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The following report(s) 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_mpl1p_wp006_nsdp_v01

Request ID: cder_mpl1p_wp006_nsdp_v01

Request Description: This report contains estimates of the length of follow-up time for new users of immunosuppressive drugs (adalimumab, alemtuzumab, certolizumab, dalfampridine, dimethyl fumarate, etanercept, fingolimod, glatiramer acetate, golimumab, infliximab, interferon beta-1A, interferon beta-1B, mitoxantrone, natalizumab, pegylated interferon beta-1A, teriflunomide, and ustekinumab) and for patients diagnosed with Crohn's disease, multiple sclerosis, psoriasis, and ulcerative colitis in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.0.0, and a Rapid Analytic Development and Response (RADaR) module

Data Source: Data from January 1, 2000 to the most recent available data from 16 health plans contributing to the SDD were included in this report (see Appendix A for data availability dates for each Data Partner). This request was distributed to Data Partners on June 30, 2017.

Study Design: The purpose of this request was to examine follow-up time for patients with incident exposures to select immunosuppressive drugs used to treat multiple sclerosis or psoriasis. The number of patients with incident exposures and follow-up time was stratified by age group and year. In addition, follow-up time for patients with prevalent Crohn's disease, multiple sclerosis, psoriasis, and ulcerative colitis diagnoses was examined and stratified by age group.

Cohort Eligibility Criteria: Patients were required to be continuously enrolled in plans with both medical and drug coverage for at least six months (183 days) before their index date, during which gaps in coverage of up to 45 days were allowed. The first valid exposure per patient was included. Members who had an exposure in the six months before their exposure of interest were excluded from the cohort. The following age groups were included in the cohort: 18-30, 31-64, and 65+ years.

Analysis 1, Exposures of Interest: The exposures of interest were immunosuppressive drugs used to treat multiple sclerosis and psoriasis. The drugs were defined using National Drug Codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) codes. Please refer to Appendix B for specific codes and Appendix C for generic names and brand names.

Analysis 2, Events of Interest: The events of interest were diagnoses of Crohn's disease, multiple sclerosis, psoriasis, and ulcerative colitis. The conditions were defined using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. Please refer to Appendix D for specific codes.

Follow-Up Time: The number of patients with follow-up time was assessed in one-year increments from 0-16+ years. Percentages of patients with follow-up time within each stratum were assessed in the following increments: <3, 3+, 4+, 5+, 6+, 7+, 8+, 9+, 10+, 11+, 12+, 13+, 14+, 15+, and 16+ years. Follow-up began on the day of the first exposure or event of interest and continued until either 1) the end of a patient's enrollment, 2) death, or 3) the end of Data Partners' data.

Please refer to Appendices E and F for detailed specifications of parameters used in this request.

Limitations: Algorithms used to define exposures and events are imperfect; thus, it is possible that there may be misclassification.

Notes: 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.

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

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

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

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

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

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

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

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"

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

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

Event Deduplication - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences

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. Extension days are added after any episode gaps have been bridged

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition

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

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

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

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

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

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

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

requester-specified code.

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

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

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

*all terms may not be used in this report

Table 1a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Age Group

		Number of Users by Years of Follow-Up Time															
Age Group (Years)	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Adalimumab																	
18-30	7,281	4,263	2,332	1,359	876	580	371	248	129	59	22	10	6	6	0	0	0
31-64	31,915	20,342	12,380	7,910	5,442	4,209	2,865	2,174	1,270	707	430	232	182	84	0	0	0
65+	2,403	1,824	1,211	865	623	460	322	268	196	105	72	37	27	10	0	0	0
Alemtuzumab																	
18-30	24	9	2	1	2	4	0	0	0	0	0	0	0	0	0	0	0
31-64	453	138	48	41	32	19	12	7	7	7	2	1	2	0	0	0	0
65+	184	85	30	22	13	7	8	4	6	1	2	1	0	0	0	0	0
Certolizumab																	
18-30	962	584	354	231	130	83	41	20	1	0	0	0	0	0	0	0	0
31-64	4,243	2,731	1,771	991	660	443	274	110	6	0	0	0	0	0	0	0	0
65+	521	374	230	193	112	73	45	12	0	0	0	0	0	0	0	0	0
Dalfampridine																	
18-30	90	59	34	22	8	11	16	0	0	0	0	0	0	0	0	0	0
31-64	2,566	1,835	1,218	928	719	668	807	0	0	0	0	0	0	0	0	0	0
65+	214	206	139	106	71	77	115	0	0	0	0	0	0	0	0	0	0
Dimethyl Fumarate																	
18-30	576	393	274	106	0	0	0	0	0	0	0	0	0	0	0	0	0
31-64	4,289	3,497	3,290	1,676	0	0	0	0	0	0	0	0	0	0	0	0	0
65+	177	188	181	87	0	0	0	0	0	0	0	0	0	0	0	0	0
Etanercept																	
18-30	3,422	2,204	1,491	908	623	434	285	199	142	88	51	46	30	17	4	4	3
31-64	21,806	15,861	11,081	7,728	5,491	4,106	2,984	2,453	1,641	1,318	843	612	464	406	68	124	59
65+	1,894	1,571	1,283	929	715	534	377	299	212	194	125	83	48	44	7	10	8
Fingolimod																	
18-30	370	220	118	55	33	40	0	0	0	0	0	0	0	0	0	0	0
31-64	2,074	1,475	1,010	641	497	402	3	0	0	0	0	0	0	0	0	0	0
65+	42	30	27	7	11	9	0	0	0	0	0	0	0	0	0	0	0
Glatiramer Acetate																	
18-30	1,349	876	524	357	221	186	112	97	49	41	21	9	17	18	12	5	4
31-64	7,024	4,747	3,139	2,269	1,903	1,361	1,081	841	545	363	276	182	142	136	125	113	35
65+	238	170	117	85	66	50	43	36	23	15	6	3	7	2	1	3	0
Golimumab																	
18-30	571	315	195	84	51	45	15	5	0	0	0	0	0	0	0	0	0
31-64	3,765	2,522	1,720	1,008	625	506	426	128	0	0	0	0	0	0	0	0	0
65+	517	372	242	86	61	44	45	20	0	0	0	0	0	0	0	0	0
Infliximab																	
18-30	3,662	2,336	1,472	925	673	434	353	186	101	74	24	28	16	7	14	10	0
31-64	11,272	7,949	5,411	3,731	2,790	2,162	1,979	1,304	711	517	302	163	130	118	113	87	18
65+	2,165	1,685	1,379	1,033	924	728	760	493	350	212	82	50	29	18	20	11	1
Interferon Beta-1A																	
18-30	990	705	469	350	273	209	129	90	67	42	28	27	12	10	20	13	5
31-64	4,851	3,501	2,588	2,054	1,715	1,313	932	756	464	420	269	220	167	131	148	157	57
65+	150	131	119	89	91	68	33	27	26	13	3	6	6	7	2	3	1

