

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-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 Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-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 the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-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 to09y05_mpr_wp31_v01

<u>Request Description</u>	This report investigated prevalence and incidence of progressive multifocal leukoencephalopathy (PML), clostridium difficile, and cytomegalovirus (CMV) diagnoses among members with Crohn's disease or ulcerative colitis in the Mini-Sentinel Distributed Database (MSDD). One run of MP9 was required. The time window for the request was January 1, 2000 to May 31, 2013. Results provide counts of prevalent and incident numbers of patients, claims, eligible members, member-years, claims per patient, and patients per 1,000 eligible members. The package was distributed to 18 Data Partners on April 25, 2014; this report contains information from 18 Data Partners. Please review the notes below.
<u>Request ID</u>	to09y05_mpr_wp31_v01
<u>Glossary</u>	Glossary of Terms in Modular Program 9
<u>Table 1a</u>	Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, and Pre-Existing Condition Lookback Period
<u>Table 1b</u>	Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, and Pre-Existing Condition Lookback Period
<u>Table 2a</u>	Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Age Group
<u>Table 2b</u>	Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Age Group
<u>Table 3a</u>	Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Sex
<u>Table 3b</u>	Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Sex
<u>Table 4a</u>	Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year
<u>Table 4b</u>	Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year
<u>Appendix A</u>	International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Included in this Request
<u>Appendix B</u>	Specifications for Requests TO09Y04_MPR_WP31_V01
<u>Appendix C</u>	Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner as of Request Send Date (April 25, 2014)

Notes:

When interpreting changes in raw counts of patients over time, it is important to understand the way in which the MSDD population is constructed. For example, one large Data Partner has data beginning in 2004, while a second large Data Partner has data beginning in 2007. Increases in the raw numbers of diagnosis/procedure patients or drug product users in these years are likely due to the introduction of these Data Partners. Thus, year-to-year changes should not be interpreted as trends in diagnoses, procedures, or drug products.

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.

Glossary of Terms in Modular Program 9*

Care Setting - Contains the care settings considered for the individual diagnosis or procedure codes of interest. The following are valid entries:

IP: inpatient hospital stays

IS: non-acute institutional stays

ED: emergency department visits

AV: ambulatory visits

OA: other ambulatory visits.

Claims - For the prevalent-based cohort, all claims for members with the diagnosis/procedure of interest will be included in the claims column. For the incident-based cohort, a member must have a claim that meets the criteria specified for incidence type and washout period. If a member has more than one claim on the index date, all claims identified on that date will be included in the number of claims. Claims identified any time after the index date are not included in the claims column.

Eligible Members (incidence-based cohort) - Number of members eligible for incident diagnosis (defined by the washout period) with drug and/or medical coverage during the query period.

Eligible Members (prevalence-based cohort) - Number of members with at least one day of drug and/or medical coverage during the query period.

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

Incidence Type (incidence-based cohort) - *Minimum incidence type* will only consider the first claim in the query period as long as it is the first claim in the user's entire available history. *Single incidence type* will consider the first claim in the query period that satisfies the washout period criteria. That is, incidence is defined as the first claim during the query period with no evidence of a prior claim during the previous washout period days. *Multiple incidence type* will use the washout period to establish incidence and consider all qualifying incident claims.

"Incident with Respect to" Codes - National Drug Codes (NDCs) and/or procedure and/or diagnosis codes to be used to refine the incident definition for the exposure(s) of interest. For example, if a requester is examining exposure to DRUG A but wants incidence of DRUG A to be defined with respect to DRUG A and DRUG B, the Incident with Respect to Code fields would include both DRUG A and DRUG B codes.

Incident Only Care Setting - Contains the care settings considered for the individual diagnosis or procedure codes included as "Incident with Respect to" codes.

Member-years (incidence-based cohort) - Sum of all years of enrollment with drug and/or medical coverage in the query period preceded by a washout period

Member-Years (prevalence-based cohort) - Sum of all years members are enrolled with drug and/or medical coverage during the query period.

Query Period - Period in which the modular program looks for diagnoses of interest.

Washout Period (incidence-based cohort) - Number of days a patient is required to have no evidence of prior claim of interest and continuous drug and/or medical coverage.

*all terms may not be used in this report

Table 1a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, and Pre-Existing Condition Lookback Period

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period	7,600	21,105	427,395	453,572	2.78	17.78
365-day lookback period	8,185	22,284	427,399	641,879	2.72	19.15
<i>Cytomegalovirus</i>						
183-day lookback period	464	957	427,395	453,572	2.06	1.09
365-day lookback period	508	1,034	427,399	641,879	2.04	1.19
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period	3	4	427,395	453,572	1.33	0.01
365-day lookback period	4	6	427,399	641,879	1.50	0.01
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period	4,092	9,304	353,533	439,668	2.27	11.57
365-day lookback period	4,455	10,022	353,540	570,235	2.25	12.60
<i>Cytomegalovirus</i>						
183-day lookback period	258	491	353,533	439,668	1.90	0.73
365-day lookback period	285	536	353,540	570,235	1.88	0.81
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period	5	6	353,533	439,668	1.20	0.01
365-day lookback period	5	6	353,540	570,235	1.20	0.01

Table 1b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, and Pre-Existing Condition Lookback Period

