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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 1 of 3)

Request ID: cder_mpl1r_wp020_nsdp_v02

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

Exposure of Interest: The exposure of interest was use of TNF alpha inhibitor drugs, including adalimumab, certolizumab, etanercept, golimumab, and infliximab. 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.

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

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) 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 condition

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

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.

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 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 the occurrence of the incident query code.

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/U ser	Days Supplied/Dispensing
2011								
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab								
	116,946	750,851	48,589,230	39,900,095.6	2.41	158.68	6.42	24.71
Adalimumab								
	41,325	261,295	48,589,230	39,900,095.6	0.85	191.21	6.32	30.24
Certolizumab								
	4,004	23,810	48,589,230	39,900,095.6	0.08	150.95	5.95	25.39
Etanercept								
	46,201	295,367	48,589,230	39,900,095.6	0.95	195.15	6.39	30.53
Golimumab								
	3,466	19,018	48,589,230	39,900,095.6	0.07	173.48	5.49	31.62
Infliximab								
	28,719	151,361	48,589,230	39,900,095.6	0.59	15.08	5.27	2.86
2012								
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab								
	130,232	843,469	51,772,040	42,627,307.1	2.52	159.57	6.48	24.64
Adalimumab								
	46,394	299,253	51,772,040	42,627,307.1	0.90	193.74	6.45	30.04
Certolizumab								
	5,167	30,838	51,772,040	42,627,307.1	0.10	152.77	5.97	25.60
Etanercept								
	50,614	324,083	51,772,040	42,627,307.1	0.98	194.08	6.40	30.31
Golimumab								
	4,058	23,108	51,772,040	42,627,307.1	0.08	180.97	5.69	31.78
Infliximab								
	31,346	166,187	51,772,040	42,627,307.1	0.61	14.22	5.30	2.68

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2013								
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab								
	134,520	876,726	51,887,084	42,434,119.2	2.59	160.67	6.52	24.65
Adalimumab								
	49,554	316,436	51,887,084	42,434,119.2	0.96	191.37	6.39	29.97
Certolizumab								
	6,068	36,413	51,887,084	42,434,119.2	0.12	152.75	6.00	25.45
Etanercept								
	50,964	330,700	51,887,084	42,434,119.2	0.98	194.79	6.49	30.02
Golimumab								
	4,703	26,874	51,887,084	42,434,119.2	0.09	178.78	5.71	31.29
Infliximab								
	31,200	166,303	51,887,084	42,434,119.2	0.60	13.96	5.33	2.62
2014								
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab								
	142,674	908,338	54,003,729	43,664,247.3	2.64	158.22	6.37	24.85
Adalimumab								
	55,075	344,893	54,003,729	43,664,247.3	1.02	189.41	6.26	30.25
Certolizumab								
	7,141	41,111	54,003,729	43,664,247.3	0.13	147.54	5.76	25.63
Etanercept								
	50,736	324,043	54,003,729	43,664,247.3	0.94	191.72	6.39	30.02
Golimumab								
	5,954	32,155	54,003,729	43,664,247.3	0.11	155.79	5.40	28.85
Infliximab								
	31,919	166,136	54,003,729	43,664,247.3	0.59	13.59	5.20	2.61

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Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K Eligible Members	Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
2015								
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab								
	135,138	744,670	51,107,784	34,039,632.4	2.64	127.59	5.51	23.15
Adalimumab								
	58,483	321,379	51,107,784	34,039,632.4	1.14	152.29	5.50	27.71
Certolizumab								
	6,764	34,606	51,107,784	34,039,632.4	0.13	119.31	5.12	23.32
Etanercept								
	41,899	233,890	51,107,784	34,039,632.4	0.82	155.56	5.58	27.87
Golimumab								
	5,482	27,151	51,107,784	34,039,632.4	0.11	124.36	4.95	25.11
Infliximab								
	28,688	127,644	51,107,784	34,039,632.4	0.56	11.48	4.45	2.58
2011-2015								
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab								
	297,208	4,124,054	98,822,924	202,665,401.5	3.01	339.05	13.88	24.43
Adalimumab								
	130,248	1,543,256	98,822,924	202,665,401.5	1.32	350.96	11.85	29.62
Certolizumab								
	17,153	166,778	98,822,924	202,665,401.5	0.17	243.77	9.72	25.07
Etanercept								
	112,495	1,508,083	98,822,924	202,665,401.5	1.14	400.12	13.41	29.85
Golimumab								
	13,775	128,306	98,822,924	202,665,401.5	0.14	274.83	9.31	29.51
Infliximab								
	70,773	777,631	98,822,924	202,665,401.5	0.72	29.36	10.99	2.67