Table 1a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Age Group

Age Group (Years)	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Interferon Beta-1B																	
18-30	320	207	135	97	66	57	35	31	19	13	7	14	9	8	7	2	1
31-64	1,452	1,165	777	546	454	402	309	289	174	130	77	58	54	70	83	34	18
65+	58	68	32	26	21	17	7	5	10	2	5	3	3	2	1	2	0
Mitoxantrone																	
18-30	36	18	9	10	8	5	3	3	5	1	4	1	0	1	0	1	0
31-64	835	375	221	143	122	71	93	68	57	46	33	36	13	17	17	8	1
65+	1,010	335	167	100	56	39	35	15	26	11	5	2	2	2	0	0	1
Natalizumab																	
18-30	504	303	191	114	92	61	46	31	9	6	2	0	0	0	0	0	0
31-64	2,544	1,726	1,259	900	747	484	337	229	180	85	15	3	0	0	0	0	0
65+	61	46	30	39	33	13	13	6	9	4	0	1	0	0	0	0	0
Pegylated Interferon Beta-1A																	
18-30	45	26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31-64	364	427	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65+	30	45	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Teriflunomide																	
18-30	60	22	18	12	0	0	0	0	0	0	0	0	0	0	0	0	0
31-64	1,707	1,006	502	382	5	0	0	0	0	0	0	0	0	0	0	0	0
65+	132	98	53	25	0	0	0	0	0	0	0	0	0	0	0	0	0
Ustekinumab																	
18-30	960	527	268	158	82	48	18	0	0	0	0	0	0	0	0	0	0
31-64	5,676	3,218	1,951	1,106	683	388	237	22	0	0	0	0	0	0	0	0	0
65+	347	234	156	103	71	60	24	3	0	0	0	0	0	0	0	0	0

Table 1b: Proportion of Patients with Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Age Group

Age Group (Years)	Number of Users by Years of Follow-Up Time															Total (n)
	<3	3+	4+	5+	6+	7+	8+	9+	10+	11+	12+	13+	14+	15+	16+	
Adalimumab																
18-30	79.1%	20.9%	13.2%	8.2%	4.9%	2.7%	1.3%	0.6%	0.3%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	17,542
31-64	71.7%	28.3%	19.5%	13.5%	8.8%	5.6%	3.2%	1.8%	1.0%	0.6%	0.3%	0.1%	0.0%	0.0%	0.0%	90,142
65+	64.6%	35.4%	25.2%	17.8%	12.3%	8.5%	5.3%	3.0%	1.7%	0.9%	0.4%	0.1%	0.0%	0.0%	0.0%	8,423
Alemtuzumab																
18-30	83.3%	16.7%	14.3%	9.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	42
31-64	83.1%	16.9%	11.6%	7.4%	4.9%	3.4%	2.5%	1.6%	0.7%	0.4%	0.3%	0.0%	0.0%	0.0%	0.0%	769
65+	82.4%	17.6%	11.6%	8.0%	6.1%	3.9%	2.8%	1.1%	0.8%	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	363
Certolizumab																
18-30	79.0%	21.0%	11.4%	6.0%	2.6%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2,406
31-64	77.9%	22.1%	13.3%	7.4%	3.5%	1.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	11,229
65+	72.1%	27.9%	15.5%	8.3%	3.7%	0.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1,560
Dalfampridine																
18-30	76.3%	23.8%	14.6%	11.3%	6.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	240
31-64	64.3%	35.7%	25.1%	16.9%	9.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	8,741
65+	60.2%	39.8%	28.3%	20.7%	12.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	928
Dimethyl Fumarate																
18-30	92.1%	7.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1,349
31-64	86.9%	13.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	12,752
65+	86.3%	13.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	633
Etanercept																
18-30	71.5%	28.5%	19.4%	13.1%	8.7%	5.9%	3.9%	2.4%	1.6%	1.0%	0.6%	0.3%	0.1%	0.1%	0.0%	9,951
31-64	63.3%	36.7%	26.7%	19.6%	14.2%	10.4%	7.2%	5.1%	3.3%	2.2%	1.5%	0.9%	0.3%	0.2%	0.1%	77,045
65+	57.0%	43.0%	31.9%	23.3%	16.9%	12.4%	8.8%	6.2%	3.9%	2.4%	1.4%	0.8%	0.3%	0.2%	0.1%	8,333
Fingolimod																
18-30	84.7%	15.3%	8.7%	4.8%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	836
31-64	74.7%	25.3%	14.8%	6.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6,102
65+	78.6%	21.4%	15.9%	7.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	126
Glatiramer Acetate																
18-30	70.5%	29.5%	20.3%	14.6%	9.9%	7.0%	4.5%	3.3%	2.2%	1.7%	1.4%	1.0%	0.5%	0.2%	0.1%	3,898
31-64	61.4%	38.6%	29.3%	21.4%	15.8%	11.4%	7.9%	5.7%	4.2%	3.0%	2.3%	1.7%	1.1%	0.6%	0.1%	24,282
65+	60.7%	39.3%	29.5%	21.8%	16.1%	11.1%	6.9%	4.3%	2.5%	1.8%	1.5%	0.7%	0.5%	0.3%	0.0%	865
Golimumab																
18-30	84.4%	15.6%	9.1%	5.1%	1.6%	0.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1,281
31-64	74.8%	25.2%	15.7%	9.9%	5.2%	1.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10,700
65+	81.5%	18.5%	12.3%	7.9%	4.7%	1.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1,387
Infliximab																
18-30	72.4%	27.6%	18.6%	12.1%	7.9%	4.5%	2.7%	1.7%	1.0%	0.7%	0.5%	0.3%	0.2%	0.1%	0.0%	10,315
31-64	63.6%	36.4%	26.8%	19.6%	14.0%	8.9%	5.6%	3.7%	2.4%	1.6%	1.2%	0.9%	0.6%	0.3%	0.0%	38,757
65+	52.6%	47.4%	37.0%	27.7%	20.4%	12.7%	7.8%	4.3%	2.1%	1.3%	0.8%	0.5%	0.3%	0.1%	0.0%	9,940
Interferon Beta-1A																
18-30	62.9%	37.1%	26.9%	19.0%	12.9%	9.1%	6.5%	4.6%	3.3%	2.5%	1.7%	1.4%	1.1%	0.5%	0.1%	3,439
31-64	55.4%	44.6%	34.2%	25.5%	18.8%	14.1%	10.3%	7.9%	5.8%	4.5%	3.3%	2.5%	1.8%	1.1%	0.3%	19,743
65+	51.6%	48.4%	36.9%	25.2%	16.4%	12.1%	8.6%	5.3%	3.6%	3.2%	2.5%	1.7%	0.8%	0.5%	0.1%	775

Table 1b: Proportion of Patients with Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Age Group

