

## 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 2 of 3)

**Request ID:** cder\_mpl1r\_wp020\_nsdp\_v02

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

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

**Data Source:** 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.

**Study Design:** 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 GC-SF drugs including, filgrastim, pegfilgrastim, and granulocyte macrophage colony-stimulating factor (GMC-SF). These were defined using National Drug Codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) Level II procedure codes. Please see Appendix

**Cohort Eligibility Criteria:** 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.

**Limitations:** Algorithms to define exposures and events are imperfect and, therefore, exposures and events may be misclassified.

**Notes:** 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@sentinelssystem.org](mailto:qf@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. 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.

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

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

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

**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**

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
<b>2011</b>								
<b>Filgrastim, Pegfilgrastim, granulocyte macrophage colony-stimulating factor (GMC-SF)</b>								
	49,951	270,227	48,589,230	39,900,095.6	1.03	14.39	5.41	2.66
<b>Filgrastim</b>								
	20,055	127,068	48,589,230	39,900,095.6	0.41	20.38	6.34	3.22
<b>GMC-SF</b>								
	1,459	19,207	48,589,230	39,900,095.6	0.03	24.07	13.16	1.83
<b>Pegfilgrastim</b>								
	34,054	123,952	48,589,230	39,900,095.6	0.70	8.08	3.64	2.22
<b>2012</b>								
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>								
	53,477	286,220	51,772,040	42,627,307.1	1.03	14.15	5.35	2.64
<b>Filgrastim</b>								
	21,362	138,600	51,772,040	42,627,307.1	0.41	21.01	6.49	3.24
<b>GMC-SF</b>								
	1,140	13,799	51,772,040	42,627,307.1	0.02	20.10	12.10	1.66
<b>Pegfilgrastim</b>								
	36,705	133,821	51,772,040	42,627,307.1	0.71	7.78	3.65	2.13
<b>2013</b>								
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>								
	50,440	262,522	51,887,084	42,434,119.2	0.97	13.48	5.20	2.59
<b>Filgrastim</b>								
	20,258	127,534	51,887,084	42,434,119.2	0.39	19.78	6.30	3.14
<b>GMC-SF</b>								
	875	10,513	51,887,084	42,434,119.2	0.02	16.33	12.01	1.36
<b>Pegfilgrastim</b>								
	34,310	124,475	51,887,084	42,434,119.2	0.66	7.74	3.63	2.13

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Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
<b>2014</b>								
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>								
	50,546	258,083	54,003,729	43,664,247.3	0.94	13.40	5.11	2.62
<b>Filgrastim</b>								
	20,136	126,033	54,003,729	43,664,247.3	0.37	18.43	6.26	2.94
<b>GMC-SF</b>								
	837	9,018	54,003,729	43,664,247.3	0.02	37.65	10.77	3.49
<b>Pegfilgrastim</b>								
	34,405	123,032	54,003,729	43,664,247.3	0.64	7.99	3.58	2.24
<b>2015</b>								
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>								
	40,246	195,204	51,107,784	34,039,632.4	0.79	12.98	4.85	2.68
<b>Filgrastim</b>								
	16,614	101,417	51,107,784	34,039,632.4	0.33	18.10	6.10	2.97
<b>GMC-SF</b>								
	604	6,082	51,107,784	34,039,632.4	0.01	32.52	10.07	3.23
<b>Pegfilgrastim</b>								
	26,408	87,705	51,107,784	34,039,632.4	0.52	7.65	3.32	2.30
<b>2011-2015</b>								
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>								
	198,091	1,272,256	98,822,924	202,665,401.5	2.00	16.94	6.42	2.64
<b>Filgrastim</b>								
	82,667	620,652	98,822,924	202,665,401.5	0.84	23.35	7.51	3.11
<b>GMC-SF</b>								
	4,126	58,619	98,822,924	202,665,401.5	0.04	29.92	14.21	2.11
<b>Pegfilgrastim</b>								
	137,280	592,985	98,822,924	202,665,401.5	1.39	9.49	4.32	2.20