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period	3,890	4,201	402,545	400,210	1.08	9.66
365-day lookback period	4,596	4,946	406,060	585,758	1.08	11.32
<i>Cytomegalovirus</i>						
183-day lookback period	331	346	409,145	406,885	1.05	0.81
365-day lookback period	380	396	409,319	593,856	1.04	0.93
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period	2	2	409,349	407,404	1.00	0.00
365-day lookback period	3	3	409,436	594,519	1.00	0.01
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period	2,853	3,068	332,159	384,919	1.08	8.59
365-day lookback period	3,258	3,509	333,278	513,561	1.08	9.78
<i>Cytomegalovirus</i>						
183-day lookback period	194	203	333,945	389,095	1.05	0.58
365-day lookback period	222	232	334,085	518,539	1.05	0.66
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period	3	3	334,040	389,353	1.00	0.01
365-day lookback period	3	3	334,122	518,859	1.00	0.01

Table 2a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Age Group

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period						
0-17 years	229	339	14,490	14,498	1.48	15.80
18-44 years	1,407	2,397	165,068	161,444	1.70	8.52
45-64 years	1,956	4,259	184,359	187,372	2.18	10.61
65+ years	4,039	14,110	86,906	90,257	3.49	46.48
365-day lookback period						
0-17 years	247	360	14,474	18,570	1.46	17.07
18-44 years	1,504	2,538	165,490	222,324	1.69	9.09
45-64 years	2,128	4,586	186,232	270,624	2.16	11.43
65+ years	4,341	14,800	88,327	130,360	3.41	49.15
<i>Cytomegalovirus</i>						
183-day lookback period						
0-17 years	25	72	14,490	14,498	2.88	1.73
18-44 years	187	286	165,068	161,444	1.53	1.13
45-64 years	179	389	184,359	187,372	2.17	0.97
65+ years	74	210	86,906	90,257	2.84	0.85
365-day lookback period						
0-17 years	27	76	14,474	18,570	2.81	1.87
18-44 years	200	309	165,490	222,324	1.55	1.21
45-64 years	195	420	186,232	270,624	2.15	1.05
65+ years	87	229	88,327	130,360	2.63	0.98
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
0-17 years	0	0	14,490	14,498	---	0.00
18-44 years	1	1	165,068	161,444	1.00	0.01
45-64 years	2	3	184,359	187,372	1.50	0.01
65+ years	0	0	86,906	90,257	---	0.00
365-day lookback period						
0-17 years	0	0	14,474	18,570	---	0.00
18-44 years	2	3	165,490	222,324	1.50	0.01
45-64 years	2	3	186,232	270,624	1.50	0.01
65+ years	0	0	88,327	130,360	---	0.00

Table 2a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Age Group

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period						
0-17 years	223	319	21,898	24,329	1.43	10.18
18-44 years	1,199	1,960	159,413	183,017	1.63	7.52
45-64 years	1,227	2,769	140,817	169,963	2.26	8.71
65+ years	1,463	4,256	52,934	62,359	2.91	27.64
365-day lookback period						
0-17 years	239	338	21,874	29,243	1.41	10.93
18-44 years	1,275	2,085	159,946	231,417	1.64	7.97
45-64 years	1,339	2,969	142,152	224,605	2.22	9.42
65+ years	1,625	4,630	53,846	84,969	2.85	30.18
<i>Cytomegalovirus</i>						
183-day lookback period						
0-17 years	10	14	21,898	24,329	1.40	0.46
18-44 years	92	148	159,413	183,017	1.61	0.58
45-64 years	114	219	140,817	169,963	1.92	0.81
65+ years	43	110	52,934	62,359	2.56	0.81
365-day lookback period						
0-17 years	12	16	21,874	29,243	1.33	0.55
18-44 years	99	155	159,946	231,417	1.57	0.62
45-64 years	127	249	142,152	224,605	1.96	0.89
65+ years	48	116	53,846	84,969	2.42	0.89
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
0-17 years	0	0	21,898	24,329	---	0.00
18-44 years	2	3	159,413	183,017	1.50	0.01
45-64 years	2	2	140,817	169,963	1.00	0.01
65+ years	1	1	52,934	62,359	1.00	0.02
365-day lookback period						
0-17 years	0	0	21,874	29,243	---	0.00
18-44 years	2	3	159,946	231,417	1.50	0.01
45-64 years	2	2	142,152	224,605	1.00	0.01
65+ years	1	1	53,846	84,969	1.00	0.02

Table 2b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Age Group

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period						
0-17 years	166	179	13,470	12,547	1.08	12.32
18-44 years	988	1,045	154,449	138,878	1.06	6.40
45-64 years	1,094	1,156	175,528	167,916	1.06	6.23
65+ years	1,642	1,821	80,301	80,869	1.11	20.45
365-day lookback period						
0-17 years	184	197	13,529	16,547	1.07	13.60
18-44 years	1,096	1,155	155,417	198,791	1.05	7.05
45-64 years	1,293	1,363	178,549	250,273	1.05	7.24
65+ years	2,023	2,231	83,413	120,147	1.10	24.25
<i>Cytomegalovirus</i>						
183-day lookback period						
0-17 years	19	20	13,581	12,790	1.05	1.40
18-44 years	138	141	155,258	140,379	1.02	0.89
45-64 years	120	129	177,421	169,931	1.08	0.68
65+ years	54	56	84,343	83,786	1.04	0.64
365-day lookback period						
0-17 years	21	22	13,575	16,821	1.05	1.55
18-44 years	153	156	155,756	200,563	1.02	0.98
45-64 years	138	147	179,344	252,732	1.07	0.77
65+ years	68	71	85,765	123,740	1.04	0.79
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
0-17 years	0	0	13,590	12,808	---	0.00
18-44 years	1	1	155,321	140,610	1.00	0.01
45-64 years	1	1	177,531	170,113	1.00	0.01
65+ years	0	0	84,390	83,873	---	0.00
365-day lookback period						
0-17 years	0	0	13,579	16,843	---	0.00
18-44 years	2	2	155,789	200,846	1.00	0.01
45-64 years	1	1	179,418	252,968	1.00	0.01
65+ years	0	0	85,802	123,862	---	0.00