Age Group (Years)	Number of Users by Years of Follow-Up Time															Total (n)
	<3	3+	4+	5+	6+	7+	8+	9+	10+	11+	12+	13+	14+	15+	16+	
Interferon Beta-1B																
18-30	64.4%	35.6%	26.2%	19.7%	14.2%	10.8%	7.8%	5.9%	4.7%	4.0%	2.6%	1.8%	1.0%	0.3%	0.1%	1,028
31-64	55.7%	44.3%	35.3%	27.9%	21.3%	16.2%	11.5%	8.6%	6.5%	5.2%	4.3%	3.4%	2.2%	0.9%	0.3%	6,092
65+	60.3%	39.7%	29.8%	21.8%	15.3%	12.6%	10.7%	6.9%	6.1%	4.2%	3.1%	1.9%	1.1%	0.8%	0.0%	262
Mitoxantrone																
18-30	60.0%	40.0%	30.5%	22.9%	18.1%	15.2%	12.4%	7.6%	6.7%	2.9%	1.9%	1.9%	1.0%	1.0%	0.0%	105
31-64	66.4%	33.6%	27.0%	21.3%	18.0%	13.7%	10.6%	7.9%	5.8%	4.3%	2.6%	2.0%	1.2%	0.4%	0.0%	2,156
65+	83.7%	16.3%	10.7%	7.6%	5.5%	3.5%	2.7%	1.3%	0.7%	0.4%	0.3%	0.2%	0.1%	0.1%	0.1%	1,806
Natalizumab																
18-30	73.4%	26.6%	18.2%	11.4%	6.9%	3.5%	1.3%	0.6%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1,359
31-64	65.0%	35.0%	24.4%	15.7%	10.0%	6.0%	3.3%	1.2%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	8,509
65+	53.7%	46.3%	31.0%	18.0%	12.9%	7.8%	5.5%	2.0%	0.4%	0.4%	0.0%	0.0%	0.0%	0.0%	0.0%	255
Pegylated Interferon Beta-1A																
18-30	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	71
31-64	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	792
65+	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	75
Teriflunomide																
18-30	89.3%	10.7%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	112
31-64	89.3%	10.7%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	3,602
65+	91.9%	8.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	308
Ustekinumab																
18-30	85.2%	14.8%	7.2%	3.2%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2,061
31-64	81.7%	18.3%	10.0%	4.9%	2.0%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	13,281
65+	73.8%	26.2%	15.8%	8.7%	2.7%	0.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	998

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Adalimumab																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	53	69	174	46	40	26	25	24	16	12	13	15	42	99	0	0	0
2004	110	287	53	45	45	46	22	29	18	15	22	72	173	1	0	0	0
2005	191	71	55	40	35	41	26	27	27	33	89	190	0	0	0	0	0
2006	301	181	188	140	87	96	67	72	70	161	400	2	0	0	0	0	0
2007	614	534	407	291	278	171	177	150	274	645	0	0	0	0	0	0	0
2008	2,004	1,535	954	730	478	519	325	697	1,186	5	0	0	0	0	0	0	0
2009	3,039	2,140	1,453	840	947	579	918	1,686	4	0	0	0	0	0	0	0	0
2010	2,778	1,997	1,221	1,162	732	1,131	1,995	5	0	0	0	0	0	0	0	0	0
2011	2,855	1,828	1,699	1,046	1,456	2,636	3	0	0	0	0	0	0	0	0	0	0
2012	2,448	2,096	1,359	1,817	2,837	4	0	0	0	0	0	0	0	0	0	0	0
2013	3,155	2,122	2,822	3,971	6	0	0	0	0	0	0	0	0	0	0	0	0
2014	3,389	4,208	5,523	6	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	8,610	9,347	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	12,042	14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alemtuzumab																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0
2002	2	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
2003	4	3	4	2	0	2	2	0	1	0	1	0	1	0	0	0	0
2004	12	14	7	3	0	0	1	0	1	0	0	2	1	0	0	0	0
2005	13	1	1	2	0	0	0	0	1	1	1	0	0	0	0	0	0
2006	20	8	2	3	4	0	1	2	0	1	2	0	0	0	0	0	0
2007	38	20	6	8	5	3	2	3	2	6	0	0	0	0	0	0	0
2008	62	24	8	6	7	3	3	3	8	0	0	0	0	0	0	0	0
2009	58	25	18	14	5	3	1	3	0	0	0	0	0	0	0	0	0
2010	52	19	8	5	3	7	10	0	0	0	0	0	0	0	0	0	0
2011	41	23	8	1	3	11	0	0	0	0	0	0	0	0	0	0	0
2012	51	23	8	9	18	0	0	0	0	0	0	0	0	0	0	0	0
2013	27	9	5	11	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	13	8	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	62	54	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	206	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Certolizumab																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	67	51	38	23	18	21	11	30	7	0	0	0	0	0	0	0	0
2009	297	194	153	97	99	49	104	112	0	0	0	0	0	0	0	0	0
2010	446	327	203	187	133	183	245	0	0	0	0	0	0	0	0	0	0
2011	427	311	267	150	220	346	0	0	0	0	0	0	0	0	0	0	0
2012	502	427	240	392	432	0	0	0	0	0	0	0	0	0	0	0	0
2013	691	407	575	566	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	665	856	879	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	1,218	1,116	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	1,413	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Dalfampridine																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2010	863	627	407	417	297	398	937	0	0	0	0	0	0	0	0	0	0
2011	295	208	199	123	168	358	1	0	0	0	0	0	0	0	0	0	0
2012	215	188	115	205	333	0	0	0	0	0	0	0	0	0	0	0	0
2013	241	167	211	310	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	233	312	459	1	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	407	598	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	616	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Dimethyl Fumarate																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2012	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2013	1,490	1,079	1,587	1,867	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	1,072	1,427	2,158	2	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	1,088	1,571	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	1,390	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Etanercept																	
2000	63	54	33	26	39	55	16	11	18	8	13	5	10	10	15	37	69
2001	42	42	26	35	79	27	14	11	19	13	14	13	12	12	36	101	1
2002	28	30	33	52	23	18	15	8	10	6	11	4	11	36	25	0	0
2003	150	152	352	96	88	57	74	60	47	32	35	34	115	408	3	0	0
2004	248	427	146	118	82	94	78	55	56	64	57	173	392	1	0	0	0
2005	386	183	132	119	111	84	73	58	53	54	185	507	2	0	0	0	0
2006	674	465	408	299	236	217	135	170	161	347	698	5	0	0	0	0	0
2007	1,069	913	641	517	410	294	284	220	402	1,067	6	0	0	0	0	0	0
2008	1,965	1,504	1,029	779	512	544	385	629	1,226	9	0	0	0	0	0	0	0
2009	2,740	1,856	1,342	838	848	558	835	1,727	3	0	0	0	0	0	0	0	0
2010	2,226	1,625	997	915	608	922	1,734	2	0	0	0	0	0	0	0	0	0
2011	2,219	1,426	1,353	830	1,145	2,199	3	0	0	0	0	0	0	0	0	0	0
2012	2,271	1,983	1,249	1,725	2,621	5	0	0	0	0	0	0	0	0	0	0	0
2013	2,578	1,755	2,283	3,205	27	0	0	0	0	0	0	0	0	0	0	0	0
2014	2,376	3,029	3,821	11	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	3,051	4,186	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	5,029	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Fingolimod																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2010	42	27	25	17	15	41	3	0	0	0	0	0	0	0	0	0	0
2011	449	270	247	147	246	410	0	0	0	0	0	0	0	0	0	0	0
2012	191	216	132	186	280	0	0	0	0	0	0	0	0	0	0	0	0
2013	247	180	260	353	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	307	430	490	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	510	601	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	739	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glatiramer Acetate																	
2000	31	20	19	18	8	20	11	6	3	3	5	6	3	3	3	11	38
2001	55	51	40	38	52	23	22	5	21	16	7	6	14	19	33	109	1
2002	57	44	38	62	26	20	22	17	21	13	7	10	11	45	102	1	0
2003	67	46	80	32	27	28	16	15	13	10	14	14	37	86	0	0	0
2004	68	77	48	34	34	25	15	15	14	17	17	44	101	3	0	0	0
2005	88	59	43	36	37	25	21	18	16	15	63	114	0	0	0	0	0
2006	181	107	95	73	38	64	36	40	23	85	190	0	0	0	0	0	0
2007	268	209	158	108	105	66	63	55	133	258	0	0	0	0	0	0	0
2008	680	506	330	247	142	152	100	219	373	2	0	0	0	0	0	0	0
2009	949	659	437	259	273	171	285	583	0	0	0	0	0	0	0	0	0
2010	883	603	369	330	237	349	645	1	0	0	0	0	0	0	0	0	0
2011	743	463	396	264	354	654	0	0	0	0	0	0	0	0	0	0	0
2012	720	556	307	460	856	0	0	0	0	0	0	0	0	0	0	0	0
2013	570	427	534	749	1	0	0	0	0	0	0	0	0	0	0	0	0
2014	618	725	885	1	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	1,067	1,239	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	1,565	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Golimumab																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	348	190	156	105	95	67	117	153	0	0	0	0	0	0	0	0	0
2010	458	324	197	202	123	189	368	0	0	0	0	0	0	0	0	0	0
2011	311	198	191	112	174	339	1	0	0	0	0	0	0	0	0	0	0
2012	380	361	183	254	345	0	0	0	0	0	0	0	0	0	0	0	0
2013	484	314	433	505	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	605	756	997	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	902	1,065	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	1,365	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Infliximab																	
2000	32	27	16	12	9	36	10	8	7	3	2	9	1	7	2	20	19
2001	73	69	59	64	87	39	19	22	24	18	12	12	17	15	46	87	0
2002	100	91	67	121	61	36	39	41	28	18	18	20	32	64	98	1	0
2003	80	82	119	58	29	34	26	22	12	17	9	20	45	56	1	0	0
2004	103	252	64	33	32	38	15	19	14	17	12	72	79	1	0	0	0
2005	212	71	40	45	42	34	21	32	24	22	72	108	1	0	0	0	0
2006	351	269	205	166	124	102	87	83	70	159	282	0	0	0	0	0	0
2007	576	523	342	271	242	178	154	124	229	548	1	0	0	0	0	0	0
2008	1,204	969	651	465	353	316	236	437	754	1	0	0	0	0	0	0	0
2009	1,597	1,135	778	501	531	372	553	1,195	0	0	0	0	0	0	0	0	0
2010	1,490	1,052	703	609	455	682	1,932	0	0	0	0	0	0	0	0	0	0
2011	1,281	834	787	530	764	1,453	0	0	0	0	0	0	0	0	0	0	0
2012	1,165	1,038	709	919	1,656	4	0	0	0	0	0	0	0	0	0	0	0
2013	1,393	947	1,276	1,895	2	0	0	0	0	0	0	0	0	0	0	0	0
2014	1,358	1,640	2,445	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	2,308	2,969	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	3,775	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Interferon Beta-1A																	
2000	37	28	31	28	24	28	9	5	13	9	10	8	9	3	9	27	63
2001	62	61	49	33	86	30	15	18	20	12	12	15	7	6	40	144	0
2002	51	43	32	88	35	23	26	12	12	15	10	15	9	44	120	2	0
2003	56	47	99	33	30	26	27	13	13	20	8	13	39	95	1	0	0
2004	71	95	50	32	29	34	24	15	18	15	12	54	120	0	0	0	0
2005	118	64	39	35	49	21	24	10	16	16	70	147	1	0	0	0	0
2006	214	154	118	78	60	60	46	40	32	100	178	1	0	0	0	0	0
2007	299	255	197	129	128	93	73	59	109	288	0	0	0	0	0	0	0
2008	636	451	283	208	135	148	95	195	323	0	0	0	0	0	0	0	0
2009	863	612	396	248	258	171	254	506	1	0	0	0	0	0	0	0	0
2010	722	482	306	284	163	275	501	0	0	0	0	0	0	0	0	0	0
2011	658	454	361	204	369	681	0	0	0	0	0	0	0	0	0	0	0
2012	577	451	278	395	713	0	0	0	0	0	0	0	0	0	0	0	0
2013	420	288	372	697	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	270	382	565	1	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	415	469	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	520	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Interferon Beta-1B																	
2000	17	8	16	7	8	25	2	6	4	2	7	0	4	2	2	10	19
2001	28	21	18	18	36	11	7	8	7	14	2	3	4	6	28	28	0
2002	41	25	27	53	14	9	10	9	11	10	3	8	4	22	59	0	0
2003	21	21	37	11	5	9	10	13	5	2	3	5	17	50	2	0	0
2004	20	43	14	17	9	6	8	5	7	9	6	20	36	0	0	0	0
2005	35	16	5	9	8	7	5	4	7	0	18	39	1	0	0	0	0
2006	41	39	28	22	15	20	7	9	12	22	50	0	0	0	0	0	0
2007	106	78	69	33	38	27	23	20	40	86	0	0	0	0	0	0	0
2008	220	164	105	76	60	49	25	82	110	0	0	0	0	0	0	0	0
2009	296	201	127	70	71	52	78	169	0	0	0	0	0	0	0	0	0
2010	228	124	100	74	55	93	176	0	0	0	0	0	0	0	0	0	0
2011	148	90	63	69	54	168	0	0	0	0	0	0	0	0	0	0	0
2012	124	83	57	83	168	0	0	0	0	0	0	0	0	0	0	0	0
2013	72	53	79	127	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	78	110	199	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	123	364	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	232	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2a: Summary of Follow-Up Time After Incident Use of Immunosuppressive Drugs in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Drug and Year

