spherocytosis or spherocytic anemia	14 (9.2)	6 (7.9)	20 (8.8)
Hemoglobin C disease	2 (1.3)	1 (1.3)	3 (1.3)
Hemoglobinopathy	1 (0.7)	0 (0.0)	1 (0.4)
Hemolytic anemia	1 (0.7)	0 (0.0)	1 (0.4)
Pyruvate kinase deficiency disease	2 (1.3)	1 (1.3)	3 (1.3)
Sickle cell disease, sickle cell anemia, or thalassemia sickle cell	126 (82.9)	63 (82.9)	189 (82.9)

APPENDIX B

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 estimates. 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, as these states 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 sources, 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.[6] 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 for the rating and made a topic-specific or variable-specific judgment about inclusion or exclusion for analysis. We made decisions on whether to include data 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 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 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.[6] 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 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 when matching is based only on age
- Drug uptake, if applicable

In the case that 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 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.[7]

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.

Identifying Deferiprone Claims

We identified members who had used deferiprone based on the National Drug Codes (NDCs) listed on their pharmacy claims. We searched for any claim with these NDCs in records for 2019 through 2021 for all nondually enrolled members who were enrolled to Medicaid at any point in those 3 years. The NDCs for deferiprone are:

- Ferriprox: 10122-0101-50, 10122-0100-10, 10122-0103-05, 10122-0104-01, 10122-0104-05, 52609-0006-01, 52609-0007-05, 52609-4502-07, 52609-4503-07, 52609-4503-04
- Generic: 51672-4196-01, 51672-4237-04, 00054-0576-25, 00054-0711-19, 00054-0711-23, 00054-0711-28

Comorbid Conditions

We used the Chronic Disability Payment System (CDPS) algorithm to identify prevalence of affected body systems and relevant comorbidities in the cohort of Medicaid members with deferiprone claims.[8] The CDPS hierarchical method classifies members into risk groups by body system using ICD-10 (*International Statistical Classification of Diseases and Related Health Problems, 10th Revision*) diagnosis codes in medical claims. There are multiple risk groups per body system; a member may only be assigned to 1 risk group. Once categorized, we aggregated risk groups into whole-system categories (e.g., cardiovascular, pulmonary). We identified comorbidities in medical claims through ICD-10 diagnosis codes, where usage of a code from the determined value set was considered an indication of the individual having that condition.

Medication Adherence

Medication adherence was calculated using the Medication Possession Ratio, a member-level estimation calculated as the proportion of days' supply during a given period for the year 2021. The numerator is the number of days' supply obtained, starting at the date of the first fill of the year, and the denominator is the total number of days between the first fill and December 31, 2021. This method assumes the medication is prescribed for daily, continuous use, and that the member took their medication as prescribed.

Cost Estimates

We first estimated the total national Medicaid spending on deferiprone in years 2019 through 2021 based on deferiprone claims we observed in pharmacy claims. Because the treatment dosage is dependent on patient body weight, we first identified the number of claims and number of days' supply for each formulation for each patient group based on their sex and age. We calculated the corresponding total quantity based on median body weight for that sex-age group reported by the Centers for Disease Control and Prevention.[9] We then converted total quantity into a dollar cost using the per-package wholesale acquisition cost (WAC) in each year reported in various sources[10-13] and applying the statutorily required 23.1% rebate[14] to these prices (Exhibit B1). We assumed that each

member using this drug received the starting dosage of 75 mg/kg/day in their first 30-day supply, and the full dose of 99 mg/kg/day thereafter. We estimated that 7% of all claims are for the starting dose.

EXHIBIT B1

Annual wholesale acquisition cost (WAC) for deferiprone

Dosage form[a] (strength)	Package size	2019 to 2020 annual price, $	2021 annual price, $	Current annual price,[b] $
Ferriprox oral tablet (500 mg)	100 tablets	278,699	316,061	335,012
Ferriprox oral tablet (1,000 mg)	50 tablets	278,699	316,061	335,012
Ferriprox oral tablet, twice a day (1,000 mg)	50 tablets	-[c]	395,076	479,369
Ferriprox solution (100 mg/mL)	500 mL	278,699	316,061	383,555
Generic oral tablet (500 mg)	100 tablets	-[c]	269,282	269,282
Generic oral tablet (1,000 mg)	50 tablets	-[c]	-[c]	305,530

Note. [a] Unless labeled otherwise, all dosage forms are indicated for thrice per day. [b] Costs are annualized based on 80 kg (176 lbs) body weight and assuming a daily dosage of 6000 mg (75 mg/kg/day). [c] Not yet on the market.