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			
2011									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
0-21 Years	6,243	34,667	14,022,220	11,122,404.3	0.45	113.94	5.55	20.52	
22-44 Years	40,082	231,272	17,218,140	12,950,289.1	2.33	140.76	5.77	24.40	
45-64 Years	60,094	395,937	14,146,782	11,618,070.8	4.25	171.45	6.59	26.02	
65+ Years	13,468	88,975	4,700,986	4,209,331.4	2.86	141.12	6.61	21.36	
Adalimumab									
0-21 Years	2,142	12,369	14,022,220	11,122,404.3	0.15	168.78	5.77	29.23	
22-44 Years	15,883	91,496	17,218,140	12,950,289.1	0.92	172.01	5.76	29.86	
45-64 Years	20,989	135,092	14,146,782	11,618,070.8	1.48	196.80	6.44	30.58	
65+ Years	3,276	22,338	4,700,986	4,209,331.4	0.70	206.75	6.82	30.32	
Certolizumab									
0-21 Years	202	1,133	14,022,220	11,122,404.3	0.01	147.50	5.61	26.30	
22-44 Years	1,706	9,779	17,218,140	12,950,289.1	0.10	149.32	5.73	26.05	
45-64 Years	1,845	11,038	14,146,782	11,618,070.8	0.13	154.94	5.98	25.90	
65+ Years	328	1,860	4,700,986	4,209,331.4	0.07	103.74	5.67	18.29	
Etanercept									
00-21 Years	1,792	9,591	14,022,220	11,122,404.3	0.13	158.85	5.35	29.68	
22-44 Years	14,146	77,372	17,218,140	12,950,289.1	0.82	165.88	5.47	30.33	
45-64 Years	26,470	173,125	14,146,782	11,618,070.8	1.87	200.72	6.54	30.69	
65+ Years	4,944	35,279	4,700,986	4,209,331.4	1.05	216.85	7.14	30.39	
Golimumab									
0-21 Years	74	356	14,022,220	11,122,404.3	0.01	145.11	4.81	30.16	
22-44 Years	1,082	5,424	17,218,140	12,950,289.1	0.06	156.72	5.01	31.26	
45-64 Years	2,138	11,909	14,146,782	11,618,070.8	0.15	176.74	5.57	31.73	
65+ Years	243	1,329	4,700,986	4,209,331.4	0.05	177.44	5.47	32.44	
Infliximab									
0-21 Years	2,404	11,218	14,022,220	11,122,404.3	0.17	10.24	4.67	2.19	
22-44 Years	9,607	47,201	17,218,140	12,950,289.1	0.56	14.48	4.91	2.95	
45-64 Years	12,157	64,773	14,146,782	11,618,070.8	0.86	16.07	5.33	3.02	
65+ Years	5,190	28,169	4,700,986	4,209,331.4	1.10	14.27	5.43	2.63	

