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FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request cder_mpl1r_wp071

Request ID: cder_mpl1r_wp071_nsdv_v01

Request Description: The goal of this request was to estimate the number of patients with sickle cell anemia (SCA), the number of SCA patients who were dispensed hydroxyurea, and the average number of hospitalizations and emergency department visits per person-year among those patients in the Sentinel Distributed Database (SDD). This is report 1 of 2. Report 2 examines utilization patterns of hydroxyurea among patients with SCA in the SDD.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 5.2.1

Data Source: Data from January 1, 2000 to September 30, 2015 from 17 Data Partners contributing to the SDD were included in this report. This request was distributed on February 28, 2018. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: This request was designed to identify SCA or hydroxyurea dispensing events and hospitalizations for two different cohorts. The number of qualifying patients with the exposure and outcomes of interest for each cohort were stratified by age group, race, and Census Bureau region. See Appendix B for a list of states and territories included in each Census Bureau region.

Events of Interest: There were two events of interest in this request for the two cohorts identified. For the first cohort, the event of interest was a diagnosis of SCA in any care setting during the request period. SCA was identified using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes. For the second cohort, the event of interest was a dispensing of hydroxyurea during the request period. Hydroxyurea was defined using National Drug Codes (NDCs). Please see Appendices C and D for a list of ICD-9-CM diagnosis codes and a list of brand and generic drug names used to define the events of interest in this request.

Cohort Eligibility Criteria: The following age groups were included in both cohorts: 0-1, 2-5, 6-11, 12-17, 18-49, and 50+ years. Age groups were defined by either the age on the date of the first SCA diagnosis (SCA cohort) or the age on the date of the first eligible hydroxyurea dispensing (hydroxyurea cohort). For both cohorts, patients were required to be enrolled in health plans with both medical and drug coverage on the date of their event of interest. Further inclusion criteria for each cohort is described below:

SCA cohort: There is no additional inclusion or exclusion criteria for this cohort.

Hydroxyurea cohort: Patients included in the hydroxyurea cohort were required to have a diagnosis of SCA at any time in their available history prior to their dispensing of hydroxyurea.

Follow-Up Time:

SCA cohort: Follow-up began on the day of the first SCA diagnosis and continued until the first occurrence of any of the following: 1) disenrollment; 2) death; 3) the end date of the data provided by each Data Partner; or 4) the end of the query period.

Overview for Request cder_mpl1r_wp071, continued

Hydroxyurea cohort: Follow-up began on the day of the first valid hydroxyurea dispensing and was determined by the length of exposure episodes. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supply were less than 30 days. All valid episodes during the query period were included and continued until the first occurrence of any of the following: 1) disenrollment; 2) death; 3) the end date of the data provided by each Data Partner; 4) the end of the last exposure episode; or 5) the end of the query period.

Outcomes of Interest:

SCA cohort: There were two outcomes of interest: 1) a dispensing of hydroxyurea, and 2) encounters in the emergency department or inpatient hospital setting. All encounters that occurred during the follow-up period were included.

Hydroxyurea cohort: The outcomes of interest were encounters in the emergency department or inpatient hospital setting. All encounters that occurred during the follow-up period were included.

Please see Appendix E for the specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define exposures, outcomes, and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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**Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Tool***

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions days are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1a. Summary of Hydroxyurea Use, Hospitalizations, and Emergency Department (ED) Visits Among Patients with Sickle Cell Anemia (SCA) in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Age Group

Age Group	SCA Patients	SCA Patients Dispensed Hydroxyurea		Mean Number of Hospitalizations and ED Visits per Person-Year Among all SCA Patients
		Number	Percent	
0-1 years	6,978	283	4.06%	1.30
2-5 years	4,538	348	7.67%	1.12
6-11 years	3,958	652	16.47%	1.63
12-17 years	4,476	718	16.04%	2.56
18-49 years	44,756	8,217	18.36%	4.76
50+ years	30,900	1,439	4.66%	2.13

Table 1b. Summary of Hydroxyurea Use, Hospitalizations, and Emergency Department (ED) Visits Among Patients with Sickle Cell Anemia (SCA) in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Race and Age Group