Number of Users by Years of Follow-Up Time																	
Year	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Mitoxantrone																	
2000	36	10	6	10	6	3	2	2	1	0	0	0	0	0	2	2	2
2001	73	24	16	13	27	7	6	4	4	4	5	2	1	1	5	7	0
2002	76	29	13	34	7	4	10	4	4	3	1	6	1	10	10	0	0
2003	50	32	40	12	7	5	8	8	6	1	4	3	5	9	0	0	0
2004	48	61	23	7	6	8	6	2	1	2	6	14	8	0	0	0	0
2005	73	17	18	5	10	1	4	1	3	2	11	14	0	0	0	0	0
2006	98	44	25	20	7	8	9	3	6	15	15	0	0	0	0	0	0
2007	149	70	40	21	21	6	12	11	13	31	0	0	0	0	0	0	0
2008	288	115	45	31	16	16	10	20	50	0	0	0	0	0	0	0	0
2009	293	102	50	21	10	14	20	31	0	0	0	0	0	0	0	0	0
2010	185	81	38	23	20	24	44	0	0	0	0	0	0	0	0	0	0
2011	122	40	31	16	13	18	0	0	0	0	0	0	0	0	0	0	0
2012	100	30	17	14	36	1	0	0	0	0	0	0	0	0	0	0	0
2013	78	21	13	26	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	63	19	22	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	65	33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	83	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Natalizumab																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	10	4	2	1	2	2	0	1	2	1	3	4	0	0	0	0	0
2006	39	21	26	12	20	10	13	4	6	31	14	0	0	0	0	0	0
2007	102	100	75	53	45	31	26	25	39	63	0	0	0	0	0	0	0
2008	237	204	149	92	62	67	43	78	151	0	0	0	0	0	0	0	0
2009	310	177	113	95	81	57	73	158	0	0	0	0	0	0	0	0	0
2010	239	186	114	97	83	127	241	0	0	0	0	0	0	0	0	0	0
2011	308	194	147	97	194	264	0	0	0	0	0	0	0	0	0	0	0
2012	318	257	175	239	385	0	0	0	0	0	0	0	0	0	0	0	0
2013	265	177	248	367	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	259	298	429	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	400	457	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	622	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Year	Number of Users by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Pegylated Interferon Beta-1A																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2012	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2013	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	31	111	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	207	387	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	201	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Teriflunomide																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2010	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2012	40	30	18	61	5	0	0	0	0	0	0	0	0	0	0	0	0
2013	237	162	231	357	0	0	0	0	0	0	0	0	0	0	0	0	0
2014	175	305	323	1	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	546	629	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	900	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Ustekinumab																	
2000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2001	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2002	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2003	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2004	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2005	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2006	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2007	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2008	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2009	107	65	58	22	34	21	62	25	0	0	0	0	0	0	0	0	0
2010	384	272	164	176	105	137	217	0	0	0	0	0	0	0	0	0	0
2011	420	296	262	151	238	338	0	0	0	0	0	0	0	0	0	0	0
2012	449	395	233	339	456	0	0	0	0	0	0	0	0	0	0	0	0
2013	650	428	567	677	3	0	0	0	0	0	0	0	0	0	0	0	0
2014	783	915	1,085	2	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	1,469	1,607	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	2,719	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Multiple Sclerosis Drugs																	
2000	121	66	72	63	46	76	24	19	21	14	22	14	16	8	16	50	122
2001	218	157	123	102	202	72	50	35	52	46	26	26	26	32	106	288	1
2002	227	142	110	237	83	56	68	42	48	41	21	39	25	121	291	3	0
2003	198	149	260	90	69	70	63	49	38	33	30	35	99	240	3	0	0
2004	219	290	142	93	78	73	54	37	41	43	41	134	266	3	0	0	0
2005	337	161	108	88	106	56	54	34	45	35	166	318	2	0	0	0	0
2006	593	373	294	208	144	162	112	98	79	254	449	1	0	0	0	0	0
2007	962	732	545	352	342	226	199	173	336	732	0	0	0	0	0	0	0
2008	2,123	1,464	920	660	422	435	276	597	1,015	2	0	0	0	0	0	0	0
2009	2,769	1,776	1,141	707	698	468	711	1,450	1	0	0	0	0	0	0	0	0
2010	2,351	1,522	960	830	576	916	1,620	1	0	0	0	0	0	0	0	0	0
2011	2,469	1,534	1,253	798	1,233	2,206	0	0	0	0	0	0	0	0	0	0	0
2012	2,121	1,646	992	1,447	2,461	1	0	0	0	0	0	0	0	0	0	0	0
2013	3,406	2,396	3,329	4,554	1	0	0	0	0	0	0	0	0	0	0	0	0
2014	2,886	3,815	5,077	5	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	4,483	5,804	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	6,458	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Psoriasis Drugs																	
2000	95	81	49	38	48	91	26	19	25	11	15	14	11	17	17	57	88
2001	115	111	85	99	166	66	33	33	43	31	26	25	29	27	82	188	1
2002	128	121	100	173	84	54	54	49	38	24	29	24	43	100	123	1	0
2003	283	303	645	200	157	117	125	106	75	61	57	69	202	563	4	0	0
2004	461	966	263	196	159	178	115	103	88	96	91	317	644	3	0	0	0
2005	789	325	227	204	188	159	120	117	104	109	346	805	3	0	0	0	0
2006	1,326	915	801	605	447	415	289	325	301	667	1,380	7	0	0	0	0	0
2007	2,259	1,970	1,390	1,079	930	643	615	494	905	2,260	7	0	0	0	0	0	0
2008	5,240	4,059	2,672	1,997	1,361	1,400	957	1,793	3,173	15	0	0	0	0	0	0	0
2009	8,128	5,580	3,940	2,403	2,554	1,646	2,589	4,898	7	0	0	0	0	0	0	0	0
2010	7,782	5,597	3,485	3,251	2,156	3,244	6,491	7	0	0	0	0	0	0	0	0	0
2011	7,513	4,893	4,559	2,819	3,997	7,311	7	0	0	0	0	0	0	0	0	0	0
2012	7,215	6,300	3,973	5,446	8,347	13	0	0	0	0	0	0	0	0	0	0	0
2013	8,951	5,973	7,956	10,819	38	0	0	0	0	0	0	0	0	0	0	0	0
2014	9,176	11,404	14,750	19	0	0	0	0	0	0	0	0	0	0	0	0	0
2015	17,558	20,290	32	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	26,343	24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	20	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 3a: Summary of Follow-Up Time for Patients Diagnosed with Crohn's Disease, Multiple Sclerosis, Psoriasis, or Ulcerative Colitis in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Condition and Age Group

