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Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Request cder_mpl1r_wp060

Request ID: cder_mpl1r_wp060

Report Description: The goal of this report was to estimate the number of incident users of Qsymia (combination product of phentermine and topiramate), phentermine, topiramate, and concomitant phentermine and topiramate in the Sentinel Distributed Database (SDD). The report also estimated number of incident users amongst individuals with a history of either epilepsy or seizures, with a history of migraines, and with no history of those conditions. This is report 2 of 2. The first report characterizes the uptake and utilization of Qsymia (phentermine+topiramate), phentermine, and topiramate, including the distribution of days supply, length of treatment episodes, and time to drug initiation.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis tool, version 4.1.3

Data Source: Data from September 17, 2012 to April 30, 2017 from 16 Data Partners contributing to the SDD were included in this report. This request was distributed on August 17, 2017. See Appendix A for a list of the dates of available data for each Data Partner.

Study Design: The request was designed to calculate background rates of the exposures of interest. The number of qualifying individuals with the exposures of interest were calculated overall and stratified by age group, sex, and year.

Exposures of Interest: There were four exposures of interest in this request: Qsymia, phentermine, topiramate, and concomitant phentermine and topiramate, defined as incident phentermine and incident topiramate use initiated within 14 days of each other, regardless of initiation sequence. See Appendix B for generic and brand names used to define the exposures of interest.

Cohort Eligibility Criteria: There were four cohorts evaluated in this report. All cohorts required the following criteria: Individuals were required to be continuously enrolled in health plans with both medical and drug coverage for at least 183 days prior to their first qualifying dispensing date, during which gaps in coverage of up to 30 days were allowed. Individuals were excluded if they had evidence of Qsymia, phentermine, or topiramate in the 183 days prior to the first qualifying dispensing date of the exposure of interest. The following age groups were included in all four cohorts: 18-44, 45-64, and 65+ years. All qualifying incident dispensings that occurred between September 17, 2012 and April 30, 2017 were included, and a gap of 30 days was allowed between dispensings to be considered part of the same episode. The end date of each exposure episode was extended by 30 additional days. There were no additional inclusion or exclusion criteria applied in the first cohort. In the second cohort, individuals were required to have evidence of an epilepsy or seizure diagnosis within 183 days of their exposure drug use. In the third cohort, individuals were required to have evidence of a migraine diagnosis within 183 days of their exposure drug use. In the fourth cohort, individuals were required to have no evidence of an epilepsy, seizure, or migraine diagnosis within 183 days of their exposure. Please refer to Appendix C for specific codes used to define these inclusion and exclusion criteria.

Baseline Characteristics: The following characteristics were assessed in the baseline period: ischemic stroke, myocardial infarction, and both ischemic stroke and myocardial infarction. Occurrence of these characteristics was evaluated in the 183 days prior to the first qualifying dispensing date of an exposure of interest. Please refer to Appendix D for a list of the specific codes used to define characteristics.

Limitations: Algorithms to define exposures and baseline characteristics are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

Please see the Appendix E for the specifications of parameters to be used in the analyses for this request.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator, forms the

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

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

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

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

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

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

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

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

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

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

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

Event Deduplication - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

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

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions days are added after any episode gaps have been bridged

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

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

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

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

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

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

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

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

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



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 1. Summary of Incident Qsymia, Phentermine, and Topiramate Use with Baseline Characteristics in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort

	Number of Patients	Recorded History of Ischemic Stroke		Recorded History of Myocardial Infarction		Recorded History of Ischemic Stroke or Myocardial Infarction	
		Number of Patients	%	Number of Patients	%	Number of Patients	%
All Users							
Qsymia	6,540	12	0.18	12	0.18	24	0.37
Phentermine	86,796	214	0.25	68	0.08	282	0.32
Topiramate	432,642	8,684	2.01	1,192	0.28	9,666	2.23
Concomitant Topiramate and Phentermine	3,519	7	0.20	5	0.14	12	0.34
Baseline Diagnosis of Epilepsy or Seizure							
Qsymia	6	0	0.00	0	0.00	0	0.00
Phentermine	277	5	1.81	0	0.00	5	1.81
Topiramate	16,424	1,364	8.30	151	0.92	1,465	8.92
Concomitant Topiramate and Phentermine	12	0	0.00	0	0.00	0	0.00
Baseline Diagnosis of Migraine							
Qsymia	287	1	0.35	1	0.35	2	0.70
Phentermine	4,330	32	0.74	6	0.14	38	0.88
Topiramate	188,362	4,745	2.52	426	0.23	5,080	2.70
Concomitant Topiramate and Phentermine	337	1	0.30	0	0.00	1	0.30
No Baseline Diagnosis of Epilepsy, Seizure, or Migraine							
Qsymia	6,259	11	0.18	11	0.18	22	0.35
Phentermine	82,912	180	0.22	62	0.07	242	0.29
Topiramate	242,890	3,207	1.32	669	0.28	3,789	1.56
Concomitant Topiramate and Phentermine	3,180	6	0.19	5	0.16	11	0.35

Table 2. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
All Users								
Qsymia	6,540	6,824	23,725	681,099	688,694	104.14	3.63	28.71
Phentermine	86,796	99,356	220,742	6,824,232	6,792,997	78.62	2.54	30.91
Topiramate	432,642	464,975	1,539,879	52,749,269	110,058,065	121.92	3.56	34.26
Concomitant Topiramate and Phentermine	3,519	3,630	6,504	277,854	6,297	78.96	1.85	42.72
Baseline Diagnosis of Epilepsy or Seizure								
Qsymia	6	6	24	624	624	104.00	4.00	26.00
Phentermine	277	286	601	18,711	19,354	67.55	2.17	31.13
Topiramate	16,424	17,038	74,774	2,628,607	6,600,963	160.05	4.55	35.15
Concomitant Topiramate and Phentermine	12	12	20	799	20	66.58	1.67	39.95
Baseline Diagnosis of Migraine								
Qsymia	287	293	941	26,769	27,201	93.27	3.28	28.45
Phentermine	4,330	4,587	10,154	313,476	311,703	72.40	2.35	30.87
Topiramate	188,362	197,774	698,717	24,238,679	52,405,122	128.68	3.71	34.69
Concomitant Topiramate and Phentermine	337	340	579	23,919	562	70.98	1.72	41.31
No Baseline Diagnosis of Epilepsy, Seizure, or Migraine								
Qsymia	6,259	6,527	22,767	653,858	661,021	104.47	3.64	28.72
Phentermine	82,912	94,535	210,083	6,495,171	6,465,226	78.34	2.53	30.92
Topiramate	242,890	257,326	796,002	26,902,932	53,505,657	110.76	3.28	33.80
Concomitant Topiramate and Phentermine	3,180	3,279	5,906	253,157	5,716	79.61	1.86	42.86

Table 3. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Age Group

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
All Users								
Qsymia								
18-44 Years	2,657	2,743	9,280	265,064	268,532	99.76	3.49	28.56
45-64 Years	3,449	3,607	13,088	377,237	380,877	109.38	3.79	28.82
65+ Years	451	474	1,357	38,798	39,285	86.03	3.01	28.59
Phentermine								
18-44 Years	42,788	48,556	105,362	3,233,042	3,213,620	75.56	2.46	30.69
45-64 Years	36,708	41,663	96,399	3,002,278	2,994,901	81.79	2.63	31.14
65+ Years	8,017	9,137	18,981	588,912	584,476	73.46	2.37	31.03
Topiramate								
18-44 Years	233,962	250,249	807,490	26,423,605	55,589,101	112.94	3.45	32.72
45-64 Years	170,633	182,976	632,625	22,225,197	46,213,024	130.25	3.71	35.13
65+ Years	29,905	31,750	99,764	4,100,467	8,255,941	137.12	3.34	41.10
Concomitant Topiramate and Phentermine								
18-44 Years	1,591	1,639	2,972	118,547	2,880	74.51	1.87	39.89
45-64 Years	1,552	1,598	2,836	125,939	2,736	81.15	1.83	44.41
65+ Years	385	393	696	33,368	681	86.67	1.81	47.94
Baseline Diagnosis of Epilepsy or Seizure								
Qsymia								
18-44 Years	3	3	8	202	202	67.33	2.67	25.25
45-64 Years	3	3	16	422	422	140.67	5.33	26.38
65+ Years	0	0	0	0	0	---	---	---
Phentermine								
18-44 Years	106	108	235	7,590	8,040	71.60	2.22	32.30
45-64 Years	132	137	287	8,777	8,971	66.49	2.17	30.58
65+ Years	39	41	79	2,344	2,344	60.10	2.03	29.67
Topiramate								
18-44 Years	8,964	9,298	40,487	1,368,102	3,567,276	152.62	4.52	33.79
45-64 Years	6,154	6,374	28,703	1,032,024	2,517,879	167.70	4.66	35.96
65+ Years	1,340	1,366	5,584	228,481	515,809	170.51	4.17	40.92
Concomitant Topiramate and Phentermine								
18-44 Years	2	2	4	120	4	60.00	2.00	30.00
45-64 Years	8	8	12	499	12	62.38	1.50	41.58
65+ Years	2	2	4	180	4	90.00	2.00	45.00