Race, Age Group	SCA Patients Dispensed Hydroxyurea	Average Number of Hospitalizations and ED Visits per Person-Year Among all SCA Patients
American Indian or Alaska Native		
0-1 years	0.00%	0.82
2-5 years	0.00%	1.13
6-11 years	33.33%	0.78
12-17 years	50.00%	3.35
18-49 years	25.64%	7.24
50+ years	2.82%	2.13
Asian		
0-1 years	0.00%	0.44
2-5 years	4.26%	0.31
6-11 years	0.00%	0.30
12-17 years	0.00%	1.30
18-49 years	5.79%	1.62
50+ years	1.75%	1.34
Black or African American		
0-1 years	6.58%	1.42
2-5 years	10.44%	1.35
6-11 years	20.56%	2.31
12-17 years	18.37%	3.68
18-49 years	29.74%	6.46
50+ years	7.52%	2.64
Native Hawaiian or Other Pacific Islander		
0-1 years	8.70%	0.50
2-5 years	0.00%	0.13
6-11 years	0.00%	0.10
12-17 years	0.00%	0.00
18-49 years	15.00%	0.94
50+ years	3.13%	1.28
White		
0-1 years	0.82%	0.98
2-5 years	0.45%	0.79
6-11 years	2.93%	0.85
12-17 years	0.54%	1.96
18-49 years	3.30%	2.67
50+ years	1.15%	1.74
Unknown		
0-1 years	3.70%	1.32
2-5 years	8.13%	1.13
6-11 years	16.54%	1.37
12-17 years	17.20%	1.94
18-49 years	9.29%	2.17
50+ years	4.15%	1.46

Table 1c. Summary of Hydroxyurea Use, Hospitalizations, and Emergency Department (ED) Visits Among Patients with Sickle Cell Anemia (SCA) in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015 by Census Region and Age Group

Region, Age Group	SCA Patients	SCA Patients Dispensed Hydroxyurea		Average Number of Hospitalizations and ED Visits per Person-Year Among all SCA Patients
		Number	Percent	
Northeast				
0-1 years	609	34	5.58%	1.37
2-5 years	575	36	6.26%	0.98
6-11 years	611	102	16.69%	1.29
12-17 years	711	107	15.05%	1.47
18-49 years	6,589	1,149	17.44%	4.24
50+ years	5,412	198	3.66%	1.71
Midwest				
0-1 years	*****	*****	3.06%	0.93
2-5 years	*****	*****	4.75%	0.89
6-11 years	492	74	15.04%	1.30
12-17 years	489	79	16.16%	1.67
18-49 years	6,289	1,387	22.05%	5.51
50+ years	5,782	247	4.27%	2.16
South				
0-1 years	4,588	200	4.36%	1.41
2-5 years	2,651	254	9.58%	1.27
6-11 years	2,276	400	17.57%	1.85
12-17 years	2,691	441	16.39%	2.96
18-49 years	25,637	4,971	19.39%	4.99
50+ years	15,939	839	5.26%	2.32
West				
0-1 years	728	22	3.02%	0.82
2-5 years	604	27	4.47%	0.55
6-11 years	*****	*****	14.18%	1.04
12-17 years	403	66	16.38%	1.87
18-49 years	3,735	631	16.89%	3.33
50+ years	3,356	143	4.26%	1.92
Invalid				
0-1 years	*****	*****	0.00%	1.36
2-5 years	*****	*****	9.09%	1.22
6-11 years	*****	*****	27.27%	1.36
12-17 years	*****	*****	22.22%	2.13
18-49 years	*****	*****	12.24%	2.34
50+ years	*****	*****	6.90%	0.58

Table 1c. Summary of Hydroxyurea Use, Hospitalizations, and Emergency Department (ED) Visits Among Patients with Sickle Cell Anemia (SCA) in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015 by Census Region and Age Group

Region, Age Group	SCA Patients	SCA Patients Dispensed Hydroxyurea		Average Number of Hospitalizations and ED Visits per Person-Year Among all SCA Patients
		Number	Percent	
Missing				
0-1 years	*****	*****	1.22%	1.58
2-5 years	*****	*****	2.68%	1.51
6-11 years	*****	*****	9.64%	1.20
12-17 years	*****	*****	12.79%	1.85
18-49 years	2,436	68	2.79%	2.00
50+ years	*****	*****	2.98%	1.71
Other				
0-1 years	*****	*****	50.00%	2.52
2-5 years	*****	*****	0.00%	0.28
6-11 years	0	*****	-	-
12-17 years	*****	*****	100.00%	1.10
18-49 years	21	*****	23.81%	15.52
50+ years	80	*****	1.25%	1.43