Age Group (Years)	Number of Patients by Years of Follow-Up Time																
	<1	1-<2	2-<3	3-<4	4-<5	5-<6	6-<7	7-<8	8-<9	9-<10	10-<11	11-<12	12-<13	13-<14	14-<15	15-<16	16+
Crohn's Disease																	
18-30	32,227	18,921	11,152	7,063	4,485	3,077	2,029	1,600	733	430	348	140	108	97	71	91	24
31-64	87,176	56,685	36,552	25,271	17,225	13,142	9,360	8,300	4,863	2,880	2,309	921	783	530	560	698	385
65+	19,141	12,289	8,824	6,811	5,145	3,747	2,945	2,415	2,015	983	650	221	199	140	111	112	63
Multiple Sclerosis																	
18-30	11,670	6,782	4,048	2,441	1,649	1,219	752	680	378	220	152	91	64	54	74	50	40
31-64	75,236	50,880	32,945	22,381	15,282	11,978	8,526	8,493	5,750	2,845	2,607	1,146	986	710	743	1,032	870
65+	11,263	6,888	4,772	3,346	2,532	1,839	1,296	1,166	1,008	446	418	146	147	83	85	74	49
Psoriasis																	
18-30	67,545	38,364	23,122	14,401	9,388	6,538	4,300	3,166	1,535	1,179	671	441	380	356	318	281	124
31-64	289,314	183,938	121,661	83,390	58,288	44,269	31,777	27,661	16,605	11,888	8,483	5,050	4,086	3,777	3,607	3,659	2,234
65+	60,447	44,515	32,510	24,977	19,160	15,071	11,794	10,223	8,523	4,719	3,125	1,587	1,327	1,186	1,007	899	535
Ulcerative Colitis																	
18-30	29,483	17,049	10,066	6,388	3,965	2,761	1,795	1,360	681	412	298	150	131	93	96	96	50
31-64	111,940	68,317	44,480	30,863	21,376	16,469	11,779	10,193	5,971	3,892	2,733	1,334	1,147	965	916	1,074	534
65+	35,962	20,216	13,993	10,814	8,206	6,278	4,977	3,992	3,285	1,658	971	382	280	243	202	232	103

Table 3b: Proportion of Patients with Follow-Up Time After Diagnosis of Crohn's Disease, Multiple Sclerosis, Psoriasis, or Ulcerative Colitis in the Sentinel Distributed Database from January 1, 2000 to the Latest Available Data, by Condition and Age Group