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			
2012									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
0-21 Years	7,306	41,437	14,597,079	11,577,381.5	0.50	114.49	5.67	20.19	
22-44 Years	44,212	258,008	18,294,282	13,774,102.3	2.42	141.58	5.84	24.26	
45-64 Years	66,402	439,833	15,176,829	12,454,017.2	4.38	172.37	6.62	26.02	
65+ Years	15,720	104,191	5,375,933	4,821,806.1	2.92	142.45	6.63	21.49	
Adalimumab									
0-21 Years	2,490	15,160	14,597,079	11,577,381.5	0.17	178.20	6.09	29.27	
22-44 Years	17,646	103,814	18,294,282	13,774,102.3	0.96	174.92	5.88	29.73	
45-64 Years	23,424	153,392	15,176,829	12,454,017.2	1.54	198.38	6.55	30.29	
65+ Years	3,903	26,887	5,375,933	4,821,806.1	0.73	207.90	6.89	30.18	
Certolizumab									
0-21 Years	254	1,366	14,597,079	11,577,381.5	0.02	145.50	5.38	27.05	
22-44 Years	2,138	12,261	18,294,282	13,774,102.3	0.12	153.00	5.73	26.68	
45-64 Years	2,427	14,523	15,176,829	12,454,017.2	0.16	157.00	5.98	26.24	
65+ Years	458	2,688	5,375,933	4,821,806.1	0.09	96.61	5.87	16.46	
Etanercept									
0-21 Years	2,025	10,727	14,597,079	11,577,381.5	0.14	156.89	5.30	29.62	
22-44 Years	15,011	83,606	18,294,282	13,774,102.3	0.82	165.98	5.57	29.80	
45-64 Years	29,033	188,849	15,176,829	12,454,017.2	1.91	198.41	6.50	30.50	
65+ Years	5,848	40,901	5,375,933	4,821,806.1	1.09	214.30	6.99	30.64	
Golimumab									
0-21 Years	89	398	14,597,079	11,577,381.5	0.01	140.94	4.47	31.52	
22-44 Years	1,275	6,711	18,294,282	13,774,102.3	0.07	163.91	5.26	31.14	
45-64 Years	2,508	14,419	15,176,829	12,454,017.2	0.17	183.66	5.75	31.95	
65+ Years	276	1,580	5,375,933	4,821,806.1	0.05	189.21	5.72	33.05	
Infliximab									
0-21 Years	2,887	13,786	14,597,079	11,577,381.5	0.20	8.85	4.78	1.85	
22-44 Years	10,597	51,616	18,294,282	13,774,102.3	0.58	13.73	4.87	2.82	
45-64 Years	12,798	68,650	15,176,829	12,454,017.2	0.84	15.36	5.36	2.86	
65+ Years	5,854	32,135	5,375,933	4,821,806.1	1.09	13.35	5.49	2.43	

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			
2013									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
0-21 Years	7,632	43,742	14,412,691	11,338,825.4	0.53	115.39	5.73	20.13	
22-44 Years	45,760	267,669	18,447,587	13,757,283.4	2.48	142.32	5.85	24.33	
45-64 Years	68,408	456,477	15,140,652	12,387,536.5	4.52	173.24	6.67	25.96	
65+ Years	16,203	108,838	5,518,558	4,950,473.9	2.94	146.24	6.72	21.77	
Adalimumab									
0-21 Years	2,795	16,736	14,412,691	11,338,825.4	0.19	175.64	5.99	29.33	
22-44 Years	18,964	110,174	18,447,587	13,757,283.4	1.03	172.90	5.81	29.76	
45-64 Years	24,686	159,493	15,140,652	12,387,536.5	1.63	195.09	6.46	30.20	
65+ Years	4,319	30,033	5,518,558	4,950,473.9	0.78	207.81	6.95	29.89	
Certolizumab									
0-21 Years	240	1,342	14,412,691	11,338,825.4	0.02	150.05	5.59	26.84	
22-44 Years	2,490	14,060	18,447,587	13,757,283.4	0.13	152.87	5.65	27.07	
45-64 Years	2,874	17,479	15,140,652	12,387,536.5	0.19	159.23	6.08	26.18	
65+ Years	575	3,532	5,518,558	4,950,473.9	0.10	91.48	6.14	14.89	
Etanercept									
0-21 Years	1,987	10,884	14,412,691	11,338,825.4	0.14	159.47	5.48	29.11	
22-44 Years	14,877	83,308	18,447,587	13,757,283.4	0.81	165.92	5.60	29.63	
45-64 Years	29,381	194,298	15,140,652	12,387,536.5	1.94	199.43	6.61	30.16	
65+ Years	5,971	42,210	5,518,558	4,950,473.9	1.08	214.80	7.07	30.39	
Golimumab									
0-21 Years	105	449	14,412,691	11,338,825.4	0.01	132.65	4.28	31.02	
22-44 Years	1,539	7,845	18,447,587	13,757,283.4	0.08	157.08	5.10	30.81	
45-64 Years	2,807	16,696	15,140,652	12,387,536.5	0.19	187.16	5.95	31.47	
65+ Years	332	1,884	5,518,558	4,950,473.9	0.06	180.04	5.67	31.73	
Infliximab									
0-21 Years	2,967	14,331	14,412,691	11,338,825.4	0.21	7.72	4.83	1.60	
22-44 Years	10,663	52,282	18,447,587	13,757,283.4	0.58	13.41	4.90	2.74	
45-64 Years	12,680	68,511	15,140,652	12,387,536.5	0.84	15.20	5.40	2.81	
65+ Years	5,663	31,179	5,518,558	4,950,473.9	1.03	13.60	5.51	2.47	