We also estimate the projected annual total national costs associated with covering deferiprone in Medicaid. Deferiprone is indicated for the treatment of transfusional iron overload in patients with thalassemia syndromes, sickle cell disease, or other anemias. In the provider guide published by the manufacturer, the appropriate primary ICD-10 diagnosis code for this indication is E83.111: hemochromatosis due to repeated red blood cell transfusions, which should be accompanied by a secondary diagnosis code that specifies the type of anemia.[15] However, we identified that 23.2% of Medicaid members with deferiprone claims in 2021 did not have the primary diagnosis code E83.111 in any of their inpatient or outpatient claims, implying that this diagnosis code does not sufficiently identify those who receive the treatment. Accordingly, our cost estimates are based on the number of deferiprone claims we saw in pharmacy claims in 2019 through 2021, projected out using the results of a quadratic time series trend analysis of state-level quarterly data on the number of deferiprone prescriptions reimbursed by Medicaid from the State Drug Utilization Data (SDUD) in the 5 years from 2019 through 2023.[16] We assume the sex and age composition of patients using the drug will mimic the sex and age composition observed in TAF in 2021 (Exhibit B2). We assume 23% market share for the generic version of the drug in Medicaid based on the market share observed in SDUD in 2023 and use the current WAC[17] with the statutorily required rebates applied. The model inputs and sources are summarized in Exhibit B2.

EXHIBIT B2

Share of deferiprone claims for each formulation by age and sex of patients, 2021

Patient group	Oral solution, 100 mg/mL	Oral tablet, 500 mg or 1,000 mg, thrice a day	Oral tablet, 1,000 mg, twice a day
Age, years			
3 to 7	31%	3%	2
8 to 10	25	4	4
11 to 14	31	9	18
15 to 19	8	20	22
20 to 29	4	31	29
30 to 64	1	33	24
Sex			
Female	58	62	52
Male	42	38	48

EXHIBIT B3

Other modeling inputs for deferiprone cost estimates

Input name	Input	Source	Sensitivity analysis bounds
Federal rebates[a]	23.1%	SSA §1927(c)(1)(B)(i)[14]	--
Number of prescriptions for 30-day supply[b]	3,985	Data, SDUD[16]	3,300 to 4,600
Share of starting dose	7%	Data	3% to 15%
Share of generics	23%	SDUD[16]	15% to 35%
Share of Ferriprox formulations			
Solution (100 mg/mL)	30%	Data	--
Oral tablet (500mg and 1000 mg)	8%	Data	--
Oral tablet twice a day (1000 mg)	62%	Data	--
Share of generic formulations			
Oral tablet (500mg)	22%	SDUD[16]	--
Oral tablet (1000 mg)	78%	SDUD[16]	--

Notes. [a] Do not include state-negotiated supplemental rebates. [b] Includes estimated claims volume in Alabama and Utah.
Abbreviations. SDUD: State Drug Utilization Data.

The 2 states excluded from our analyses due to data availability (Alabama and Utah) are included in the national cost estimates by the estimated deferiprone usage rate and use patterns set at the average rates observed in other states with similar transfusional iron overload prevalence.

With a focus 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 treatment-as-usual or consider 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 consider uncertainty in number of deferiprone claims over time using the 95% confidence interval for the point estimates in our trend analysis, as well as the uncertainties in the percentage of patients on starting dose and the share of generics.