**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	Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
					Eligible Members			
<b>2011</b>								
<b>Filgrastim, Pegfilgrastim, granulocyte macrophage colony-stimulating factor (GMC-SF)</b>								
0-21 Years	1,263	5,990	14,022,220	11,122,404.3	0.09	35.50	4.74	7.48
22-44 Years	6,388	30,752	17,218,140	12,950,289.1	0.37	17.29	4.81	3.59
45-64 Years	25,468	131,243	14,146,782	11,618,070.8	1.80	14.80	5.15	2.87
65+ Years	17,167	102,242	4,700,986	4,209,331.4	3.65	10.86	5.96	1.82
<b>Filgrastim</b>								
0-21 Years	898	4,149	14,022,220	11,122,404.3	0.06	35.96	4.62	7.78
22-44 Years	2,465	13,039	17,218,140	12,950,289.1	0.14	23.23	5.29	4.39
45-64 Years	9,909	57,507	14,146,782	11,618,070.8	0.70	21.11	5.80	3.64
65+ Years	6,896	52,373	4,700,986	4,209,331.4	1.47	15.95	7.59	2.10
<b>GMC-SF</b>								
0-21 Years	57	304	14,022,220	11,122,404.3	0.00	25.89	5.33	4.86
22-44 Years	121	1,204	17,218,140	12,950,289.1	0.01	25.57	9.95	2.57
45-64 Years	663	8,434	14,146,782	11,618,070.8	0.05	24.48	12.72	1.92
65+ Years	622	9,265	4,700,986	4,209,331.4	0.13	23.01	14.90	1.55
<b>Pegfilgrastim</b>								
0-21 Years	454	1,537	14,022,220	11,122,404.3	0.03	24.37	3.39	7.20
22-44 Years	4,490	16,509	17,218,140	12,950,289.1	0.26	11.16	3.68	3.04
45-64 Years	17,741	65,302	14,146,782	11,618,070.8	1.25	8.55	3.68	2.32
65+ Years	11,577	40,604	4,700,986	4,209,331.4	2.46	5.38	3.51	1.53
<b>2012</b>								
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>								
0-21 Years	1,232	5,626	14,597,079	11,577,381.5	0.08	34.66	4.57	7.59
22-44 Years	6,506	32,352	18,294,282	13,774,102.3	0.36	16.55	4.97	3.33
45-64 Years	26,687	135,331	15,176,829	12,454,017.2	1.76	15.30	5.07	3.02
65+ Years	19,458	112,911	5,375,933	4,821,806.1	3.62	10.19	5.80	1.76
<b>Filgrastim</b>								
0-21 Years	852	3,953	14,597,079	11,577,381.5	0.06	37.00	4.64	7.98
22-44 Years	2,592	14,161	18,294,282	13,774,102.3	0.14	21.87	5.46	4.00
45-64 Years	10,452	60,911	15,176,829	12,454,017.2	0.69	23.10	5.83	3.96
65+ Years	7,585	59,575	5,375,933	4,821,806.1	1.41	15.71	7.85	2.00

**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		Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
<b>GMC-SF</b>									
0-21 Years	35	108	14,597,079	11,577,381.5	0.00	19.46	3.09	6.31	
22-44 Years	103	1,313	18,294,282	13,774,102.3	0.01	28.45	12.75	2.23	
45-64 Years	512	6,214	15,176,829	12,454,017.2	0.03	20.96	12.14	1.73	
65+ Years	501	6,164	5,375,933	4,821,806.1	0.09	17.11	12.30	1.39	
<b>Pegfilgrastim</b>									
0-21 Years	453	1,565	14,597,079	11,577,381.5	0.03	23.19	3.45	6.71	
22-44 Years	4,538	16,878	18,294,282	13,774,102.3	0.25	10.60	3.72	2.85	
45-64 Years	18,522	68,206	15,176,829	12,454,017.2	1.22	8.43	3.68	2.29	
65+ Years	13,457	47,172	5,375,933	4,821,806.1	2.50	5.25	3.51	1.50	
<b>2013</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
00-21 Years	1,160	5,689	14,412,691	11,338,825.4	0.08	37.27	4.90	7.60	
22-44 Years	5,991	27,960	18,447,587	13,757,283.4	0.32	15.83	4.67	3.39	
45-64 Years	24,735	121,463	15,140,652	12,387,536.5	1.63	14.10	4.91	2.87	
65+ Years	18,897	107,410	5,518,558	4,950,473.9	3.42	10.23	5.68	1.80	
<b>Filgrastim</b>									
0-21 Years	772	3,749	14,412,691	11,338,825.4	0.05	35.76	4.86	7.36	
22-44 Years	2,457	12,127	18,447,587	13,757,283.4	0.13	21.40	4.94	4.34	
45-64 Years	9,526	54,095	15,140,652	12,387,536.5	0.63	21.09	5.68	3.71	
65+ Years	7,604	57,563	5,518,558	4,950,473.9	1.38	15.72	7.57	2.08	
<b>GMC-SF</b>									
0-21 Years	34	240	14,412,691	11,338,825.4	0.00	15.03	7.06	2.13	
22-44 Years	70	842	18,447,587	13,757,283.4	0.00	18.74	12.03	1.56	
45-64 Years	380	4,079	15,140,652	12,387,536.5	0.03	15.68	10.73	1.46	
65+ Years	396	5,352	5,518,558	4,950,473.9	0.07	16.43	13.52	1.22	
<b>Pegfilgrastim</b>									
0-21 Years	473	1,700	14,412,691	11,338,825.4	0.03	31.96	3.59	8.89	
22-44 Years	4,085	14,991	18,447,587	13,757,283.4	0.22	10.04	3.67	2.73	
45-64 Years	17,255	63,289	15,140,652	12,387,536.5	1.14	8.23	3.67	2.24	
65+ Years	12,724	44,495	5,518,558	4,950,473.9	2.31	5.29	3.50	1.51	