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			
2014									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
0-21 Years	8,091	45,999	14,380,620	11,259,150.4	0.56	114.00	5.69	20.05	
22-44 Years	48,381	276,846	19,348,669	14,229,089.4	2.50	140.44	5.72	24.54	
45-64 Years	71,498	463,892	15,956,648	12,787,729.3	4.48	169.95	6.49	26.19	
65+ Years	18,137	121,601	6,031,519	5,388,278.2	3.01	149.18	6.70	22.25	
Adalimumab									
0-21 Years	3,083	18,135	14,380,620	11,259,150.4	0.21	174.79	5.88	29.71	
22-44 Years	21,049	120,336	19,348,669	14,229,089.4	1.09	172.01	5.72	30.09	
45-64 Years	27,103	170,994	15,956,648	12,787,729.3	1.70	192.14	6.31	30.46	
65+ Years	5,084	35,428	6,031,519	5,388,278.2	0.84	209.38	6.97	30.05	
Certolizumab									
0-21 Years	250	1,172	14,380,620	11,259,150.4	0.02	129.56	4.69	27.64	
22-44 Years	2,883	15,744	19,348,669	14,229,089.4	0.15	150.53	5.46	27.57	
45-64 Years	3,401	19,612	15,956,648	12,787,729.3	0.21	153.88	5.77	26.68	
65+ Years	715	4,583	6,031,519	5,388,278.2	0.12	89.37	6.41	13.94	
Etanercept									
0-21 Years	1,911	10,559	14,380,620	11,259,150.4	0.13	159.60	5.53	28.88	
22-44 Years	14,183	77,704	19,348,669	14,229,089.4	0.73	162.56	5.48	29.67	
45-64 Years	29,205	188,965	15,956,648	12,787,729.3	1.83	194.86	6.47	30.12	
65+ Years	6,626	46,815	6,031,519	5,388,278.2	1.10	215.15	7.07	30.45	
Golimumab									
0-21 Years	163	676	14,380,620	11,259,150.4	0.01	118.14	4.15	28.49	
22-44 Years	2,001	10,051	19,348,669	14,229,089.4	0.10	147.71	5.02	29.41	
45-64 Years	3,274	18,120	15,956,648	12,787,729.3	0.21	162.98	5.53	29.45	
65+ Years	632	3,308	6,031,519	5,388,278.2	0.10	125.21	5.23	23.92	
Infliximab									
0-21 Years	3,191	15,457	14,380,620	11,259,150.4	0.22	8.43	4.84	1.74	
22-44 Years	11,066	53,011	19,348,669	14,229,089.4	0.57	12.56	4.79	2.62	
45-64 Years	12,634	66,201	15,956,648	12,787,729.3	0.79	15.45	5.24	2.95	
65+ Years	5,764	31,467	6,031,519	5,388,278.2	0.96	12.60	5.46	2.31	