Table 2b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Age Group

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period						
0-17 years	184	192	20,379	21,053	1.04	9.03
18-44 years	887	945	147,390	156,274	1.07	6.02
45-64 years	895	965	133,653	151,375	1.08	6.70
65+ years	887	966	50,053	56,217	1.09	17.72
365-day lookback period						
0-17 years	201	209	20,394	25,882	1.04	9.86
18-44 years	970	1,036	148,186	203,810	1.07	6.55
45-64 years	1,018	1,099	135,304	205,418	1.08	7.52
65+ years	1,069	1,165	51,429	78,451	1.09	20.79
<i>Cytomegalovirus</i>						
183-day lookback period						
0-17 years	9	9	20,436	21,323	1.00	0.44
18-44 years	65	66	147,779	157,614	1.02	0.44
45-64 years	86	93	134,206	152,709	1.08	0.64
65+ years	34	35	51,019	57,450	1.03	0.67
365-day lookback period						
0-17 years	11	11	20,424	26,187	1.00	0.54
18-44 years	73	74	148,389	205,363	1.01	0.49
45-64 years	100	108	135,571	207,007	1.08	0.74
65+ years	38	39	51,930	79,981	1.03	0.73
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
0-17 years	0	0	20,441	21,335	---	0.00
18-44 years	0	0	147,818	157,712	---	0.00
45-64 years	2	2	134,246	152,824	1.00	0.01
65+ years	1	1	51,040	57,483	1.00	0.02
365-day lookback period						
0-17 years	0	0	20,426	26,201	---	0.00
18-44 years	0	0	148,405	205,484	---	0.00
45-64 years	2	2	135,586	207,149	1.00	0.01
65+ years	1	1	51,944	80,025	1.00	0.02

Table 3a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Sex

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period						
Female	4,630	12,907	233,271	239,999	2.79	19.85
Male	2,967	8,195	194,006	213,474	2.76	15.29
Unknown	3	3	118	99	1.00	25.42
365-day lookback period						
Female	4,970	13,651	233,274	342,221	2.75	21.31
Male	3,212	8,630	194,007	299,528	2.69	16.56
Unknown	3	3	118	129	1.00	25.42
<i>Cytomegalovirus</i>						
183-day lookback period						
Female	208	437	233,271	239,999	2.10	0.89
Male	256	520	194,006	213,474	2.03	1.32
Unknown	0	0	118	99	---	0.00
365-day lookback period						
Female	229	476	233,274	342,221	2.08	0.98
Male	279	558	194,007	299,528	2.00	1.44
Unknown	0	0	118	129	---	0.00
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
Female	2	2	233,271	239,999	1.00	0.01
Male	1	2	194,006	213,474	2.00	0.01
Unknown	0	0	118	99	---	0.00
365-day lookback period						
Female	2	2	233,274	342,221	1.00	0.01
Male	2	4	194,007	299,528	2.00	0.01
Unknown	0	0	118	129	---	0.00

Table 3a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Sex

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period						
Female	2,471	5,550	197,487	245,822	2.25	12.51
Male	1,621	3,754	155,964	193,770	2.32	10.39
Unknown	0	0	82	77	---	0.00
365-day lookback period						
Female	2,690	6,000	197,489	319,110	2.23	13.62
Male	1,765	4,022	155,969	251,025	2.28	11.32
Unknown	0	0	82	99	---	0.00
<i>Cytomegalovirus</i>						
183-day lookback period						
Female	127	209	197,487	245,822	1.65	0.64
Male	131	282	155,964	193,770	2.15	0.84
Unknown	0	0	82	77	---	0.00
365-day lookback period						
Female	138	225	197,489	319,110	1.63	0.70
Male	147	311	155,969	251,025	2.12	0.94
Unknown	0	0	82	99	---	0.00
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
Female	2	2	197,487	245,822	1.00	0.01
Male	3	4	155,964	193,770	1.33	0.02
Unknown	0	0	82	77	---	0.00
365-day lookback period						
Female	2	2	197,489	319,110	1.00	0.01
Male	3	4	155,969	251,025	1.33	0.02
Unknown	0	0	82	99	---	0.00

Table 3b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Sex

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period						
Female	2,320	2,506	219,700	211,316	1.08	10.56
Male	1,570	1,695	182,753	188,812	1.08	8.59
Unknown	0	0	92	82	---	0.00
365-day lookback period						
Female	2,742	2,948	221,958	311,951	1.08	12.35
Male	1,854	1,998	184,008	273,695	1.08	10.08
Unknown	0	0	94	112	---	0.00
<i>Cytomegalovirus</i>						
183-day lookback period						
Female	155	161	223,848	215,520	1.04	0.69
Male	176	185	185,200	191,283	1.05	0.95
Unknown	0	0	97	83	---	0.00
365-day lookback period						
Female	177	183	223,934	317,065	1.03	0.79
Male	203	213	185,288	276,678	1.05	1.10
Unknown	0	0	97	113	---	0.00
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
Female	2	2	223,942	215,738	1.00	0.01
Male	0	0	185,310	191,583	---	0.00
Unknown	0	0	97	83	---	0.00
365-day lookback period						
Female	2	2	223,985	317,329	1.00	0.01
Male	1	1	185,354	277,077	1.00	0.01
Unknown	0	0	97	113	---	0.00

