Modular Program Report



Disclaimer

The following report provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

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_wp020_nsdp_v02 (Report 3 of 3)

Request ID: cder_mpl1r_wp020_nsdp_v02

<u>Query Description</u>: This query investigated use of intravenous (IV) iron. Separate reports in this request examine tumor necrosis factor (TNF) alpha inhibitor drugs, granulocyte colony-stimulating factor (GC-SF) drugs. This is report 3 of 3. Report 1 presents results on TNF alpha inhibitor drugs and report 2 presents results on GC-SF drugs.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.0.2

<u>Data Source:</u> Data from January 1, 2011 to December 31, 2015, from 16 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed on August 10, 2016. See Appendix A for a list of the dates of available data for each Data Partner.

<u>Study Design:</u> This request was designed to assess use of injectable products in three classes during 2011 to 2015. The number of qualifying patients with prevalent use of the drug(s) of interest were calculated overall and by year, and stratified by age group and sex.

Exposure of Interest: The exposure of interest was use of IV iron drugs including, ferumoxytol, ferric carboxymaltose, iron dextran, ferric gluconate, and iron sucrose. These were defined using National Drug Codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) Level II procedure codes. Please see Appendix B for specific HCPCS codes.

<u>Cohort Eligibility Criteria:</u> Patients were required to be continuously enrolled for at least one day and without gaps of more than 45 days in plans with both medical and drug coverage. The following age groups were included in the cohort: 0-21, 22-44, 45-64, and 65+ years.

<u>Limitations:</u> Algorithms to define exposures and events are imperfect and, therefore, exposures and events may be misclassified.

<u>Notes:</u> The output of "Dispensings/Administrations" quantifies all codes, both NDCs and HCPCS, observed for the relevant exposure of interest. Amount and days supplied have been removed for this report due to the combination of NDC and HCPCS used to define the exposure. This in part due to the fact that "Amount Supplied" for injectable drugs does not accurately reflect the number of vials.

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

Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelsystem.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. This is equivalent to the "RxAmt" value in the Sentinel Common Data Model.

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). Along with the Principal Diagnosis Indicator, forms the

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: (1) 01: Cohort includes only the first valid treatment episode during the query period; (2) 02: Cohort includes all valid treatment episodes during the query period; (3)

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.

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"

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive

Event Deduplication - specifies how events are counted by the MP algorithm: (0) 0: Counts all occurrences of an HOI during an exposure episode; (1) 1: de-duplicates occurrences of the same HOI code and code type on the same day; (2) 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 (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing **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 Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be 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.

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



Treatment Episode Truncation Indicator - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at

Users - number of members with exposure during the query period. Member must have no evidence of exposure(s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

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

^{**}incident treatment episodes must be incident to both the exposure and the event



Table 1: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug and Year

					New Users/1K			
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings /User	Supplied/Dispensing
2011								
Ferric Carboxyma		uconate, Ferumoxyt		ın, Iron Sucrose				
	57,015	416,204	48,589,230	39,900,095.6	1.17	7.83	7.30	1.07
Ferric Carboxyma	ltose							
	0	0	48,589,230	39,900,095.6	0.00			
Ferric Gluconate								
	6,860	46,297	48,589,230	39,900,095.6	0.14	7.39	6.75	1.09
Ferumoxytol								
	6,577	14,538	48,589,230	39,900,095.6	0.14	2.40	2.21	1.09
Iron Dextran								
	11,709	32,391	48,589,230	39,900,095.6	0.24	3.90	2.77	1.41
Iron Sucrose								
	34,146	322,978	48,589,230	39,900,095.6	0.70	9.80	9.46	1.04
2012			, ,	, ,				
Ferric Carboxyma	ltose. Ferric Gl	uconate, Ferumoxyt	ol. Iron Dextra	ın. Iron Sucrose				
	62,602	439,439	51,772,040	42,627,307.1	1.21	7.33	7.02	1.04
Ferric Carboxyma	· ·	,	0 = 7. 1 = 70 10	,				
	0	0	51,772,040	42,627,307.1	0.00			
Ferric Gluconate			0 = 7. 1 = 70 10	,,				
	7,707	58,060	51,772,040	42,627,307.1	0.15	7.81	7.53	1.04
Ferumoxytol	.,		31,7,2,040	.2,027,307.1	0.13	7.01	7.55	1.07
. c. dilloxy to	8,383	18,683	51,772,040	42,627,307.1	0.16	2.32	2.23	1.04
Iron Dextran	0,303	10,003	31,772,040	72,027,307.1	0.10	2.32	2.23	1.04
II OII DEXCIAII	12,135	31,632	E1 772 040	42 627 207 1	0.23	2 50	2.61	1.37
Inon Cuavasa	12,133	31,032	51,772,040	42,627,307.1	0.23	3.58	2.01	1.57
Iron Sucrose	26.422	224.064	E4 770 045	42.627.227.1	0.70	0.00	0.00	4.04
	36,422	331,064	51,772,040	42,627,307.1	0.70	9.22	9.09	1.01