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			
2015									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
0-21 Years	7,490	37,060	12,636,192	8,084,251.4	0.59	94.67	4.95	19.13	
22-44 Years	45,617	228,580	18,297,759	11,147,068.0	2.49	115.14	5.01	22.98	
45-64 Years	67,825	378,902	15,382,119	10,150,975.7	4.41	135.98	5.59	24.34	
65+ Years	16,872	100,128	6,148,311	4,657,337.2	2.74	121.94	5.93	20.55	
Adalimumab									
0-21 Years	3,060	16,284	12,636,192	8,084,251.4	0.24	145.69	5.32	27.38	
22-44 Years	22,407	113,585	18,297,759	11,147,068.0	1.22	139.79	5.07	27.58	
45-64 Years	28,960	159,659	15,382,119	10,150,975.7	1.88	153.38	5.51	27.82	
65+ Years	5,186	31,851	6,148,311	4,657,337.2	0.84	170.87	6.14	27.82	
Certolizumab									
0-21 Years	181	901	12,636,192	8,084,251.4	0.01	125.09	4.98	25.13	
22-44 Years	2,572	12,468	18,297,759	11,147,068.0	0.14	123.77	4.85	25.53	
45-64 Years	3,407	17,091	15,382,119	10,150,975.7	0.22	122.81	5.02	24.48	
65+ Years	714	4,146	6,148,311	4,657,337.2	0.12	66.73	5.81	11.49	
Etanercept									
0-21 Years	1,558	7,556	12,636,192	8,084,251.4	0.12	131.46	4.85	27.11	
22-44 Years	10,982	53,072	18,297,759	11,147,068.0	0.60	134.22	4.83	27.77	
45-64 Years	24,457	136,844	15,382,119	10,150,975.7	1.59	156.66	5.60	28.00	
65+ Years	5,721	36,418	6,148,311	4,657,337.2	0.93	176.14	6.37	27.67	
Golimumab									
0-21 Years	123	577	12,636,192	8,084,251.4	0.01	123.07	4.69	26.23	
22-44 Years	1,701	8,283	18,297,759	11,147,068.0	0.09	129.00	4.87	26.49	
45-64 Years	3,023	15,062	15,382,119	10,150,975.7	0.20	128.12	4.98	25.71	
65+ Years	715	3,229	6,148,311	4,657,337.2	0.12	83.75	4.52	18.54	
Infliximab									
0-21 Years	2,904	11,742	12,636,192	8,084,251.4	0.23	7.12	4.04	1.76	
22-44 Years	9,924	41,172	18,297,759	11,147,068.0	0.54	10.94	4.15	2.64	
45-64 Years	11,224	50,246	15,382,119	10,150,975.7	0.73	12.83	4.48	2.87	
65+ Years	5,138	24,484	6,148,311	4,657,337.2	0.84	10.91	4.77	2.29	



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 Days			
2011-2015									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
0-21 Years	18,810	202,905	28,228,305	53,382,013.0	0.67	215.84	10.79	20.01	
22-44 Years	111,527	1,262,375	39,787,392	65,857,832.2	2.80	273.13	11.32	24.13	
45-64 Years	151,193	2,135,041	29,461,166	59,398,329.6	5.13	363.60	14.12	25.75	
65+ Years	35,409	523,733	9,554,903	24,027,226.8	3.71	318.35	14.79	21.52	
Adalimumab									
0-21 Years	7,687	78,684	28,228,305	53,382,013.0	0.27	296.72	10.24	28.99	
22-44 Years	53,444	539,405	39,787,392	65,857,832.2	1.34	296.58	10.09	29.39	
45-64 Years	64,888	778,630	29,461,166	59,398,329.6	2.20	358.20	12.00	29.85	
65+ Years	11,090	146,537	9,554,903	24,027,226.8	1.16	391.06	13.21	29.60	
Certolizumab									
0-21 Years	729	5,914	28,228,305	53,382,013.0	0.03	216.46	8.11	26.68	
22-44 Years	7,139	64,312	39,787,392	65,857,832.2	0.18	240.20	9.01	26.66	
45-64 Years	8,246	79,743	29,461,166	59,398,329.6	0.28	250.58	9.67	25.91	
65+ Years	1,660	16,809	9,554,903	24,027,226.8	0.17	146.04	10.13	14.42	
Etanercept									
0-21 Years	5,006	49,317	28,228,305	53,382,013.0	0.18	285.46	9.85	28.98	
22-44 Years	36,103	375,062	39,787,392	65,857,832.2	0.91	307.07	10.39	29.56	
45-64 Years	64,960	882,081	29,461,166	59,398,329.6	2.20	407.25	13.58	29.99	
65+ Years	13,391	201,623	9,554,903	24,027,226.8	1.40	451.14	15.06	29.96	
Golimumab									
0-21 Years	371	2,456	28,228,305	53,382,013.0	0.01	193.00	6.62	29.15	
22-44 Years	4,659	38,314	39,787,392	65,857,832.2	0.12	243.68	8.22	29.63	
45-64 Years	7,894	76,206	29,461,166	59,398,329.6	0.27	289.43	9.65	29.98	
65+ Years	1,371	11,330	9,554,903	24,027,226.8	0.14	214.53	8.26	25.96	
Infliximab									
0-21 Years	7,624	66,534	28,228,305	53,382,013.0	0.27	15.82	8.73	1.81	
22-44 Years	26,331	245,282	39,787,392	65,857,832.2	0.66	25.64	9.32	2.75	
45-64 Years	29,187	318,381	29,461,166	59,398,329.6	0.99	31.66	10.91	2.90	
65+ Years	11,859	147,434	9,554,903	24,027,226.8	1.24	30.18	12.43	2.43	