**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		Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
					Eligible Members	Eligible Members			
<b>2014</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
0-21 Years	1,141	5,553	14,380,620	11,259,150.4	0.08	38.11	4.87	7.83	
22-44 Years	6,016	27,930	19,348,669	14,229,089.4	0.31	16.62	4.64	3.58	
45-64 Years	24,328	115,404	15,956,648	12,787,729.3	1.52	13.53	4.74	2.85	
65+ Years	19,385	109,196	6,031,519	5,388,278.2	3.21	10.56	5.63	1.88	
<b>Filgrastim</b>									
0-21 Years	689	3,101	14,380,620	11,259,150.4	0.05	36.40	4.50	8.09	
22-44 Years	2,381	11,866	19,348,669	14,229,089.4	0.12	21.52	4.98	4.32	
45-64 Years	9,238	50,305	15,956,648	12,787,729.3	0.58	18.69	5.45	3.43	
65+ Years	7,928	60,761	6,031,519	5,388,278.2	1.31	15.40	7.66	2.01	
<b>GMC-SF</b>									
0-21 Years	75	590	14,380,620	11,259,150.4	0.01	32.45	7.87	4.13	
22-44 Years	77	992	19,348,669	14,229,089.4	0.00	49.86	12.88	3.87	
45-64 Years	338	3,648	15,956,648	12,787,729.3	0.02	44.41	10.79	4.11	
65+ Years	356	3,788	6,031,519	5,388,278.2	0.06	28.73	10.64	2.70	
<b>Pegfilgrastim</b>									
00-21 Years	511	1,862	14,380,620	11,259,150.4	0.04	31.27	3.64	8.58	
22-44 Years	4,157	15,072	19,348,669	14,229,089.4	0.21	10.80	3.63	2.98	
45-64 Years	17,070	61,451	15,956,648	12,787,729.3	1.07	8.29	3.60	2.30	
65+ Years	12,873	44,647	6,031,519	5,388,278.2	2.13	5.64	3.47	1.63	
<b>2015</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
0-21 Years	904	3,986	12,636,192	8,084,251.4	0.07	36.19	4.41	8.21	
22-44 Years	4,475	19,039	18,297,759	11,147,068.0	0.24	15.91	4.25	3.74	
45-64 Years	18,763	84,723	15,382,119	10,150,975.7	1.22	13.27	4.52	2.94	
65+ Years	16,329	87,456	6,148,311	4,657,337.2	2.66	10.37	5.36	1.94	
<b>Filgrastim</b>									
0-21 Years	562	2,559	12,636,192	8,084,251.4	0.04	35.59	4.55	7.82	
22-44 Years	1,906	8,808	18,297,759	11,147,068.0	0.10	20.22	4.62	4.38	
45-64 Years	7,523	40,235	15,382,119	10,150,975.7	0.49	18.42	5.35	3.44	
65+ Years	6,708	49,815	6,148,311	4,657,337.2	1.09	15.45	7.43	2.08	