Table 3b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Sex

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period						
Female	1,728	1,848	185,537	215,093	1.07	9.31
Male	1,125	1,220	146,555	169,760	1.08	7.68
Unknown	0	0	67	66	---	0.00
365-day lookback period						
Female	1,970	2,118	186,244	287,238	1.08	10.58
Male	1,288	1,391	146,967	226,235	1.08	8.76
Unknown	0	0	67	88	---	0.00
<i>Cytomegalovirus</i>						
183-day lookback period						
Female	97	102	186,656	217,678	1.05	0.52
Male	97	101	147,222	171,351	1.04	0.66
Unknown	0	0	67	66	---	0.00
365-day lookback period						
Female	107	112	186,728	290,333	1.05	0.57
Male	115	120	147,290	228,118	1.04	0.78
Unknown	0	0	67	88	---	0.00
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
Female	1	1	186,693	217,810	1.00	0.01
Male	2	2	147,280	171,477	1.00	0.01
Unknown	0	0	67	66	---	0.00
365-day lookback period						
Female	1	1	186,740	290,494	1.00	0.01
Male	2	2	147,315	228,277	1.00	0.01
Unknown	0	0	67	88	---	0.00

Table 4a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period						
2000	41	51	9,915	4,542	1.24	4.14
2001	40	55	12,975	6,071	1.38	3.08
2002	80	97	13,844	6,474	1.21	5.78
2003	55	82	14,771	6,921	1.49	3.72
2004	90	127	16,740	7,891	1.41	5.38
2005	94	137	18,126	8,762	1.46	5.19
2006	315	570	46,416	22,315	1.81	6.79
2007	552	1,218	62,477	29,159	2.21	8.84
2008	1,145	2,588	126,548	60,473	2.26	9.05
2009	1,214	3,046	142,610	68,613	2.51	8.51
2010	1,237	2,988	141,495	68,901	2.42	8.74
2011	1,432	3,963	139,933	69,056	2.77	10.23
2012	1,474	4,161	136,612	67,779	2.82	10.79
2013	649	2,022	94,787	26,616	3.12	6.85
365-day lookback period						
2000	43	53	9,915	5,396	1.23	4.34
2001	44	59	14,985	9,143	1.34	2.94
2002	86	108	16,151	9,910	1.26	5.32
2003	68	101	17,082	10,467	1.49	3.98
2004	97	140	19,161	11,831	1.44	5.06
2005	105	150	20,764	13,011	1.43	5.06
2006	333	590	48,755	28,682	1.77	6.83
2007	600	1,283	70,126	41,761	2.14	8.56
2008	1,205	2,704	134,837	79,910	2.24	8.94
2009	1,303	3,239	161,984	99,107	2.49	8.04
2010	1,330	3,141	160,578	99,053	2.36	8.28
2011	1,544	4,162	158,707	99,118	2.70	9.73
2012	1,613	4,413	154,805	96,766	2.74	10.42
2013	716	2,141	115,107	37,724	2.99	6.22

Table 4a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
<i>Cytomegalovirus</i>						
183-day lookback period						
2000	7	10	9,915	4,542	1.43	0.71
2001	3	3	12,975	6,071	1.00	0.23
2002	7	8	13,844	6,474	1.14	0.51
2003	6	8	14,771	6,921	1.33	0.41
2004	9	11	16,740	7,891	1.22	0.54
2005	8	11	18,126	8,762	1.38	0.44
2006	23	54	46,416	22,315	2.35	0.50
2007	27	48	62,477	29,159	1.78	0.43
2008	63	113	126,548	60,473	1.79	0.50
2009	77	173	142,610	68,613	2.25	0.54
2010	76	117	141,495	68,901	1.54	0.54
2011	64	118	139,933	69,056	1.84	0.46
2012	89	192	136,612	67,779	2.16	0.65
2013	37	91	94,787	26,616	2.46	0.39
365-day lookback period						
2000	8	11	9,915	5,396	1.38	0.81
2001	5	6	14,985	9,143	1.20	0.33
2002	8	9	16,151	9,910	1.13	0.50
2003	7	9	17,082	10,467	1.29	0.41
2004	12	14	19,161	11,831	1.17	0.63
2005	8	11	20,764	13,011	1.38	0.39
2006	24	55	48,755	28,682	2.29	0.49
2007	31	52	70,126	41,761	1.68	0.44
2008	69	121	134,837	79,910	1.75	0.51
2009	80	177	161,984	99,107	2.21	0.49
2010	87	133	160,578	99,053	1.53	0.54
2011	72	133	158,707	99,118	1.85	0.45
2012	94	203	154,805	96,766	2.16	0.61
2013	42	100	115,107	37,724	2.38	0.36
<i>Progressive multifocal leukoencephalopathy</i>						

Table 4a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
183-day lookback period						
2000	0	0	9,915	4,542	---	0.00
2001	1	1	12,975	6,071	1.00	0.08
2002	0	0	13,844	6,474	---	0.00
2003	0	0	14,771	6,921	---	0.00
2004	0	0	16,740	7,891	---	0.00
2005	0	0	18,126	8,762	---	0.00
2006	0	0	46,416	22,315	---	0.00
2007	0	0	62,477	29,159	---	0.00
2008	0	0	126,548	60,473	---	0.00
2009	0	0	142,610	68,613	---	0.00
2010	1	2	141,495	68,901	2.00	0.01
2011	0	0	139,933	69,056	---	0.00
2012	1	1	136,612	67,779	1.00	0.01
2013	0	0	94,787	26,616	---	0.00
365-day lookback period						
2000	0	0	9,915	5,396	---	0.00
2001	1	1	14,985	9,143	1.00	0.07
2002	0	0	16,151	9,910	---	0.00
2003	0	0	17,082	10,467	---	0.00
2004	0	0	19,161	11,831	---	0.00
2005	0	0	20,764	13,011	---	0.00
2006	0	0	48,755	28,682	---	0.00
2007	0	0	70,126	41,761	---	0.00
2008	0	0	134,837	79,910	---	0.00
2009	0	0	161,984	99,107	---	0.00
2010	1	2	160,578	99,053	2.00	0.01
2011	0	0	158,707	99,118	---	0.00
2012	2	3	154,805	96,766	1.50	0.01
2013	0	0	115,107	37,724	---	0.00

Pre-Existing Condition of Crohn's Disease

Clostridium difficile

Table 4a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
183-day lookback period						
2000	13	16	8,788	4,554	1.23	1.48
2001	31	34	10,470	5,671	1.10	2.96
2002	39	46	11,204	6,098	1.18	3.48
2003	49	61	11,961	6,479	1.24	4.10
2004	64	92	13,983	7,575	1.44	4.58
2005	64	100	15,288	8,361	1.56	4.19
2006	169	306	41,043	21,909	1.81	4.12
2007	270	519	54,342	28,579	1.92	4.97
2008	558	944	111,359	59,767	1.69	5.01
2009	600	1,161	121,883	66,454	1.94	4.92
2010	684	1,396	120,471	66,126	2.04	5.68
2011	793	1,811	120,725	66,900	2.28	6.57
2012	843	1,900	118,825	65,739	2.25	7.09
2013	359	918	84,803	25,457	2.56	4.23
365-day lookback period						
2000	16	19	8,789	5,171	1.19	1.82
2001	33	36	11,763	7,779	1.09	2.81
2002	46	55	12,579	8,307	1.20	3.66
2003	55	68	13,410	8,864	1.24	4.10
2004	72	104	15,391	10,172	1.44	4.68
2005	67	103	16,957	11,268	1.54	3.95
2006	178	315	42,588	26,245	1.77	4.18
2007	291	545	59,586	37,491	1.87	4.88
2008	596	998	117,458	73,776	1.67	5.07
2009	653	1,248	136,268	87,675	1.91	4.79
2010	741	1,494	133,491	86,724	2.02	5.55
2011	861	1,926	133,142	87,481	2.24	6.47
2012	929	2,092	131,597	85,985	2.25	7.06
2013	397	1,019	98,970	33,297	2.57	4.01

Cytomegalovirus

183-day lookback period

Table 4a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
2000	1	1	8,788	4,554	1.00	0.11
2001	2	6	10,470	5,671	3.00	0.19
2002	4	5	11,204	6,098	1.25	0.36
2003	2	3	11,961	6,479	1.50	0.17
2004	5	8	13,983	7,575	1.60	0.36
2005	3	5	15,288	8,361	1.67	0.20
2006	9	22	41,043	21,909	2.44	0.22
2007	20	30	54,342	28,579	1.50	0.37
2008	26	47	111,359	59,767	1.81	0.23
2009	42	83	121,883	66,454	1.98	0.34
2010	52	99	120,471	66,126	1.90	0.43
2011	54	81	120,725	66,900	1.50	0.45
2012	40	59	118,825	65,739	1.48	0.34
2013	25	42	84,803	25,457	1.68	0.29
<i>365-day lookback period</i>						
2000	1	1	8,789	5,171	1.00	0.11
2001	3	7	11,763	7,779	2.33	0.26
2002	4	5	12,579	8,307	1.25	0.32
2003	2	3	13,410	8,864	1.50	0.15
2004	5	9	15,391	10,172	1.80	0.32
2005	3	5	16,957	11,268	1.67	0.18
2006	10	23	42,588	26,245	2.30	0.23
2007	22	32	59,586	37,491	1.45	0.37
2008	28	49	117,458	73,776	1.75	0.24
2009	45	87	136,268	87,675	1.93	0.33
2010	58	110	133,491	86,724	1.90	0.43
2011	59	88	133,142	87,481	1.49	0.44
2012	47	70	131,597	85,985	1.49	0.36
2013	27	47	98,970	33,297	1.74	0.27
<i>Progressive multifocal leukoencephalopathy</i>						
<i>183-day lookback period</i>						
2000	0	0	8,788	4,554	---	0.00

Table 4a. Summary of Prevalent Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	Patients	Claims	Eligible Members	Member-Years	Claims per Patient	Patients per 1,000 Eligible Members
2001	0	0	10,470	5,671	---	0.00
2002	0	0	11,204	6,098	---	0.00
2003	0	0	11,961	6,479	---	0.00
2004	0	0	13,983	7,575	---	0.00
2005	0	0	15,288	8,361	---	0.00
2006	0	0	41,043	21,909	---	0.00
2007	1	1	54,342	28,579	1.00	0.02
2008	0	0	111,359	59,767	---	0.00
2009	1	1	121,883	66,454	1.00	0.01
2010	1	2	120,471	66,126	2.00	0.01
2011	1	1	120,725	66,900	1.00	0.01
2012	0	0	118,825	65,739	---	0.00
2013	1	1	84,803	25,457	1.00	0.01
365-day lookback period						
2000	0	0	8,789	5,171	---	0.00
2001	0	0	11,763	7,779	---	0.00
2002	0	0	12,579	8,307	---	0.00
2003	0	0	13,410	8,864	---	0.00
2004	0	0	15,391	10,172	---	0.00
2005	0	0	16,957	11,268	---	0.00
2006	0	0	42,588	26,245	---	0.00
2007	1	1	59,586	37,491	1.00	0.02
2008	0	0	117,458	73,776	---	0.00
2009	1	1	136,268	87,675	1.00	0.01
2010	1	2	133,491	86,724	2.00	0.01
2011	1	1	133,142	87,481	1.00	0.01
2012	0	0	131,597	85,985	---	0.00
2013	1	1	98,970	33,297	1.00	0.01

Table 4b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Ulcerative Colitis						
<i>Clostridium difficile</i>						
183-day lookback period						
2000	18	18	9,226	2,712	1.00	1.95
2001	26	26	12,600	5,742	1.00	2.06
2002	56	60	13,455	6,065	1.07	4.16
2003	38	41	14,317	6,483	1.08	2.65
2004	50	54	16,179	7,254	1.08	3.09
2005	50	50	17,460	8,177	1.00	2.86
2006	121	124	43,470	16,354	1.02	2.78
2007	244	257	59,402	25,671	1.05	4.11
2008	489	522	118,135	46,925	1.07	4.14
2009	586	623	136,661	62,818	1.06	4.29
2010	589	636	135,519	63,018	1.08	4.35
2011	691	751	133,493	63,088	1.09	5.18
2012	677	752	130,191	61,964	1.11	5.20
2013	255	287	85,540	23,940	1.13	2.98
365-day lookback period						
2000	20	20	9,234	3,559	1.00	2.17
2001	31	31	14,609	8,777	1.00	2.12
2002	63	67	15,769	9,457	1.06	4.00
2003	50	53	16,615	9,970	1.06	3.01
2004	58	62	18,594	11,133	1.07	3.12
2005	61	62	20,099	12,358	1.02	3.03
2006	141	144	45,915	22,634	1.02	3.07
2007	298	311	67,167	38,102	1.04	4.44
2008	552	591	126,759	66,107	1.07	4.35
2009	686	730	156,321	92,905	1.06	4.39
2010	690	741	154,781	92,761	1.07	4.46
2011	811	875	152,474	92,690	1.08	5.32
2012	821	906	148,546	90,453	1.10	5.53
2013	314	353	105,631	34,852	1.12	2.97

Table 4b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
<i>Cytomegalovirus</i>						
183-day lookback period						
2000	2	2	9,257	2,726	1.00	0.22
2001	3	3	12,657	5,774	1.00	0.24
2002	6	6	13,542	6,118	1.00	0.44
2003	4	4	14,439	6,550	1.00	0.28
2004	6	7	16,339	7,336	1.17	0.37
2005	5	5	17,661	8,284	1.00	0.28
2006	12	12	43,970	16,548	1.00	0.27
2007	14	14	60,243	26,032	1.00	0.23
2008	39	40	119,815	47,671	1.03	0.33
2009	60	66	138,607	63,829	1.10	0.43
2010	58	59	137,467	64,058	1.02	0.42
2011	43	43	135,681	64,292	1.00	0.32
2012	56	61	132,478	63,234	1.09	0.42
2013	23	24	87,150	24,435	1.04	0.26
365-day lookback period						
2000	3	3	9,262	3,573	1.00	0.32
2001	4	4	14,652	8,816	1.00	0.27
2002	7	7	15,839	9,521	1.00	0.44
2003	5	5	16,721	10,056	1.00	0.30
2004	9	10	18,737	11,234	1.11	0.48
2005	5	5	20,267	12,492	1.00	0.25
2006	12	12	46,285	22,862	1.00	0.26
2007	19	19	67,830	38,533	1.00	0.28
2008	45	47	128,010	66,976	1.04	0.35
2009	65	71	157,792	94,113	1.09	0.41
2010	69	70	156,375	94,021	1.01	0.44
2011	50	50	154,273	94,159	1.00	0.32
2012	60	65	150,498	92,025	1.08	0.40
2013	27	28	107,287	35,475	1.04	0.25

Table 4b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
2000	0	0	9,264	2,728	---	0.00
2001	1	1	12,662	5,777	1.00	0.08
2002	0	0	13,554	6,126	---	0.00
2003	0	0	14,450	6,559	---	0.00
2004	0	0	16,356	7,347	---	0.00
2005	0	0	17,677	8,294	---	0.00
2006	0	0	43,998	16,564	---	0.00
2007	0	0	60,288	26,058	---	0.00
2008	0	0	119,886	47,716	---	0.00
2009	0	0	138,696	63,898	---	0.00
2010	0	0	137,581	64,142	---	0.00
2011	0	0	135,823	64,385	---	0.00
2012	1	1	132,623	63,333	1.00	0.01
2013	0	0	87,277	24,479	---	0.00
365-day lookback period						
2000	0	0	9,266	3,576	---	0.00
2001	1	1	14,657	8,821	1.00	0.07
2002	0	0	15,847	9,531	---	0.00
2003	0	0	16,733	10,068	---	0.00
2004	0	0	18,752	11,249	---	0.00
2005	0	0	20,284	12,508	---	0.00
2006	0	0	46,313	22,882	---	0.00
2007	0	0	67,867	38,567	---	0.00
2008	0	0	128,073	67,032	---	0.00
2009	0	0	157,877	94,199	---	0.00
2010	0	0	156,489	94,125	---	0.00
2011	0	0	154,418	94,278	---	0.00
2012	2	2	150,649	92,154	1.00	0.01
2013	0	0	107,423	35,529	---	0.00