Percentage of Patients by Years of Follow-Up Time																
Age Group (Years)	<3	3+	4+	5+	6+	7+	8+	9+	10+	11+	12+	13+	14+	15+	16+	Total (n)
Crohn's Disease																
18-30	75.4%	24.6%	16.0%	10.6%	6.9%	4.4%	2.5%	1.6%	1.1%	0.6%	0.5%	0.3%	0.2%	0.1%	0.0%	82,596
31-64	67.4%	32.6%	23.1%	16.7%	11.8%	8.3%	5.2%	3.4%	2.3%	1.4%	1.1%	0.8%	0.6%	0.4%	0.1%	267,640
65+	61.2%	38.8%	28.5%	20.7%	15.0%	10.5%	6.8%	3.8%	2.3%	1.3%	0.9%	0.6%	0.4%	0.3%	0.1%	65,811
Multiple Sclerosis																
18-30	74.1%	25.9%	17.9%	12.4%	8.4%	5.9%	3.7%	2.5%	1.7%	1.2%	0.9%	0.7%	0.5%	0.3%	0.1%	30,364
31-64	65.6%	34.4%	25.2%	18.8%	13.9%	10.4%	6.9%	4.5%	3.3%	2.3%	1.8%	1.4%	1.1%	0.8%	0.4%	242,410
65+	64.5%	35.5%	26.1%	19.0%	13.8%	10.2%	6.9%	4.1%	2.8%	1.6%	1.2%	0.8%	0.6%	0.3%	0.1%	35,558
Psoriasis																
18-30	75.0%	25.00%	16.7%	11.2%	7.4%	4.9%	3.1%	2.2%	1.5%	1.1%	0.8%	0.6%	0.4%	0.2%	0.1%	172,109
31-64	66.1%	33.9%	24.6%	18.1%	13.2%	9.7%	6.6%	4.8%	3.4%	2.5%	1.9%	1.5%	1.1%	0.7%	0.2%	899,687
65+	56.9%	43.1%	32.8%	24.8%	18.6%	13.7%	9.5%	6.0%	4.0%	2.7%	2.1%	1.5%	1.0%	0.6%	0.2%	241,605
Ulcerative Colitis																
18-30	75.6%	24.4%	15.9%	10.6%	6.9%	4.5%	2.7%	1.8%	1.2%	0.8%	0.6%	0.4%	0.3%	0.2%	0.1%	74,874
31-64	67.3%	32.7%	23.5%	17.1%	12.1%	8.6%	5.6%	3.8%	2.6%	1.8%	1.4%	1.0%	0.8%	0.5%	0.2%	333,983
65+	62.8%	37.2%	27.6%	20.2%	14.6%	10.2%	6.6%	3.6%	2.2%	1.3%	0.9%	0.7%	0.5%	0.3%	0.1%	111,794

Appendix A: Dates of Available Data for Each Data Partner up to Request Date (June 30, 2017)

Data Partner ID	Start Date	End Date
DP01	1/1/2000	10/31/2014
DP02	1/1/2000	12/31/2016
DP03	1/1/2000	11/30/2016
DP04	1/1/2000	10/31/2015
DP05	1/1/2000	6/30/2016
DP06	1/1/2008	11/30/2016
DP07	1/1/2004	9/30/2016
DP08	1/1/2008	6/30/2016
DP09	1/1/2005	10/31/2016
DP10	1/1/2000	11/30/2016
DP11	1/1/2000	5/31/2015
DP12	1/1/2007	10/31/2016
DP13	1/1/2012	3/31/2016
DP14	1/1/2000	3/31/2017
DP15	1/1/2006	10/31/2016
DP16	1/1/2000	12/31/2015

Appendix B: List of Healthcare Common Procedure Coding System (HCPCS) Codes and Descriptions Used to Define Immunosuppressive Drugs in this Request

Code	Description
Adalimumab	
J0135	INJECTION ADALIMUMAB 20 MG
Alemtuzumab	
Q9979	INJECTION ALEMTUZUMAB 1 MG
J0202	INJECTION ALEMTUZUMAB 1 MG
J9010	INJECTION ALEMTUZUMAB 10 MG
S0087	INJECTION ALEMTUZUMAB 30 MG
C9110	INJ ALEMTUZUMAB, PER 10 MG/ ML
Certolizumab Pegol	
C9249	INJECTION CERTOLIZUMAB PEGOL 1 MG
J0718	INJECTION CERTOLIZUMAB PEGOL 1 MG
J0717	INJECTION CERTOLIZUMAB PEGOL 1 MG
Etanercept	
J1438	INJECTION ETANERCEPT 25 MG
Glatiramer Acetate	
J1595	INJECTION GLATIRAMER ACETATE 20 MG
Q2010	INJECTION GLATIRAMER ACETATE PER DOSE
Golimumab	
J1602	INJECTION GOLIMUMAB 1 MG FOR INTRAVENOUS USE
Infliximab	
Q5102	INJECTION INFlixIMAB BIOSIMILAR 10 MG
J1745	INJECTION INFlixIMAB EXCLUDES BIOSIMILAR 10 MG
Interferon Beta-1A	
Q3027	INJECTION INTERFERON BETA-1A 1 MCG IM USE
Q3028	INJECTION INTERFERON BETA-1A 1 MCG SUBQ USE,
Q3025	INJECTION INTRFER BETA1A 11 MCG IM USE
Q3026	INJECTION INTERFERON BETA-1A 11 MCG SUBQ USE
J1826	INJECTION INTERFERON BETA-1A 30 MCG
J1825	INJECTION INTERFERON BETA-1A 33 MCG
Interferon Beta-1B	
J1830	INJECTION INTERFERON BETA-1B 0.25 MG
Ustekinumab	
J3357	USTEKINUMAB FOR SUBCUTANEOUS INJECTION 1 MG
J1602	INJECTION GOLIMUMAB 1 MG FOR INTRAVENOUS USE

Appendix C: List of Generic Names and Brand Names Used to Define Immunosuppressive Drugs in this Request

Generic Name	Brand Name
ADALIMUMAB	Humira
ADALIMUMAB	Humira Pediatric Crohn's Start
ADALIMUMAB	Humira Pen
ADALIMUMAB	Humira Pen Crohn's-UC-HS Start
ADALIMUMAB	Humira Pen Psoriasis-Uveitis
ALEMTUZUMAB	Lemtrada
ALEMTUZUMAB	Campath
CERTOLIZUMAB PEGOL	Cimzia
CERTOLIZUMAB PEGOL	Cimzia Powder for Reconst
CERTOLIZUMAB PEGOL	Cimzia Starter Kit
DALFAMPRIDINE	Ampyra
DIMETHYL FUMARATE	Tecfidera
DIMETHYL FUMARATE	dimethyl fumarate (bulk)
ETANERCEPT	Enbrel
ETANERCEPT	Enbrel SureClick
FINGOLIMOD HCL	Gilenya
GLATIRAMER ACETATE	Copaxone
GLATIRAMER ACETATE	Glatopa
GOLIMUMAB	Simponi
GOLIMUMAB	Simponi ARIA
INFLIXIMAB	Remicade
INFLIXIMAB-DYYB	Inflectra
INTERFERON BETA-1A	Avonex
INTERFERON BETA-1A/ALBUMIN HUMAN	Avonex (with albumin)
INTERFERON BETA-1A/ALBUMIN HUMAN	Rebif (with albumin)
INTERFERON BETA-1A/ALBUMIN HUMAN	Rebif Rebidose
INTERFERON BETA-1A/ALBUMIN HUMAN	Rebif Titration Pack
INTERFERON BETA-1B	Betaseron
INTERFERON BETA-1B	Extavia
MITOXANTRONE HCL	mitoxantrone

Appendix C: List of Generic Names and Brand Names Used to Define Immunosuppressive Drugs in this Request