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

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
2011									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
Female	68,841	439,105	24,756,626	20,438,864.3	2.78	156.43	6.38	24.52	
Male	48,099	311,708	23,830,329	19,459,428.9	2.02	161.90	6.48	24.98	
Unknown	6	38	2,275	1,802.4	2.64	108.50	6.33	17.13	
Adalimumab									
Female	23,452	144,541	24,756,626	20,438,864.3	0.95	186.86	6.16	30.32	
Male	17,873	116,754	23,830,329	19,459,428.9	0.75	196.92	6.53	30.14	
Unknown	0	0	2,275	1,802.4	0.00	---	---	---	
Certolizumab									
Female	2,729	15,929	24,756,626	20,438,864.3	0.11	148.08	5.84	25.37	
Male	1,275	7,881	23,830,329	19,459,428.9	0.05	157.11	6.18	25.42	
Unknown	0	0	2,275	1,802.4	0.00	---	---	---	
Etanercept									
Female	27,434	173,691	24,756,626	20,438,864.3	1.11	193.03	6.33	30.49	
Male	18,763	121,653	23,830,329	19,459,428.9	0.79	198.27	6.48	30.58	
Unknown	4	23	2,275	1,802.4	1.76	159.00	5.75	27.65	
Golimumab									
Female	2,479	13,304	24,756,626	20,438,864.3	0.10	169.84	5.37	31.65	
Male	987	5,714	23,830,329	19,459,428.9	0.04	182.64	5.79	31.55	
Unknown	0	0	2,275	1,802.4	0.00	---	---	---	
Infliximab									
Female	17,144	91,640	24,756,626	20,438,864.3	0.69	15.51	5.35	2.90	
Male	11,573	59,706	23,830,329	19,459,428.9	0.49	14.45	5.16	2.80	
Unknown	2	15	2,275	1,802.4	0.88	7.50	7.50	1.00	

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

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
2012									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
Female	76,033	489,180	26,334,546	21,784,822.9	2.89	157.17	6.43	24.43	
Male	54,194	354,240	25,434,930	20,840,453.7	2.13	162.93	6.54	24.93	
Unknown	5	49	2,564	2,030.5	1.95	201.80	9.80	20.59	
Adalimumab									
Female	25,925	163,521	26,334,546	21,784,822.9	0.98	189.77	6.31	30.09	
Male	20,468	135,723	25,434,930	20,840,453.7	0.80	198.78	6.63	29.98	
Unknown	1	9	2,564	2,030.5	0.39	270.00	9.00	30.00	
Certolizumab									
Female	3,525	20,779	26,334,546	21,784,822.9	0.13	150.69	5.89	25.56	
Male	1,642	10,059	25,434,930	20,840,453.7	0.06	157.24	6.13	25.67	
Unknown	0	0	2,564	2,030.5	0.00	---	---	---	
Etanercept									
Female	29,946	189,524	26,334,546	21,784,822.9	1.14	191.61	6.33	30.28	
Male	20,666	134,534	25,434,930	20,840,453.7	0.81	197.63	6.51	30.36	
Unknown	2	25	2,564	2,030.5	0.78	362.00	12.50	28.96	
Golimumab									
Female	2,793	15,667	26,334,546	21,784,822.9	0.11	177.74	5.61	31.69	
Male	1,265	7,441	25,434,930	20,840,453.7	0.05	188.09	5.88	31.98	
Unknown	0	0	2,564	2,030.5	0.00	---	---	---	
Infliximab									
Female	18,534	99,689	26,334,546	21,784,822.9	0.70	14.29	5.38	2.66	
Male	12,810	66,483	25,434,930	20,840,453.7	0.50	14.12	5.19	2.72	
Unknown	2	15	2,564	2,030.5	0.78	7.50	7.50	1.00	