Table 3. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Age Group

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Baseline Diagnosis of Migraine								
Qsymia								
18-44 Years	144	146	482	13,566	13,730	94.21	3.35	28.15
45-64 Years	135	139	434	12,524	12,792	92.77	3.21	28.86
65+ Years	8	8	25	679	679	84.88	3.13	27.16
Phentermine								
18-44 Years	2,509	2,645	5,768	177,608	176,082	70.79	2.30	30.79
45-64 Years	1,689	1,782	4,026	124,645	124,487	73.80	2.38	30.96
65+ Years	151	160	360	11,223	11,134	74.32	2.38	31.18
Topiramate								
18-44 Years	115,843	121,295	413,022	13,770,557	30,001,951	118.87	3.57	33.34
45-64 Years	65,162	68,213	257,560	9,260,871	20,010,382	142.12	3.95	35.96
65+ Years	7,902	8,266	28,135	1,207,251	2,392,789	152.78	3.56	42.91
Concomitant Topiramate and Phentermine								
18-44 Years	215	218	379	15,158	368	70.50	1.76	39.99
45-64 Years	110	110	180	7,712	175	70.11	1.64	42.84
65+ Years	12	12	20	1,049	20	87.42	1.67	52.45
No Baseline Diagnosis of Epilepsy, Seizure, or Migraine								
Qsymia								
18-44 Years	2,513	2,595	8,793	251,370	254,674	100.03	3.50	28.59
45-64 Years	3,316	3,466	12,642	364,369	367,741	109.88	3.81	28.82
65+ Years	443	466	1,332	38,119	38,606	86.05	3.01	28.62
Phentermine								
18-44 Years	40,574	45,826	99,399	3,049,388	3,030,994	75.16	2.45	30.68
45-64 Years	35,145	39,769	92,136	2,870,270	2,863,082	81.67	2.62	31.15
65+ Years	7,859	8,940	18,548	575,513	571,151	73.23	2.36	31.03
Topiramate								
18-44 Years	117,585	123,859	370,550	11,833,953	23,367,012	100.64	3.15	31.94
45-64 Years	104,783	111,019	358,010	12,346,254	24,665,556	117.83	3.42	34.49
65+ Years	21,353	22,448	67,442	2,722,725	5,473,089	127.51	3.16	40.37
Concomitant Topiramate and Phentermine								
18-44 Years	1,379	1,419	2,589	103,269	2,508	74.89	1.88	39.89
45-64 Years	1,438	1,481	2,645	117,749	2,550	81.88	1.84	44.52
65+ Years	371	379	672	32,139	658	86.63	1.81	47.83

Table 4. Summary of Incident Qsymia, Phentermine, Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Sex

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
All Users								
Qsymia								
Female	5,144	5,351	18,048	517,638	523,794	100.63	3.51	28.68
Male	1,396	1,473	5,677	163,461	164,900	117.09	4.07	28.79
Unknown	0	0	0	0	0	---	---	---
Phentermine								
Female	71,712	82,427	181,692	5,611,796	5,579,645	78.25	2.53	30.89
Male	15,081	16,925	39,043	1,212,254	1,213,170	80.38	2.59	31.05
Unknown	3	4	7	182	182	60.67	2.33	26.00
Topiramate								
Female	349,403	376,981	1,272,182	43,513,089	90,716,266	124.54	3.64	34.20
Male	83,220	87,974	267,640	9,234,384	19,337,706	110.96	3.22	34.50
Unknown	19	20	57	1,796	4,093	94.53	3.00	31.51
Concomitant Topiramate and Phentermine								
Female	2,829	2,927	5,240	219,632	5,071	77.64	1.85	41.91
Male	690	703	1,264	58,222	1,226	84.38	1.83	46.06
Unknown	0	0	0	0	0	---	---	---
Baseline Diagnosis of Epilepsy or Seizure								
Qsymia								
Female	5	5	17	430	430	86.00	3.40	25.29
Male	1	1	7	194	194	194.00	7.00	27.71
Unknown	0	0	0	0	0	---	---	---
Phentermine								
Female	226	233	492	15,284	15,803	67.63	2.18	31.07
Male	51	53	109	3,427	3,551	67.20	2.14	31.44
Unknown	0	0	0	0	0	---	---	---
Topiramate								
Female	12,197	12,681	55,289	1,930,578	4,826,944	158.28	4.53	34.92
Male	4,227	4,357	19,485	698,029	1,774,020	165.14	4.61	35.82
Unknown	0	0	0	0	0	---	---	---
Concomitant Topiramate and Phentermine								
Female	9	9	15	406	15	45.11	1.67	27.07
Male	3	3	5	393	5	131.00	1.67	78.60
Unknown	0	0	0	0	0	---	---	---

Table 4. Summary of Incident Qsymia, Phentermine, Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Sex

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Baseline Diagnosis of Migraine								
Qsymia								
Female	269	275	875	24,934	25,352	92.69	3.25	28.50
Male	18	18	66	1,835	1,849	101.94	3.67	27.80
Unknown	0	0	0	0	0	---	---	---
Phentermine								
Female	4,089	4,335	9,534	294,713	292,959	72.07	2.33	30.91
Male	241	252	620	18,763	18,744	77.85	2.57	30.26
Unknown	0	0	0	0	0	---	---	---
Topiramate								
Female	162,673	171,111	616,001	21,345,629	46,164,004	131.22	3.79	34.65
Male	25,681	26,655	82,704	2,892,692	6,240,456	112.64	3.22	34.98
Unknown	8	8	12	358	662	44.75	1.50	29.83
Concomitant Topiramate and Phentermine								
Female	313	316	537	21,640	521	69.14	1.72	40.30
Male	24	24	42	2,279	41	94.96	1.75	54.26
Unknown	0	0	0	0	0	---	---	---
No Baseline Diagnosis of Epilepsy, Seizure, or Migraine								
Qsymia								
Female	4,882	5,073	17,163	492,426	498,164	100.87	3.52	28.69
Male	1,377	1,454	5,604	161,432	162,857	117.23	4.07	28.81
Unknown	0	0	0	0	0	---	---	---
Phentermine								
Female	68,079	77,907	171,757	5,304,705	5,273,950	77.92	2.52	30.88
Male	14,830	16,624	38,319	1,190,284	1,191,095	80.26	2.58	31.06
Unknown	3	4	7	182	182	60.67	2.33	26.00
Topiramate								
Female	187,437	199,128	625,624	21,086,624	41,774,110	112.50	3.34	33.70
Male	55,441	58,186	170,333	5,814,870	11,728,116	104.88	3.07	34.14
Unknown	12	12	45	1,438	3,431	119.83	3.75	31.96
Concomitant Topiramate and Phentermine								
Female	2,517	2,603	4,689	197,607	4,536	78.51	1.86	42.14
Male	663	676	1,217	55,550	1,180	83.79	1.84	45.65
Unknown	0	0	0	0	0	---	---	---

Table 5. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Year

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
All Users								
Qsymia								
2012	110	110	352	10,586	10,642	96.24	3.20	30.07
2013	1,332	1,334	5,007	145,840	147,502	109.49	3.76	29.13
2014	2,039	2,043	7,553	218,793	220,583	107.30	3.70	28.97
2015	1,936	1,942	7,188	208,702	211,241	107.80	3.71	29.03
2016	1,363	1,366	3,591	96,528	98,042	70.82	2.63	26.88
2017	29	29	34	650	685	22.41	1.17	19.12
Phentermine								
2012	5,140	5,140	11,134	362,520	362,511	70.53	2.17	32.56
2013	20,475	20,636	46,492	1,447,351	1,449,494	70.69	2.27	31.13
2014	22,990	23,178	52,349	1,644,192	1,642,167	71.52	2.28	31.41
2015	25,440	25,661	60,886	1,909,447	1,899,679	75.06	2.39	31.36
2016	22,483	22,598	46,932	1,390,700	1,374,816	61.86	2.09	29.63
2017	2,143	2,143	2,949	70,022	64,330	32.67	1.38	23.74
Topiramate								
2012	31,095	31,095	118,092	4,082,464	8,723,489	131.29	3.80	34.57
2013	108,304	108,872	413,528	14,353,338	30,348,931	132.53	3.82	34.71
2014	111,154	111,732	411,653	14,371,428	30,085,685	129.29	3.70	34.91
2015	112,823	113,391	371,177	12,744,408	26,180,734	112.96	3.29	34.34
2016	94,332	94,651	219,557	7,060,452	14,404,980	74.85	2.33	32.16
2017	5,234	5,234	5,872	137,179	314,246	26.21	1.12	23.36
Concomitant Topiramate and Phentermine								
2012	189	189	345	15,257	335	80.72	1.83	44.22
2013	722	723	1,307	53,198	1,293	73.68	1.81	40.70
2014	810	812	1,455	61,358	1,433	75.75	1.80	42.17
2015	901	901	1,602	77,157	1,579	85.63	1.78	48.16
2016	879	879	1,570	64,457	1,497	73.33	1.79	41.06
2017	126	126	225	6,427	160	51.01	1.79	28.56

Table 5. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Year

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Baseline Diagnosis of Epilepsy or Seizure								
Qsymia								
2012	0	0	0	0	0	---	---	---
2013	0	0	0	0	0	---	---	---
2014	4	4	15	360	360	90.00	3.75	24.00
2015	2	2	9	264	264	132.00	4.50	29.33
2016	0	0	0	0	0	---	---	---
2017	0	0	0	0	0	---	---	---
Phentermine								
2012	12	12	31	971	1,001	80.92	2.58	31.32
2013	51	51	114	3,439	4,089	67.43	2.24	30.17
2014	63	63	147	4,928	4,944	78.22	2.33	33.52
2015	71	71	143	4,441	4,456	62.55	2.01	31.06
2016	81	81	152	4,616	4,580	56.99	1.88	30.37
2017	8	8	14	316	285	39.50	1.75	22.57
Topiramate								
2012	1,135	1,135	6,120	218,739	559,078	192.72	5.39	35.74
2013	3,941	3,952	21,087	743,404	1,903,839	188.63	5.35	35.25
2014	4,093	4,105	20,394	736,635	1,812,279	179.97	4.98	36.12
2015	4,271	4,284	18,168	633,263	1,581,075	148.27	4.25	34.86
2016	3,386	3,397	8,803	291,847	730,837	86.19	2.60	33.15
2017	165	165	202	4,719	13,854	28.60	1.22	23.36
Concomitant Topiramate and Phentermine								
2012	2	2	3	81	3	40.50	1.50	27.00
2013	1	1	2	60	2	60.00	2.00	30.00
2014	2	2	3	87	3	43.50	1.50	29.00
2015	2	2	3	141	3	70.50	1.50	47.00
2016	5	5	9	430	9	86.00	1.80	47.78
2017	0	0	0	0	0	---	---	---

Table 5. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Year

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
Baseline Diagnosis of Migraine								
Qsymia								
2012	3	3	21	626	626	208.67	7.00	29.81
2013	46	46	178	5,074	5,225	110.30	3.87	28.51
2014	80	80	292	8,423	8,565	105.29	3.65	28.85
2015	101	101	299	8,736	8,822	86.50	2.96	29.22
2016	62	62	149	3,890	3,943	62.74	2.40	26.11
2017	1	1	2	20	20	20.00	2.00	10.00
Phentermine								
2012	205	205	404	13,471	13,313	65.71	1.97	33.34
2013	907	912	2,097	65,087	64,695	71.76	2.31	31.04
2014	1,023	1,026	2,300	73,892	74,122	72.23	2.25	32.13
2015	1,213	1,214	2,918	91,317	90,573	75.28	2.41	31.29
2016	1,072	1,075	2,232	64,916	64,543	60.56	2.08	29.08
2017	155	155	203	4,793	4,458	30.92	1.31	23.61
Topiramate								
2012	13,507	13,507	55,146	1,909,687	4,244,093	141.38	4.08	34.63
2013	46,523	46,668	191,078	6,679,530	14,677,076	143.57	4.11	34.96
2014	47,287	47,432	188,236	6,665,175	14,394,172	140.95	3.98	35.41
2015	47,971	48,111	166,816	5,802,140	12,310,125	120.95	3.48	34.78
2016	39,557	39,651	94,747	3,114,893	6,622,639	78.74	2.40	32.88
2017	2,405	2,405	2,694	67,254	157,017	27.96	1.12	24.96
Concomitant Topiramate and Phentermine								
2012	16	16	27	1,055	27	65.94	1.69	39.07
2013	68	68	120	5,419	119	79.69	1.76	45.16
2014	70	70	115	4,680	114	66.86	1.64	40.70
2015	91	91	157	6,061	156	66.60	1.73	38.61
2016	86	86	145	6,427	138	74.73	1.69	44.32
2017	9	9	15	277	9	30.78	1.67	18.47

Table 5. Summary of Incident Qsymia, Phentermine, and Topiramate Use in the Sentinel Distributed Database from September 17, 2012 to April 30, 2017 by Cohort and Year

	New Users	Total Episodes	Dispensings	Days Supplied	Amount Supplied	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing
No Baseline Diagnosis of Epilepsy, Seizure, or Migraine								
Qsymia								
2012	107	107	331	9,960	10,016	93.08	3.09	30.09
2013	1,286	1,288	4,829	140,766	142,277	109.46	3.76	29.15
2014	1,957	1,961	7,253	210,162	211,810	107.39	3.71	28.98
2015	1,833	1,839	6,880	199,702	202,155	108.95	3.75	29.03
2016	1,301	1,304	3,442	92,638	94,099	71.21	2.65	26.91
2017	28	28	32	630	665	22.50	1.14	19.69
Phentermine								
2012	4,923	4,923	10,699	348,078	348,198	70.70	2.17	32.53
2013	19,531	19,679	44,302	1,379,455	1,381,551	70.63	2.27	31.14
2014	21,937	22,105	49,929	1,566,466	1,564,162	71.41	2.28	31.37
2015	24,181	24,392	57,853	1,814,589	1,805,551	75.04	2.39	31.37
2016	21,347	21,454	44,565	1,321,633	1,306,158	61.91	2.09	29.66
2017	1,982	1,982	2,735	64,950	59,608	32.77	1.38	23.75
Topiramate								
2012	16,927	16,927	59,286	2,043,311	4,129,152	120.71	3.50	34.47
2013	59,625	59,889	209,274	7,202,643	14,443,868	120.80	3.51	34.42
2014	61,666	61,921	211,154	7,253,593	14,548,524	117.63	3.42	34.35
2015	62,576	62,834	193,498	6,560,925	12,898,399	104.85	3.09	33.91
2016	52,875	53,012	119,719	3,775,056	7,335,772	71.40	2.26	31.53
2017	2,743	2,743	3,071	67,404	149,941	24.57	1.12	21.95
Concomitant Topiramate and Phentermine								
2012	171	171	315	14,121	306	82.58	1.84	44.83
2013	653	654	1,185	47,719	1,172	73.08	1.81	40.27
2014	738	740	1,337	56,591	1,316	76.68	1.81	42.33
2015	809	809	1,443	70,976	1,421	87.73	1.78	49.19
2016	788	788	1,416	57,600	1,350	73.10	1.80	40.68
2017	117	117	210	6,150	151	52.56	1.79	29.29

Appendix A. List of Dates of Available Data for Each Data Partner (DP) in the Sentinel Distributed Database as of Request Distribution Date (August 17, 2017)