**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		Days Supplied/User	Dispensings/User	Days Supplied/Dispensing
					Eligible Members	Eligible Members			
<b>GMC-SF</b>									
0-21 Years	50	208	12,636,192	8,084,251.4	0.00	32.36	4.16	7.78	
22-44 Years	42	415	18,297,759	11,147,068.0	0.00	48.17	9.88	4.87	
45-64 Years	226	2,438	15,382,119	10,150,975.7	0.01	39.72	10.79	3.68	
65+ Years	288	3,021	6,148,311	4,657,337.2	0.05	24.39	10.49	2.33	
<b>Pegfilgrastim</b>									
0-21 Years	378	1,219	12,636,192	8,084,251.4	0.03	29.36	3.22	9.11	
22-44 Years	2,937	9,816	18,297,759	11,147,068.0	0.16	10.43	3.34	3.12	
45-64 Years	12,596	42,050	15,382,119	10,150,975.7	0.82	8.06	3.34	2.41	
65+ Years	10,631	34,620	6,148,311	4,657,337.2	1.73	5.52	3.26	1.70	
<b>2011-2015</b>									
<b>Filgrastim, GM-CSF, Pegfilgrastim</b>									
0-21 Years	4,415	26,844	28,228,305	53,382,013.0	0.16	46.88	6.08	7.71	
22-44 Years	24,648	138,033	39,787,392	65,857,832.2	0.62	19.64	5.60	3.51	
45-64 Years	98,113	588,164	29,461,166	59,398,329.6	3.33	17.45	5.99	2.91	
65+ Years	73,156	519,215	9,554,903	24,027,226.8	7.66	13.01	7.10	1.83	
<b>Filgrastim</b>									
0-21 Years	3,035	17,511	28,228,305	53,382,013.0	0.11	44.98	5.77	7.80	
22-44 Years	10,237	60,001	39,787,392	65,857,832.2	0.26	25.04	5.86	4.27	
45-64 Years	39,520	263,053	29,461,166	59,398,329.6	1.34	24.36	6.66	3.66	
65+ Years	30,648	280,087	9,554,903	24,027,226.8	3.21	18.74	9.14	2.05	
<b>GMC-SF</b>									
0-21 Years	209	1,450	28,228,305	53,382,013.0	0.01	32.15	6.94	4.63	
22-44 Years	350	4,766	39,787,392	65,857,832.2	0.01	37.71	13.62	2.77	
45-64 Years	1,778	24,813	29,461,166	59,398,329.6	0.06	32.01	13.96	2.29	
65+ Years	1,829	27,590	9,554,903	24,027,226.8	0.19	25.50	15.08	1.69	
<b>Pegfilgrastim</b>									
0-21 Years	1,817	7,883	28,228,305	53,382,013.0	0.06	35.09	4.34	8.09	
22-44 Years	17,240	73,266	39,787,392	65,857,832.2	0.43	12.46	4.25	2.93	
45-64 Years	69,404	300,298	29,461,166	59,398,329.6	2.36	9.98	4.33	2.31	
65+ Years	50,166	211,538	9,554,903	24,027,226.8	5.25	6.61	4.22	1.57	

**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		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Eligible Members			
<b>2011</b>									
<b>Filgrastim, Pegfilgrastim, granulocyte macrophage colony-stimulating factor (GMC-SF)</b>									
Female	31,503	169,285	24,756,626	20,438,864.3	1.27	14.35	5.37	2.67	
Male	18,447	100,937	23,830,329	19,459,428.9	0.77	14.46	5.47	2.64	
Unknown	1	5	2,275	1,802.4	0.44	5.00	5.00	1.00	
<b>Filgrastim</b>									
Female	11,897	75,812	24,756,626	20,438,864.3	0.48	20.75	6.37	3.26	
Male	8,158	51,256	23,830,329	19,459,428.9	0.34	19.84	6.28	3.16	
Unknown	0	0	2,275	1,802.4	0.00	---	---	---	
<b>GMC-SF</b>									
Female	781	11,141	24,756,626	20,438,864.3	0.03	19.78	14.27	1.39	
Male	678	8,066	23,830,329	19,459,428.9	0.03	29.01	11.90	2.44	
Unknown	0	0	2,275	1,802.4	0.00	---	---	---	
<b>Pegfilgrastim</b>									
Female	22,285	82,332	24,756,626	20,438,864.3	0.90	8.52	3.69	2.31	
Male	11,768	41,615	23,830,329	19,459,428.9	0.49	7.26	3.54	2.05	
Unknown	1	5	2,275	1,802.4	0.44	5.00	5.00	1.00	
<b>2012</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
Female	33,646	178,620	26,334,546	21,784,822.9	1.28	14.00	5.31	2.64	
Male	19,828	107,585	25,434,930	20,840,453.7	0.78	14.42	5.43	2.66	
Unknown	3	15	2,564	2,030.5	1.17	5.00	5.00	1.00	
<b>Filgrastim</b>									
Female	12,618	82,077	26,334,546	21,784,822.9	0.48	21.04	6.50	3.23	
Male	8,744	56,523	25,434,930	20,840,453.7	0.34	20.98	6.46	3.24	
Unknown	0	0	2,564	2,030.5	0.00	---	---	---	
<b>GMC-SF</b>									
Female	610	7,820	26,334,546	21,784,822.9	0.02	16.84	12.82	1.31	
Male	530	5,979	25,434,930	20,840,453.7	0.02	23.85	11.28	2.11	
Unknown	0	0	2,564	2,030.5	0.00	---	---	---	
<b>Pegfilgrastim</b>									