MITOXANTRONE HCL	Novantrone
NATALIZUMAB	Tysabri
PEGINTERFERON BETA-1A	Plegridy
TERIFLUNOMIDE	Aubagio
USTEKINUMAB	Stelara



Appendix D: List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Crohn's Disease, Multiple Sclerosis, Psoriasis, and Ulcerative Colitis in this Request

Code	Description	Code Type
Crohn's Disease		
555.0	Regional enteritis of small intestine	ICD-9-CM
555	Regional enteritis	ICD-9-CM
555.1	Regional enteritis of large intestine	ICD-9-CM
555.2	Regional enteritis of small intestine with large intestine	ICD-9-CM
555.9	Regional enteritis of unspecified site	ICD-9-CM
K50	Crohn's disease [regional enteritis]	ICD-10-CM
K50.0	Crohn's disease of small intestine	ICD-10-CM
K50.00	Crohn's disease of small intestine without complications	ICD-10-CM
K50.01	Crohn's disease of small intestine with complications	ICD-10-CM
K50.011	Crohn's disease of small intestine with rectal bleeding	ICD-10-CM
K50.012	Crohn's disease of small intestine with intestinal obstruction	ICD-10-CM
K50.013	Crohn's disease of small intestine with fistula	ICD-10-CM
K50.014	Crohn's disease of small intestine with abscess	ICD-10-CM
K50.018	Crohn's disease of small intestine with other complication	ICD-10-CM
K50.019	Crohn's disease of small intestine with unspecified complications	ICD-10-CM
K50.1	Crohn's disease of large intestine	ICD-10-CM
K50.10	Crohn's disease of large intestine without complications	ICD-10-CM
K50.11	Crohn's disease of large intestine with complications	ICD-10-CM
K50.111	Crohn's disease of large intestine with rectal bleeding	ICD-10-CM
K50.112	Crohn's disease of large intestine with intestinal obstruction	ICD-10-CM
K50.113	Crohn's disease of large intestine with fistula	ICD-10-CM
K50.114	Crohn's disease of large intestine with abscess	ICD-10-CM
K50.118	Crohn's disease of large intestine with other complication	ICD-10-CM
K50.119	Crohn's disease of large intestine with unspecified complications	ICD-10-CM
K50.8	Crohn's disease of both small and large intestine	ICD-10-CM
K50.80	Crohn's disease of both small and large intestine without complications	ICD-10-CM
K50.81	Crohn's disease of both small and large intestine with complications	ICD-10-CM
K50.811	Crohn's disease of both small and large intestine with rectal bleeding	ICD-10-CM



Appendix D: List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Crohn's Disease, Multiple Sclerosis, Psoriasis, and Ulcerative Colitis in this Request

Code	Description	Code Type
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction	ICD-10-CM
K50.813	Crohn's disease of both small and large intestine with fistula	ICD-10-CM
K50.814	Crohn's disease of both small and large intestine with abscess	ICD-10-CM
K50.818	Crohn's disease of both small and large intestine with other complication	ICD-10-CM
K50.819	Crohn's disease of both small and large intestine with unspecified complications	ICD-10-CM
K50.9	Crohn's disease, unspecified	ICD-10-CM
K50.90	Crohn's disease, unspecified, without complications	ICD-10-CM
K50.91	Crohn's disease, unspecified, with complications	ICD-10-CM
K50.911	Crohn's disease, unspecified, with rectal bleeding	ICD-10-CM
K50.912	Crohn's disease, unspecified, with intestinal obstruction	ICD-10-CM
K50.913	Crohn's disease, unspecified, with fistula	ICD-10-CM
K50.914	Crohn's disease, unspecified, with abscess	ICD-10-CM
K50.918	Crohn's disease, unspecified, with other complication	ICD-10-CM
K50.919	Crohn's disease, unspecified, with unspecified complications	ICD-10-CM
Multiple Sclerosis		
340	Multiple Sclerosis	ICD-9-CM
G35	Multiple Sclerosis	ICD-10-CM
Psoriasis		
696	Psoriasis and similar disorders	ICD-9-CM
696.0	Psoriatic arthropathy	ICD-9-CM
696.1	Other psoriasis	ICD-9-CM
L40	Psoriasis	ICD-10-CM
L40.0	Psoriasis vulgaris	ICD-10-CM
L40.1	Generalized pustular psoriasis	ICD-10-CM
L40.4	Guttate psoriasis	ICD-10-CM
L40.5	Arthropathic psoriasis	ICD-10-CM
L40.50	Arthropathic psoriasis, unspecified	ICD-10-CM
L40.8	Other psoriasis	ICD-10-CM
L40.9	Psoriasis, unspecified	ICD-10-CM
L403	Pustulosis palmaris et plantaris	ICD-10-CM
L402	Acrodermatitis continua	ICD-10-CM



Appendix D: List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Crohn's Disease, Multiple Sclerosis, Psoriasis, and Ulcerative Colitis in this Request

Code	Description	Code Type
L4059	Other psoriatic arthropathy	ICD-10-CM
L4054	Psoriatic juvenile arthropathy	ICD-10-CM
L4051	Distal interphalangeal psoriatic arthropathy	ICD-10-CM
L4052	Psoriatic arthritis mutilans	ICD-10-CM
L4053	Psoriatic spondylitis	ICD-10-CM
Ulcerative Colitis		
556	Ulcerative colitis	ICD-9-CM
556.0	Ulcerative (chronic) enterocolitis	ICD-9-CM
556.1	Ulcerative (chronic) ileocolitis	ICD-9-CM
556.2	Ulcerative (chronic) proctitis	ICD-9-CM
556.3	Ulcerative (chronic) proctosigmoiditis	ICD-9-CM
556.4	Pseudopolyposis of colon	ICD-9-CM
556.5	Left sided ulcerative (chronic) colitis	ICD-9-CM
556.6	Universal ulcerative (chronic) colitis	ICD-9-CM
556.8	Other ulcerative colitis	ICD-9-CM
556.9	Unspecified ulcerative colitis	ICD-9-CM
K51	Ulcerative colitis	ICD-10-CM
K51.0	Ulcerative (chronic) pancolitis	ICD-10-CM
K51.00	Ulcerative (chronic) pancolitis without complications	ICD-10-CM
K51.01	Ulcerative (chronic) pancolitis with complications	ICD-10-CM
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding	ICD-10-CM
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction	ICD-10-CM
K51.013	Ulcerative (chronic) pancolitis with fistula	ICD-10-CM
K51.014	Ulcerative (chronic) pancolitis with abscess	ICD-10-CM
K51.018	Ulcerative (chronic) pancolitis with other complication	ICD-10-CM
K51.019	Ulcerative (chronic) pancolitis with unspecified complications	ICD-10-CM
K51.2	Ulcerative (chronic) proctitis	ICD-10-CM
K51.20	Ulcerative (chronic) proctitis without complications	ICD-10-CM
K51.21	Ulcerative (chronic) proctitis with complications	ICD-10-CM
K51.211	Ulcerative (chronic) proctitis with rectal bleeding	ICD-10-CM
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction	ICD-10-CM



Appendix D: List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Crohn's Disease, Multiple Sclerosis, Psoriasis, and Ulcerative Colitis in this Request