Table 1: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug and Year

		Dispensings/	Eligible		New Users/1K Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings /User	Supplied/Dispensing
2013								
Ferric Carboxyma		uconate, Ferumoxyt						
	63,770	420,184	51,887,084	42,434,119.2	1.23	6.87	6.59	1.04
Ferric Carboxyma								
	0	0	51,887,084	42,434,119.2	0.00			
Ferric Gluconate								
	7,204	49,969	51,887,084	42,434,119.2	0.14	7.05	6.94	1.02
Ferumoxytol								
	9,586	21,470	51,887,084	42,434,119.2	0.18	2.38	2.24	1.06
Iron Dextran								
	11,876	29,569	51,887,084	42,434,119.2	0.23	3.46	2.49	1.39
Iron Sucrose								
	37,116	319,176	51,887,084	42,434,119.2	0.72	8.71	8.60	1.01
2014								
Ferric Carboxyma	ltose, Ferric Gl	uconate, Ferumoxyt	ol, Iron Dextr	an, Iron Sucrose				
	67,528	428,485	54,003,729	43,664,247.3	1.25	6.81	6.35	1.07
Ferric Carboxyma	ltose							
	17	21	54,003,729	43,664,247.3	0.00	17.12	1.24	13.86
Ferric Gluconate								
	6,622	42,011	54,003,729	43,664,247.3	0.12	6.44	6.34	1.02
Ferumoxytol								
	11,298	24,782	54,003,729	43,664,247.3	0.21	2.34	2.19	1.07
Iron Dextran								
	11,951	29,147	54,003,729	43,664,247.3	0.22	4.28	2.44	1.75
Iron Sucrose								
	39,317	332,524	54,003,729	43,664,247.3	0.73	8.64	8.46	1.02
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Table 1: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug and Year

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings /User	Days Supplied/Dispensing
2015								
Ferric Carboxym	•	uconate, Ferumoxyt	-	•				
	59,703	323,389	51,107,784	34,039,632.4	1.17	6.03	5.42	1.11
Ferric Carboxym	naltose							
	5,974	11,627	51,107,784	34,039,632.4	0.12	2.00	1.95	1.03
Ferric Gluconate	9							
	5,063	28,519	51,107,784	34,039,632.4	0.10	5.65	5.63	1.00
Ferumoxytol								
	8,448	17,622	51,107,784	34,039,632.4	0.17	2.28	2.09	1.09
Iron Dextran								
	9,453	22,901	51,107,784	34,039,632.4	0.18	5.53	2.42	2.28
Iron Sucrose								
	32,348	242,720	51,107,784	34,039,632.4	0.63	7.66	7.50	1.02
2011-2015								
Ferric Carboxym	naltose, Ferric Gl	uconate, Ferumoxyt	ol, Iron Dextra	an, Iron Sucrose				
	217,461	2,027,701	98,822,924	202,665,401.5	2.20	9.95	9.32	1.07
Ferric Carboxym	naltose							
	5,989	11,648	98,822,924	202,665,401.5	0.06	2.04	1.94	1.05
Ferric Gluconate	9							
	24,492	224,856	98,822,924	202,665,401.5	0.25	9.51	9.18	1.04
Ferumoxytol								
	36,002	97,095	98,822,924	202,665,401.5	0.36	2.88	2.70	1.07
Iron Dextran								
	45,819	145,640	98,822,924	202,665,401.5	0.46	5.10	3.18	1.60
Iron Sucrose								
	120,619	1,548,462	98,822,924	202,665,401.5	1.22	13.11	12.84	1.02
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Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

					New Users/1K			
		Dispensings/	Eligible	_	Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings/User	Supplied/Dispensing
2011								
Ferumoxytol, Ferric Carb								
0-21 Years	797	3,946	14,022,220	11,122,404.3	0.06	5.39	4.95	1.09
22-44 Years	12,258	66,411	17,218,140	12,950,289.1	0.71	6.06	5.42	1.12
45-64 Years	21,558	167,562	14,146,782	11,618,070.8	1.52	8.30	7.77	1.07
65+ Years	22,916	178,285	4,700,986	4,209,331.4	4.87	8.26	7.78	1.06
Ferric Carboxymaltose								
0-21 Years	0	0	14,022,220	11,122,404.3	0.00			
22-44 Years	0	0	17,218,140	12,950,289.1	0.00			
45-64 Years	0	0	14,146,782	11,618,070.8	0.00			
65+ Years	0	0	4,700,986	4,209,331.4	0.00			
Ferric Gluconate								
0-21 Years	136	694	14,022,220	11,122,404.3	0.01	5.10	5.10	1.00
22-44 Years	1,506	8,548	17,218,140	12,950,289.1	0.09	6.20	5.68	1.09
45-64 Years	2,645	17,925	14,146,782	11,618,070.8	0.19	7.42	6.78	1.10
65+ Years	2,628	19,130	4,700,986	4,209,331.4	0.56	7.99	7.28	1.10
Ferumoxytol								
0-21 Years	48	97	14,022,220	11,122,404.3	0.00	2.02	2.02	1.00
22-44 Years	1,186	2,553	17,218,140	12,950,289.1	0.07	2.30	2.15	1.07
45-64 Years	2,202	4,898	14,146,782	11,618,070.8	0.16	2.31	2.22	1.04
65+ Years	3,162	6,990	4,700,986	4,209,331.4	0.67	2.49	2.21	1.12
Iron Dextran								
0-21 Years	217	685	14,022,220	11,122,404.3	0.02	3.82	3.16	1.21
22-44 Years	3,669	9,168	17,218,140	12,950,289.1	0.21	3.27	2.50	1.31
45-64 Years	4,557	12,167	14,146,782	11,618,070.8	0.32	3.69	2.67	1.38
65+ Years	3,315	10,371	4,700,986	4,209,331.4	0.71	4.82	3.13	1.54
Iron Sucrose	,		. ,					
0-21 Years	428	2,470	14,022,220	11,122,404.3	0.03	6.25	5.77	1.08
22-44 Years	6,374	46,142	17,218,140	12,950,289.1	0.37	7.89	7.24	1.09
45-64 Years	13,006	132,572	14,146,782	11,618,070.8	0.92	10.57	10.19	1.04



Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

					New Users/1K			
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	•	Dispensings/User	Supplied/Dispensing
65+ Years	14,724	141,794	4,700,986	4,209,331.4	3.13	9.81	9.63	1.02
2012								
Ferric Carboxymaltose, F	erric Gluconate	, Ferumoxytol, Iron	Dextran, Iron	Sucrose				
0-21 Years	904	4,091	14,597,079	11,577,381.5	0.06	4.73	4.53	1.04
22-44 Years	12,969	66,921	18,294,282	13,774,102.3	0.71	5.53	5.16	1.07
45-64 Years	23,030	170,078	15,176,829	12,454,017.2	1.52	7.69	7.39	1.04
65+ Years	26,209	198,349	5,375,933	4,821,806.1	4.88	7.84	7.57	1.04
Ferric Carboxymaltose								
0-21 Years	0	0	14,597,079	11,577,381.5	0.00			
22-44 Years	0	0	18,294,282	13,774,102.3	0.00			
45-64 Years	0	0	15,176,829	12,454,017.2	0.00			
65+ Years	0	0	5,375,933	4,821,806.1	0.00			
Ferric Gluconate								
0-21 Years	141	805	14,597,079	11,577,381.5	0.01	5.90	5.71	1.03
22-44 Years	1,684	9,833	18,294,282	13,774,102.3	0.09	6.07	5.84	1.04
45-64 Years	2,853	20,693	15,176,829	12,454,017.2	0.19	7.49	7.25	1.03
65+ Years	3,095	26,729	5,375,933	4,821,806.1	0.58	8.98	8.64	1.04
Ferumoxytol								
0-21 Years	75	144	14,597,079	11,577,381.5	0.01	1.92	1.92	1.00
22-44 Years	1,424	3,123	18,294,282	13,774,102.3	0.08	2.23	2.19	1.02
45-64 Years	2,682	5,958	15,176,829	12,454,017.2	0.18	2.23	2.22	1.00
65+ Years	4,226	9,458	5,375,933	4,821,806.1	0.79	2.41	2.24	1.08
Iron Dextran								
0-21 Years	203	579	14,597,079	11,577,381.5	0.01	3.39	2.85	1.19
22-44 Years	3,575	8,369	18,294,282	13,774,102.3	0.20	3.02	2.34	1.29
45-64 Years	4,714	12,025	15,176,829	12,454,017.2	0.31	3.29	2.55	1.29
65+ Years	3,697	10,659	5,375,933	4,821,806.1	0.69	4.46	2.88	1.55
Iron Sucrose								
0-21 Years	515	2,563	14,597,079	11,577,381.5	0.04	5.07	4.98	1.02



Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1k Eligible Members	Days	Dispensings/Licer	Days Supplied/Dispensing
22-44 Years	6,690	45,596	18,294,282	13,774,102.3	0.37	7.12	6.82	1.04
45-64 Years	·	131,402			0.89	9.93	9.71	1.02
65+ Years	13,529 16,041	151,503	15,176,829 5,375,933	12,454,017.2 4,821,806.1	2.98	9.93 9.41	9.44	1.00
2013	10,041	131,303	3,373,933	4,021,000.1	2.96	9.41	9.44	1.00
Ferric Carboxymaltose	. Ferric Gluconate	. Ferumoxytol. Iror	Dextran, Iron	Sucrose				
0-21 Years	901	3,985	14,412,691	11,338,825.4	0.06	4.62	4.42	1.04
22-44 Years	13,438	66,521	18,447,587	13,757,283.4	0.73	5.25	4.95	1.06
45-64 Years	23,438	163,434	15,140,652	12,387,536.5	1.55	7.19	6.97	1.03
65+ Years	26,545	186,244	5,518,558	4,950,473.9	4.81	7.34	7.02	1.05
Ferric Carboxymaltose	· · · · · · · · · · · · · · · · · · ·	,		.,,				
0-21 Years	0	0	14,412,691	11,338,825.4	0.00			
22-44 Years	0	0	18,447,587	13,757,283.4	0.00			
45-64 Years	0	0	15,140,652	12,387,536.5	0.00			
65+ Years	0	0	5,518,558	4,950,473.9	0.00			
Ferric Gluconate								
0-21 Years	151	755	14,412,691	11,338,825.4	0.01	4.99	5.00	1.00
22-44 Years	1,617	8,996	18,447,587	13,757,283.4	0.09	5.62	5.56	1.01
45-64 Years	2,647	17,864	15,140,652	12,387,536.5	0.17	6.77	6.75	1.00
65+ Years	2,852	22,354	5,518,558	4,950,473.9	0.52	8.07	7.84	1.03
Ferumoxytol								
0-21 Years	70	150	14,412,691	11,338,825.4	0.00	2.13	2.14	0.99
22-44 Years	1,675	3,648	18,447,587	13,757,283.4	0.09	2.21	2.18	1.01
45-64 Years	3,003	6,754	15,140,652	12,387,536.5	0.20	2.30	2.25	1.02
65+ Years	4,862	10,918	5,518,558	4,950,473.9	0.88	2.49	2.25	1.11
Iron Dextran								
0-21 Years	188	640	14,412,691	11,338,825.4	0.01	3.61	3.40	1.06
22-44 Years	3,455	7,340	18,447,587	13,757,283.4	0.19	2.76	2.12	1.30
45-64 Years	4,554	11,079	15,140,652	12,387,536.5	0.30	3.05	2.43	1.25
65+ Years	3,726	10,510	5,518,558	4,950,473.9	0.68	4.56	2.82	1.62



Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

					New Users/1K			
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings/User	Supplied/Dispensing
Iron Sucrose								
0-21 Years	520	2,440	14,412,691	11,338,825.4	0.04	4.96	4.69	1.06
22-44 Years	7,097	46,537	18,447,587	13,757,283.4	0.38	6.80	6.56	1.04
45-64 Years	13,973	127,737	15,140,652	12,387,536.5	0.92	9.29	9.14	1.02
65+ Years	15,933	142,462	5,518,558	4,950,473.9	2.89	8.96	8.94	1.00
2014								
Ferric Carboxymaltose, Fe	erric Gluconate,	Ferumoxytol, Iron I	Dextran, Iron S	ucrose				
0-21 Years	997	4,409	14,380,620	11,259,150.4	0.07	5.01	4.42	1.13
22-44 Years	14,349	68,454	19,348,669	14,229,089.4	0.74	5.39	4.77	1.13
45-64 Years	24,552	167,348	15,956,648	12,787,729.3	1.54	7.21	6.82	1.06
65+ Years	28,177	188,274	6,031,519	5,388,278.2	4.67	7.13	6.68	1.07
Ferric Carboxymaltose								
0-21 Years	1	1	14,380,620	11,259,150.4	0.00	7.00	1.00	7.00
22-44 Years	5	5	19,348,669	14,229,089.4	0.00	17.80	1.00	17.80
45-64 Years	7	11	15,956,648	12,787,729.3	0.00	21.57	1.57	13.73
65+ Years	4	4	6,031,519	5,388,278.2	0.00	11.00	1.00	11.00
Ferric Gluconate								
0-21 Years	136	630	14,380,620	11,259,150.4	0.01	4.72	4.63	1.02
22-44 Years	1,473	7,491	19,348,669	14,229,089.4	0.08	5.25	5.09	1.03
45-64 Years	2,441	15,193	15,956,648	12,787,729.3	0.15	6.29	6.22	1.01
65+ Years	2,638	18,697	6,031,519	5,388,278.2	0.44	7.18	7.09	1.01
Ferumoxytol								
0-21 Years	120	236	14,380,620	11,259,150.4	0.01	1.97	1.97	1.00
22-44 Years	2,002	4,289	19,348,669	14,229,089.4	0.10	2.23	2.14	1.04
45-64 Years	3,483	7,717	15,956,648	12,787,729.3	0.22	2.30	2.22	1.04
65+ Years	5,728	12,540	6,031,519	5,388,278.2	0.95	2.40	2.19	1.10
Iron Dextran								
0-21 Years	175	604	14,380,620	11,259,150.4	0.01	5.05	3.45	1.46
22-44 Years	3,291	6,582	19,348,669	14,229,089.4	0.17	3.67	2.00	1.83



Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

					New Users/1k	(
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings/User	Supplied/Dispensing
45-64 Years	4,463	10,281	15,956,648	12,787,729.3	0.28	3.87	2.30	1.68
65+ Years	4,079	11,680	6,031,519	5,388,278.2	0.68	5.13	2.86	1.79
Iron Sucrose								
0-21 Years	592	2,938	14,380,620	11,259,150.4	0.04	5.45	4.96	1.10
22-44 Years	7,949	50,087	19,348,669	14,229,089.4	0.41	6.67	6.30	1.06
45-64 Years	14,760	134,146	15,956,648	12,787,729.3	0.93	9.23	9.09	1.02
65+ Years	16,399	145,353	6,031,519	5,388,278.2	2.72	8.98	8.86	1.01
2015								
Ferric Carboxymaltose, Fe	rric Gluconate	, Ferumoxytol, Iron	Dextran, Iron	Sucrose				
0-21 Years	815	3,263	12,636,192	8,084,251.4	0.06	4.60	4.00	1.15
22-44 Years	12,502	51,017	18,297,759	11,147,068.0	0.68	4.93	4.08	1.21
45-64 Years	21,140	121,259	15,382,119	10,150,975.7	1.37	6.35	5.74	1.11
65+ Years	25,626	147,850	6,148,311	4,657,337.2	4.17	6.26	5.77	1.08
Ferric Carboxymaltose								
0-21 Years	58	108	12,636,192	8,084,251.4	0.00	1.84	1.86	0.99
22-44 Years	1,389	2,671	18,297,759	11,147,068.0	0.08	1.99	1.92	1.04
45-64 Years	2,102	4,100	15,382,119	10,150,975.7	0.14	2.01	1.95	1.03
65+ Years	2,442	4,748	6,148,311	4,657,337.2	0.40	1.97	1.94	1.01
Ferric Gluconate								
0-21 Years	89	439	12,636,192	8,084,251.4	0.01	4.93	4.93	1.00
22-44 Years	987	4,648	18,297,759	11,147,068.0	0.05	4.79	4.71	1.02
45-64 Years	1,733	9,970	15,382,119	10,150,975.7	0.11	5.78	5.75	1.01
65+ Years	2,281	13,462	6,148,311	4,657,337.2	0.37	5.89	5.90	1.00
Ferumoxytol								
0-21 Years	69	140	12,636,192	8,084,251.4	0.01	2.03	2.03	1.00
22-44 Years	1,476	3,064	18,297,759	11,147,068.0	0.08	2.33	2.08	1.12
45-64 Years	2,631	5,569	15,382,119	10,150,975.7	0.17	2.31	2.12	1.09
65+ Years	4,301	8,849	6,148,311	4,657,337.2	0.70	2.24	2.06	1.09
Iron Dextran								



Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

					New Users/1k			
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings/User	Supplied/Dispensing
0-21 Years	129	463	12,636,192	8,084,251.4	0.01	5.21	3.59	1.45
22-44 Years	2,477	5,175	18,297,759	11,147,068.0	0.14	5.24	2.09	2.51
45-64 Years	3,382	7,658	15,382,119	10,150,975.7	0.22	5.30	2.26	2.34
65+ Years	3,491	9,605	6,148,311	4,657,337.2	0.57	5.94	2.75	2.16
Iron Sucrose								
0-21 Years	490	2,113	12,636,192	8,084,251.4	0.04	4.89	4.31	1.13
22-44 Years	6,490	35,459	18,297,759	11,147,068.0	0.35	5.81	5.46	1.06
45-64 Years	11,795	93,962	15,382,119	10,150,975.7	0.77	8.13	7.97	1.02
65+ Years	13,841	111,186	6,148,311	4,657,337.2	2.25	8.08	8.03	1.01
2011-2015								
Ferric Carboxymaltose	, Ferric Gluconate	, Ferumoxytol, Iron	Dextran, Iron	Sucrose				
0-21 Years	3,630	19,694	28,228,305	53,382,013.0	0.13	5.91	5.43	1.09
22-44 Years	50,188	319,324	39,787,392	65,857,832.2	1.26	7.08	6.36	1.11
45-64 Years	79,992	789,681	29,461,166	59,398,329.6	2.72	10.45	9.87	1.06
65+ Years	88,299	899,002	9,554,903	24,027,226.8	9.24	10.77	10.18	1.06
Ferric Carboxymaltose								
0-21 Years	59	109	28,228,305	53,382,013.0	0.00	1.93	1.85	1.05
22-44 Years	1,394	2,676	39,787,392	65,857,832.2	0.04	2.05	1.92	1.07
45-64 Years	2,108	4,111	29,461,166	59,398,329.6	0.07	2.08	1.95	1.07
65+ Years	2,445	4,752	9,554,903	24,027,226.8	0.26	1.99	1.94	1.02
Ferric Gluconate								
0-21 Years	502	3,323	28,228,305	53,382,013.0	0.02	6.69	6.62	1.01
22-44 Years	5,801	39,516	39,787,392	65,857,832.2	0.15	7.09	6.81	1.04
45-64 Years	9,095	81,645	29,461,166	59,398,329.6	0.31	9.27	8.98	1.03
65+ Years	9,514	100,372	9,554,903	24,027,226.8	1.00	10.95	10.55	1.04
Ferumoxytol								
0-21 Years	345	767	28,228,305	53,382,013.0	0.01	2.22	2.22	1.00
22-44 Years	6,487	16,677	39,787,392	65,857,832.2	0.16	2.70	2.57	1.05
45-64 Years	11,698	30,896	29,461,166	59,398,329.6	0.40	2.74	2.64	1.04



Table 2: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Age Group

					New Users/1K	(
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings/User	Supplied/Dispensing
65+ Years	17,846	48,755	9,554,903	24,027,226.8	1.87	3.00	2.73	1.10
Iron Dextran								
0-21 Years	824	2,971	28,228,305	53,382,013.0	0.03	4.55	3.61	1.26
22-44 Years	13,811	36,634	39,787,392	65,857,832.2	0.35	4.15	2.65	1.57
45-64 Years	17,502	53,210	29,461,166	59,398,329.6	0.59	4.65	3.04	1.53
65+ Years	14,347	52,825	9,554,903	24,027,226.8	1.50	6.35	3.68	1.72
Iron Sucrose								
0-21 Years	2,061	12,524	28,228,305	53,382,013.0	0.07	6.54	6.08	1.08
22-44 Years	25,838	223,821	39,787,392	65,857,832.2	0.65	9.17	8.66	1.06
45-64 Years	44,839	619,819	29,461,166	59,398,329.6	1.52	14.13	13.82	1.02
65+ Years	50,744	692,298	9,554,903	24,027,226.8	5.31	13.74	13.64	1.01