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 2a. Summary of Hospitalizations and Emergency Department (ED) Visits Among Sickle Cell Anemia (SCA) Patients Treated with Hydroxyurea in the Sentinel Distributed Database(SDD) between January 1, 2000 and September 30, 2015, by Age Group

Age Group	SCA Patients Dispensed Hydroxyurea	Average Number of Hospitalizations and ED Visits per Person-Year Among SCA Patients Treated with Hydroxyurea
0-1 years	71	2.34
2-5 years	352	2.05
6-11 years	821	2.14
12-17 years	967	2.58
18-49 years	8,621	6.44
50+ years	1,685	3.22

Table 2b. Summary of Hospitalizations and Emergency Department (ED) Visits Among Sickle Cell Anemia (SCA) Patients Treated with Hydroxyurea in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Race and Age Group

Race, Age Group	Average Number of Hospitalizations and ED Visits per Person-Year Among SCA Patients Treated with Hydroxyurea
American Indian or Alaska Native	
0-1 years	-
2-5 years	-
6-11 years	0.00
12-17 years	2.62
18-49 years	10.03
50+ years	2.10
Asian	
0-1 years	-
2-5 years	0
6-11 years	-
12-17 years	0
18-49 years	3
50+ years	4
Black or African American	
0-1 years	1.97
2-5 years	1.80
6-11 years	1.96
12-17 years	2.84
18-49 years	6.98
50+ years	3.50
Native Hawaiian or Other Pacific Islander	
0-1 years	3.27
2-5 years	1.61
6-11 years	0.00
12-17 years	-
18-49 years	2.08
50+ years	1.78
White	
0-1 years	-
2-5 years	3.18
6-11 years	0.94
12-17 years	0.54
18-49 years	5.02
50+ years	2.01
Unknown	
0-1 years	2.41
2-5 years	2.11
6-11 years	2.25
12-17 years	2.49
18-49 years	4.27
50+ years	1.83

Table 2c. Summary of Hospitalizations and Emergency Department (ED) Visits Among Sickle Cell Anemia (SCA) Patients Treated with Hydroxyurea in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Census Region and Age Group

Region, Age Group	SCA Patients Dispensed Hydroxyurea	Average Number of Hospitalizations and ED Visits per Person-Year Among SCA Patients Treated with Hydroxyurea
Northeast		
0-1 years	*****	1.75
2-5 years	44	1.63
6-11 years	99	2.16
12-17 years	124	2.48
18-49 years	1,174	5.44
50+ years	235	2.69
Midwest		
0-1 years	15	1.87
2-5 years	30	1.59
6-11 years	93	2.05
12-17 years	101	2.48
18-49 years	1,395	6.08
50+ years	297	3.85
South		
0-1 years	40	2.44
2-5 years	248	2.23
6-11 years	518	2.28
12-17 years	614	2.76
18-49 years	5,284	7.00
50+ years	971	3.28
West		
0-1 years	*****	2.55
2-5 years	*****	2.01
6-11 years	91	1.61
12-17 years	105	1.50
18-49 years	692	4.77
50+ years	170	2.64
Invalid		
0-1 years	0	-
2-5 years	*****	0.00
6-11 years	*****	4.25
12-17 years	*****	0.93
18-49 years	*****	5.54
50+ years	*****	4.33

Table 2c. Summary of Hospitalizations and Emergency Department (ED) Visits Among Sick Cell Anemia (SCA) Patients Treated with Hydroxyurea in the Sentinel Distributed Database (SDD) between January 1, 2000 and September 30, 2015, by Census Region and Age Group

Region, Age Group	SCA Patients Dispensed Hydroxyurea	Average Number of Hospitalizations and ED Visits per Person-Year Among SCA Patients Treated with Hydroxyurea
Missing		
0-1 years	*****	16.60
2-5 years	*****	1.98
6-11 years	*****	1.22
12-17 years	*****	3.49
18-49 years	65	4.08
50+ years	*****	1.40
Other		
0-1 years	0	-
2-5 years	*****	1.18
6-11 years	0	-
12-17 years	*****	0.00
18-49 years	*****	4.03
50+ years	*****	0.00

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of the Request End Date (September 30, 2015)