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

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
2013									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
Female	77,929	503,006	26,342,361	21,657,213.8	2.96	158.12	6.45	24.50	
Male	56,585	373,668	25,542,374	20,775,193.6	2.22	164.19	6.60	24.86	
Unknown	6	52	2,349	1,711.7	2.55	191.17	8.67	22.06	
Adalimumab									
Female	27,322	170,643	26,342,361	21,657,213.8	1.04	187.66	6.25	30.05	
Male	22,230	145,779	25,542,374	20,775,193.6	0.87	195.93	6.56	29.88	
Unknown	2	14	2,349	1,711.7	0.85	205.00	7.00	29.29	
Certolizumab									
Female	4,171	24,706	26,342,361	21,657,213.8	0.16	149.66	5.92	25.27	
Male	1,897	11,707	25,542,374	20,775,193.6	0.07	159.55	6.17	25.85	
Unknown	0	0	2,349	1,711.7	0.00	---	---	---	
Etanercept									
Female	30,224	192,359	26,342,361	21,657,213.8	1.15	190.86	6.36	29.99	
Male	20,738	138,316	25,542,374	20,775,193.6	0.81	200.50	6.67	30.06	
Unknown	2	25	2,349	1,711.7	0.85	362.00	12.50	28.96	
Golimumab									
Female	3,127	17,523	26,342,361	21,657,213.8	0.12	175.76	5.60	31.37	
Male	1,576	9,351	25,542,374	20,775,193.6	0.06	184.77	5.93	31.14	
Unknown	0	0	2,349	1,711.7	0.00	---	---	---	
Infliximab									
Female	18,172	97,775	26,342,361	21,657,213.8	0.69	13.89	5.38	2.58	
Male	13,026	68,515	25,542,374	20,775,193.6	0.51	14.06	5.26	2.67	
Unknown	2	13	2,349	1,711.7	0.85	6.50	6.50	1.00	

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

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
2014									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
Female	82,010	517,998	27,391,670	22,265,611.9	2.99	155.84	6.32	24.67	
Male	60,658	390,297	26,609,808	21,397,051.7	2.28	161.43	6.43	25.09	
Unknown	6	43	2,251	1,583.7	2.67	169.50	7.17	23.65	
Adalimumab									
Female	30,161	185,279	27,391,670	22,265,611.9	1.10	185.82	6.14	30.25	
Male	24,912	159,602	26,609,808	21,397,051.7	0.94	193.75	6.41	30.24	
Unknown	2	12	2,251	1,583.7	0.89	168.00	6.00	28.00	
Certolizumab									
Female	4,877	28,018	27,391,670	22,265,611.9	0.18	145.57	5.74	25.34	
Male	2,264	13,093	26,609,808	21,397,051.7	0.09	151.81	5.78	26.25	
Unknown	0	0	2,251	1,583.7	0.00	---	---	---	
Etanercept									
Female	29,970	188,258	27,391,670	22,265,611.9	1.09	188.03	6.28	29.93	
Male	20,764	135,761	26,609,808	21,397,051.7	0.78	197.04	6.54	30.14	
Unknown	2	24	2,251	1,583.7	0.89	337.00	12.00	28.08	
Golimumab									
Female	3,911	20,448	27,391,670	22,265,611.9	0.14	148.68	5.23	28.44	
Male	2,043	11,707	26,609,808	21,397,051.7	0.08	169.38	5.73	29.56	
Unknown	0	0	2,251	1,583.7	0.00	---	---	---	
Infliximab									
Female	18,297	95,995	27,391,670	22,265,611.9	0.67	13.63	5.25	2.60	
Male	13,620	70,134	26,609,808	21,397,051.7	0.51	13.54	5.15	2.63	
Unknown	2	7	2,251	1,583.7	0.89	3.50	3.50	1.00	

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

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
2015									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
Female	76,892	422,013	25,824,365	17,294,563.1	2.98	126.01	5.49	22.96	
Male	58,242	322,633	25,281,057	16,743,782.1	2.30	129.67	5.54	23.41	
Unknown	4	24	2,362	1,287.2	1.69	126.75	6.00	21.13	
Adalimumab									
Female	31,684	170,955	25,824,365	17,294,563.1	1.23	149.50	5.40	27.71	
Male	26,797	150,414	25,281,057	16,743,782.1	1.06	155.59	5.61	27.72	
Unknown	2	10	2,362	1,287.2	0.85	131.00	5.00	26.20	
Certolizumab									
Female	4,670	23,438	25,824,365	17,294,563.1	0.18	116.00	5.02	23.11	
Male	2,094	11,168	25,281,057	16,743,782.1	0.08	126.70	5.33	23.76	
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