**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		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Eligible Members			
Female	23,937	88,723	26,334,546	21,784,822.9	0.91	0.91	8.16	3.71	2.20
Male	12,765	45,083	25,434,930	20,840,453.7	0.50	0.50	7.05	3.53	2.00
Unknown	3	15	2,564	2,030.5	1.17	1.17	5.00	5.00	1.00
<b>2013</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
Female	31,818	163,588	26,342,361	21,657,213.8	1.21	1.21	13.51	5.14	2.63
Male	18,618	98,908	25,542,374	20,775,193.6	0.73	0.73	13.44	5.31	2.53
Unknown	4	26	2,349	1,711.7	1.70	1.70	6.50	6.50	1.00
<b>Filgrastim</b>									
Female	12,044	75,390	26,342,361	21,657,213.8	0.46	0.46	20.24	6.26	3.23
Male	8,211	52,129	25,542,374	20,775,193.6	0.32	0.32	19.11	6.35	3.01
Unknown	3	15	2,349	1,711.7	1.28	1.28	5.00	5.00	1.00
<b>GMC-SF</b>									
Female	459	6,067	26,342,361	21,657,213.8	0.02	0.02	15.62	13.22	1.18
Male	416	4,446	25,542,374	20,775,193.6	0.02	0.02	17.11	10.69	1.60
Unknown	0	0	2,349	1,711.7	0.00	0.00	---	---	---
<b>Pegfilgrastim</b>									
Female	22,386	82,131	26,342,361	21,657,213.8	0.85	0.85	8.00	3.67	2.18
Male	11,921	42,333	25,542,374	20,775,193.6	0.47	0.47	7.25	3.55	2.04
Unknown	3	11	2,349	1,711.7	1.28	1.28	3.67	3.67	1.00
<b>2014</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
Female	32,238	162,877	27,391,670	22,265,611.9	1.18	1.18	13.34	5.05	2.64
Male	18,301	95,165	26,609,808	21,397,051.7	0.69	0.69	13.51	5.20	2.60
Unknown	7	41	2,251	1,583.7	3.11	3.11	25.29	5.86	4.32
<b>Filgrastim</b>									
Female	12,122	76,251	27,391,670	22,265,611.9	0.44	0.44	19.38	6.29	3.08
Male	8,012	49,777	26,609,808	21,397,051.7	0.30	0.30	16.99	6.21	2.74
Unknown	2	5	2,251	1,583.7	0.89	0.89	20.50	2.50	8.20
<b>GMC-SF</b>									

**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		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Eligible Members			
Female	390	4,481	27,391,670	22,265,611.9	0.01	0.01	25.48	11.49	2.22
Male	447	4,537	26,609,808	21,397,051.7	0.02	0.02	48.26	10.15	4.75
Unknown	0	0	2,251	1,583.7	0.00	0.00	---	---	---
<b>Pegfilgrastim</b>									
Female	22,789	82,145	27,391,670	22,265,611.9	0.83	0.83	8.13	3.60	2.26
Male	11,610	40,851	26,609,808	21,397,051.7	0.44	0.44	7.71	3.52	2.19
Unknown	6	36	2,251	1,583.7	2.67	2.67	22.67	6.00	3.78
<b>2015</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
Female	25,545	123,193	25,824,365	17,294,563.1	0.99	0.99	13.20	4.82	2.74
Male	14,695	72,000	25,281,057	16,743,782.1	0.58	0.58	12.58	4.90	2.57
Unknown	6	11	2,362	1,287.2	2.54	2.54	1.83	1.83	1.00
<b>Filgrastim</b>									
Female	10,168	62,502	25,824,365	17,294,563.1	0.39	0.39	19.37	6.15	3.15
Male	6,445	38,914	25,281,057	16,743,782.1	0.25	0.25	16.10	6.04	2.67
Unknown	1	1	2,362	1,287.2	0.42	0.42	1.00	1.00	1.00
<b>GMC-SF</b>									
Female	283	3,214	25,824,365	17,294,563.1	0.01	0.01	22.04	11.36	1.94
Male	321	2,868	25,281,057	16,743,782.1	0.01	0.01	41.76	8.93	4.67
Unknown	0	0	2,362	1,287.2	0.00	0.00	---	---	---
<b>Pegfilgrastim</b>									
Female	17,232	57,477	25,824,365	17,294,563.1	0.67	0.67	7.78	3.34	2.33
Male	9,171	30,218	25,281,057	16,743,782.1	0.36	0.36	7.39	3.29	2.24
Unknown	5	10	2,362	1,287.2	2.12	2.12	2.00	2.00	1.00
<b>2011-2015</b>									
<b>Filgrastim, GMC-SF, Pegfilgrastim</b>									
Female	125,720	797,563	49,910,753	103,441,076.0	2.52	2.52	16.86	6.34	2.66
Male	72,357	474,595	48,906,968	99,215,910.0	1.48	1.48	17.07	6.56	2.60
Unknown	14	98	5,203	8,415.5	2.69	2.69	16.71	7.00	2.39
<b>Filgrastim</b>									

**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		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members				
Female	49,265	372,032	49,910,753	103,441,076.0	0.99		24.12	7.55	3.19
Male	33,397	248,599	48,906,968	99,215,910.0	0.68		22.22	7.44	2.98
Unknown	5	21	5,203	8,415.5	0.96		11.40	4.20	2.71
<b>GMC-SF</b>									
Female	2,158	32,723	49,910,753	103,441,076.0	0.04		22.73	15.16	1.50
Male	1,968	25,896	48,906,968	99,215,910.0	0.04		37.81	13.16	2.87
Unknown	0	0	5,203	8,415.5	0.00		---	---	---
<b>Pegfilgrastim</b>									
Female	90,447	392,808	49,910,753	103,441,076.0	1.81		9.77	4.34	2.25
Male	46,822	200,100	48,906,968	99,215,910.0	0.96		8.95	4.27	2.09
Unknown	11	77	5,203	8,415.5	2.11		16.09	7.00	2.30



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

<b>DP ID</b>	<b>Start Date</b>	<b>End Date</b>
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 Identify Granulocyte Colony-Stimulating Factor (GCSF) Products of Interest in this Request**

<b>Code</b>	<b>Code Type</b>
<b>Filgrastim</b>	
J1440	HCPCS
J1441	HCPCS
J1442	HCPCS
J1446	HCPCS
J1447	HCPCS
Q5101	HCPCS
<b>Pegfilgrastim</b>	
C9119	HCPCS
J2505	HCPCS
Q4053	HCPCS
S0135	HCPCS
<b>GMCSF</b>	
J2820	HCPCS

**Appendix C: Specifications for Request ID: cder\_mpl1r\_wp020\_nsdp\_v02**

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool was 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 (GC-SF) drugs in the Sentinel Distributed Database (SDD). In total, 31 scenarios were examined with 31 different exposures. This was a Level 1 - Type 1 analysis looking at prevalent use of the drugs. Results were reported separately for each therapeutic class. Report 2 presents results on GC-SF 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

Scenario	Drug/Exposure			Pre-Existing Condition	Event/Outcome	
	Exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Pre-Existing Condition	Event/ Outcome
28	Filgrastim, Pegfilgrastim, GMC-SF	NA	0	02	None	Dummy
29	Filgrastim	NA	0	02	None	Dummy
30	Pegfilgrastim	NA	0	02	None	Dummy
31	GMC-SF	NA	0	02	None	Dummy

International Classification of Diseases, Ninth Revision (ICD-9-CM), International Classification of 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 (NDCs) 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.