DP ID	Start Date	End Date
DP01	1/1/2000	10/31/2014
DP02	6/1/2007	9/30/2015
DP03	1/1/2000	9/30/2015
DP04	1/1/2008	9/30/2015
DP05	1/1/2006	9/30/2015
DP06	1/1/2000	9/30/2015
DP07	1/1/2008	9/30/2015
DP08	1/1/2010	9/30/2015
DP09	1/1/2000	9/30/2015
DP10	1/1/2000	5/31/2015
DP11	1/1/2000	9/30/2015
DP12	1/1/2000	9/30/2015
DP13	1/1/2005	9/30/2015
DP14	1/1/2004	9/30/2015
DP15	1/1/2000	9/30/2015
DP16	1/1/2000	9/30/2015
DP17	1/1/2012	9/30/2015

Appendix B. List of States and Territories Included in Each Census Bureau Region

Census Bureau Region	States and Territories
Northeast	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, New Jersey, New York, Pennsylvania
Midwest	Illinois, Indiana, Michigan, Ohio, Wisconsin, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
South	Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia, Alabama, Kentucky, Mississippi, Tennessee, Arkansas, Louisiana, Oklahoma, Texas
West	Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming, Alaska, California, Hawaii, Washington
Other	Northern Mariana Islands, Marshall Islands, Puerto Rico, US Virgin Islands, American Samoa, Micronesia, Guam, Palau

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Sickle Cell Anemia in this Request

Code	Description	Code Type
282.6	Sickle-cell disease	ICD-9-CM
282.60	Sickle-cell disease, unspecified	ICD-9-CM
282.61	Hb-SS disease without crisis	ICD-9-CM
282.62	Hb-SS disease with crisis	ICD-9-CM
282.63	Sickle-cell/Hb-C disease without crisis	ICD-9-CM
282.64	Sickle-cell/Hb-C disease with crisis	ICD-9-CM
282.68	Other sickle-cell disease without crisis	ICD-9-CM
282.69	Other sickle-cell disease with crisis	ICD-9-CM

Appendix D. List of Generic and Brand Drug Names Used to Define Hydroxyurea in this Request

Generic Name	Brand Name
HYDROXYUREA	Droxia
HYDROXYUREA	Hydrea
HYDROXYUREA	hydroxyurea
HYDROXYUREA	hydroxyurea (bulk)
HYDROXYUREA	Mylocel

Appendix E. Specifications for Parameters for this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 5.2.1, to examine the use of hydroxyurea among patients with sickle cell anemia in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2000 to September 30, 2015
Enrollment Requirement: 0 days
Enrollment Gap: 45 days
Coverage Requirement: Medical and Drug
Age Groups: 0-1, 2-5, 6-11, 12-17, 18-49, 50+ years
Results Stratified by: Age, Race, Geographic Location

Scenario	Exposure							Pre-existing Conditions				Outcome								
	Exposure	Incidence Criteria	Washout (Days)	Minimum Episode Duration (Days)	Episode Gap (Days)	Episode Extension (Days)	Intent to Treat (Days)	Cohort Definition	Censor due to Query End	Censor due to Evidence of Death	Inclusion or Exclusion Condition	Caresetting	Look-back	Outcome	Care Setting	Washout (Days)	Blackout Period (Days)	Events	Function	
1	Sickle Cell Anemia	None	0	N/A	N/A	N/A	7,000	Include the first valid episode per patient	Yes	Yes				No Outcome					Person time for SCA patients (denominator in tables 1a-1c)	
2	Sickle Cell Anemia	None	0	N/A	N/A	N/A	7,000	Include the first valid episode per patient	Yes	Yes				Hospitalizations, ED Visits	Emergency Department or Inpatient Hospital Stay (ED or IP)	0	0	Include all events	Hospitalizations for SCA patients (numerator in tables 1a-1c)	
3	Sickle Cell Anemia	None	0	N/A	N/A	N/A	7,000	Include the first valid episode per patient	Yes	Yes				Hydroxyurea		0	0	Include the first event	Patients with SCA dispensed hydroxyurea (tables 1a-1c)	
4	Hydroxyurea	None	0	0	30	0	N/A	Include all valid episodes during the query period	Yes	Yes	Sickle Cell Anemia	Include	Any	Any time prior to index date	No Outcome				Person time for SCA patients taking hydroxyurea (denominator in tables 2a-2c)	
5	Hydroxyurea	None	0	0	30	0	N/A	Include all valid episodes during the query period	Yes	Yes	Sickle Cell Anemia	Include	Any	Any time prior to index date	Hospitalizations, ED Visits	ED or IP	0	0	Include all events	Hospitalizations for SCA patients taking hydroxyurea (numerator in tables 2a-2c)

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes are provided by Optum360.

National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus".