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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\_wp013

**Request ID:** cder\_mpl1p\_wp013\_nsdv\_v01

**Request Description:** The goals of this request were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database (SDD).

**Sentinel Routine Querying Module:** Cohort Identification and Descriptive Analysis (CIDA) module, version 5.3.1 with additional programming

**Data Source:** We included data from September 21, 2010 to January 31, 2018 from 17 Data Partners contributing to the SDD in this request. We distributed the request to Data Partners on June 26, 2018. Please see Appendix A for dates of available data for each Data Partner.

**Study Design:** We designed this request to identify exposures and outcomes. The number of qualifying patients with the exposures of interest were calculated by age group, sex, and Health and Human Services (HHS) region. Please see Appendix B for a list of U.S. states and territories and their corresponding HHS regions.

**Exposures of Interest:** Our exposures of interest were Copaxone, Glatopa, Gilenya, and glatiramer (unspecified brand name), which were defined using National Drug Codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) codes. Please see Appendix C for a list of generic and brand name drugs used to define exposures. Please see Appendix D for specific HCPCS procedure codes used to define exposures. Additional analyses were conducted for "never-exposed" cohorts. The same cohort eligibility criteria were applied to the never-exposed cohorts as to the exposed cohorts except that members with evidence of an index (first qualifying exposure) defining code (i.e., exposure) at any point during the member's enrollment history were excluded from the analysis.

**Outcome of Interest:** Our outcome of interest was MS relapse, which was defined using International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes, as well as NDCs. Please see Appendix E for specific ICD-9-CM and ICD-10-CM codes. Please see Appendix F for generic and brand drug names used to define the outcomes in this request. The following five outcome algorithms were used to define MS relapse:

1. MS diagnosis in the inpatient care setting in the primary diagnosis position
2. MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days of MS diagnosis
3. MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days of MS diagnosis
4. MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days of MS diagnosis
5. MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days of MS diagnosis

**Cohort Eligibility Criteria:** Individuals with index exposures that occurred between September 21, 2010 and January 31, 2018 were included. Individuals included in the cohort were required to be continuously enrolled in health plans with medical and drug coverage for at least 365 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 18-34, 35-44, 45-54, and 55-64 years. Two main cohorts were assessed: individuals with prevalent MS versus incident MS. Prevalent MS was defined as evidence of at least one inpatient or two outpatient claims  $\geq 30$  days apart in the 183 days prior to their index date. Incident MS was defined as evidence of at least one inpatient or two outpatient claims  $\geq 30$  days apart in the 183 days prior to their index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date.

### Overview for Request cder\_mpl1p\_wp013

Separate incidence and truncation criteria were applied to each exposure:

- 1) Copaxone, 20 mg: Members were excluded if they had evidence of Copaxone (20 or 40 mg), Glatopa, or glatiramer use in the 365 days prior to the index date. Treatment episodes were truncated if members showed evidence of Copaxone (40 mg) or Glatopa after the index date.
- 2) Glatopa: Members were excluded if they had evidence of Copaxone (20 or 40 mg), Glatopa, or glatiramer use in the 365 days prior to the index date. Treatment episodes were truncated if members showed evidence of Copaxone (20 or 40 mg) after the index date.
- 3) Gilenya: Members were excluded if they had evidence of a Gilenya dispensing in the 365 days prior to the index date.
- 4) Copaxone, 40 mg: Members were excluded if they had evidence of a Copaxone (20 or 40 mg), Glatopa, glatiramer dispensing in the 365 days prior to the index date. Treatment episodes were truncated if members showed evidence of Copaxone (20 mg) or Glatopa after the index date.
- 5) Glatiramer: Members were excluded if they had evidence of a Copaxone (20 or 40 mg), Glatopa, glatiramer dispensing in the 365 days prior to the index date. Treatment episodes were truncated if members showed evidence of Copaxone (20 or 40 mg) or Glatopa after the index date.

**Follow-Up Time:** We determined follow-up time by the length of the exposure episodes. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supplied were 15 days or less. The end date of each exposure episode was extended by 15 additional days. A minimum episode duration of 90 days was required to be considered a valid episode. Outcomes were not assessed until day 91 of the exposure episodes or later. Follow-up began on the day of the first exposure of interest and continued until the first occurrence of any of the following: 1) disenrollment; 2) the end date of the data provided by each Data Partner (see Appendix A); 3) the end of the exposure episode; 4) occurrence of outcome; or 5) death. Only the first valid exposure episode that occurred during the study period was included for each patient.

**Baseline Characteristics:** We assessed the following characteristics during the baseline period: age, sex, race, year, Charlson/Elixhauser combined comorbidity score<sup>1</sup>, health service utilization, and corticosteroid dispensing. Occurrence of these characteristics was evaluated in the 365 days prior to and including the index date. Please refer to Appendix F generic and brand drug names used to define corticosteroids.

**Please see Appendices G and H for the specifications of parameters used in the analyses for this request.**

**Limitations:** Algorithms used to define the exposure, outcomes, exclusions, and covariates are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

**Notes:** Please contact the Sentinel Operations Center ([info@sentinelssystem.org](mailto:info@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tooldocumentation/browse>).

<sup>1</sup>Gagne, J. J., Glynn, R. J., Avorn, J., Levin, R., Schneeweiss, S. (2011). "A combined comorbidity score predicted mortality in elderly patients better than existing scores." *J Clin Epidemiol* 64(7):749-759.

## Table of Contents

<b><u>Glossary</u></b>	List of Terms Found in this Report and their Definitions
<b><u>Table 1a</u></b>	Baseline Characteristics for New Users of Multiple Sclerosis (MS) Drugs with Prevalent MS in the Sentinel Distributed Database (SDD) from September 21, 2010 to January 31, 2018
<b><u>Table 1b</u></b>	Baseline Characteristics for New Users of Multiple Sclerosis (MS) Drugs with Incident MS Sentinel Distributed Database (SDD) from September 21, 2010 to January 31, 2018
<b><u>Table 2a</u></b>	Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018
<b><u>Table 2b</u></b>	Never Exposed Members with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018
<b><u>Table 3a</u></b>	Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group
<b><u>Table 3b</u></b>	Never Exposed Members with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group
<b><u>Table 4a</u></b>	Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex
<b><u>Table 4b</u></b>	Never Exposed Members with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex
<b><u>Table 5a</u></b>	Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region
<b><u>Table 5b</u></b>	Never Exposed Members with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region
<b><u>Appendix A</u></b>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 26, 2018)
<b><u>Appendix B</u></b>	List of States and Territories Included in Each Health and Human Services (HHS) Region
<b><u>Appendix C</u></b>	List of Generic and Brand Drug Names Used to Define Exposures in this Request
<b><u>Appendix D</u></b>	List of Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Exposures in this Request
<b><u>Appendix E</u></b>	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 Multiple Sclerosis in this Request
<b><u>Appendix F</u></b>	List of Generic and Brand Drug Names Used to Define Corticosteroids in this Request
<b><u>Appendix G</u></b>	Specifications for Parameters used in the Request
<b><u>Appendix H</u></b>	Pictorial Summary of the Study Design Parameters and Cohort Eligibility Criteria in this Request

**Glossary of Terms for Analyses Using  
Cohort Identification and Descriptive Analysis (CIDA) Module\***

**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). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

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

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

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

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

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

**Charlson/Elixhauser Combined Comorbidity Score** - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

**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 valid treatment episodes during the query period until an event occurs.

**Computed Start Marketing Date** - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

**Days Supplied** - number of days supplied for all dispensings in qualifying treatment episodes.

**Eligible Members** - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

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

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

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

**Event Deduplication** - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (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 of the same HOI group on the same day (e.g., de-duplicates at the group level).

**Exposure Episode Length** - number of days after exposure initiation that is considered "exposed time."

**Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions 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 (diagnosis/procedure/drug dispensing).

**Maximum Episode Duration** - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

**Member-Years** - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

**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 requests.

**Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

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

**Switch Evaluation Step Value** - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

**Switch Gap Inclusion Indicator** - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

**Switch Pattern Cohort Inclusion Date** - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

**Switch Pattern Cohort Inclusion Strategy** - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

**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. Baseline Characteristics for New Users of Multiple Sclerosis (MS) Drugs with Prevalent MS in the Sentinel Distributed Database (SDD) from September 21, 2010 to January 31, 2018**

Characteristic	Copaxone, 20 mg		Glatopa		Gilenya		Copaxone, 40 mg		Glatiramer	
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
Unique Patients	5,422	100.0%	145	100.0%	7,589	100.0%	4,813	100.0%	108	100.0%
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean age (years)	46.2	9.9	45.2	10.4	44.9	9.7	46.6	10.3	46.8	9.8
Age (years)	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
18-34	889	16.4%	28	19.3%	1,325	17.5%	792	16.5%	19	17.6%
35-44	1,452	26.8%	44	30.3%	2,418	31.9%	1,236	25.7%	25	23.1%
45-54	1,873	34.5%	42	29.0%	2,541	33.5%	1,552	32.2%	37	34.3%
55-64	1,208	22.3%	31	21.4%	1,305	17.2%	1,233	25.6%	27	25.0%
Sex										
Female	4,116	75.9%	109	75.2%	5,693	75.0%	3,791	78.8%	84	77.8%
Male	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Other	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Race										
American Indian or Alaska Native	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Asian	36	0.7%	*****	*****	41	0.5%	22	0.5%	*****	*****
Black or African American	578	10.7%	*****	*****	747	9.8%	431	9.0%	*****	*****
Native Hawaiian or Other Pacific Islander	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%
Unknown	1,538	28.4%	36	24.8%	2,496	32.9%	2,038	42.3%	59	54.6%
White	3,247	59.9%	88	60.7%	4,278	56.4%	2,300	47.8%	39	36.1%
Year										
2010	250	4.6%	0	0.0%	75	1.0%	0	0.0%	*****	*****
2011	1,739	32.1%	0	0.0%	1,938	25.5%	0	0.0%	20	18.5%
2012	1,717	31.7%	0	0.0%	1,186	15.6%	0	0.0%	25	23.1%
2013	1,175	21.7%	0	0.0%	1,146	15.1%	0	0.0%	19	17.6%
2014	338	6.2%	0	0.0%	1,328	17.5%	1,345	27.9%	27	25.0%
2015	171	3.2%	40	27.6%	1,063	14.0%	1,900	39.5%	*****	*****
2016	17	0.3%	70	48.3%	541	7.1%	1,002	20.8%	*****	*****
2017	15	0.3%	35	24.1%	312	4.1%	566	11.8%	*****	*****

**Table 1a. Baseline Characteristics for New Users of Multiple Sclerosis (MS) Drugs with Prevalent MS in the Sentinel Distributed Database (SDD) from September 21, 2010 to January 31, 2018**

	Copaxone, 20 mg		Glatopa		Gilenya		Copaxone, 40 mg		Glatiramer	
<b>Recorded History of:</b>	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Charlson/Elixhauser combined comorbidity score <sup>1</sup>	1	1.7	0.8	1.1	0.7	1.3	1.1	1.8	1.3	1.6
Corticosteroid use	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>
	2,062	38.0%	41	28.3%	2,693	35.5%	1,900	39.5%	37	34.3%
<b>Health Service Utilization Intensity:</b>	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of ambulatory encounters (AV)	23.1	15.8	15.4	11.8	23	15.4	24	19.7	30.4	26.5
Number of emergency room encounters	1	2.7	1	2.4	0.7	1.6	1.1	2.3	3.4	15
Number of inpatient hospital encounters	0.5	1	0.4	0.9	0.3	0.8	0.5	0.9	1.2	2.7
Number of non-acute institutional encounters (IS)	0.1	0.5	0	0.4	0.1	0.5	0.1	1	0.2	1
Number of other ambulatory encounters	7.4	13.3	12.7	13	5.4	8.9	6.3	12.1	11	20.3
Number of filled prescriptions	40	35.8	23	27.9	36.8	33.1	39.6	36.7	28.2	28.5
Number of generics	10.2	6.8	7.4	6.3	9.3	6.4	10.7	7.3	9.4	7.6
Number of drug classes	9.1	5.7	6.9	5.6	8.4	5.4	9.5	6.2	8.2	6.1

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 1b. Baseline Characteristics for New Users of Multiple Sclerosis (MS) Drugs with Incident MS in the Sentinel Distributed Database (SDD) from September 21, 2010 to January 31, 2018**

Characteristic	Copaxone, 20 mg		Glatopa		Gilenya		Copaxone, 40 mg		Glatiramer	
	Number	e	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
Unique Patients	1,803	100.0%	70	100.0%	1,039	100.0%	1,558	100.0%	26	100.0%
<b>Demographics</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>
Mean age (years)	43.5	10.2	42.6	9.4	42.9	9.8	43	10.5	45.6	10.2
Age (years)	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>
18-34	433	24.0%	*****	*****	236	22.7%	405	26.0%	*****	*****
35-44	554	30.7%	28	40.0%	337	32.4%	479	30.7%	*****	*****
45-54	529	29.3%	19	27.1%	334	32.1%	430	27.6%	*****	*****
55-64	287	15.9%	*****	*****	132	12.7%	244	15.7%	*****	*****
Sex										
Female	1,340	74.3%	53	75.7%	751	72.3%	1,188	76.3%	*****	*****
Male	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Other	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Race										
American Indian or Alaska Native	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%
Asian	20	1.1%	*****	*****	*****	*****	*****	*****	0	0.0%
Black or African American	156	8.7%	*****	*****	89	8.6%	105	6.7%	*****	*****
Native Hawaiian or Other Pacific Islander	*****	*****	*****	*****	*****	*****	0	0.0%	0	0.0%
Unknown	672	37.3%	19	27.1%	515	49.6%	866	55.6%	*****	*****
White	949	52.6%	40	57.1%	424	40.8%	574	36.8%	*****	*****
Year										
2010	103	5.7%	0	0.0%	*****	*****	0	0.0%	*****	*****
2011	589	32.7%	0	0.0%	166	16.0%	0	0.0%	*****	*****
2012	499	27.7%	0	0.0%	117	11.3%	0	0.0%	*****	*****
2013	424	23.5%	0	0.0%	141	13.6%	0	0.0%	*****	*****
2014	125	6.9%	0	0.0%	192	18.5%	362	23.2%	*****	*****
2015	52	2.9%	17	24.3%	179	17.2%	551	35.4%	*****	*****
2016	*****	*****	36	51.4%	157	15.1%	399	25.6%	0	0.0%
2017	*****	*****	17	24.3%	*****	*****	246	15.8%	0	0.0%

**Table 1b. Baseline Characteristics for New Users of Multiple Sclerosis (MS) Drugs with Incident MS in the Sentinel Distributed Database (SDD) from September 21, 2010 to January 31, 2018**

	Copaxone, 20 mg		Glatopa		Gilenya		Copaxone, 40 mg		Glatiramer	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
<b>Recorded History of:</b>										
Charlson/Elixhauser combined comorbidity score <sup>1</sup>	0.7	1.3	0.6	0.8	0.5	1.1	0.8	1.5	0.3	0.8
	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>	<b>Number</b>	<b>Percentage</b>
Corticosteroid use	741	41.1%	22	31.4%	340	32.7%	674	43.3%	11	42.3%
<b>Health Service Utilization Intensity:</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>	<b>Mean</b>	<b>Standard Deviation</b>
Number of ambulatory encounters (AV)	19.6	14	15.2	9.2	16.9	13.5	20	15.4	17.7	11.3
Number of emergency room encounters	1	2.6	1.1	2	0.5	1.1	1	2.2	0.6	0.9
Number of inpatient hospital encounters	0.5	0.8	0.4	0.7	0.2	0.6	0.4	0.8	0.6	0.6
Number of non-acute institutional encounters (IS)	0	0.3	0	0.2	0	0.3	0.1	0.4	0	0
Number of other ambulatory encounters	4.7	6.7	11.7	8.5	3.9	5.8	4.3	7.4	3.2	4
Number of filled prescriptions	26.2	27.1	15.4	11.5	18.9	22.3	26.3	27.5	13.8	13
Number of generics	8.1	5.9	6.5	4.4	6.1	5.1	8.6	6.7	5.8	4.2
Number of drug classes	7.3	5	5.9	3.7	5.7	4.5	7.7	5.6	5.2	3.7

<sup>1</sup>Charlson/Elixhauser combined comorbidity score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 2a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018**

	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
Outcome Definition 1 (Inpatient) <sup>3</sup>	5,422	204,581	26.50	4,267.0	199	46.64
Outcome Definition 2 (Outpatient with 7 Day Gap) <sup>4</sup>	5,422	160,298	33.82	3,853.4	728	188.92
Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap) <sup>5</sup>	5,422	160,173	33.85	3,777.7	850	225.00
Outcome Definition 4 (Outpatient with 30 Day Gap) <sup>6</sup>	5,422	160,298	33.82	3,741.1	871	232.82
Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap) <sup>7</sup>	5,422	160,173	33.85	3,674.1	978	266.19
<b>Prevalent MS Inclusion Criteria: Glatopa</b>						
Outcome Definition 1 (Inpatient)	145	204,591	0.71	*****	*****	46.89
Outcome Definition 2 (Outpatient with 7 Day Gap)	145	160,914	0.90	*****	*****	83.14
Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	145	160,790	0.90	83.1	11	132.37
Outcome Definition 4 (Outpatient with 30 Day Gap)	145	160,914	0.90	*****	*****	122.70
Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	145	160,790	0.90	80.4	14	174.13
<b>Prevalent MS Inclusion Criteria: Gilenya</b>						
Outcome Definition 1 (Inpatient)	7,589	229,443	33.08	8,458.4	244	28.85
Outcome Definition 2 (Outpatient with 7 Day Gap)	7,589	183,548	41.35	7,492.5	1,099	146.68
Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	7,589	183,405	41.38	7,388.1	1,232	166.75
Outcome Definition 4 (Outpatient with 30 Day Gap)	7,589	183,548	41.35	7,232.7	1,322	182.78
Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	7,589	183,405	41.38	7,140.0	1,441	201.82
<b>Prevalent MS Inclusion Criteria: Copaxone, 40mg</b>						
No Outcome	4,813	219,669	21.91	1,505.2	N/A	N/A
<b>Prevalent MS Inclusion Criteria: Glatiramer</b>						
No Outcome	108	219,669	0.49	0.3	N/A	N/A
<b>Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
Outcome Definition 1 (Inpatient)	1,803	122,040	14.77	1,537.0	54	35.13
Outcome Definition 2 (Outpatient with 7 Day Gap)	1,803	81,564	22.11	1,403.4	220	156.76
Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	1,803	81,493	22.12	1,382.5	256	185.17
Outcome Definition 4 (Outpatient with 30 Day Gap)	1,803	81,564	22.11	1,370.5	264	192.63
Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	1,803	81,493	22.12	1,350.7	295	218.41

**Table 2a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018**

	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Members with an Outcome per 1,000 Years at Risk
<b>Incident MS Inclusion Criteria: Glatopa</b>						
Outcome Definition 1 (Inpatient)	70	122,042	0.57	45.4	0	0.00
Outcome Definition 2 (Outpatient with 7 Day Gap)	70	81,638	0.86	*****	*****	66.52
Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	70	81,567	0.86	*****	*****	66.52
Outcome Definition 4 (Outpatient with 30 Day Gap)	70	81,638	0.86	*****	*****	115.74
Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	70	81,567	0.86	*****	*****	115.74
<b>Incident MS Inclusion Criteria: Gilenya</b>						
Outcome Definition 1 (Inpatient)	1,039	139,543	7.45	*****	*****	6.89
Outcome Definition 2 (Outpatient with 7 Day Gap)	1,039	94,015	11.05	1,075.0	90	83.72
Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	1,039	93,933	11.06	1,072.2	94	87.67
Outcome Definition 4 (Outpatient with 30 Day Gap)	1,039	94,015	11.05	1,052.0	117	111.22
Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	1,039	93,933	11.06	1,050.0	120	114.29
<b>Incident MS Inclusion Criteria: Copaxone, 40mg</b>						
No Outcome	1,558	133,344	11.68	569.5	N/A	N/A
<b>Incident MS Inclusion Criteria: Glatiramer</b>						
No Outcome	26	133,344	0.19	0.1	N/A	N/A

<sup>1</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 2b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018**

	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
Never Exposed: Outcome Definition 1 (Inpatient) <sup>3</sup>	176,287	N/A	.	423,285.8	8,497	20.07
Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap) <sup>4</sup>	141,198	N/A	.	293,495.1	21,954	74.80
Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	141,097	N/A	.	287,719.6	24,726	85.94
Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap) <sup>6</sup>	141,198	N/A	.	284,897.3	26,319	92.38
Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	141,097	N/A	.	279,570.3	28,827	103.11
<b>Never Exposed: Prevalent MS Inclusion Criteria: Glatopa</b>						
Never Exposed: Outcome Definition 1 (Inpatient)	198,227	N/A	.	464,062.9	9,822	21.17
Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)	157,665	N/A	.	319,891.1	25,185	78.73
Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	157,545	N/A	.	313,544.4	28,336	90.37
Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)	157,665	N/A	.	310,426.0	30,088	96.92
Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	157,545	N/A	.	304,581.8	32,936	108.14
<b>Never Exposed: Prevalent MS Inclusion Criteria: Gilenya</b>						
Never Exposed: Outcome Definition 1 (Inpatient)	216,429	N/A	.	537,676.4	11,158	20.75
Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)	175,477	N/A	.	373,656.1	29,974	80.22
Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	175,351	N/A	.	365,778.8	33,555	91.74
Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)	175,477	N/A	.	361,795.3	35,778	98.89
Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	175,351	N/A	.	354,594.1	38,986	109.95
<b>Never Exposed: Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
Never Exposed: Outcome Definition 1 (Inpatient)	107,766	N/A	.	233,944.9	2,910	12.44
Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)	74,001	N/A	.	148,894.0	7,547	50.69
Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	73,940	N/A	.	147,375.3	8,404	57.02
Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)	74,001	N/A	.	145,795.4	9,330	63.99
Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)	73,940	N/A	.	144,354.6	10,122	70.12

**Table 2b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018**

	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Incident MS Inclusion Criteria: Glatopa</b>						
Never Exposed: Outcome Definition 1 (Inpatient)	117,489	N/A	.	250,433.4	3,228	12.89
Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)	79,936	N/A	.	158,534.1	8,378	52.85
Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	79,869	N/A	.	156,848.3	9,321	59.43
Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)	79,936	N/A	.	155,238.0	10,316	66.45
Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day	79,869	N/A	.	153,641.5	11,188	72.82
<b>Never Exposed: Incident MS Inclusion Criteria: Gilenya</b>						
Never Exposed: Outcome Definition 1 (Inpatient)	133,567	N/A	.	300,368.5	3,964	13.20
Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)	91,138	N/A	.	186,859.1	10,438	55.86
Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)	91,062	N/A	.	184,729.6	11,569	62.63
Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)	91,138	N/A	.	182,623.3	12,800	70.09
Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day	91,062	N/A	.	180,606.0	13,836	76.61

<sup>1</sup>The same cohort eligibility criteria were applied to the never-exposed cohorts as to the exposed cohorts except that members with evidence of an index defining code (i.e., exposure) at any point during the member's enrollment history were excluded from the analysis

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

**Table 3a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
<i>Outcome Definition 1 (Inpatient)<sup>3</sup></i>						
18-34	889	24,392	36.45	616.4	21	34.07
35-44	1,452	49,726	29.20	1,119.3	63	56.29
45-54	1,873	79,257	23.63	1,501.4	79	52.62
55-64	1,208	83,359	14.49	1,029.9	36	34.95
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)<sup>4</sup></i>						
18-34	889	17,514	50.76	558.6	116	207.66
35-44	1,452	36,571	39.70	1,012.0	215	212.45
45-54	1,873	60,129	31.15	1,346.9	243	180.41
55-64	1,208	64,826	18.63	935.9	154	164.55
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)<sup>5</sup></i>						
18-34	889	17,491	50.83	552.6	130	235.25
35-44	1,452	36,538	39.74	990.1	249	251.49
45-54	1,873	60,068	31.18	1,315.3	292	222.00
55-64	1,208	64,792	18.64	919.6	179	194.65
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)<sup>6</sup></i>						
18-34	889	17,514	50.76	546.8	132	241.40
35-44	1,452	36,571	39.70	987.2	250	253.24
45-54	1,873	60,129	31.15	1,308.3	291	222.43
55-64	1,208	64,826	18.63	898.8	198	220.29
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)<sup>7</sup></i>						
18-34	889	17,491	50.83	540.9	145	268.07
35-44	1,452	36,538	39.74	967.8	278	287.25
45-54	1,873	60,068	31.18	1,281.0	335	261.51
55-64	1,208	64,792	18.64	884.4	220	248.76
<b>Prevalent MS Inclusion Criteria: Glatopa</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
18-34	28	24,396	1.15	*****	*****	79.37
35-44	44	49,879	0.88	31.0	0	0.00
45-54	42	79,465	0.53	*****	*****	38.76
55-64	31	83,601	0.37	*****	*****	126.58
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	28	17,593	1.59	13.5	0	0.00
35-44	44	36,820	1.20	*****	*****	68.73
45-54	42	60,417	0.70	*****	*****	155.64
55-64	31	65,093	0.48	*****	*****	62.89

**Table 3a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

<b>Age Group (Years)</b>	<b>Exposed Members</b>	<b>Eligible Members<sup>1</sup></b>	<b>Exposed Members per 1,000 Eligible Members</b>	<b>Years at Risk</b>	<b>Exposed Members with an Outcome</b>	<b>Exposed Members with an Outcome per 1,000 Years at Risk</b>
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	28	17,571	1.59	*****	*****	79.37
35-44	44	36,787	1.20	*****	*****	68.73
45-54	42	60,356	0.70	*****	*****	195.31
55-64	31	65,059	0.48	*****	*****	191.08
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	28	17,593	1.59	13.5	0	0.00
35-44	44	36,820	1.20	*****	*****	68.73
45-54	42	60,417	0.70	*****	*****	257.51
55-64	31	65,093	0.48	*****	*****	128.21
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	28	17,571	1.59	*****	*****	79.37
35-44	44	36,787	1.20	*****	*****	68.73
45-54	42	60,356	0.70	*****	*****	300.43
55-64	31	65,059	0.48	*****	*****	259.74
<b>Prevalent MS Inclusion Criteria: Gilenya</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
18-34	1,325	27,355	48.44	1,253.0	35	27.93
35-44	2,418	56,132	43.08	2,743.6	76	27.70
45-54	2,541	90,005	28.23	2,947.2	82	27.82
55-64	1,305	94,340	13.83	1,514.5	51	33.67
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	1,325	20,172	65.69	1,107.7	183	165.21
35-44	2,418	42,244	57.24	2,411.2	357	148.06
45-54	2,541	69,631	36.49	2,643.9	349	132.00
55-64	1,305	74,593	17.49	1,329.7	210	157.93
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	1,325	20,144	65.78	1,099.9	198	180.02
35-44	2,418	42,202	57.30	2,376.6	392	164.94
45-54	2,541	69,563	36.53	2,602.4	403	154.86
55-64	1,305	74,550	17.51	1,309.3	239	182.54
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	1,325	20,172	65.69	1,089.7	211	193.63
35-44	2,418	42,244	57.24	2,310.2	436	188.73
45-54	2,541	69,631	36.49	2,542.0	433	170.34
55-64	1,305	74,593	17.49	1,290.8	242	187.48

**Table 3a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	1,325	20,144	65.78	1,081.9	225	207.97
35-44	2,418	42,202	57.30	2,279.0	468	205.35
45-54	2,541	69,563	36.53	2,505.3	480	191.59
55-64	1,305	74,550	17.51	1,273.8	268	210.39
<b>Prevalent MS Inclusion Criteria: Copaxone, 40mg</b>						
<i>No Outcome</i>						
18-34	792	26,785	29.57	223.8	N/A	N/A
35-44	1,236	53,873	22.94	378.9	N/A	N/A
45-54	1,552	85,068	18.24	501.7	N/A	N/A
55-64	1,233	89,917	13.71	400.8	N/A	N/A
<b>Prevalent MS Inclusion Criteria: Glatiramer</b>						
<i>No Outcome</i>						
18-34	19	26,785	0.71	0.1	N/A	N/A
35-44	25	53,896	0.46	0.1	N/A	N/A
45-54	37	85,106	0.43	0.1	N/A	N/A
55-64	27	89,964	0.30	0.1	N/A	N/A
<b>Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
18-34	433	14,435	30.00	*****	*****	19.31
35-44	554	27,315	20.28	457.9	16	34.94
45-54	529	43,281	12.22	482.8	20	41.43
55-64	287	45,571	6.30	*****	*****	42.02
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	433	9,091	47.63	289.4	52	179.68
35-44	554	17,487	31.68	416.6	62	148.82
45-54	529	28,588	18.50	436.8	69	157.97
55-64	287	30,712	9.34	260.5	37	142.03
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	433	9,074	47.72	285.7	57	199.51
35-44	554	17,478	31.70	412.6	72	174.50
45-54	529	28,555	18.53	429.7	81	188.50
55-64	287	30,695	9.35	254.5	46	180.75

**Table 3a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

<b>Age Group (Years)</b>	<b>Exposed Members</b>	<b>Eligible Members<sup>1</sup></b>	<b>Exposed Members per 1,000 Eligible Members</b>	<b>Years at Risk</b>	<b>Exposed Members with an Outcome</b>	<b>Exposed Members with an Outcome per 1,000 Years at Risk</b>
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	433	9,091	47.63	282.2	62	219.70
35-44	554	17,487	31.68	409.4	70	170.98
45-54	529	28,588	18.50	427.5	84	196.49
55-64	287	30,712	9.34	251.4	48	190.93
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	433	9,074	47.72	278.5	66	236.98
35-44	554	17,478	31.70	405.7	79	194.73
45-54	529	28,555	18.53	421.0	94	223.28
55-64	287	30,695	9.35	245.5	56	228.11
<b>Incident MS Inclusion Criteria: Glatopa</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
18-34	*****	*****	1.04	5.4	0	0.00
35-44	28	27,340	1.02	21.1	0	0.00
45-54	19	43,303	0.44	11.6	0	0.00
55-64	*****	*****	0.18	7.2	0	0.00
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	*****	*****	1.65	5.4	0	0.00
35-44	28	17,528	1.60	*****	*****	47.62
45-54	19	28,608	0.66	*****	*****	86.96
55-64	*****	*****	0.26	*****	*****	140.85
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	*****	*****	1.65	5.4	0	0.00
35-44	28	17,519	1.60	*****	*****	47.62
45-54	19	28,575	0.66	*****	*****	86.96
55-64	*****	*****	0.26	*****	*****	140.85
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	*****	*****	1.65	5.4	0	0.00
35-44	28	17,528	1.60	*****	*****	47.62
45-54	19	28,608	0.66	*****	*****	200.00
55-64	*****	*****	0.26	*****	*****	294.12
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	*****	*****	1.65	5.4	0	0.00
35-44	28	17,519	1.60	*****	*****	47.62
45-54	19	28,575	0.66	*****	*****	200.00
55-64	*****	*****	0.26	*****	*****	294.12

**Table 3a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Incident MS Inclusion Criteria: Gilenya</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
18-34	236	16,636	14.19	*****	*****	4.56
35-44	337	31,680	10.64	*****	*****	10.99
45-54	334	50,112	6.67	*****	*****	2.49
55-64	132	51,892	2.54	*****	*****	11.37
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	236	10,637	22.19	205.6	20	97.28
35-44	337	20,568	16.38	343.1	28	81.61
45-54	334	33,197	10.06	372.5	29	77.85
55-64	132	34,940	3.78	153.8	13	84.53
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	236	10,618	22.23	205.5	21	102.19
35-44	337	20,557	16.39	341.2	30	87.92
45-54	334	33,161	10.07	372.5	29	77.85
55-64	132	34,919	3.78	152.9	14	91.56
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	236	10,637	22.19	203.3	24	118.05
35-44	337	20,568	16.38	336.1	38	113.06
45-54	334	33,197	10.06	361.8	39	107.79
55-64	132	34,940	3.78	150.9	16	106.03
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	236	10,618	22.23	203.2	25	123.03
35-44	337	20,557	16.39	334.2	40	119.69
45-54	334	33,161	10.07	361.8	39	107.79
55-64	132	34,919	3.78	150.9	16	106.03

**Table 3a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Incident MS Inclusion Criteria: Copaxone, 40mg</b>						
<i>No Outcome</i>						
18-34	405	16,144	25.09	124.4	N/A	N/A
35-44	479	29,886	16.03	166.6	N/A	N/A
45-54	430	47,104	9.13	175.8	N/A	N/A
55-64	244	49,948	4.89	102.7	N/A	N/A
<b>Incident MS Inclusion Criteria: Glatiramer</b>						
<i>No Outcome</i>						
18-34	*****	*****	0.31	0.0	N/A	N/A
35-44	*****	*****	0.23	0.0	N/A	N/A
45-54	*****	*****	0.19	0.0	N/A	N/A
55-64	*****	*****	0.10	0.0	N/A	N/A

<sup>1</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 3b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)<sup>3</sup></i>						
18-34	20,045	N/A	.	40,280.8	1,107	27.48
35-44	36,795	N/A	.	84,846.9	2,015	23.75
45-54	58,792	N/A	.	147,407.8	2,925	19.84
55-64	60,655	N/A	.	150,750.2	2,450	16.25
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)<sup>4</sup></i>						
18-34	14,866	N/A	.	26,314.2	2,347	89.19
35-44	28,640	N/A	.	56,352.0	5,040	89.44
45-54	47,252	N/A	.	101,759.9	7,603	74.72
55-64	50,440	N/A	.	109,068.9	6,964	63.85
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)<sup>5</sup></i>						
18-34	14,846	N/A	.	25,744.1	2,611	101.42
35-44	28,619	N/A	.	55,148.8	5,634	102.16
45-54	47,212	N/A	.	99,671.2	8,571	85.99
55-64	50,420	N/A	.	107,155.4	7,910	73.82
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)<sup>6</sup></i>						
18-34	14,866	N/A	.	25,608.3	2,733	106.72
35-44	28,640	N/A	.	54,543.1	5,933	108.78
45-54	47,252	N/A	.	98,769.1	9,103	92.16
55-64	50,440	N/A	.	105,976.9	8,550	80.68
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)<sup>7</sup></i>						
18-34	14,846	N/A	.	25,083.9	2,973	118.52
35-44	28,619	N/A	.	53,454.7	6,460	120.85
45-54	47,212	N/A	.	96,840.6	9,981	103.07
55-64	50,420	N/A	.	104,191.1	9,413	90.34

**Table 3b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Prevalent MS Inclusion Criteria: Glatopa</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
18-34	22,971	N/A	.	45,223.9	1,292	28.57
35-44	42,540	N/A	.	95,402.8	2,393	25.08
45-54	66,383	N/A	.	161,920.7	3,380	20.87
55-64	66,333	N/A	.	161,515.4	2,757	17.07
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	16,969	N/A	.	29,267.5	2,785	95.16
35-44	32,863	N/A	.	62,943.5	5,976	94.94
45-54	52,960	N/A	.	111,137.1	8,701	78.29
55-64	54,873	N/A	.	116,543.1	7,723	66.27
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	16,948	N/A	.	28,627.8	3,100	108.29
35-44	32,836	N/A	.	61,612.1	6,654	108.00
45-54	52,909	N/A	.	108,841.9	9,792	89.97
55-64	54,852	N/A	.	114,462.6	8,790	76.79
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	16,969	N/A	.	28,481.1	3,221	113.09
35-44	32,863	N/A	.	60,904.8	7,004	115.00
45-54	52,960	N/A	.	107,847.0	10,397	96.41
55-64	54,873	N/A	.	113,193.2	9,466	83.63
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	16,948	N/A	.	27,891.2	3,510	125.85
35-44	32,836	N/A	.	59,707.8	7,604	127.35
45-54	52,909	N/A	.	105,729.9	11,384	107.67
55-64	54,852	N/A	.	111,252.8	10,438	93.82
<b>Never Exposed: Prevalent MS Inclusion Criteria: Gilenya</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
18-34	24,698	N/A	.	51,436.9	1,377	26.77
35-44	45,666	N/A	.	109,772.4	2,652	24.16
45-54	72,912	N/A	.	189,067.5	3,887	20.56
55-64	73,153	N/A	.	187,399.6	3,242	17.30
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	18,643	N/A	.	33,779.1	3,232	95.68
35-44	36,123	N/A	.	73,427.9	6,939	94.50
45-54	59,264	N/A	.	130,666.1	10,497	80.33
55-64	61,447	N/A	.	135,783.1	9,306	68.54
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	18,620	N/A	.	33,029.2	3,567	108.00
35-44	36,096	N/A	.	71,732.4	7,710	107.48

**Table 3b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
45-54	59,213	N/A	.	127,839.6	11,724	91.71
55-64	61,422	N/A	.	133,177.5	10,554	79.25
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	18,643	N/A	.	32,847.6	3,712	113.01
35-44	36,123	N/A	.	70,903.9	8,149	114.93
45-54	59,264	N/A	.	126,426.5	12,517	99.01
55-64	61,447	N/A	.	131,617.3	11,400	86.61
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	18,620	N/A	.	32,157.7	4,018	124.95
35-44	36,096	N/A	.	69,397.8	8,810	126.95
45-54	59,213	N/A	.	123,835.0	13,630	110.07
55-64	61,422	N/A	.	129,203.6	12,528	96.96
<b>Never Exposed: Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
18-34	12,096	N/A	.	23,039.7	379	16.45
35-44	21,981	N/A	.	46,181.3	634	13.73
45-54	35,626	N/A	.	80,596.0	964	11.96
55-64	38,063	N/A	.	84,127.9	933	11.09
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	8,001	N/A	.	14,335.1	844	58.88
35-44	14,756	N/A	.	28,557.3	1,695	59.35
45-54	24,548	N/A	.	51,153.1	2,584	50.52
55-64	26,696	N/A	.	54,848.6	2,424	44.19
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	7,988	N/A	.	14,142.7	934	66.04
35-44	14,749	N/A	.	28,290.9	1,866	65.96
45-54	24,520	N/A	.	50,624.2	2,883	56.95
55-64	26,683	N/A	.	54,317.5	2,721	50.09
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	8,001	N/A	.	14,092.0	988	70.11
35-44	14,756	N/A	.	27,939.2	2,048	73.30
45-54	24,548	N/A	.	50,064.9	3,220	64.32
55-64	26,696	N/A	.	53,699.2	3,074	57.24
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	7,988	N/A	.	13,908.2	1,073	77.15
35-44	14,749	N/A	.	27,692.2	2,202	79.52
45-54	24,520	N/A	.	49,566.9	3,495	70.51
55-64	26,683	N/A	.	53,187.3	3,352	63.02

**Table 3b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Incident MS Inclusion Criteria: Glatopa</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
18-34	13,324	N/A	.	24,743.7	423	17.10
35-44	24,532	N/A	.	50,380.6	724	14.37
45-54	39,013	N/A	.	86,564.6	1,063	12.28
55-64	40,620	N/A	.	88,744.5	1,018	11.47
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	8,727	N/A	.	15,307.6	944	61.67
35-44	16,308	N/A	.	30,950.9	1,939	62.65
45-54	26,621	N/A	.	54,610.5	2,880	52.74
55-64	28,280	N/A	.	57,665.1	2,615	45.35
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	8,712	N/A	.	15,098.1	1,043	69.08
35-44	16,301	N/A	.	30,646.6	2,133	69.60
45-54	26,590	N/A	.	54,016.7	3,207	59.37
55-64	28,266	N/A	.	57,086.9	2,938	51.47
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	8,727	N/A	.	15,044.6	1,104	73.38
35-44	16,308	N/A	.	30,288.6	2,327	76.83
45-54	26,621	N/A	.	53,448.2	3,577	66.92
55-64	28,280	N/A	.	56,456.6	3,308	58.59
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	8,712	N/A	.	14,845.2	1,197	80.63
35-44	16,301	N/A	.	30,005.7	2,503	83.42
45-54	26,590	N/A	.	52,891.0	3,877	73.30
55-64	28,266	N/A	.	55,899.6	3,611	64.60

**Table 3b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Age Group**

Age Group (Years)	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Incident MS Inclusion Criteria: Gilenya</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
18-34	15,334	N/A	.	30,314.3	528	17.42
35-44	27,966	N/A	.	61,812.9	908	14.69
45-54	44,502	N/A	.	104,214.1	1,321	12.68
55-64	45,765	N/A	.	104,027.1	1,207	11.60
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
18-34	10,031	N/A	.	18,260.7	1,198	65.61
35-44	18,799	N/A	.	37,503.0	2,452	65.38
45-54	30,438	N/A	.	64,544.2	3,642	56.43
55-64	31,870	N/A	.	66,551.2	3,146	47.27
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
18-34	10,015	N/A	.	18,019.8	1,315	72.98
35-44	18,790	N/A	.	37,086.0	2,684	72.37
45-54	30,405	N/A	.	63,801.6	4,031	63.18
55-64	31,852	N/A	.	65,822.2	3,539	53.77
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
18-34	10,031	N/A	.	17,932.9	1,386	77.29
35-44	18,799	N/A	.	36,600.4	2,932	80.11
45-54	30,438	N/A	.	63,067.9	4,474	70.94
55-64	31,870	N/A	.	65,022.1	4,008	61.64
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
18-34	10,015	N/A	.	17,700.9	1,497	84.57
35-44	18,790	N/A	.	36,208.8	3,138	86.66
45-54	30,405	N/A	.	62,373.1	4,830	77.44
55-64	31,852	N/A	.	64,323.3	4,371	67.95

<sup>1</sup>The same cohort eligibility criteria were applied to the never-exposed cohorts as to the exposed cohorts except that members with evidence of an index defining code (i.e., exposure) at any point during the member's enrollment history were excluded from the analysis

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

**Table 4a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria: Copaxone, 20 mg</b>						
<i>Outcome Definition 1 (Inpatient)<sup>3</sup></i>						
Female	4,116	152,424	27.00	3,121.4	154	49.34
Male	*****	*****	25.04	1,145.6	45	39.28
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)<sup>4</sup></i>						
Female	4,116	119,677	34.39	2,798.1	580	207.28
Male	*****	*****	32.16	1,055.2	148	140.26
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)<sup>5</sup></i>						
Female	4,116	119,586	34.42	2,744.8	670	244.10
Male	*****	*****	32.18	1,032.9	180	174.27
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)<sup>6</sup></i>						
Female	4,116	119,677	34.39	2,707.9	696	257.03
Male	*****	*****	32.16	1,033.3	175	169.36
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)<sup>7</sup></i>						
Female	4,116	119,586	34.42	2,660.0	774	290.98
Male	*****	*****	32.18	1,014.1	204	201.16
Other	*****	*****	0.00	0.0	0	.
<b>Prevalent MS Inclusion Criteria: Glatopa</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
Female	109	152,428	0.72	*****	*****	54.05
Male	*****	*****	0.69	*****	*****	33.67
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	109	120,154	0.91	*****	*****	128.68
Male	*****	*****	0.88	*****	*****	0.00
Other	*****	*****	0.00	0.0	0	.

**Table 4a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	109	120,062	0.91	*****	*****	187.27
Male	*****	*****	0.88	*****	*****	33.67
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	109	120,154	0.91	*****	*****	149.25
Male	*****	*****	0.88	*****	*****	71.68
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	109	120,062	0.91	*****	*****	209.52
Male	*****	*****	0.88	*****	*****	107.53
Other	*****	*****	0.00	0.0	0	.
<b>Prevalent MS Inclusion Criteria: Gilenya</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
Female	5,693	171,298	33.23	6,214.2	182	29.29
Male	*****	*****	32.61	2,244.2	62	27.63
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	5,693	137,406	41.43	5,480.6	859	156.73
Male	*****	*****	41.10	2,012.0	240	119.28
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	5,693	137,296	41.47	5,401.1	953	176.45
Male	*****	*****	41.13	1,987.0	279	140.41
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	5,693	137,406	41.43	5,260.8	1,043	198.26
Male	*****	*****	41.10	1,971.8	279	141.50
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	5,693	137,296	41.47	5,190.3	1,127	217.14
Male	*****	*****	41.13	1,949.7	314	161.05
Other	*****	*****	0.00	0.0	0	.
<b>Prevalent MS Inclusion Criteria: Copaxone, 40mg</b>						
<i>No Outcome</i>						
Female	3,791	163,421	23.20	1,167.9	N/A	N/A
Male	*****	*****	18.17	337.3	N/A	N/A
Other	*****	*****	0.00	0.0	N/A	N/A

**Table 4a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria: Glatiramer</b>						
<i>No Outcome</i>						
Female	84	163,421	0.51	0.2	N/A	N/A
Male	*****	*****	0.43	0.1	N/A	N/A
Other	*****	*****	0.00	0.0	N/A	N/A
<b>Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
Female	1,340	90,736	14.77	1,089.8	39	35.79
Male	*****	*****	14.79	447.3	15	33.53
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	1,340	60,164	22.27	996.1	164	164.64
Male	*****	*****	21.64	407.3	56	137.49
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	1,340	60,107	22.29	981.5	189	192.56
Male	*****	*****	21.65	401.0	67	167.08
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	1,340	60,164	22.27	970.1	199	205.13
Male	*****	*****	21.64	400.4	65	162.34
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	1,340	60,107	22.29	956.5	219	228.96
Male	*****	*****	21.65	394.2	76	192.80
Other	*****	*****	0.00	0.0	0	.
<b>Incident MS Inclusion Criteria: Glatopa</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
Female	53	90,737	0.58	28.2	0	0.00
Male	*****	*****	0.54	17.2	0	0.00
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	53	60,223	0.88	*****	*****	107.53
Male	*****	*****	0.79	*****	*****	0.00
Other	*****	*****	0.00	0.0	0	.

**Table 4a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	53	60,166	0.88	*****	*****	107.53
Male	*****	*****	0.79	*****	*****	0.00
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	53	60,223	0.88	*****	*****	107.53
Male	*****	*****	0.79	*****	*****	130.72
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	53	60,166	0.88	*****	*****	107.53
Male	*****	*****	0.79	*****	*****	130.72
Other	*****	*****	0.00	0.0	0	.
<b>Incident MS Inclusion Criteria: Gilenya</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
Female	751	104,015	7.22	*****	*****	6.03
Male	*****	*****	8.11	*****	*****	9.04
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	751	69,553	10.80	766.8	64	83.46
Male	*****	*****	11.78	308.1	26	84.39
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	751	69,485	10.81	765.9	66	86.17
Male	*****	*****	11.78	306.3	28	91.41
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	751	69,553	10.80	751.8	83	110.40
Male	*****	*****	11.78	300.2	34	113.26
Other	*****	*****	0.00	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	751	69,485	10.81	751.7	84	111.75
Male	*****	*****	11.78	298.3	36	120.68
Other	*****	*****	0.00	0.0	0	.

**Table 4a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Incident MS Inclusion Criteria: Copaxone, 40mg</b>						
<i>No Outcome</i>						
Female	1,188	98,859	12.02	434.3	N/A	N/A
Male	*****	*****	10.73	135.2	N/A	N/A
Other	*****	*****	0.00	0.0	N/A	N/A
<b>Incident MS Inclusion Criteria: Glatiramer</b>						
<i>No Outcome</i>						
Female	18	98,859	0.18	0.1	N/A	N/A
Male	*****	*****	0.23	0.0	N/A	N/A
Other	*****	*****	0.00	0.0	N/A	N/A

<sup>1</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 4b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)<sup>3</sup></i>						
Female	130,478	N/A	.	315,685.5	6,221	19.71
Male	*****	N/A	.	*****	*****	21.15
Other	*****	N/A	.	*****	*****	40.00
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)<sup>4</sup></i>						
Female	104,809	N/A	.	217,544.0	17,321	79.62
Male	*****	N/A	.	75,926.7	4,633	61.02
Other	*****	N/A	.	24.5	0	0.00
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)<sup>5</sup></i>						
Female	104,732	N/A	.	213,460.9	19,272	90.28
Male	*****	N/A	.	*****	*****	73.45
Other	*****	N/A	.	*****	*****	46.95
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)<sup>6</sup></i>						
Female	104,809	N/A	.	210,538.6	20,847	99.02
Male	*****	N/A	.	74,334.3	5,472	73.61
Other	*****	N/A	.	24.5	0	0.00
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)<sup>7</sup></i>						
Female	104,732	N/A	.	206,800.8	22,594	109.25
Male	*****	N/A	.	*****	*****	85.67
Other	*****	N/A	.	*****	*****	46.95
<b>Never Exposed: Prevalent MS Inclusion Criteria: Glatopa</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
Female	147,556	N/A	.	347,491.7	7,239	20.83
Male	*****	N/A	.	*****	*****	22.15
Other	*****	N/A	.	*****	*****	34.97
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	117,732	N/A	.	238,180.4	19,960	83.80
Male	*****	N/A	.	81,683.5	5,225	63.97
Other	*****	N/A	.	27.2	0	0.00

**Table 4b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	117,642	N/A	.	233,695.6	22,184	94.93
Male	*****	N/A	.	*****	*****	77.06
Other	*****	N/A	.	*****	*****	41.67
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	117,732	N/A	.	230,472.3	23,924	103.80
Male	*****	N/A	.	79,926.4	6,164	77.12
Other	*****	N/A	.	27.2	0	0.00
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	117,642	N/A	.	226,366.1	25,916	114.49
Male	*****	N/A	.	*****	*****	89.77
Other	*****	N/A	.	*****	*****	41.67
<b>Never Exposed: Prevalent MS Inclusion Criteria: Gilenya</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
Female	161,500	N/A	.	404,614.1	8,227	20.33
Male	*****	N/A	.	*****	*****	22.02
Other	*****	N/A	.	*****	*****	41.15
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	131,306	N/A	.	279,281.9	23,825	85.31
Male	*****	N/A	.	94,350.4	6,149	65.17
Other	*****	N/A	.	23.8	0	0.00
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	131,209	N/A	.	273,704.9	26,357	96.30
Male	*****	N/A	.	*****	*****	78.18
Other	*****	N/A	.	*****	*****	48.54
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	131,306	N/A	.	269,662.3	28,509	105.72
Male	*****	N/A	.	92,109.2	7,269	78.92
Other	*****	N/A	.	23.8	0	0.00
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	131,209	N/A	.	264,595.6	30,751	116.22
Male	*****	N/A	.	*****	*****	91.51
Other	*****	N/A	.	*****	*****	48.54

**Table 4b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
Female	79,609	N/A	.	174,336.5	2,133	12.23
Male	*****	N/A	.	*****	*****	13.02
Other	*****	N/A	.	*****	*****	40.00
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	54,294	N/A	.	109,435.1	5,959	54.45
Male	*****	N/A	.	39,444.0	1,588	40.26
Other	*****	N/A	.	15.0	0	0.00
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	54,247	N/A	.	108,414.9	6,544	60.36
Male	*****	N/A	.	*****	*****	47.73
Other	*****	N/A	.	*****	*****	84.75
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	54,294	N/A	.	106,939.7	7,388	69.09
Male	*****	N/A	.	38,840.7	1,942	50.00
Other	*****	N/A	.	15.0	0	0.00
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	54,247	N/A	.	105,980.5	7,918	74.71
Male	*****	N/A	.	*****	*****	57.43
Other	*****	N/A	.	*****	*****	84.75
<b>Never Exposed: Incident MS Inclusion Criteria: Glatopa</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
Female	87,292	N/A	.	187,477.5	2,372	12.65
Male	*****	N/A	.	*****	*****	13.59
Other	*****	N/A	.	*****	*****	38.61
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	58,959	N/A	.	117,007.9	6,639	56.74
Male	*****	N/A	.	41,511.2	1,739	41.89
Other	*****	N/A	.	15.0	0	0.00
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	58,907	N/A	.	115,865.0	7,289	62.91
Male	*****	N/A	.	*****	*****	49.57
Other	*****	N/A	.	*****	*****	84.75
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	58,959	N/A	.	114,349.5	8,194	71.66
Male	*****	N/A	.	40,873.6	2,122	51.92
Other	*****	N/A	.	15.0	0	0.00

**Table 4b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Sex**

Sex	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	58,907	N/A	.	113,275.4	8,785	77.55
Male	*****	N/A	.	*****	*****	59.52
Other	*****	N/A	.	*****	*****	84.75
<b>Never Exposed: Incident MS Inclusion Criteria: Gilenya</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
Female	99,569	N/A	.	226,019.4	2,905	12.85
Male	*****	N/A	.	*****	*****	14.23
Other	*****	N/A	.	*****	*****	50.76
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
Female	67,420	N/A	.	138,412.7	8,306	60.01
Male	*****	N/A	.	48,437.7	2,132	44.02
Other	*****	N/A	.	8.7	0	0.00
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
Female	67,359	N/A	.	136,949.5	9,093	66.40
Male	*****	N/A	.	*****	*****	51.81
Other	*****	N/A	.	*****	*****	181.82
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
Female	67,420	N/A	.	134,984.7	10,212	75.65
Male	*****	N/A	.	47,629.8	2,588	54.34
Other	*****	N/A	.	8.7	0	0.00
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
Female	67,359	N/A	.	133,610.4	10,918	81.72
Male	*****	N/A	.	*****	*****	62.08
Other	*****	N/A	.	*****	*****	181.82

<sup>1</sup>The same cohort eligibility criteria were applied to the never-exposed cohorts as to the exposed cohorts except that members with evidence of an index defining code (i.e., exposure) at any point during the member's enrollment history were excluded from the analysis

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
<i>Outcome Definition 1 (Inpatient)<sup>3</sup></i>						
HHS Region 01	482	17,111	28.17	385.7	12	31.11
HHS Region 02	403	16,296	24.73	338.4	16	47.28
HHS Region 03	550	20,929	26.28	456.1	21	46.04
HHS Region 04	987	41,529	23.77	715.6	32	44.72
HHS Region 05	1,015	40,835	24.86	784.7	51	64.99
HHS Region 06	517	16,306	31.71	396.2	25	63.10
HHS Region 07	208	9,271	22.44	*****	*****	64.84
HHS Region 08	314	9,424	33.32	*****	*****	24.20
HHS Region 09	691	23,002	30.04	558.5	23	41.18
HHS Region 10	204	8,308	24.55	*****	*****	18.01
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	20.83	3.7	0	0.00
Missing	*****	*****	33.68	33.5	0	0.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)<sup>4</sup></i>						
HHS Region 01	482	13,355	36.09	358.6	44	122.70
HHS Region 02	403	12,299	32.77	295.5	68	230.12
HHS Region 03	550	16,351	33.64	423.9	70	165.13
HHS Region 04	987	32,412	30.45	612.7	147	239.92
HHS Region 05	1,015	32,099	31.62	710.2	146	205.58
HHS Region 06	517	12,657	40.85	349.4	82	234.69
HHS Region 07	208	7,445	27.94	120.7	33	273.41
HHS Region 08	314	7,266	43.21	270.4	35	129.44
HHS Region 09	691	18,509	37.33	527.4	70	132.73
HHS Region 10	204	6,656	30.65	*****	*****	186.79
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	27.03	3.7	0	0.00
Missing	*****	*****	42.18	*****	*****	160.77
Other	0	0	.	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)<sup>5</sup></i>						
HHS Region 01	482	13,348	36.11	355.4	52	146.31
HHS Region 02	403	12,293	32.78	287.3	79	274.97
HHS Region 03	550	16,340	33.66	410.2	85	207.22
HHS Region 04	987	32,386	30.48	601.0	167	277.87
HHS Region 05	1,015	32,056	31.66	692.6	176	254.11
HHS Region 06	517	12,643	40.89	341.8	99	289.64

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 07	208	7,440	27.96	118.9	36	302.78
HHS Region 08	314	7,262	43.24	269.8	37	137.14
HHS Region 09	691	18,503	37.35	516.5	84	162.63
HHS Region 10	204	6,653	30.66	*****	*****	200.67
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	27.03	3.7	0	0.00
Missing	*****	*****	42.18	*****	*****	160.77
Other	0	0	.	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)<sup>6</sup></i>						
HHS Region 01	482	13,355	36.09	354.9	54	152.16
HHS Region 02	403	12,299	32.77	288.7	78	270.18
HHS Region 03	550	16,351	33.64	407.2	92	225.93
HHS Region 04	987	32,412	30.45	586.3	178	303.60
HHS Region 05	1,015	32,099	31.62	684.2	173	252.85
HHS Region 06	517	12,657	40.85	343.1	93	271.06
HHS Region 07	208	7,445	27.94	117.6	39	331.63
HHS Region 08	314	7,266	43.21	264.7	43	162.45
HHS Region 09	691	18,509	37.33	512.5	84	163.90
HHS Region 10	204	6,656	30.65	*****	*****	209.04
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	27.03	3.7	0	0.00
Missing	*****	*****	42.18	*****	*****	200.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)<sup>7</sup></i>						
HHS Region 01	482	13,348	36.11	351.9	61	173.34
HHS Region 02	403	12,293	32.78	282.1	88	311.95
HHS Region 03	550	16,340	33.66	394.6	104	263.56
HHS Region 04	987	32,386	30.48	576.8	194	336.34
HHS Region 05	1,015	32,056	31.66	669.1	200	298.91
HHS Region 06	517	12,643	40.89	336.0	109	324.40
HHS Region 07	208	7,440	27.96	116.2	41	352.84
HHS Region 08	314	7,262	43.24	264.1	45	170.39
HHS Region 09	691	18,503	37.35	501.6	97	193.38
HHS Region 10	204	6,653	30.66	*****	*****	223.12
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	27.03	3.7	0	0.00
Missing	*****	*****	42.18	*****	*****	200.00
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria: Glatopa</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	*****	*****	0.23	0.9	0	0.00
HHS Region 02	*****	*****	0.12	*****	*****	5,000.00
HHS Region 03	15	20,930	0.72	*****	*****	133.33
HHS Region 04	*****	*****	0.10	2.0	0	0.00
HHS Region 05	13	40,836	0.32	3.1	0	0.00
HHS Region 06	*****	*****	0.18	0.8	0	0.00
HHS Region 07	*****	*****	0.11	0.5	0	0.00
HHS Region 08	12	9,425	1.27	*****	*****	119.05
HHS Region 09	63	23,004	2.74	*****	*****	23.36
HHS Region 10	19	8,308	2.29	12.2	0	0.00
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	6.94	0.6	0	0.00
Missing	*****	*****	5.61	6.2	0	0.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	*****	*****	0.30	0.9	0	0.00
HHS Region 02	*****	*****	0.16	0.3	0	0.00
HHS Region 03	15	16,414	0.91	7.6	0	0.00
HHS Region 04	*****	*****	0.12	2.0	0	0.00
HHS Region 05	13	32,203	0.40	3.1	0	0.00
HHS Region 06	*****	*****	0.24	*****	*****	1,250.00
HHS Region 07	*****	*****	0.13	0.5	0	0.00
HHS Region 08	12	7,303	1.64	9.3	0	0.00
HHS Region 09	63	18,595	3.39	*****	*****	97.80
HHS Region 10	19	6,682	2.84	12.2	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	8.93	0.6	0	0.00
Missing	*****	*****	6.98	*****	*****	338.98
Other	0	0	.	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	*****	*****	0.30	0.9	0	0.00
HHS Region 02	*****	*****	0.16	*****	*****	5,000.00
HHS Region 03	15	16,403	0.91	*****	*****	133.33
HHS Region 04	*****	*****	0.12	2.0	0	0.00
HHS Region 05	13	32,160	0.40	3.1	0	0.00
HHS Region 06	*****	*****	0.24	*****	*****	1,250.00
HHS Region 07	*****	*****	0.13	0.5	0	0.00

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 08	12	7,300	1.64	*****	*****	119.05
HHS Region 09	63	18,589	3.39	*****	*****	122.55
HHS Region 10	19	6,679	2.84	12.2	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	8.93	0.6	0	0.00
Missing	*****	*****	6.98	*****	*****	338.98
Other	0	0	.	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	*****	*****	0.30	0.9	0	0.00
HHS Region 02	*****	*****	0.16	0.3	0	0.00
HHS Region 03	15	16,414	0.91	*****	*****	163.93
HHS Region 04	*****	*****	0.12	*****	*****	833.33
HHS Region 05	13	32,203	0.40	3.1	0	0.00
HHS Region 06	*****	*****	0.24	*****	*****	1,250.00
HHS Region 07	*****	*****	0.13	0.5	0	0.00
HHS Region 08	12	7,303	1.64	9.3	0	0.00
HHS Region 09	63	18,595	3.39	*****	*****	123.15
HHS Region 10	19	6,682	2.84	12.2	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	8.93	0.6	0	0.00
Missing	*****	*****	6.98	*****	*****	338.98
Other	0	0	.	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	*****	*****	0.30	0.9	0	0.00
HHS Region 02	*****	*****	0.16	*****	*****	5,000.00
HHS Region 03	15	16,403	0.91	*****	*****	333.33
HHS Region 04	*****	*****	0.12	*****	*****	833.33
HHS Region 05	13	32,160	0.40	3.1	0	0.00
HHS Region 06	*****	*****	0.24	*****	*****	1,250.00
HHS Region 07	*****	*****	0.13	0.5	0	0.00
HHS Region 08	12	7,300	1.64	*****	*****	119.05
HHS Region 09	63	18,589	3.39	*****	*****	148.15
HHS Region 10	19	6,679	2.84	12.2	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	8.93	0.6	0	0.00
Missing	*****	*****	6.98	*****	*****	338.98
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria: Gilenya</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	680	19,512	34.85	792.9	17	21.44
HHS Region 02	535	18,472	28.96	577.6	17	29.43
HHS Region 03	730	23,459	31.12	797.3	25	31.36
HHS Region 04	1,543	45,562	33.87	1,561.1	56	35.87
HHS Region 05	1,513	45,642	33.15	1,720.6	62	36.03
HHS Region 06	698	18,483	37.76	779.0	26	33.38
HHS Region 07	425	10,186	41.72	478.3	13	27.18
HHS Region 08	408	10,716	38.07	*****	*****	15.47
HHS Region 09	665	26,302	25.28	737.3	15	20.34
HHS Region 10	308	9,328	33.02	*****	*****	14.20
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	25.48	1.4	0	0.00
Missing	*****	*****	49.32	143.6	0	0.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	680	15,630	43.51	729.9	82	112.34
HHS Region 02	535	14,273	37.48	513.9	68	132.32
HHS Region 03	730	18,733	38.97	715.1	88	123.06
HHS Region 04	1,543	36,158	42.67	1,356.5	257	189.46
HHS Region 05	1,513	36,458	41.50	1,475.6	261	176.88
HHS Region 06	698	14,689	47.52	697.1	109	156.36
HHS Region 07	425	8,290	51.27	413.8	72	174.00
HHS Region 08	408	8,480	48.11	458.0	51	111.35
HHS Region 09	665	21,749	30.58	670.8	72	107.33
HHS Region 10	308	7,628	40.38	329.5	27	81.94
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	32.52	1.4	0	0.00
Missing	*****	*****	59.88	130.9	12	91.67
Other	0	0	.	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	680	15,623	43.53	720.1	90	124.98
HHS Region 02	535	14,264	37.51	504.4	81	160.59
HHS Region 03	730	18,720	39.00	703.6	105	149.23
HHS Region 04	1,543	36,127	42.71	1,335.2	288	215.70
HHS Region 05	1,513	36,414	41.55	1,446.9	292	201.81

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 06	698	14,670	47.58	687.4	118	171.66
HHS Region 07	425	8,284	51.30	412.1	79	191.70
HHS Region 08	408	8,475	48.14	456.3	57	124.92
HHS Region 09	665	21,744	30.58	663.8	82	123.53
HHS Region 10	308	7,625	40.39	325.9	28	85.92
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	32.79	1.4	0	0.00
Missing	*****	*****	59.88	130.9	12	91.67
Other	0	0	.	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	680	15,630	43.51	711.5	104	146.17
HHS Region 02	535	14,273	37.48	500.5	77	153.85
HHS Region 03	730	18,733	38.97	685.0	115	167.88
HHS Region 04	1,543	36,158	42.67	1,287.0	325	252.53
HHS Region 05	1,513	36,458	41.50	1,420.9	299	210.43
HHS Region 06	698	14,689	47.52	672.1	126	187.47
HHS Region 07	425	8,290	51.27	405.3	84	207.25
HHS Region 08	408	8,480	48.11	443.0	61	137.70
HHS Region 09	665	21,749	30.58	655.5	85	129.67
HHS Region 10	308	7,628	40.38	325.4	31	95.27
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	32.52	1.4	0	0.00
Missing	*****	*****	59.88	125.3	15	119.71
Other	0	0	.	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	680	15,623	43.53	702.1	111	158.10
HHS Region 02	535	14,264	37.51	491.1	89	181.23
HHS Region 03	730	18,720	39.00	677.1	127	187.56
HHS Region 04	1,543	36,127	42.71	1,266.9	352	277.84
HHS Region 05	1,513	36,414	41.55	1,394.0	329	236.01
HHS Region 06	698	14,670	47.58	664.5	135	203.16
HHS Region 07	425	8,284	51.30	403.6	91	225.47
HHS Region 08	408	8,475	48.14	441.2	67	151.86
HHS Region 09	665	21,744	30.58	650.3	93	143.01
HHS Region 10	308	7,625	40.39	322.7	32	99.16
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	32.79	1.4	0	0.00
Missing	*****	*****	59.88	125.3	15	119.71
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Prevalent MS Inclusion Criteria: Copaxone, 40mg</b>						
<i>No Outcome</i>						
HHS Region 01	448	18,294	24.49	146.9	N/A	N/A
HHS Region 02	408	17,556	23.24	131.1	N/A	N/A
HHS Region 03	546	22,529	24.24	166.2	N/A	N/A
HHS Region 04	1,034	44,772	23.09	293.9	N/A	N/A
HHS Region 05	797	43,757	18.21	248.9	N/A	N/A
HHS Region 06	510	17,631	28.93	159.5	N/A	N/A
HHS Region 07	218	9,872	22.08	71.5	N/A	N/A
HHS Region 08	171	10,104	16.92	56.9	N/A	N/A
HHS Region 09	530	24,636	21.51	182.8	N/A	N/A
HHS Region 10	135	8,834	15.28	42.2	N/A	N/A
HHS Region 11	0	*****	0.00	0.0	N/A	N/A
Invalid	*****	*****	6.45	0.5	N/A	N/A
Missing	*****	*****	9.82	4.7	N/A	N/A
Other	0	0	.	0.0	N/A	N/A
<b>Prevalent MS Inclusion Criteria: Glatiramer</b>						
<i>No Outcome</i>						
HHS Region 01	*****	*****	0.27	0.0	N/A	N/A
HHS Region 02	*****	*****	0.57	0.0	N/A	N/A
HHS Region 03	*****	*****	0.31	0.0	N/A	N/A
HHS Region 04	17	44,772	0.38	0.0	N/A	N/A
HHS Region 05	12	43,757	0.27	0.0	N/A	N/A
HHS Region 06	*****	*****	0.28	0.0	N/A	N/A
HHS Region 07	*****	*****	0.10	0.0	N/A	N/A
HHS Region 08	*****	*****	0.20	0.0	N/A	N/A
HHS Region 09	46	24,636	1.87	0.1	N/A	N/A
HHS Region 10	*****	*****	0.34	0.0	N/A	N/A
HHS Region 11	0	*****	0.00	0.0	N/A	N/A
Invalid	0	155	0.00	0.0	N/A	N/A
Missing	0	1,528	0.00	0.0	N/A	N/A
Other	0	0	.	0.0	N/A	N/A
<b>Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	181	10,075	17.97	*****	*****	38.89
HHS Region 02	118	8,983	13.14	*****	*****	49.75
HHS Region 03	189	12,358	15.29	*****	*****	18.54
HHS Region 04	328	24,309	13.49	281.5	16	56.84
HHS Region 05	310	24,305	12.75	*****	*****	36.78
HHS Region 06	179	9,737	18.38	*****	*****	37.43
HHS Region 07	55	5,551	9.91	*****	*****	72.46
HHS Region 08	106	5,635	18.81	102.0	0	0.00

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 09	253	15,009	16.86	*****	*****	18.60
HHS Region 10	65	5,006	12.98	*****	*****	31.95
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	0	*****	0.00	0.0	0	.
Missing	19	977	19.45	12.3	0	0.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	181	6,673	27.12	142.8	21	147.06
HHS Region 02	118	5,956	19.81	88.6	14	158.01
HHS Region 03	189	8,341	22.66	149.2	22	147.45
HHS Region 04	328	15,886	20.65	247.2	44	177.99
HHS Region 05	310	16,273	19.05	248.8	48	192.93
HHS Region 06	179	6,430	27.84	116.2	31	266.78
HHS Region 07	55	3,619	15.20	*****	*****	172.84
HHS Region 08	106	3,778	28.06	*****	*****	92.40
HHS Region 09	253	10,451	24.21	203.3	16	78.70
HHS Region 10	65	3,424	18.98	*****	*****	121.95
HHS Region 11	0	0	.	0.0	0	.
Invalid	0	70	0.00	0.0	0	.
Missing	19	663	28.66	*****	*****	82.64
Other	0	0	.	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	181	6,671	27.13	139.9	24	171.55
HHS Region 02	118	5,949	19.84	85.0	18	211.76
HHS Region 03	189	8,333	22.68	147.3	24	162.93
HHS Region 04	328	15,868	20.67	240.9	56	232.46
HHS Region 05	310	16,259	19.07	247.3	53	214.31
HHS Region 06	179	6,418	27.89	115.7	34	293.86
HHS Region 07	55	3,617	15.21	*****	*****	225.00
HHS Region 08	106	3,776	28.07	*****	*****	92.40
HHS Region 09	253	10,446	24.22	199.9	19	95.05
HHS Region 10	65	3,423	18.99	*****	*****	157.62
HHS Region 11	0	0	.	0.0	0	.
Invalid	0	70	0.00	0.0	0	.
Missing	19	663	28.66	*****	*****	82.64
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	181	6,673	27.12	142.5	22	154.39
HHS Region 02	118	5,956	19.81	86.3	17	196.99
HHS Region 03	189	8,341	22.66	145.0	31	213.79
HHS Region 04	328	15,886	20.65	241.3	56	232.08
HHS Region 05	310	16,273	19.05	238.7	56	234.60
HHS Region 06	179	6,430	27.84	114.1	33	289.22
HHS Region 07	55	3,619	15.20	*****	*****	224.44
HHS Region 08	106	3,778	28.06	96.3	12	124.61
HHS Region 09	253	10,451	24.21	196.9	20	101.57
HHS Region 10	65	3,424	18.98	*****	*****	121.95
HHS Region 11	0	0	.	0.0	0	.
Invalid	0	70	0.00	0.0	0	.
Missing	19	663	28.66	*****	*****	82.64
Other	0	0	.	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	181	6,671	27.13	139.9	24	171.55
HHS Region 02	118	5,949	19.84	82.7	21	253.93
HHS Region 03	189	8,333	22.68	143.1	33	230.61
HHS Region 04	328	15,868	20.67	235.3	66	280.49
HHS Region 05	310	16,259	19.07	237.2	61	257.17
HHS Region 06	179	6,418	27.89	113.5	36	317.18
HHS Region 07	55	3,617	15.21	*****	*****	250.63
HHS Region 08	106	3,776	28.07	96.3	12	124.61
HHS Region 09	253	10,446	24.22	193.5	22	113.70
HHS Region 10	65	3,423	18.99	*****	*****	157.62
HHS Region 11	0	0	.	0.0	0	.
Invalid	0	70	0.00	0.0	0	.
Missing	19	663	28.66	*****	*****	82.64
Other	0	0	.	0.0	0	.
<b>Incident MS Inclusion Criteria: Glatopa</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	*****	*****	0.30	0.5	0	0.00
HHS Region 02	*****	*****	0.11	0.0	0	.
HHS Region 03	*****	*****	0.73	5.3	0	0.00
HHS Region 04	*****	*****	0.12	0.6	0	0.00
HHS Region 05	*****	*****	0.25	1.9	0	0.00
HHS Region 06	0	9,738	0.00	0.0	0	.
HHS Region 07	0	5,551	0.00	0.0	0	.
HHS Region 08	*****	*****	0.89	4.8	0	0.00
HHS Region 09	31	15,009	2.07	21.6	0	0.00
HHS Region 10	*****	*****	1.20	5.5	0	0.00

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	10.64	0.6	0	0.00
Missing	*****	*****	5.12	4.6	0	0.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	*****	*****	0.45	0.5	0	0.00
HHS Region 02	*****	*****	0.17	0.0	0	.
HHS Region 03	*****	*****	1.08	5.3	0	0.00
HHS Region 04	*****	*****	0.19	0.6	0	0.00
HHS Region 05	*****	*****	0.37	1.9	0	0.00
HHS Region 06	0	6,439	0.00	0.0	0	.
HHS Region 07	0	3,621	0.00	0.0	0	.
HHS Region 08	*****	*****	1.32	4.8	0	0.00
HHS Region 09	31	10,468	2.96	*****	*****	93.46
HHS Region 10	*****	*****	1.75	5.5	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	14.29	0.6	0	0.00
Missing	*****	*****	7.53	*****	*****	227.27
Other	0	0	.	0.0	0	.
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	*****	*****	0.45	0.5	0	0.00
HHS Region 02	*****	*****	0.17	0.0	0	.
HHS Region 03	*****	*****	1.08	5.3	0	0.00
HHS Region 04	*****	*****	0.19	0.6	0	0.00
HHS Region 05	*****	*****	0.37	1.9	0	0.00
HHS Region 06	0	6,427	0.00	0.0	0	.
HHS Region 07	0	3,619	0.00	0.0	0	.
HHS Region 08	*****	*****	1.32	4.8	0	0.00
HHS Region 09	31	10,463	2.96	*****	*****	93.46
HHS Region 10	*****	*****	1.75	5.5	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	14.29	0.6	0	0.00
Missing	*****	*****	7.53	*****	*****	227.27
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	*****	*****	0.45	0.5	0	0.00
HHS Region 02	*****	*****	0.17	0.0	0	.
HHS Region 03	*****	*****	1.08	*****	*****	270.27
HHS Region 04	*****	*****	0.19	0.6	0	0.00
HHS Region 05	*****	*****	0.37	1.9	0	0.00
HHS Region 06	0	6,439	0.00	0.0	0	.
HHS Region 07	0	3,621	0.00	0.0	0	.
HHS Region 08	*****	*****	1.32	4.8	0	0.00
HHS Region 09	31	10,468	2.96	*****	*****	142.18
HHS Region 10	*****	*****	1.75	5.5	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	14.29	0.6	0	0.00
Missing	*****	*****	7.53	*****	*****	227.27
Other	0	0	.	0.0	0	.
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	*****	*****	0.45	0.5	0	0.00
HHS Region 02	*****	*****	0.17	0.0	0	.
HHS Region 03	*****	*****	1.08	*****	*****	270.27
HHS Region 04	*****	*****	0.19	0.6	0	0.00
HHS Region 05	*****	*****	0.37	1.9	0	0.00
HHS Region 06	0	6,427	0.00	0.0	0	.
HHS Region 07	0	3,619	0.00	0.0	0	.
HHS Region 08	*****	*****	1.32	4.8	0	0.00
HHS Region 09	31	10,463	2.96	*****	*****	142.18
HHS Region 10	*****	*****	1.75	5.5	0	0.00
HHS Region 11	0	0	.	0.0	0	.
Invalid	*****	*****	14.29	0.6	0	0.00
Missing	*****	*****	7.53	*****	*****	227.27
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Incident MS Inclusion Criteria: Gilenya</b>						
<i>Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	94	11,814	7.96	*****	*****	8.25
HHS Region 02	64	10,301	6.21	65.0	0	0.00
HHS Region 03	103	14,111	7.30	93.6	0	0.00
HHS Region 04	184	26,947	6.83	*****	*****	15.74
HHS Region 05	218	27,634	7.89	*****	*****	7.90
HHS Region 06	89	11,200	7.95	95.4	0	0.00
HHS Region 07	52	6,228	8.35	43.2	0	0.00
HHS Region 08	77	6,671	11.54	91.5	0	0.00
HHS Region 09	108	17,541	6.16	*****	*****	15.37
HHS Region 10	34	5,824	5.84	46.0	0	0.00
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	9.62	0.2	0	0.00
Missing	*****	*****	12.86	30.8	0	0.00
Other	0	0	.	0.0	0	.
<i>Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	94	7,917	11.87	*****	*****	50.13
HHS Region 02	64	6,874	9.31	*****	*****	49.75
HHS Region 03	103	9,608	10.72	*****	*****	66.96
HHS Region 04	184	17,627	10.44	167.0	23	137.72
HHS Region 05	218	18,613	11.71	231.7	21	90.63
HHS Region 06	89	7,475	11.91	*****	*****	113.51
HHS Region 07	52	4,048	12.85	*****	*****	153.06
HHS Region 08	77	4,585	16.79	*****	*****	45.77
HHS Region 09	108	12,365	8.73	*****	*****	64.05
HHS Region 10	34	4,016	8.47	*****	*****	25.13
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	13.51	0.2	0	0.00
Missing	*****	*****	18.47	*****	*****	73.80
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	94	7,913	11.88	*****	*****	59.32
HHS Region 02	64	6,866	9.32	*****	*****	49.75
HHS Region 03	103	9,599	10.73	*****	*****	66.96
HHS Region 04	184	17,607	10.45	167.0	23	137.72
HHS Region 05	218	18,595	11.72	231.6	22	94.99
HHS Region 06	89	7,462	11.93	*****	*****	113.51
HHS Region 07	52	4,046	12.85	*****	*****	153.06
HHS Region 08	77	4,583	16.80	*****	*****	45.77
HHS Region 09	108	12,360	8.74	*****	*****	80.71
HHS Region 10	34	4,015	8.47	*****	*****	25.13
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	13.51	0.2	0	0.00
Missing	*****	*****	18.47	*****	*****	73.80
Other	0	0	.	0.0	0	.
<i>Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	94	7,917	11.87	*****	*****	50.76
HHS Region 02	64	6,874	9.31	*****	*****	67.11
HHS Region 03	103	9,608	10.72	*****	*****	79.01
HHS Region 04	184	17,627	10.44	161.4	31	192.07
HHS Region 05	218	18,613	11.71	225.5	28	124.17
HHS Region 06	89	7,475	11.91	87.4	13	148.74
HHS Region 07	52	4,048	12.85	*****	*****	179.49
HHS Region 08	77	4,585	16.79	*****	*****	57.87
HHS Region 09	108	12,365	8.73	122.3	12	98.12
HHS Region 10	34	4,016	8.47	*****	*****	25.13
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	13.51	0.2	0	0.00
Missing	*****	*****	18.47	*****	*****	127.12
Other	0	0	.	0.0	0	.

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<i>Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	94	7,913	11.88	*****	*****	60.14
HHS Region 02	64	6,866	9.32	*****	*****	67.11
HHS Region 03	103	9,599	10.73	*****	*****	79.01
HHS Region 04	184	17,607	10.45	161.4	31	192.07
HHS Region 05	218	18,595	11.72	225.4	29	128.66
HHS Region 06	89	7,462	11.93	87.4	13	148.74
HHS Region 07	52	4,046	12.85	*****	*****	179.49
HHS Region 08	77	4,583	16.80	*****	*****	57.87
HHS Region 09	108	12,360	8.74	122.2	13	106.38
HHS Region 10	34	4,015	8.47	*****	*****	25.13
HHS Region 11	0	*****	0.00	0.0	0	.
Invalid	*****	*****	13.51	0.2	0	0.00
Missing	*****	*****	18.47	*****	*****	127.12
Other	0	0	.	0.0	0	.

**Incident MS Inclusion Criteria: Copaxone, 40mg**

<i>No Outcome</i>						
HHS Region 01	156	10,987	14.20	61.9	N/A	N/A
HHS Region 02	135	9,863	13.69	54.2	N/A	N/A
HHS Region 03	180	13,566	13.27	56.2	N/A	N/A
HHS Region 04	307	26,708	11.49	94.5	N/A	N/A
HHS Region 05	262	26,557	9.87	88.8	N/A	N/A
HHS Region 06	167	10,718	15.58	67.1	N/A	N/A
HHS Region 07	60	6,007	9.99	24.4	N/A	N/A
HHS Region 08	69	6,147	11.22	28.3	N/A	N/A
HHS Region 09	185	16,242	11.39	82.1	N/A	N/A
HHS Region 10	*****	*****	5.93	11.0	N/A	N/A
HHS Region 11	0	*****	0.00	0.0	N/A	N/A
Invalid	0	103	0.00	0.0	N/A	N/A
Missing	*****	*****	4.78	0.9	N/A	N/A
Other	0	0	.	0.0	N/A	N/A

**Table 5a. Copaxone, Glatopa, Gilenya, and Glatiramer Users and Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Exposed Members	Eligible Members <sup>1</sup>	Exposed Members per 1,000 Eligible Members	Years at Risk	Exposed Members with an Outcome	Exposed Members with an Outcome per 1,000 Years at Risk
<b>Incident MS Inclusion Criteria: Glatiramer</b>						
<i>No Outcome</i>						
HHS Region 01	0	10,987	0.00	0.0	N/A	N/A
HHS Region 02	*****	*****	0.20	0.0	N/A	N/A
HHS Region 03	*****	*****	0.15	0.0	N/A	N/A
HHS Region 04	*****	*****	0.07	0.0	N/A	N/A
HHS Region 05	0	26,557	0.00	0.0	N/A	N/A
HHS Region 06	0	10,718	0.00	0.0	N/A	N/A
HHS Region 07	0	6,007	0.00	0.0	N/A	N/A
HHS Region 08	*****	*****	0.16	0.0	N/A	N/A
HHS Region 09	19	16,242	1.17	0.1	N/A	N/A
HHS Region 10	0	5,399	0.00	0.0	N/A	N/A
HHS Region 11	0	*****	0.00	0.0	N/A	N/A
Invalid	0	103	0.00	0.0	N/A	N/A
Missing	0	1,046	0.00	0.0	N/A	N/A
Other	0	0	.	0.0	N/A	N/A

<sup>1</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

<sup>2</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date

<sup>3</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>4</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>5</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>7</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>Incident MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart in the 183 days prior to index date and no evidence of MS diagnosis in the 365 to 184 day period preceding index date

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Prevalent MS Inclusion Criteria:<sup>2</sup> Copaxone, 20 mg</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)<sup>3</sup></i>						
HHS Region 01	14,341	N/A	.	35,514.3	481	13.54
HHS Region 02	14,282	N/A	.	32,615.7	857	26.28
HHS Region 03	18,178	N/A	.	44,322.7	1,085	24.48
HHS Region 04	36,380	N/A	.	83,452.7	1,764	21.14
HHS Region 05	35,668	N/A	.	85,547.7	2,016	23.57
HHS Region 06	14,026	N/A	.	32,218.8	731	22.69
HHS Region 07	8,168	N/A	.	20,663.1	415	20.08
HHS Region 08	7,843	N/A	.	19,492.9	250	12.83
HHS Region 09	19,153	N/A	.	48,081.2	716	14.89
HHS Region 10	7,037	N/A	.	18,483.1	154	8.33
HHS Region 11	*****	N/A	.	6.9	0	0.00
Invalid	*****	N/A	.	*****	*****	25.71
Missing	1,080	N/A	.	*****	*****	8.29
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)<sup>4</sup></i>						
HHS Region 01	11,472	N/A	.	25,217.1	1,398	55.44
HHS Region 02	11,034	N/A	.	22,653.2	1,446	63.83
HHS Region 03	14,557	N/A	.	30,600.4	2,446	79.93
HHS Region 04	28,999	N/A	.	55,854.1	5,239	93.80
HHS Region 05	28,614	N/A	.	58,802.5	4,746	80.71
HHS Region 06	11,219	N/A	.	22,127.4	1,867	84.38
HHS Region 07	6,671	N/A	.	14,242.8	1,157	81.23
HHS Region 08	6,154	N/A	.	13,410.3	827	61.67
HHS Region 09	15,771	N/A	.	35,388.8	2,014	56.91
HHS Region 10	5,717	N/A	.	13,029.4	699	53.65
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	103	N/A	.	*****	*****	32.43
Missing	887	N/A	.	*****	*****	54.93
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)<sup>5</sup></i>						
HHS Region 01	11,466	N/A	.	24,848.8	1,575	63.38
HHS Region 02	11,030	N/A	.	22,021.2	1,758	79.83
HHS Region 03	14,551	N/A	.	29,815.4	2,811	94.28
HHS Region 04	28,977	N/A	.	54,722.2	5,768	105.41
HHS Region 05	28,578	N/A	.	57,437.9	5,369	93.47
HHS Region 06	11,205	N/A	.	21,663.1	2,096	96.75
HHS Region 07	6,667	N/A	.	13,999.7	1,282	91.57
HHS Region 08	6,152	N/A	.	13,233.9	916	69.22
HHS Region 09	15,767	N/A	.	34,909.2	2,268	64.97
HHS Region 10	5,715	N/A	.	12,919.4	757	58.59
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	102	N/A	.	*****	*****	56.43
Missing	887	N/A	.	*****	*****	58.84
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)<sup>6</sup></i>						
HHS Region 01	11,472	N/A	.	24,587.7	1,725	70.16
HHS Region 02	11,034	N/A	.	22,087.8	1,742	78.87
HHS Region 03	14,557	N/A	.	29,572.8	2,943	99.52
HHS Region 04	28,999	N/A	.	53,763.6	6,312	117.40
HHS Region 05	28,614	N/A	.	56,976.2	5,649	99.15
HHS Region 06	11,219	N/A	.	21,387.6	2,244	104.92
HHS Region 07	6,671	N/A	.	13,795.9	1,396	101.19
HHS Region 08	6,154	N/A	.	13,071.2	1,001	76.58
HHS Region 09	15,771	N/A	.	34,776.8	2,344	67.40
HHS Region 10	5,717	N/A	.	12,754.4	823	64.53
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	103	N/A	.	*****	*****	43.48
Missing	887	N/A	.	*****	*****	68.06
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)<sup>7</sup></i>						
HHS Region 01	11,466	N/A	.	24,234.9	1,892	78.07
HHS Region 02	11,030	N/A	.	21,491.9	2,030	94.45
HHS Region 03	14,551	N/A	.	28,839.3	3,272	113.46
HHS Region 04	28,977	N/A	.	52,728.3	6,779	128.56
HHS Region 05	28,578	N/A	.	55,736.5	6,211	111.44
HHS Region 06	11,205	N/A	.	20,970.5	2,444	116.54
HHS Region 07	6,667	N/A	.	13,576.8	1,508	111.07
HHS Region 08	6,152	N/A	.	12,914.3	1,080	83.63
HHS Region 09	15,767	N/A	.	34,321.1	2,583	75.26
HHS Region 10	5,715	N/A	.	12,653.6	877	69.31
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	102	N/A	.	176.2	12	68.10
Missing	887	N/A	.	1,926.8	139	72.14
Other	0	N/A	.	0.0	0	.
<b>Never Exposed: Prevalent MS Inclusion Criteria: Glatopa</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	16,578	N/A	.	39,884.5	558	13.99
HHS Region 02	15,797	N/A	.	34,946.9	976	27.93
HHS Region 03	20,270	N/A	.	48,027.5	1,239	25.80
HHS Region 04	40,460	N/A	.	90,589.5	2,057	22.71
HHS Region 05	39,788	N/A	.	92,699.8	2,322	25.05
HHS Region 06	15,746	N/A	.	34,976.1	829	23.70
HHS Region 07	9,064	N/A	.	22,096.6	473	21.41
HHS Region 08	9,085	N/A	.	22,171.0	295	13.31
HHS Region 09	21,948	N/A	.	54,287.7	854	15.73
HHS Region 10	8,032	N/A	.	20,832.8	185	8.88
HHS Region 11	*****	N/A	.	6.9	0	0.00
Invalid	*****	N/A	.	*****	*****	23.66
Missing	1,319	N/A	.	*****	*****	8.51
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	13,160	N/A	.	28,098.3	1,640	58.37
HHS Region 02	12,081	N/A	.	24,017.1	1,646	68.53
HHS Region 03	16,100	N/A	.	32,995.7	2,780	84.25
HHS Region 04	32,017	N/A	.	60,219.7	5,910	98.14
HHS Region 05	31,628	N/A	.	63,269.2	5,372	84.91
HHS Region 06	12,490	N/A	.	23,917.5	2,127	88.93
HHS Region 07	7,364	N/A	.	15,203.2	1,310	86.17
HHS Region 08	7,125	N/A	.	15,164.3	1,004	66.21
HHS Region 09	17,986	N/A	.	39,742.6	2,398	60.34
HHS Region 10	6,521	N/A	.	14,635.9	845	57.73
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	109	N/A	.	*****	*****	35.39
Missing	1,084	N/A	.	*****	*****	60.09
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	13,151	N/A	.	27,707.8	1,835	66.23
HHS Region 02	12,077	N/A	.	23,341.4	1,994	85.43
HHS Region 03	16,089	N/A	.	32,135.3	3,184	99.08
HHS Region 04	31,991	N/A	.	58,967.0	6,522	110.60
HHS Region 05	31,588	N/A	.	61,778.1	6,087	98.53
HHS Region 06	12,475	N/A	.	23,422.1	2,382	101.70
HHS Region 07	7,360	N/A	.	14,940.3	1,453	97.25
HHS Region 08	7,122	N/A	.	14,965.9	1,110	74.17
HHS Region 09	17,981	N/A	.	39,174.3	2,692	68.72
HHS Region 10	6,519	N/A	.	14,511.8	911	62.78
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	108	N/A	.	*****	*****	57.89
Missing	1,084	N/A	.	*****	*****	64.30
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	13,160	N/A	.	27,378.1	2,021	73.82
HHS Region 02	12,081	N/A	.	23,415.0	1,976	84.39
HHS Region 03	16,100	N/A	.	31,896.2	3,326	104.28
HHS Region 04	32,017	N/A	.	57,943.3	7,096	122.46
HHS Region 05	31,628	N/A	.	61,301.1	6,373	103.96
HHS Region 06	12,490	N/A	.	23,106.5	2,545	110.14
HHS Region 07	7,364	N/A	.	14,728.8	1,575	106.93
HHS Region 08	7,125	N/A	.	14,772.0	1,208	81.78
HHS Region 09	17,986	N/A	.	39,010.1	2,791	71.55
HHS Region 10	6,521	N/A	.	14,304.2	996	69.63
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	109	N/A	.	*****	*****	45.73
Missing	1,084	N/A	.	*****	*****	72.46
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	13,151	N/A	.	27,003.2	2,206	81.69
HHS Region 02	12,077	N/A	.	22,776.9	2,297	100.85
HHS Region 03	16,089	N/A	.	31,091.4	3,692	118.75
HHS Region 04	31,991	N/A	.	56,806.6	7,626	134.24
HHS Region 05	31,588	N/A	.	59,947.8	7,020	117.10
HHS Region 06	12,475	N/A	.	22,660.0	2,770	122.24
HHS Region 07	7,360	N/A	.	14,491.3	1,705	117.66
HHS Region 08	7,122	N/A	.	14,599.2	1,302	89.18
HHS Region 09	17,981	N/A	.	38,472.6	3,066	79.69
HHS Region 10	6,519	N/A	.	14,189.3	1,058	74.56
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	108	N/A	.	189.0	13	68.78
Missing	1,084	N/A	.	2,354.4	181	76.88
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Prevalent MS Inclusion Criteria: Gilenya</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	18,338	N/A	.	47,222.5	654	13.85
HHS Region 02	17,557	N/A	.	41,358.1	1,149	27.78
HHS Region 03	22,192	N/A	.	55,515.9	1,425	25.67
HHS Region 04	42,816	N/A	.	100,982.6	2,232	22.10
HHS Region 05	43,033	N/A	.	105,669.2	2,623	24.82
HHS Region 06	17,295	N/A	.	40,541.3	978	24.12
HHS Region 07	9,525	N/A	.	24,494.5	488	19.92
HHS Region 08	10,072	N/A	.	26,301.7	319	12.13
HHS Region 09	25,136	N/A	.	66,962.2	1,040	15.53
HHS Region 10	8,823	N/A	.	24,359.0	211	8.66
HHS Region 11	*****	N/A	.	7.8	0	0.00
Invalid	*****	N/A	.	*****	*****	17.43
Missing	1,491	N/A	.	*****	*****	8.55
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	14,922	N/A	.	33,755.9	1,996	59.13
HHS Region 02	13,725	N/A	.	28,573.4	2,024	70.84
HHS Region 03	17,927	N/A	.	38,391.3	3,259	84.89
HHS Region 04	34,436	N/A	.	67,615.5	6,711	99.25
HHS Region 05	34,849	N/A	.	72,654.0	6,316	86.93
HHS Region 06	13,977	N/A	.	27,783.0	2,585	93.04
HHS Region 07	7,875	N/A	.	16,923.6	1,497	88.46
HHS Region 08	8,050	N/A	.	18,231.0	1,228	67.36
HHS Region 09	21,050	N/A	.	49,167.3	3,169	64.45
HHS Region 10	7,303	N/A	.	17,380.1	1,011	58.17
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	*****	*****	22.42
Missing	1,244	N/A	.	*****	*****	58.50
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	14,915	N/A	.	33,242.1	2,238	67.32
HHS Region 02	13,716	N/A	.	27,714.5	2,434	87.82
HHS Region 03	17,917	N/A	.	37,290.2	3,739	100.27
HHS Region 04	34,409	N/A	.	66,131.8	7,373	111.49
HHS Region 05	34,809	N/A	.	70,839.8	7,116	100.45

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 06	13,960	N/A	.	27,128.7	2,883	106.27
HHS Region 07	7,871	N/A	.	16,640.2	1,637	98.38
HHS Region 08	8,046	N/A	.	18,011.7	1,333	74.01
HHS Region 09	21,045	N/A	.	48,408.3	3,518	72.67
HHS Region 10	7,301	N/A	.	17,218.4	1,091	63.36
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	*****	*****	36.58
Missing	1,244	N/A	.	*****	*****	63.06
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	14,922	N/A	.	32,849.4	2,454	74.70
HHS Region 02	13,725	N/A	.	27,759.6	2,423	87.29
HHS Region 03	17,927	N/A	.	37,035.3	3,899	105.28
HHS Region 04	34,436	N/A	.	64,826.4	8,082	124.67
HHS Region 05	34,849	N/A	.	70,225.3	7,489	106.64
HHS Region 06	13,977	N/A	.	26,745.5	3,092	115.61
HHS Region 07	7,875	N/A	.	16,340.4	1,809	110.71
HHS Region 08	8,050	N/A	.	17,741.0	1,475	83.14
HHS Region 09	21,050	N/A	.	48,179.1	3,661	75.99
HHS Region 10	7,303	N/A	.	16,968.2	1,187	69.95
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	*****	*****	27.00
Missing	1,244	N/A	.	*****	*****	69.26
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	14,915	N/A	.	32,360.9	2,682	82.88
HHS Region 02	13,716	N/A	.	26,960.5	2,799	103.82
HHS Region 03	17,917	N/A	.	35,996.3	4,341	120.60
HHS Region 04	34,409	N/A	.	63,478.7	8,655	136.34
HHS Region 05	34,809	N/A	.	68,598.0	8,200	119.54
HHS Region 06	13,960	N/A	.	26,164.6	3,344	127.81
HHS Region 07	7,871	N/A	.	16,087.8	1,935	120.28
HHS Region 08	8,046	N/A	.	17,555.5	1,566	89.20
HHS Region 09	21,045	N/A	.	47,475.2	3,982	83.88
HHS Region 10	7,301	N/A	.	16,818.9	1,260	74.92
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	*****	*****	41.32
Missing	1,244	N/A	.	*****	*****	73.99
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<b>Never Exposed: Incident MS Inclusion Criteria:<sup>8</sup> Copaxone, 20 mg</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	8,706	N/A	.	18,901.0	166	8.78
HHS Region 02	8,108	N/A	.	16,687.1	287	17.20
HHS Region 03	10,999	N/A	.	24,475.8	345	14.10
HHS Region 04	21,837	N/A	.	44,817.7	587	13.10
HHS Region 05	21,802	N/A	.	46,705.6	697	14.92
HHS Region 06	8,604	N/A	.	17,951.5	262	14.59
HHS Region 07	5,017	N/A	.	11,022.8	144	13.06
HHS Region 08	4,775	N/A	.	11,035.6	75	6.80
HHS Region 09	12,762	N/A	.	30,051.4	295	9.82
HHS Region 10	4,306	N/A	.	10,294.9	41	3.98
HHS Region 11	*****	N/A	.	6.8	0	0.00
Invalid	*****	N/A	.	*****	*****	13.00
Missing	763	N/A	.	*****	*****	4.89
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	5,974	N/A	.	12,203.0	479	39.25
HHS Region 02	5,547	N/A	.	10,869.6	466	42.87
HHS Region 03	7,667	N/A	.	15,828.3	838	52.94
HHS Region 04	14,658	N/A	.	27,478.7	1,650	60.05
HHS Region 05	14,908	N/A	.	29,428.4	1,631	55.42
HHS Region 06	5,874	N/A	.	11,204.0	656	58.55
HHS Region 07	3,353	N/A	.	6,802.8	360	52.92
HHS Region 08	3,283	N/A	.	6,959.4	332	47.71
HHS Region 09	9,114	N/A	.	20,177.7	795	39.40
HHS Region 10	3,012	N/A	.	6,594.3	277	42.01
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	65	N/A	.	*****	*****	9.06
Missing	546	N/A	.	*****	*****	50.10
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	5,972	N/A	.	12,098.7	536	44.30
HHS Region 02	5,541	N/A	.	10,726.3	546	50.90
HHS Region 03	7,661	N/A	.	15,624.9	950	60.80
HHS Region 04	14,642	N/A	.	27,197.2	1,798	66.11
HHS Region 05	14,897	N/A	.	29,087.2	1,817	62.47
HHS Region 06	5,863	N/A	.	11,056.5	735	66.48
HHS Region 07	3,351	N/A	.	6,747.6	392	58.09
HHS Region 08	3,282	N/A	.	6,920.2	360	52.02
HHS Region 09	9,109	N/A	.	20,000.1	908	45.40
HHS Region 10	3,012	N/A	.	6,570.4	297	45.20
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	64	N/A	.	*****	*****	9.07
Missing	546	N/A	.	*****	*****	51.78
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	5,974	N/A	.	11,995.9	617	51.43
HHS Region 02	5,547	N/A	.	10,673.7	578	54.15
HHS Region 03	7,667	N/A	.	15,440.6	1,053	68.20
HHS Region 04	14,658	N/A	.	26,785.4	2,051	76.57
HHS Region 05	14,908	N/A	.	28,770.3	2,001	69.55
HHS Region 06	5,874	N/A	.	10,889.4	832	76.40
HHS Region 07	3,353	N/A	.	6,662.7	449	67.39
HHS Region 08	3,283	N/A	.	6,829.0	410	60.04
HHS Region 09	9,114	N/A	.	19,912.8	947	47.56
HHS Region 10	3,012	N/A	.	6,506.3	319	49.03
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	65	N/A	.	*****	*****	9.06
Missing	546	N/A	.	*****	*****	59.07
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	5,972	N/A	.	11,892.9	673	56.59
HHS Region 02	5,541	N/A	.	10,531.0	655	62.20
HHS Region 03	7,661	N/A	.	15,250.5	1,154	75.67
HHS Region 04	14,642	N/A	.	26,514.9	2,189	82.56
HHS Region 05	14,897	N/A	.	28,451.0	2,169	76.24
HHS Region 06	5,863	N/A	.	10,752.4	903	83.98

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 07	3,351	N/A	.	6,614.8	475	71.81
HHS Region 08	3,282	N/A	.	6,794.5	435	64.02
HHS Region 09	9,109	N/A	.	19,742.0	1,056	53.49
HHS Region 10	3,012	N/A	.	6,483.1	338	52.14
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	64	N/A	.	*****	*****	9.07
Missing	546	N/A	.	*****	*****	60.79
Other	0	N/A	.	0.0	0	.

**Never Exposed: Incident MS Inclusion Criteria: Glatopa**

*Never Exposed: Outcome Definition 1 (Inpatient)*

HHS Region 01	9,689	N/A	.	20,525.2	187	9.11
HHS Region 02	8,635	N/A	.	17,414.0	306	17.57
HHS Region 03	11,883	N/A	.	25,940.4	386	14.88
HHS Region 04	23,558	N/A	.	47,362.7	662	13.98
HHS Region 05	23,569	N/A	.	49,560.7	760	15.33
HHS Region 06	9,325	N/A	.	18,925.5	288	15.22
HHS Region 07	5,413	N/A	.	11,561.9	157	13.58
HHS Region 08	5,376	N/A	.	12,175.8	87	7.15
HHS Region 09	14,238	N/A	.	33,145.1	336	10.14
HHS Region 10	4,815	N/A	.	11,475.8	46	4.01
HHS Region 11	*****	N/A	.	6.8	0	0.00
Invalid	*****	N/A	.	*****	*****	12.19
Missing	897	N/A	.	*****	*****	5.06
Other	0	N/A	.	0.0	0	.

*Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)*

HHS Region 01	6,551	N/A	.	13,161.0	540	41.03
HHS Region 02	5,831	N/A	.	11,235.9	496	44.14
HHS Region 03	8,190	N/A	.	16,675.5	910	54.57
HHS Region 04	15,651	N/A	.	28,870.8	1,810	62.69
HHS Region 05	15,971	N/A	.	31,038.2	1,801	58.03
HHS Region 06	6,307	N/A	.	11,745.5	732	62.32
HHS Region 07	3,577	N/A	.	7,107.6	392	55.15
HHS Region 08	3,685	N/A	.	7,660.0	387	50.52
HHS Region 09	10,124	N/A	.	22,194.8	917	41.32
HHS Region 10	3,352	N/A	.	7,310.3	319	43.64
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	68	N/A	.	*****	*****	8.35
Missing	629	N/A	.	*****	*****	51.60
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	6,549	N/A	.	13,048.1	604	46.29
HHS Region 02	5,824	N/A	.	11,083.7	582	52.51
HHS Region 03	8,183	N/A	.	16,447.8	1,030	62.62
HHS Region 04	15,634	N/A	.	28,559.8	1,978	69.26
HHS Region 05	15,958	N/A	.	30,669.9	2,002	65.28
HHS Region 06	6,295	N/A	.	11,592.5	818	70.56
HHS Region 07	3,575	N/A	.	7,048.5	425	60.30
HHS Region 08	3,684	N/A	.	7,616.3	418	54.88
HHS Region 09	10,119	N/A	.	21,972.5	1,046	47.60
HHS Region 10	3,352	N/A	.	7,279.2	341	46.85
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	67	N/A	.	*****	*****	8.36
Missing	629	N/A	.	*****	*****	53.89
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	6,551	N/A	.	12,937.7	693	53.56
HHS Region 02	5,831	N/A	.	11,036.5	614	55.63
HHS Region 03	8,190	N/A	.	16,271.8	1,142	70.18
HHS Region 04	15,651	N/A	.	28,135.9	2,245	79.79
HHS Region 05	15,971	N/A	.	30,355.2	2,192	72.21
HHS Region 06	6,307	N/A	.	11,418.0	920	80.57
HHS Region 07	3,577	N/A	.	6,959.4	491	70.55
HHS Region 08	3,685	N/A	.	7,516.2	475	63.20
HHS Region 09	10,124	N/A	.	21,888.8	1,091	49.84
HHS Region 10	3,352	N/A	.	7,206.8	368	51.06
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	68	N/A	.	*****	*****	8.35
Missing	629	N/A	.	*****	*****	60.34
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	6,549	N/A	.	12,826.0	756	58.94
HHS Region 02	5,824	N/A	.	10,886.0	697	64.03
HHS Region 03	8,183	N/A	.	16,057.4	1,251	77.91
HHS Region 04	15,634	N/A	.	27,841.0	2,399	86.17
HHS Region 05	15,958	N/A	.	30,011.4	2,374	79.10
HHS Region 06	6,295	N/A	.	11,275.5	998	88.51
HHS Region 07	3,575	N/A	.	6,907.5	518	74.99

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
HHS Region 08	3,684	N/A	.	7,477.1	503	67.27
HHS Region 09	10,119	N/A	.	21,676.0	1,215	56.05
HHS Region 10	3,352	N/A	.	7,176.4	389	54.21
HHS Region 11	0	N/A	.	0.0	0	.
Invalid	67	N/A	.	*****	*****	8.36
Missing	629	N/A	.	*****	*****	62.70
Other	0	N/A	.	0.0	0	.
<b>Never Exposed: Incident MS Inclusion Criteria: Gilenya</b>						
<i>Never Exposed: Outcome Definition 1 (Inpatient)</i>						
HHS Region 01	11,300	N/A	.	25,457.5	240	9.43
HHS Region 02	9,912	N/A	.	21,028.2	377	17.93
HHS Region 03	13,507	N/A	.	30,853.0	497	16.11
HHS Region 04	25,756	N/A	.	54,231.5	796	14.68
HHS Region 05	26,434	N/A	.	57,936.6	898	15.50
HHS Region 06	10,673	N/A	.	22,700.6	365	16.08
HHS Region 07	5,927	N/A	.	13,274.7	179	13.48
HHS Region 08	6,327	N/A	.	15,330.5	106	6.91
HHS Region 09	16,971	N/A	.	42,501.6	423	9.95
HHS Region 10	5,585	N/A	.	14,088.2	66	4.68
HHS Region 11	*****	N/A	.	7.7	0	0.00
Invalid	*****	N/A	.	*****	*****	10.69
Missing	1,074	N/A	.	*****	*****	5.41
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 2 (Outpatient with 7 Day Gap)</i>						
HHS Region 01	7,675	N/A	.	16,028.3	691	43.11
HHS Region 02	6,693	N/A	.	13,282.3	622	46.83
HHS Region 03	9,318	N/A	.	19,551.7	1,114	56.98
HHS Region 04	17,071	N/A	.	32,345.5	2,134	65.98
HHS Region 05	18,035	N/A	.	35,909.9	2,195	61.13
HHS Region 06	7,227	N/A	.	13,762.7	939	68.23
HHS Region 07	3,913	N/A	.	7,937.3	477	60.10
HHS Region 08	4,400	N/A	.	9,567.4	493	51.53
HHS Region 09	12,079	N/A	.	27,703.2	1,294	46.71
HHS Region 10	3,887	N/A	.	8,854.7	390	44.04
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	134.4	0	0.00
Missing	765	N/A	.	1,780.8	89	49.98
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 3 (Inpatient or Outpatient with 7 Day Gap)</i>						
HHS Region 01	7,671	N/A	.	15,879.2	769	48.43
HHS Region 02	6,685	N/A	.	13,069.5	735	56.24
HHS Region 03	9,309	N/A	.	19,236.2	1,271	66.07
HHS Region 04	17,052	N/A	.	31,943.8	2,342	73.32
HHS Region 05	18,019	N/A	.	35,466.5	2,425	68.37
HHS Region 06	7,216	N/A	.	13,580.6	1,038	76.43
HHS Region 07	3,911	N/A	.	7,873.4	511	64.90
HHS Region 08	4,399	N/A	.	9,519.1	525	55.15
HHS Region 09	12,074	N/A	.	27,442.4	1,439	52.44
HHS Region 10	3,887	N/A	.	8,809.2	420	47.68
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	134.2	0	0.00
Missing	765	N/A	.	1,774.6	94	52.97
Other	0	N/A	.	0.0	0	.
<i>Never Exposed: Outcome Definition 4 (Outpatient with 30 Day Gap)</i>						
HHS Region 01	7,675	N/A	.	15,741.9	884	56.16
HHS Region 02	6,693	N/A	.	13,015.5	769	59.08
HHS Region 03	9,318	N/A	.	19,046.5	1,388	72.87
HHS Region 04	17,071	N/A	.	31,395.6	2,665	84.88
HHS Region 05	18,035	N/A	.	35,050.2	2,677	76.38
HHS Region 06	7,227	N/A	.	13,343.1	1,153	86.41
HHS Region 07	3,913	N/A	.	7,761.6	593	76.40
HHS Region 08	4,400	N/A	.	9,376.6	598	63.78
HHS Region 09	12,079	N/A	.	27,280.4	1,518	55.64
HHS Region 10	3,887	N/A	.	8,717.6	454	52.08
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	134.4	0	0.00
Missing	765	N/A	.	1,759.0	101	57.42
Other	0	N/A	.	0.0	0	.

**Table 5b. Never Exposed Members<sup>1</sup> with Multiple Sclerosis (MS) Relapse in the Sentinel Distributed Database (SDD) between September 21, 2010 and January 31, 2018, by Health and Human Services (HHS) Region**

HHS Region	Never Exposed Members	Eligible Members	Exposed Members per 1,000 Eligible Members	Years at Risk	Never Exposed Members with an Outcome	Never Exposed Members with an Outcome per 1,000 Years at Risk
<i>Never Exposed: Outcome Definition 5 (Inpatient or Outpatient with 30 Day Gap)</i>						
HHS Region 01	7,671	N/A	.	15,594.5	960	61.56
HHS Region 02	6,685	N/A	.	12,813.1	874	68.21
HHS Region 03	9,309	N/A	.	18,742.4	1,532	81.74
HHS Region 04	17,052	N/A	.	31,014.4	2,853	91.99
HHS Region 05	18,019	N/A	.	34,641.5	2,881	83.17
HHS Region 06	7,216	N/A	.	13,172.9	1,242	94.28
HHS Region 07	3,911	N/A	.	7,702.9	622	80.75
HHS Region 08	4,399	N/A	.	9,333.7	627	67.18
HHS Region 09	12,074	N/A	.	27,027.8	1,658	61.34
HHS Region 10	3,887	N/A	.	8,675.1	481	55.45
HHS Region 11	*****	N/A	.	0.8	0	0.00
Invalid	*****	N/A	.	134.2	0	0.00
Missing	765	N/A	.	1,752.7	106	60.48
Other	0	N/A	.	0.0	0	.

<sup>1</sup>The same cohort eligibility criteria were applied to the never-exposed cohorts as to the exposed cohorts except that members with evidence of an index defining code (i.e., exposure) at any point during the member's enrollment history were excluded from the analysis

<sup>2</sup>Eligible Members and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

<sup>3</sup>Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims  $\geq$  30 days apart in the 183 days prior to index date

<sup>4</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position

<sup>5</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>6</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 7 days

<sup>7</sup>MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

<sup>8</sup>MS diagnosis in the inpatient care setting with a primary diagnostic position or MS diagnosis in the outpatient care setting with evidence of a corticosteroid dispensing within 30 days

\*\*\*\*\*Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

**Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 26, 2018)**

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DP ID	Start Date*	End Date*
DP01	09/21/2010	10/31/2014
DP02	09/21/2010	5/31/2015
DP03	09/21/2010	12/31/2015
DP04	09/21/2010	12/31/2016
DP05	09/21/2010	1/31/2017
DP06	01/01/2012	6/30/2017
DP07	09/21/2010	6/30/2017
DP08	09/21/2010	6/30/2017
DP09	09/21/2010	7/31/2017
DP10	09/21/2010	8/31/2017
DP11	09/21/2010	10/31/2017
DP12	09/21/2010	10/31/2017
DP13	09/21/2010	10/31/2017
DP14	09/21/2010	11/30/2017
DP15	09/21/2010	12/17/2017
DP16	09/21/2010	12/31/2017
DP17	09/21/2010	1/31/2018

\*The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month

**Appendix B. List of States and Territories Included in Each Health and Human Services (HHS) Region**

HHS Region	States and Territories
HHS Region 1	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
HHS Region 2	New Jersey, New York, Puerto Rico, Virgin Islands
HHS Region 3	Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia
HHS Region 4	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee
HHS Region 5	Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
HHS Region 6	Arkansas, Louisiana, New Mexico, Oklahoma, Texas
HHS Region 7	Iowa, Kansas, Missouri, Nebraska
HHS Region 8	Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
HHS Region 9	Arizona, California, Hawaii, Nevada, American Samoa, Federated States of Micronesia, Guam, Palau
HHS Region 10	Alaska, Idaho, Oregon, Washington
HHS Region 11	Northern Mariana Islands, Marshall Islands

**Appendix C. List of Generic and Brand Drug Names Used to Define Exposures in this Request**

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<b>Generic Name</b>	<b>Brand Name</b>
	<b>Copaxone, 20 mg</b>
GLATIRAMER ACETATE	Copaxone
	<b>Copaxone, 40 mg</b>
GLATIRAMER ACETATE	Copaxone
	<b>Glatopa</b>
GLATIRAMER ACETATE	Glatopa
	<b>Gilenya</b>
FINGOLIMOD HCL	Gilenya

**Appendix D. List of Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Exposures in this Request**

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<b>Code</b>	<b>Description</b>	<b>Code Type</b>
	<b>Glatiramer</b>	
J1595	Injection, glatiramer acetate, 20 mg	HCPCS
Q2010	Injection, glatiramer acetate, per dose	HCPCS

**Appendix E. 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 Multiple Sclerosis in this Request**

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<b>Code</b>	<b>Description</b>	<b>Code Type</b>
340	Multiple sclerosis	ICD-9-CM
G35	Multiple sclerosis	ICD-10-CM

**Appendix F. List of Generic and Brand Drug Names Used to Define Corticosteroids in this Request**

<b>Generic Name</b>	<b>Brand Name</b>
DEXAMETHASONE	dexamethasone
DEXAMETHASONE	Decadron
DEXAMETHASONE	LoCort
DEXAMETHASONE	ZoDex
DEXAMETHASONE	DexPak 13 Day
DEXAMETHASONE	DexPak 10 day
DEXAMETHASONE	Decadron Dose Pack
DEXAMETHASONE	Baycadron
DEXAMETHASONE	Dexone
DEXAMETHASONE	ZonaCort
DEXAMETHASONE	Zema-Pak
DEXAMETHASONE	DexPak 6 Day
DEXAMETHASONE	Dexamethasone Intensol
DEXAMETHASONE SOD PHOSPHATE	Decadron
DEXAMETHASONE SODIUM PHOSPHATE IN 0.9 % SODIUM CHLORIDE	dexamethasone in 0.9 % sod chl
METHYLPREDNISOLONE	methylprednisolone
METHYLPREDNISOLONE	Medrol (Pak)
METHYLPREDNISOLONE	Medrol
METHYLPREDNISOLONE	Meprolone Unipak
METHYLPREDNISOLONE	Methylpred
METHYLPREDNISOLONE SODIUM SUCCINATE	Solu-Medrol
METHYLPREDNISOLONE SODIUM SUCCINATE	methylprednisolone sodium succ
METHYLPREDNISOLONE SODIUM SUCCINATE	A-Methapred
METHYLPREDNISOLONE SODIUM SUCCINATE/PF	Solu-Medrol (PF)
PREDNISOLONE	prednisolone
PREDNISOLONE	Millipred DP
PREDNISOLONE	Millipred
PREDNISOLONE	Prelone
PREDNISOLONE ACETATE	Flo-Pred
PREDNISOLONE SOD PHOSPHATE	Orapred ODT
PREDNISOLONE SOD PHOSPHATE	Pediapred
PREDNISOLONE SOD PHOSPHATE	prednisolone sodium phosphate
PREDNISOLONE SOD PHOSPHATE	Orapred
PREDNISOLONE SOD PHOSPHATE	Millipred
PREDNISOLONE SOD PHOSPHATE	Bubbli-Pred
PREDNISOLONE SOD PHOSPHATE	Veripred 20
PREDNISOLONE SODIUM PHOSPHATE/PEAK FLOW METER	Asmalpred
PREDNISOLONE SODIUM PHOSPHATE/PEAK FLOW METER	Asmalpred Plus
PREDNISONE	prednisone
PREDNISONE	Liquid Pred
PREDNISONE	Deltasone
PREDNISONE	Sterapred DS
PREDNISONE	Rayos
PREDNISONE	Prednisone Intensol
PREDNISONE	Sterapred
PREDNISONE	Deltasone Dose Pack
PREDNISONE	Meticorten

### Appendix G. Specifications for Parameters used in the Request

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

**Query Period:** September 21, 2010 to January 31, 2018

**Pre-Index Enrollment Requirement:** 365 days

**Enrollment Gap:** 45 days

**Coverage Requirement:** Medical and Drug Coverage

**Age Groups:** 18-34, 35-44, 45-54, 55-64 years

**Results Stratified by:** Age, Sex, and Region

Exposure											
Incident Exposure	Incidence Criteria	Truncation Criteria	Washout (Days)	Minimum Episode Duration	Episode Gap Type	Episode Gap	Episode Extension	Cohort Definition	Create Never Exposed	Censor at Death	
1	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
2	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
3	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
4	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
5	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

Exposure											
Incident Exposure	Incidence Criteria	Truncation Criteria	Washout (Days)	Minimum Episode Duration	Episode Gap Type	Episode Gap	Episode Extension	Cohort Definition	Create Never Exposed Cohort	Censor at Death	
6	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
7	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
8	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
9	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
10	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
11	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
12	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

Exposure											
Incident Exposure	Incidence Criteria	Truncation Criteria	Washout (Days)	Minimum Episode Duration	Episode Gap Type	Episode Gap	Episode Extension	Cohort Definition	Create Never Exposed Cohort	Censor at Death	
13	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
14	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
15	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
16	Copaxone, 40 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (20 mg), Glatopa	365	0	Fixed	0	0	First valid event only	No	Yes
17	Glatiramer	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone, Glatopa	365	0	Fixed	0	0	First valid event only	No	Yes
18	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

Exposure											
Incident Exposure	Incidence Criteria	Truncation Criteria	Washout (Days)	Minimum Episode Duration	Episode Gap Type	Episode Gap	Episode Extension	Cohort Definition	Create Never Exposed Cohort	Censor at Death	
19	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
20	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
21	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
22	Copaxone, 20 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (40 mg), Glatopa	365	90	Fixed	15	15	First valid event only	Yes	Yes
23	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
24	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

Exposure											
Incident Exposure	Incidence Criteria	Truncation Criteria	Washout (Days)	Minimum Episode Duration	Episode Gap Type	Episode Gap	Episode Extension	Cohort Definition	Create Never Exposed Cohort	Censor at Death	
25	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
26	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
27	Glatopa	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone	365	90	Fixed	15	15	First valid event only	Yes	Yes
28	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
29	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
30	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

Exposure											
Incident Exposure	Incidence Criteria	Truncation Criteria	Washout (Days)	Minimum Episode Duration	Episode Gap Type	Episode Gap	Episode Extension	Cohort Definition	Create Never Exposed Cohort	Censor at Death	
31	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
32	Gilenya	Gilenya	---	365	90	Fixed	15	15	First valid event only	Yes	Yes
33	Copaxone, 40 mg	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone (20 mg), Glatopa	365	0	Fixed	0	0	First valid event only	No	Yes
34	Glatiramer	Copaxone, 20/40 mg, glatopa, glatiramer	Copaxone, Glatopa	365	0	Fixed	0	0	First valid event only	No	Yes

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

IP, AV, OA\* Care Setting in the primary diagnosis position

\* Prevalent MS Algorithm: 1 inpatient **or** 2 outpatient claims ≥ 30 days apart

\*\* Incident MS Algorithm: (1 inpatient **or** 2 outpatient claims ≥ 30 days apart) **AND** no MS Dx in 365 to 184 day period preceding index date

† Relapse Algorithm 1: 1 inpatient with principal diagnosis (IPP) **or** (1 outpatient diagnosis followed by a claim for a corticosteroid within 7 days)

†† Relapse Algorithm 2: 1 IPP diagnosis **or** (1 outpatient diagnosis followed by a claim for a corticosteroid within 30 days)

### Appendix G. Specifications for Parameters used in the Request

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

	Inclusion Criteria		Exclusion Criteria		Outcome			Baseline Characteristics	
	Pre-Existing Conditions	Lookback Period	Pre-Existing Conditions	Lookback Period	Outcome	Care Setting	Washout (Days)	Blackout Period	Evaluation Characteristics Window
<b>1</b>	(1 MS diagnosis in Inpatient (IP)) or (2 MS diagnoses in Ambulatory Visit (AV) / Other Ambulatory Visit (OA))	(-183, -1)	---	---	MS diagnosis	Inpatient in the Primary Position (IPP)	0	90	Corticosteroids -365, 0
<b>2</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis and corticosteroid within 7 days	Ambulatory Visit (AV)/ Other Ambulatory Visit (OA)	0	90	Corticosteroids -365, 0
<b>3</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	Relapse Algorithm 1+	IPP or AV/OA	0	90	Corticosteroids -365, 0
<b>4</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis and corticosteroid within 30 days	AV/OA	0	90	Corticosteroids -365, 0
<b>5</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	Relapse Algorithm 2++	IPP or AV/OA	0	90	Corticosteroids -365, 0
<b>6</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis	IPP	0	90	Corticosteroids -365, 0

### Appendix G. Specifications for Parameters used in the Request

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

	Inclusion Criteria		Exclusion Criteria		Outcome			Baseline Characteristics		
	Pre-Existing Conditions	Lookback Period	Pre-Existing Conditions	Lookback Period	Outcome	Care Setting	Washout (Days)	Blackout Period	Characteristics	Evaluation Window
<b>7</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis and corticosteroid within 7 days	AV/OA	0	90	Corticosteroids	-365, 0
<b>8</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	Relapse Algorithm 1†	IPP or AV/OA	0	90	Corticosteroids	-365, 0
<b>9</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis and corticosteroid within 30 days	AV/OA	0	90	Corticosteroids	-365, 0
<b>10</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	Relapse Algorithm 2††	IPP or AV/OA	0	90	Corticosteroids	-365, 0
<b>11</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis	IPP	0	90	Corticosteroids	-365, 0
<b>12</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis and corticosteroid within 7 days	AV/OA	0	90	Corticosteroids	-365, 0

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

	Inclusion Criteria		Exclusion Criteria		Outcome			Baseline Characteristics		
	Pre-Existing Conditions	Lookback Period	Pre-Existing Conditions	Lookback Period	Outcome	Care Setting	Washout (Days)	Blackout Period	Characteristics	Evaluation Window
<b>13</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	Relapse Algorithm 1+	IPP or AV/OA	0	90	Corticosteroids	-365, 0
<b>14</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	MS diagnosis and corticosteroid within 30 days	AV/OA	0	90	Corticosteroids	-365, 0
<b>15</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	Relapse Algorithm 2++	IPP or AV/OA	0	90	Corticosteroids	-365, 0
<b>16</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	---	---	---	---	Corticosteroids	-365, 0
<b>17</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	---	---	---	---	---	---	Corticosteroids	-365, 0
<b>18</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis	IPP	0	90	Corticosteroids	-365, 0

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

	Inclusion Criteria		Exclusion Criteria		Outcome			Baseline Characteristics		
	Pre-Existing Conditions	Lookback Period	Pre-Existing Conditions	Lookback Period	Outcome	Care Setting	Washout (Days)	Blackout Period	Characteristics	Evaluation Window
<b>19</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis and corticosteroid within 7 days	AV/OA	0	90	Corticosteroids	-365, 0
<b>20</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	Relapse Algorithm 1†	IPP or AV/OA	0	90	Corticosteroids	-365, 0
<b>21</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis and corticosteroid within 30 days	AV/OA	0	90	Corticosteroids	-365, 0
<b>22</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	Relapse Algorithm 2††	IPP or AV/OA	0	90	Corticosteroids	-365, 0
<b>23</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis	IPP	0	90	Corticosteroids	-365, 0
<b>24</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis and corticosteroid within 7 days	AV/OA	0	90	Corticosteroids	-365, 0

**Appendix G. Specifications for Parameters used in the Request**

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

	Inclusion Criteria		Exclusion Criteria		Outcome			Baseline Characteristics	
	Pre-Existing Conditions	Lookback Period	Pre-Existing Conditions	Lookback Period	Outcome	Care Setting	Washout (Days)	Blackout Period	Evaluation Characteristics Window
<b>25</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	Relapse Algorithm 1+	IPP or AV/OA	0	90	Corticosteroids -365, 0
<b>26</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis and corticosteroid within 30 days	AV/OA	0	90	Corticosteroids -365, 0
<b>27</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	Relapse Algorithm 2++	IPP or AV/OA	0	90	Corticosteroids -365, 0
<b>28</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis	IPP	0	90	Corticosteroids -365, 0
<b>29</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis and corticosteroid within 7 days	AV/OA	0	90	Corticosteroids -365, 0
<b>30</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	Relapse Algorithm 1+	IPP or AV/OA	0	90	Corticosteroids -365, 0

### Appendix G. Specifications for Parameters used in the Request

The goals of this query were to 1) estimate the rate of multiple sclerosis (MS) relapses among Copaxone, Glatopa, Gilenya, and glatiramer users and 2) compare MS relapse algorithms in the Sentinel Distributed Database.

	Inclusion Criteria		Exclusion Criteria		Outcome			Baseline Characteristics	
	Pre-Existing Conditions	Lookback Period	Pre-Existing Conditions	Lookback Period	Outcome	Care Setting	Washout (Days)	Blackout Period	Evaluation Characteristics Window
<b>31</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	MS diagnosis and corticosteroid within 30 days	AV/OA	0	90	Corticosteroids -365, 0
<b>32</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	Relapse Algorithm 2††	IPP or AV/OA	0	90	Corticosteroids -365, 0
<b>33</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	---	---	---	---	Corticosteroids -365, 0
<b>34</b>	(1 MS diagnosis in IP*) or (2 MS diagnoses in AV*/OA*)	(-183, -1)	MS diagnosis	(-365, -184)	---	---	---	---	Corticosteroids -365, 0

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

\* Prevalent MS Algorithm: 1 inpatient or 2 outpatient claims ≥ 30 days apart

\*\* Incident MS Algorithm: (1 inpatient or 2 outpatient claims ≥ 30 days apart) AND no MS Dx in -365 to -184 day period preceding index date

† Relapse Algorithm 1: 1 inpatient with principal diagnosis (IPP) or (1 outpatient diagnosis followed by a claim for a corticosteroid within 7 days)

†† Relapse Algorithm 2: 1 IPP diagnosis or (1 outpatient diagnosis followed by a claim for a corticosteroid within 30 days)

## Appendix H. Pictorial Summary of the Study Design Parameters and Cohort Eligibility Criteria in this Request