Table 3: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year 2011	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
Ferumoxytol, Ferric Ca	arboxymaltose,	, Iron Dextran, Ferri	c Gluconate, Ir	on Sucrose				
Female Male Unknown	36,529 20,478 8	218,223 197,940 41	24,756,626 23,830,329 2,275	20,438,864.3 19,459,428.9 1,802.4	1.48 0.86 3.52	6.62 10.00 4.50	5.97 9.67 5.13	1.11 1.03 0.88
Ferric Carboxymaltose			_,_,	2,002	0.02		5.15	0.00
Female Male Unknown	0 0 0	0 0 0	24,756,626 23,830,329 2,275	20,438,864.3 19,459,428.9 1,802.4	0.00 0.00 0.00	 	 	
Ferric Gluconate	Ţ.		_,_,	2,002	0.00			
Female Male Unknown	4,452 2,405 3	28,229 18,055 13	24,756,626 23,830,329 2,275	20,438,864.3 19,459,428.9 1,802.4	0.18 0.10 1.32	7.07 7.98 4.33	6.34 7.51 4.33	1.11 1.06 1.00
Ferumoxytol			·					
Female Male Unknown	4,547 2,029 1	9,841 4,695 2	24,756,626 23,830,329 2,275	20,438,864.3 19,459,428.9 1,802.4	0.18 0.09 0.44	2.33 2.56 2.00	2.16 2.31 2.00	1.08 1.10 1.00
Iron Dextran			•					
Female Male Unknown	9,288 2,419 2	24,553 7,835 3	24,756,626 23,830,329 2,275	20,438,864.3 19,459,428.9 1,802.4	0.38 0.10 0.88	3.77 4.37 1.50	2.64 3.24 1.50	1.43 1.35 1.00
Iron Sucrose								
Female Male Unknown	19,613 14,531 2	155,600 167,355 23	24,756,626 23,830,329 2,275	20,438,864.3 19,459,428.9 1,802.4	0.79 0.61 0.88	8.40 11.70 9.00	7.93 11.52 11.50	1.06 1.02 0.78
2012								
Ferric Carboxymaltose		• • •	•					
Female Male Unknown	40,441 22,158 3	230,158 209,270 11	26,334,546 25,434,930 2,564	21,784,822.9 20,840,453.7 2,030.5	1.54 0.87 1.17	6.05 9.65 3.67	5.69 9.44 3.67	1.06 1.02 1.00
Ferric Carboxymaltose	9		•	· .				



Table 3: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
Female	0	0	26,334,546	21,784,822.9	0.00			
Male	0	0	25,434,930	20,840,453.7	0.00			
Unknown	0	0	2,564	2,030.5	0.00			
Ferric Gluconate	0	<u> </u>	2,304	2,030.3	0.00			
Female	4,997	33,554	26,334,546	21,784,822.9	0.19	6.93	6.71	1.03
Male	2,708	24,496	25,434,930	20,840,453.7	0.11	9.43	9.05	1.04
Unknown	2,700	10	2,564	2,030.5	0.78	5.00	5.00	1.00
Ferumoxytol	2	10	2,304	2,030.3	0.78	3.00	3.00	1.00
Female	5,751	12,571	26,334,546	21,784,822.9	0.22	2.28	2.19	1.04
Male	2,632	6,112	25,434,930	20,840,453.7	0.10	2.42	2.32	1.04
Unknown	0	0	2,564	2,030.5	0.00			
Iron Dextran	-	-			0.00			
Female	9,601	23,812	26,334,546	21,784,822.9	0.36	3.38	2.48	1.36
Male	2,533	7,819	25,434,930	20,840,453.7	0.10	4.35	3.09	1.41
Unknown	1	1	2,564	2,030.5	0.39	1.00	1.00	1.00
Iron Sucrose			,					
Female	21,367	160,221	26,334,546	21,784,822.9	0.81	7.70	7.50	1.03
Male	15,055	170,843	25,434,930	20,840,453.7	0.59	11.36	11.35	1.00
Unknown	0	0	2,564	2,030.5	0.00			
2013								
Ferric Carboxymalto	se, Ferric Glucor	ate, Ferumoxytol, I	Iron Dextran, I	ron Sucrose				
Female	41,446	223,518	26,342,361	21,657,213.8	1.57	5.71	5.39	1.06
Male	22,319	196,645	25,542,374	20,775,193.6	0.87	9.02	8.81	1.02
Unknown	5	21	2,349	1,711.7	2.13	4.20	4.20	1.00
Ferric Carboxymalto	se							
Female	0	0	26,342,361	21,657,213.8	0.00			
Male	0	0	25,542,374	20,775,193.6	0.00			
Unknown	0	0	2,349	1,711.7	0.00			
Ferric Gluconate								
Female	4,701	29,589	26,342,361	21,657,213.8	0.18	6.33	6.29	1.01