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			
Etanercept									
Female	24,669	136,796	25,824,365	17,294,563.1	0.96	153.95	5.55	27.76	
Male	17,229	97,085	25,281,057	16,743,782.1	0.68	157.86	5.63	28.01	
Unknown	1	9	2,362	1,287.2	0.42	240.00	9.00	26.67	
Golimumab									
Female	3,604	17,246	25,824,365	17,294,563.1	0.14	117.30	4.79	24.51	
Male	1,878	9,905	25,281,057	16,743,782.1	0.07	137.92	5.27	26.15	
Unknown	0	0	2,362	1,287.2	0.00	---	---	---	
Infliximab									
Female	16,254	73,578	25,824,365	17,294,563.1	0.63	11.71	4.53	2.59	
Male	12,433	54,061	25,281,057	16,743,782.1	0.49	11.18	4.35	2.57	
Unknown	1	5	2,362	1,287.2	0.42	5.00	5.00	1.00	
2011-2015									
Adalimumab, Certolizumab, Etanercept, Golimumab, Infliximab									
Female	173,706	2,371,302	49,910,753	103,441,076.0	3.48	331.08	13.65	24.25	
Male	123,492	1,752,546	48,906,968	99,215,910.0	2.53	350.25	14.19	24.68	
Unknown	10	206	5,203	8,415.5	1.92	433.10	20.60	21.02	
Adalimumab									
Female	73,545	834,939	49,910,753	103,441,076.0	1.47	336.81	11.35	29.67	
Male	56,699	708,272	48,906,968	99,215,910.0	1.16	369.31	12.49	29.56	
Unknown	4	45	5,203	8,415.5	0.77	319.50	11.25	28.40	
Certolizumab									
Female	11,816	112,870	49,910,753	103,441,076.0	0.24	237.91	9.55	24.91	
Male	5,337	53,908	48,906,968	99,215,910.0	0.11	256.73	10.10	25.42	
Unknown	0	0	5,203	8,415.5	0.00	---	---	---	
Etanercept									
Female	67,976	880,628	49,910,753	103,441,076.0	1.36	385.95	12.95	29.79	
Male	44,515	627,349	48,906,968	99,215,910.0	0.91	421.73	14.09	29.92	
Unknown	4	106	5,203	8,415.5	0.77	749.50	26.50	28.28	
Golimumab									

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

Year	New Users	Dispensings/ Administrations	Eligible Members	Member-Years	New Users/1K		Days Supplied/User	Dispensings/U ser	Days Supplied/Dispensing
					Eligible Members	Days Supplied/User			
Female	9,410	84,188	49,910,753	103,441,076.0	0.19	262.63	8.95	29.35	
Male	4,365	44,118	48,906,968	99,215,910.0	0.09	301.14	10.11	29.79	
Unknown	0	0	5,203	8,415.5	0.00	---	---	---	
Infliximab									
Female	41,444	458,677	49,910,753	103,441,076.0	0.83	29.51	11.07	2.67	
Male	29,327	318,899	48,906,968	99,215,910.0	0.60	29.14	10.87	2.68	
Unknown	2	55	5,203	8,415.5	0.38	27.50	27.50	1.00	



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 Tumor Necrosis Factor (TNF) Alpha Inhibitors of Interest in this Request

Code	Code Type
Adilimumab	
J0135	HCPCS
Certolizumab	
C9249	HCPCS
J0717	HCPCS
J0718	HCPCS
Etanercept	
J1438	HCPCS
Golimumab	
J1602	HCPCS
Infliximab	
J1745	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 1 presents results on TNF alpha inhibitor 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			Cohort Definition	Pre-Existing Condition	Event/Outcome
	Exposure	Incident w/ respect to:	Washout (days)		Pre-Existing Condition	Event/ Outcome
22	Infliximab, Etanercept, Adalimumab, Golimumab, Certolizumab	NA	0	02	None	Dummy
23	Infliximab	NA	0	02	None	Dummy
24	Etanercept	NA	0	02	None	Dummy
25	Adalimumab	NA	0	02	None	Dummy
26	Golimumab	NA	0	02	None	Dummy
27	Certolizumab	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.