Code	Description	Code Type
K51.213	Ulcerative (chronic) proctitis with fistula	ICD-10-CM
K51.214	Ulcerative (chronic) proctitis with abscess	ICD-10-CM
K51.218	Ulcerative (chronic) proctitis with other complication	ICD-10-CM
K51.219	Ulcerative (chronic) proctitis with unspecified complications	ICD-10-CM
K51.3	Ulcerative (chronic) rectosigmoiditis	ICD-10-CM
K51.30	Ulcerative (chronic) rectosigmoiditis without complications	ICD-10-CM
K51.31	Ulcerative (chronic) rectosigmoiditis with complications	ICD-10-CM
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding	ICD-10-CM
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction	ICD-10-CM
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula	ICD-10-CM
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess	ICD-10-CM
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication	ICD-10-CM
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications	ICD-10-CM
K51.4	Inflammatory polyps of colon	ICD-10-CM
K51.40	Inflammatory polyps of colon without complications	ICD-10-CM
K51.41	Inflammatory polyps of colon with complications	ICD-10-CM
K51.411	Inflammatory polyps of colon with rectal bleeding	ICD-10-CM
K51.412	Inflammatory polyps of colon with intestinal obstruction	ICD-10-CM
K51.413	Inflammatory polyps of colon with fistula	ICD-10-CM
K51.414	Inflammatory polyps of colon with abscess	ICD-10-CM
K51.418	Inflammatory polyps of colon with other complication	ICD-10-CM
K51.419	Inflammatory polyps of colon with unspecified complications	ICD-10-CM
K51.5	Left sided colitis	ICD-10-CM
K51.50	Left sided colitis without complications	ICD-10-CM
K51.51	Left sided colitis with complications	ICD-10-CM
K51.511	Left sided colitis with rectal bleeding	ICD-10-CM
K51.512	Left sided colitis with intestinal obstruction	ICD-10-CM
K51.513	Left sided colitis with fistula	ICD-10-CM
K51.514	Left sided colitis with abscess	ICD-10-CM



Appendix D: List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Crohn's Disease, Multiple Sclerosis, Psoriasis, and Ulcerative Colitis in this Request

Code	Description	Code Type
K51.518	Left sided colitis with other complication	ICD-10-CM
K51.519	Left sided colitis with unspecified complications	ICD-10-CM
K51.8	Other ulcerative colitis	ICD-10-CM
K51.80	Other ulcerative colitis without complications	ICD-10-CM
K51.81	Other ulcerative colitis with complications	ICD-10-CM
K51.811	Other ulcerative colitis with rectal bleeding	ICD-10-CM
K51.812	Other ulcerative colitis with intestinal obstruction	ICD-10-CM
K51.813	Other ulcerative colitis with fistula	ICD-10-CM
K51.814	Other ulcerative colitis with abscess	ICD-10-CM
K51.818	Other ulcerative colitis with other complication	ICD-10-CM
K51.819	Other ulcerative colitis with unspecified complications	ICD-10-CM
K51.9	Ulcerative colitis, unspecified	ICD-10-CM
K51.90	Ulcerative colitis, unspecified, without complications	ICD-10-CM
K51.91	Ulcerative colitis, unspecified, with complications	ICD-10-CM
K51.911	Ulcerative colitis, unspecified with rectal bleeding	ICD-10-CM
K51.912	Ulcerative colitis, unspecified with intestinal obstruction	ICD-10-CM
K51.913	Ulcerative colitis, unspecified with fistula	ICD-10-CM
K51.914	Ulcerative colitis, unspecified with abscess	ICD-10-CM
K51.918	Ulcerative colitis, unspecified with other complication	ICD-10-CM
K51.919	Ulcerative colitis, unspecified with unspecified complications	ICD-10-CM

Specifications for cder_mpl1p_wp006_nsdv01, Analysis 1

The Center for Drug Evaluation and Research (CDER) requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.0.0, and a Rapid Analytic Development and Response (RADaR) module, to investigate follow-up time for patients treated with immunosuppressive medications for multiple sclerosis and psoriasis.

Age Groups: 18-30, 31-64, 65+

Query Period: January 1, 2000 - Most recent available data

Coverage Requirement: Medical and Drug Coverage

Enrollment Requirement: 183 days

Enrollment Gap: 45 days

Follow-up intervals: <1y, 1- <2y 2- <3y 3-<4y 4-<5y, ...,16+y

Drug/Exposure
Follow-up

Scenario	Drug/Exposure				Follow-up		
	Exposure	Incident w/ respect to:	Care Setting	Washout (days)	Cohort Definition	Follow-up Start	Follow-up End
1	Interferon Beta-1A	Interferon Beta-1A	Any	183	Include only the first valid exposure	First exposure	Censoring
2	Interferon Beta-1B	Interferon Beta-1B	Any	183	Include only the first valid exposure	First exposure	Censoring
3	Glatiramer Acetate	Glatiramer Acetate	Any	183	Include only the first valid exposure	First exposure	Censoring
4	Pegylated Interferon Beta-1A	Pegylated Interferon Beta-1A	Any	183	Include only the first valid exposure	First exposure	Censoring
5	Teriflunomide	Teriflunomide	Any	183	Include only the first valid exposure	First exposure	Censoring
6	Fingolimod	Fingolimod	Any	183	Include only the first valid exposure	First exposure	Censoring
7	Dimethyl Fumarate	Dimethyl Fumarate	Any	183	Include only the first valid exposure	First exposure	Censoring
8	Alemtuzumab	Alemtuzumab	Any	183	Include only the first valid exposure	First exposure	Censoring
9	Mitoxantrone	Mitoxantrone	Any	183	Include only the first valid exposure	First exposure	Censoring
10	Natalizumab	Natalizumab	Any	183	Include only the first valid exposure	First exposure	Censoring

11	Etanercept	Etanercept	Any	183	Include only the first valid exposure	First exposure	Censoring
12	Infliximab	Infliximab	Any	183	Include only the first valid exposure	First exposure	Censoring
13	Adalimumab	Adalimumab	Any	183	Include only the first valid exposure	First exposure	Censoring
14	Certolizumab	Certolizumab	Any	183	Include only the first valid exposure	First exposure	Censoring
15	Golimumab	Golimumab	Any	183	Include only the first valid exposure	First exposure	Censoring
16	Ustekinumab	Ustekinumab	Any	183	Include only the first valid exposure	First exposure	Censoring
17	Dalfampridine	Dalfampridine	Any	183	Include only the first valid exposure	First exposure	Censoring

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

Specifications for cder_mpl1p_wp006_nsdp_v01, Analysis 2

The Center for Drug Evaluation and Research (CDER) requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.0.0, and a Rapid Analytic Development and Response (RADaR) module, to investigate follow-up time for patients diagnosed with psoriasis, multiple sclerosis, Crohn's disease, and ulcerative colitis

Age Groups: 18-30, 31-64, 65+
Query Period: January 1, 2000 - Most recent available data
Coverage Requirement: Medical and Drug Coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 days
Follow-up intervals: <1y, 1- <2y 2- <3y 3-<4y 4-<5y, ...,16+y

Event

Follow-up

Scenario	Event	Care Setting	Washout (days)	Cohort Definition	Follow-up Start	Follow-up End
1	Psoriasis	Any	0	Include the first valid event	First Event	Censoring
2	Multiple Sclerosis	Any	0	Include the first valid event	First Event	Censoring
3	Crohn's Disease	Any	0	Include the first valid event	First Event	Censoring
4	Ulcerative Colitis	Any	0	Include the first valid event	First Event	Censoring

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