Table 3: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
Year Male	2,501	20,374			0.10	8.40		1.03
Unknown	2,501	20,374 6	25,542,374 2,349	20,775,193.6 1,711.7	0.10	3.00	8.15 3.00	1.00
Ferumoxytol		0	2,349	1,/11./	0.83	3.00	3.00	1.00
Female	6,650	14,710	26,342,361	21,657,213.8	0.25	2.33	2.21	1.06
Male	2,935	6,756		•	0.23	2.33	2.30	1.08
	•	•	25,542,374	20,775,193.6				
Unknown	1	4	2,349	1,711.7	0.43	4.00	4.00	1.00
Iron Dextran	0.400	22 170	26.242.264	24 657 242 0	0.26	2.20	2.26	4.40
Female	9,408	22,179	26,342,361	21,657,213.8	0.36	3.30	2.36	1.40
Male	2,468	7,390	25,542,374	20,775,193.6	0.10	4.07	2.99	1.36
Unknown	0	0	2,349	1,711.7	0.00			
Iron Sucrose								
Female	21,929	157,040	26,342,361	21,657,213.8	0.83	7.31	7.16	1.02
Male	15,185	162,125	25,542,374	20,775,193.6	0.59	10.74	10.68	1.01
Unknown	2	11	2,349	1,711.7	0.85	5.50	5.50	1.00
2014								
Ferric Carboxyma	ltose, Ferric Glucon	ate, Ferumoxytol,	lron Dextran, l	ron Sucrose				
Female	44,444	227,492	27,391,670	22,265,611.9	1.62	5.67	5.12	1.11
Male	23,080	200,961	26,609,808	21,397,051.7	0.87	9.02	8.71	1.04
Unknown	4	32	2,251	1,583.7	1.78	8.00	8.00	1.00
Ferric Carboxyma	ltose							
Female	11	14	27,391,670	22,265,611.9	0.00	15.82	1.27	12.43
Male	6	7	26,609,808	21,397,051.7	0.00	19.50	1.17	16.71
Unknown	0	0	2,251	1,583.7	0.00			
Ferric Gluconate								
Female	4,362	24,653	27,391,670	22,265,611.9	0.16	5.75	5.65	1.02
Male	2,259	17,357	26,609,808	21,397,051.7	0.08	7.79	7.68	1.01
Unknown	1	1	2,251	1,583.7	0.44	1.00	1.00	1.00
Ferumoxytol								
Female	8,008	17,299	27,391,670	22,265,611.9	0.29	2.29	2.16	1.06
Male	3,290	7,483	26,609,808	21,397,051.7	0.12	2.47	2.27	1.09



Table 3: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

Year Unknown	New Users	Dispensings/ Administrations 0	Eligible Members 2,251	Member-Years 1,583.7	New Users/1K Eligible Members 0.00	Days Supplied/User 	Dispensings/User	Days Supplied/Dispensing
Iron Dextran	-		, -	,,,,,,,				
Female	9,427	21,929	27,391,670	22,265,611.9	0.34	4.14	2.33	1.78
Male	2,524	7,218	26,609,808	21,397,051.7	0.09	4.80	2.86	1.68
Unknown	0	0	2,251	1,583.7	0.00			
Iron Sucrose								
Female	23,756	163,597	27,391,670	22,265,611.9	0.87	7.13	6.89	1.04
Male	15,557	168,896	26,609,808	21,397,051.7	0.58	10.94	10.86	1.01
Unknown	4	31	2,251	1,583.7	1.78	7.75	7.75	1.00
2015								
Ferric Carboxymalt	ose, Ferric Glucon	ate, Ferumoxytol, I	ron Dextran, Ir	on Sucrose				
Female	39,809	177,165	25,824,365	17,294,563.1	1.54	5.18	4.45	1.16
Male	19,892	146,216	25,281,057	16,743,782.1	0.79	7.74	7.35	1.05
Unknown	2	8	2,362	1,287.2	0.85	4.00	4.00	1.00
Ferric Carboxymalt	tose							
Female	4,477	8,629	25,824,365	17,294,563.1	0.17	1.98	1.93	1.03
Male	1,496	2,994	25,281,057	16,743,782.1	0.06	2.04	2.00	1.02
Unknown	1	4	2,362	1,287.2	0.42	4.00	4.00	1.00
Ferric Gluconate								
Female	3,224	16,272	25,824,365	17,294,563.1	0.12	5.08	5.05	1.01
Male	1,839	12,247	25,281,057	16,743,782.1	0.07	6.67	6.66	1.00
Unknown	0	0	2,362	1,287.2	0.00			
Ferumoxytol								
Female	5,960	12,262	25,824,365	17,294,563.1	0.23	2.26	2.06	1.10
Male	2,488	5,360	25,281,057	16,743,782.1	0.10	2.33	2.15	1.08
Unknown	0	0	2,362	1,287.2	0.00			
Iron Dextran								
Female	7,338	16,912	25,824,365	17,294,563.1	0.28	5.44	2.30	2.36
Male	2,115	5,989	25,281,057	16,743,782.1	0.08	5.84	2.83	2.06
Unknown	0	0	2,362	1,287.2	0.00			



Table 3: Use of Selected Drugs in the Sentinel Distributed Database (SDD) between January 1, 2011 and December 31, 2015, by Drug, Year, and Sex