For our per-member per-month cost estimates, we used the member month counts we observed in the 2021 data, excluding any dually enrolled members. Our estimate of the state versus federal breakdown of the costs is based on the enrollment composition of members with deferiprone claims in CHIP and Medicaid expansion. We calculated the weighted national average federal matching rates for each year based on the state federal match rates, weighted by the percentage of members with deferiprone claims in each corresponding enrollment category in each state in each year. For the 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 deferiprone claims we identified using the NDCs given above. The accuracy of our analysis depends on the completeness and reliability of the pharmacy claims and NDCs recorded, as well as enrollment and demographic information (e.g., dual-enrollment, age) given for each member. While we allow an increase in market share of generics over time, we assume the age and sex composition of the members using the different formulations and the share of different formulations (e.g., solution vs. oral tablet) remain stable.

For the 2 states excluded due to data availability, our cost estimates assume deferiprone use rate and patterns in these states are like what is observed in other states with similar transfusional iron overload prevalence. 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 C

DEMOGRAPHIC INFORMATION

EXHIBIT C1

Availability of demographic information for Medicaid members included in analyses, 2019-2021

	With at least 1 deferiprone claim, 2019 to 2021		With at least 1 deferiprone claim, 2021		Without a deferiprone claim, 2021	
	n	%	n	%	n	%
Total	*429*	-	*323*	-	*77,962,901*	-
Race or ethnicity available	242	56.4	183	56.7	54,560,946	70.0
Race or ethnicity not reported[a]	129	30.1	91	28.2	17,944,884	23.0
Race or ethnicity missing[b]	58	13.5	49	15.2	5,457,071	7.0

Notes. Only nondually eligible Medicaid members aged 2 to 64 years were included in our analyses. [a] We did not report race and ethnicity from states that had "unusable" or "high-concern" data quality for race and ethnicity information, including Arizona, Connecticut, District of Columbia, Iowa, Louisiana, Massachusetts, New York, Oregon, Rhode Island, South Carolina, Tennessee, and Wyoming in all years; Arkansas, Colorado, Kansas, Maryland, and Missouri in 2019 and 2020 only; and Montana and West Virginia in 2019 only. [b] Missing in states for which race and ethnicity data is reported.

APPENDIX D

DEFERIPRONE CLAIMS, 2019 TO 2021

EXHIBIT D1

Medicaid claims for deferiprone by state, 2019-2021

State	Total deferiprone claims	Total members, 2021	Deferiprone claims per 100,000 members
United States	6,428	81,439,192	8
Alabama[a]	--	--	--
Alaska	27	231,442	12
Arizona	311	2,066,692	15
Arkansas[b]	--	--	--
California	2,302	14,068,016	16
Colorado	152	1,496,614	10
Connecticut	38	964,247	4
Delaware[b]	--	--	--
District of Columbia[b]	--	--	--
Florida	148	3,976,922	4
Georgia	142	2,258,383	6
Hawaii[b]	--	--	--
Idaho	34	402,324	8
Illinois	59	3,187,612	2
Indiana	129	1,748,824	7
Iowa	52	753,318	7
Kansas	16	426,693	4
Kentucky	38	1,613,908	2
Louisiana	222	1,693,162	13
Maine	27	328,619	8
Maryland	71	1,506,988	5
Massachusetts	284	1,798,991	16
Michigan	198	2,687,982	7
Minnesota	192	1,197,056	16
Mississippi[b]	--	--	--
Missouri	29	1,093,093	3
Montana	15	280,337	5
Nebraska[b]	--	--	--
Nevada	79	792,178	10
New Hampshire[b]	--	--	--
New Jersey	75	1,886,202	4
New Mexico[b]	--	--	--

State	Total deferiprone claims	Total members, 2021	Deferiprone claims per 100,000 members
New York	574	6,262,027	9
North Carolina	13	2,396,142	1
North Dakota[b]	--	--	--
Ohio	23	2,926,427	1
Oklahoma	37	1,052,565	4
Oregon[b]	--	--	--
Pennsylvania	264	3,183,117	8
Rhode Island	26	319,305	8
South Carolina	60	1,255,882	5
South Dakota[b]	--	--	--
Tennessee	57	1,564,046	4
Texas	559	5,515,970	10
Utah[a]	--	--	--
Vermont[b]	--	--	--
Virginia	68	1,746,297	4
Washington	15	1,955,277	1
West Virginia[b]	--	--	--
Wisconsin	58	1,241,446	5
Wyoming[b]	--	--	--

Notes. [a] Data not available. [b] Suppressed (N < 11).

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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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