Table 4b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
Pre-Existing Condition of Crohn's Disease						
<i>Clostridium difficile</i>						
183-day lookback period						
2000	5	5	8,102	2,652	1.00	0.62
2001	20	20	10,158	5,349	1.00	1.97
2002	32	33	10,849	5,701	1.03	2.95
2003	35	37	11,568	6,038	1.06	3.03
2004	48	52	13,398	6,883	1.08	3.58
2005	48	49	14,636	7,751	1.02	3.28
2006	87	90	38,008	15,446	1.03	2.29
2007	172	175	51,771	25,050	1.02	3.32
2008	325	348	103,304	45,447	1.07	3.15
2009	403	433	116,673	60,693	1.07	3.45
2010	447	479	115,066	60,329	1.07	3.88
2011	519	560	114,998	60,907	1.08	4.51
2012	521	571	113,137	59,944	1.10	4.61
2013	191	216	75,815	22,728	1.13	2.52
365-day lookback period						
2000	8	8	8,110	3,262	1.00	0.99
2001	22	22	11,436	7,433	1.00	1.92
2002	39	42	12,207	7,885	1.08	3.19
2003	40	43	13,004	8,380	1.08	3.08
2004	57	61	14,787	9,435	1.07	3.85
2005	49	50	16,294	10,605	1.02	3.01
2006	96	99	39,568	19,717	1.03	2.43
2007	195	198	56,985	33,830	1.02	3.42
2008	365	389	109,433	59,282	1.07	3.34
2009	455	490	130,951	81,640	1.08	3.47
2010	508	545	128,027	80,639	1.07	3.97
2011	586	630	127,272	81,162	1.08	4.60
2012	612	678	125,807	79,855	1.11	4.86
2013	226	254	89,774	30,438	1.12	2.52

Table 4b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
<i>Cytomegalovirus</i>						
183-day lookback period						
2000	1	1	8,117	2,658	1.00	0.12
2001	1	1	10,180	5,367	1.00	0.10
2002	3	3	10,885	5,737	1.00	0.28
2003	2	2	11,641	6,092	1.00	0.17
2004	5	6	13,481	6,950	1.20	0.37
2005	3	3	14,756	7,845	1.00	0.20
2006	7	7	38,226	15,577	1.00	0.18
2007	12	12	52,077	25,261	1.00	0.23
2008	17	18	103,895	45,832	1.06	0.16
2009	31	34	117,448	61,226	1.10	0.26
2010	36	37	115,957	60,984	1.03	0.31
2011	33	34	116,014	61,682	1.03	0.28
2012	26	27	114,305	60,822	1.04	0.23
2013	17	18	76,752	23,062	1.06	0.22
365-day lookback period						
2000	1	1	8,118	3,269	1.00	0.12
2001	2	2	11,456	7,453	1.00	0.17
2002	3	3	12,244	7,927	1.00	0.25
2003	2	2	13,072	8,447	1.00	0.15
2004	5	6	14,869	9,517	1.20	0.34
2005	3	3	16,414	10,715	1.00	0.18
2006	8	8	39,753	19,871	1.00	0.20
2007	14	14	57,246	34,079	1.00	0.24
2008	19	20	109,912	59,731	1.05	0.17
2009	34	38	131,630	82,270	1.12	0.26
2010	42	43	128,831	81,430	1.02	0.33
2011	38	39	128,248	82,080	1.03	0.30
2012	31	32	126,924	80,909	1.03	0.24
2013	20	21	90,758	30,842	1.05	0.22

Table 4b. Summary of Incident Clostridium Difficile, Cytomegalovirus, and Progressive Multifocal Leukoencephalopathy Patients in the Mini-Sentinel Distributed Database (MSDD) between January 1, 2000 and May 31, 2013, by Pre-Existing Condition, Diagnosis, Pre-Existing Condition Lookback Period, and Year

Group	New Patients	Claims	Eligible Members	Member-Years	Claims per Patient	New Patients per 1,000 Eligible Members
<i>Progressive multifocal leukoencephalopathy</i>						
183-day lookback period						
2000	0	0	8,118	2,659	---	0.00
2001	0	0	10,183	5,369	---	0.00
2002	0	0	10,888	5,739	---	0.00
2003	0	0	11,642	6,094	---	0.00
2004	0	0	13,488	6,953	---	0.00
2005	0	0	14,762	7,848	---	0.00
2006	0	0	38,236	15,584	---	0.00
2007	0	0	52,094	25,272	---	0.00
2008	0	0	103,923	45,852	---	0.00
2009	1	1	117,492	61,261	1.00	0.01
2010	0	0	116,023	61,034	---	0.00
2011	1	1	116,082	61,735	1.00	0.01
2012	0	0	114,379	60,872	---	0.00
2013	1	1	76,810	23,082	1.00	0.01
365-day lookback period						
2000	0	0	8,119	3,270	---	0.00
2001	0	0	11,458	7,456	---	0.00
2002	0	0	12,246	7,929	---	0.00
2003	0	0	13,074	8,449	---	0.00
2004	0	0	14,875	9,522	---	0.00
2005	0	0	16,420	10,720	---	0.00
2006	0	0	39,762	19,879	---	0.00
2007	0	0	57,263	34,094	---	0.00
2008	0	0	109,938	59,755	---	0.00
2009	1	1	131,668	82,313	1.00	0.01
2010	0	0	128,889	81,491	---	0.00
2011	1	1	128,310	82,144	1.00	0.01
2012	0	0	127,006	80,972	---	0.00
2013	1	1	90,815	30,867	1.00	0.01

Appendix A. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Included in this Request

Description	Diagnosis Code
Progressive multifocal leukoencephalopathy	046.3
Clostridium difficile	008.45
Cytomegalovirus	078.5
Crohn's Disease	555
Crohn's Disease	555.0
Crohn's Disease	555.1
Crohn's Disease	555.2
Crohn's Disease	555.9
Ulcerative Colitis	556
Ulcerative Colitis	556.0
Ulcerative Colitis	556.1
Ulcerative Colitis	556.2
Ulcerative Colitis	556.3
Ulcerative Colitis	556.4
Ulcerative Colitis	556.5
Ulcerative Colitis	556.6
Ulcerative Colitis	556.8
Ulcerative Colitis	556.9

Appendix B. Specifications for Requests TO09Y04_MPR_WP31_V01

Modular Program #9 was used to examine progressive multifocal leukoencephalopathy (PML), clostridium difficile, and cytomegalovirus (CMV) diagnoses among members with Crohn's disease or ulcerative colitis (see Appendix A for list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis codes used in this request). In total, 12 different scenarios were examined in this request with differing diagnoses of interest, pre-existing conditions, and pre-existing condition lookback periods. See below for a description of each of these scenarios.

Coverage Requirement	Drug and Medical Coverage
Query Period	January 1, 2000 to May 31, 2013
Enrollment Gap	45 Days
Age Stratifications	0-17, 18-44, 45-64, 65+ years

Scenario	Drug/Exposure							Pre-Existing Condition					
	Incident exposure	Incident w/ respect to:	Enrollment Days	Washout (days)	Incidence Type*	Care Setting	Principal Diagnosis	Pre-Existing Condition	Include/Exclude	Lookback Start	Lookback End	Care Setting	Principal Diagnosis
1	PML	Itself (IP Setting)	183	183	SING	IP	NO	Crohn's Disease	Include	-183	-1	ANY	NO
2	Clostridium difficile	Itself (IP Setting)	183	183	SING	IP	NO	Crohn's Disease	Include	-183	-1	ANY	NO
3	CMV	Itself (IP Setting)	183	183	SING	IP	NO	Crohn's Disease	Include	-183	-1	ANY	NO
4	PML	Itself (IP Setting)	183	183	SING	IP	NO	Crohn's Disease	Include	-365	-1	ANY	NO
5	Clostridium difficile	Itself (IP Setting)	183	183	SING	IP	NO	Crohn's Disease	Include	-365	-1	ANY	NO
6	CMV	Itself (IP Setting)	183	183	SING	IP	NO	Crohn's Disease	Include	-365	-1	ANY	NO
7	PML	Itself (IP Setting)	183	183	SING	IP	NO	Ulcerative Colitis	Include	-183	-1	ANY	NO
8	Clostridium difficile	Itself (IP Setting)	183	183	SING	IP	NO	Ulcerative Colitis	Include	-183	-1	ANY	NO
9	CMV	Itself (IP Setting)	183	183	SING	IP	NO	Ulcerative Colitis	Include	-183	-1	ANY	NO
10	PML	Itself (IP Setting)	183	183	SING	IP	NO	Ulcerative Colitis	Include	-365	-1	ANY	NO
11	Clostridium difficile	Itself (IP Setting)	183	183	SING	IP	NO	Ulcerative Colitis	Include	-365	-1	ANY	NO
12	CMV	Itself (IP Setting)	183	183	SING	IP	NO	Ulcerative Colitis	Include	-365	-1	ANY	NO

*Single incidence type for the exposure will only consider the first incident dispensing for each user during the query period that satisfies the Washout Period criteria (183 or 365 days).

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

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

Current Procedural Terminology (CPT-4) codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

Appendix C. Available Data in the Mini-Sentinel Distributed Database (MSDD) for Each Data Partner as of Request Send Date (April 25, 2014)

Data Partner ID	Start Date	End Date
DP001	1/1/2008	5/31/2013
DP002	1/1/2000	5/31/2013
DP003	1/2/2000	6/30/2012
DP004	1/1/2000	5/31/2013
DP005	1/1/2000	4/30/2012
DP006	6/1/2007	5/31/2013
DP007	1/1/2005	3/31/2013
DP008	1/1/2008	5/31/2013
DP009	1/1/2000	12/31/2012
DP010	1/1/2000	5/31/2013
DP011	1/2/2000	12/31/2012
DP012	1/1/2000	5/31/2013
DP013	1/2/2000	6/30/2012
DP014	1/1/2000	5/31/2013
DP015	1/1/2000	5/31/2013
DP016	1/1/2000	12/31/2011
DP017	1/1/2006	5/30/2013
DP018	1/31/2004	5/31/2013