					New Users/1K			
		Dispensings/	Eligible		Eligible	Days		Days
Year	New Users	Administrations	Members	Member-Years	Members	Supplied/User	Dispensings/User	Supplied/Dispensing
Iron Sucrose								
Female	19,839	123,090	25,824,365	17,294,563.1	0.77	6.42	6.20	1.03
Male	12,508	119,626	25,281,057	16,743,782.1	0.49	9.63	9.56	1.01
Unknown	1	4	2,362	1,287.2	0.42	4.00	4.00	1.00
2011-2015								
Ferric Carboxymalto	se, Ferric Glucor	nate, Ferumoxytol, I	ron Dextran, I	ron Sucrose				
Female	146,494	1,076,556	49,910,753	103,441,076.0	2.94	8.06	7.35	1.10
Male	70,952	951,032	48,906,968	99,215,910.0	1.45	13.84	13.40	1.03
Unknown	15	113	5,203	8,415.5	2.88	7.20	7.53	0.96
Ferric Carboxymalto	se							
Female	4,487	8,643	49,910,753	103,441,076.0	0.09	2.02	1.93	1.05
Male	1,501	3,001	48,906,968	99,215,910.0	0.03	2.11	2.00	1.05
Unknown	1	4	5,203	8,415.5	0.19	4.00	4.00	1.00
Ferric Gluconate								
Female	16,292	132,297	49,910,753	103,441,076.0	0.33	8.43	8.12	1.04
Male	8,196	92,529	48,906,968	99,215,910.0	0.17	11.66	11.29	1.03
Unknown	4	30	5,203	8,415.5	0.77	7.50	7.50	1.00
Ferumoxytol								
Female	25,036	66,683	49,910,753	103,441,076.0	0.50	2.84	2.66	1.06
Male	10,964	30,406	48,906,968	99,215,910.0	0.22	2.99	2.77	1.08
Unknown	2	6	5,203	8,415.5	0.38	3.00	3.00	1.00
Iron Dextran								
Female	36,245	109,385	49,910,753	103,441,076.0	0.73	4.90	3.02	1.62
Male	9,572	36,251	48,906,968	99,215,910.0	0.20	5.86	3.79	1.55
Unknown	2	4	5,203	8,415.5	0.38	2.00	2.00	1.00
Iron Sucrose								
Female	74,789	759,548	49,910,753	103,441,076.0	1.50	10.52	10.16	1.04
Male	45,823	788,845	48,906,968	99,215,910.0	0.94	17.34	17.22	1.01
Unknown	7	69	5,203	8,415.5	1.35	9.14	9.86	0.93



Appendix A: Start and End Dates of Available Data for Each Data Partner up to Request Date (August 10, 2016)

DP ID	Start Date	End Date
DP0001	1/1/2011	12/31/2014
DP0002	1/1/2011	6/30/2012
DP0003	1/1/2011	10/31/2015
DP0004	1/1/2011	12/31/2015
DP0005	1/1/2011	12/31/2015
DP0006	1/1/2011	6/30/2015
DP0007	1/1/2011	10/31/2015
DP0008	1/1/2011	9/30/2015
DP0009	1/1/2011	12/31/2015
DP0010	1/1/2011	12/31/2015
DP0011	1/1/2011	9/30/2015
DP0012	1/1/2011	12/31/2015
DP0013	1/1/2011	12/31/2015
DP0014	1/1/2011	5/31/2015
DP0015	1/1/2011	2/28/2015
DP0016	1/1/2012	6/30/2015



Appendix B: Healthcare Common Procedure Coding System (HCPCS) Codes used to Define Intravenous (IV) Iron Products of Interest in this Request

Code	Code Type
Ferumoxytol	
Q0138	HCPCS
Q0139	HCPCS
Ferric Carboxymaltose	
J1439	HCPCS
Iron Dextran	
J1750	HCPCS
J1751	HCPCS
J1752	HCPCS
J1760	HCPCS
J1770	HCPCS
J1780	HCPCS
Ferric Gluconate	
J2915	HCPCS
J2916	HCPCS
S0098	HCPCS
W0231	HCPCS
Iron Sucrose	
J1755	HCPCS
J1756	HCPCS



Appendix C: Specifications for Request ID: cder_mpl1r_wp020_nsdp_v02

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool were used to identify use of statins, angiotensin converting enzyme (ACE) inhibitors, beta blockers, intravenous (IV) iron, tumor necrosis factor (TNF) alpha inhibitors, and granulocyte colony stimulating factor (GCSF) drugs in the Sentinel Distributed Database. In total, 31 scenarios will be examined with 31 different exposures. This will be a Level 1 - Type 1 analysis looking at prevalent use of the drugs. Results are reported separately for each therapeutic class. Report 3 presents results on IV iron drugs.

Enrollment Gap: 45 days

Age Groups: 0-21, 22-44, 45-64, 65+ years

Query Period: All Years AND One year at a time: Jan 1, 2011 - Dec 31, 2015

Coverage Requirement Medical and Drug Coverage

Enrollment Requirement: 1 day

	Drug/Expos	Pre-Existing Condition	Event/Outcome			
Scenario	Exposure	Incident w/ respect to:	Washout (days)	II Cohort Definition	Pre-Existing Condition	II I Event/ Outcome
16	Ferumoxytol, Ferric Carboxymaltose, Iron Dextran, Ferric Gluconate, Iron Sucrose	NA	0	02	None	Dummy
17	Ferumoxytol	NA	0	02	None	Dummy
18	Ferric Carboxymaltose	NA	0	02	None	Dummy
19	Iron Dextran	NA	0	02	None	Dummy
20	Ferric Gluconate	NA	0	02	None	Dummy
21	Iron Sucrose	NA	0	02	None	Dummy

International Classification fo Diseases, Ninth Revision (ICD-9-CM), International Classification fo Diseases, Tenth Revision (ICD-10-CM) Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360. National Drug Codes (NCDs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

NOTE: Other scenarios can be viewed in the two other reports in this request.