DP ID	Start Date ¹	End Date ¹
DP0001	9/17/2012	10/31/2014
DP0002	9/17/2012	5/31/2015
DP0003	9/17/2012	10/31/2015
DP0004	9/17/2012	12/31/2015
DP0005	9/17/2012	3/31/2016
DP0006	9/17/2012	6/30/2016
DP0007	9/17/2012	9/30/2016
DP0008	9/17/2012	10/31/2016
DP0009	9/17/2012	11/30/2016
DP0010	9/17/2012	1/31/2017
DP0011	9/17/2012	3/31/2017
DP0012	9/17/2012	3/31/2017
DP0013	9/17/2012	3/31/2017
DP0014	9/17/2012	3/31/2017
DP0015	9/17/2012	3/31/2017
DP0016	9/17/2012	4/30/2017

¹The 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 Generic and Brand Names Used to Define Exposures in this Request

Generic Name	Brand Name
Qsymia	
PHENTERMINE HCL/TOPIRAMATE	Qsymia
Phentermine	
PHENTERMINE HCL	Phentermine
PHENTERMINE HCL	Adipex-P
PHENTERMINE HCL	Suprenza
PHENTERMINE HCL	Lomaira
Topiramate	
TOPIRAMATE	Topiramate
TOPIRAMATE	Topamax
TOPIRAMATE	Trokendi XR
TOPIRAMATE	Qudexy XR
TOPIRAMATE	Topiragen

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
Epilepsy or Seizure		
345	Epilepsy and recurrent seizures	ICD-9-CM
345.0	Generalized nonconvulsive epilepsy	ICD-9-CM
345.00	Generalized nonconvulsive epilepsy without mention of intractable epilepsy	ICD-9-CM
345.01	Generalized nonconvulsive epilepsy with intractable epilepsy	ICD-9-CM
345.1	Generalized convulsive epilepsy	ICD-9-CM
345.10	Generalized convulsive epilepsy without mention of intractable epilepsy	ICD-9-CM
345.11	Generalized convulsive epilepsy with intractable epilepsy	ICD-9-CM
345.2	Epileptic petit mal status	ICD-9-CM
345.3	Epileptic grand mal status	ICD-9-CM
345.4	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures	ICD-9-CM
345.40	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures, without mention of intractable epilepsy	ICD-9-CM
345.41	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures, with intractable epilepsy	ICD-9-CM
345.5	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures	ICD-9-CM
345.50	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures, without mention of intractable epilepsy	ICD-9-CM
345.51	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures, with intractable epilepsy	ICD-9-CM
345.6	Infantile spasms	ICD-9-CM
345.60	Infantile spasms without mention of intractable epilepsy	ICD-9-CM
345.61	Infantile spasms with intractable epilepsy	ICD-9-CM
345.7	Epilepsia partialis continua	ICD-9-CM
345.70	Epilepsia partialis continua without mention of intractable epilepsy	ICD-9-CM
345.71	Epilepsia partialis continua with intractable epilepsy	ICD-9-CM
345.8	Other forms of epilepsy and recurrent seizures	ICD-9-CM
345.80	Other forms of epilepsy and recurrent seizures, without mention of intractable epilepsy	ICD-9-CM
345.81	Other forms of epilepsy and recurrent seizures, with intractable epilepsy	ICD-9-CM
345.9	Unspecified epilepsy	ICD-9-CM
345.90	Unspecified epilepsy without mention of intractable epilepsy	ICD-9-CM
345.91	Unspecified epilepsy with intractable epilepsy	ICD-9-CM
G40	Epilepsy and recurrent seizures	ICD-10-CM
G40.0	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset	ICD-10-CM
G40.00	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable	ICD-10-CM
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus	ICD-10-CM
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus	ICD-10-CM
G40.01	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable	ICD-10-CM

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus	ICD-10-CM
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus	ICD-10-CM
G40.1	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures	ICD-10-CM
G40.10	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable	ICD-10-CM
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus	ICD-10-CM
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus	ICD-10-CM
G40.11	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable	ICD-10-CM
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus	ICD-10-CM
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus	ICD-10-CM
G40.2	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures	ICD-10-CM
G40.20	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable	ICD-10-CM
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus	ICD-10-CM
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus	ICD-10-CM
G40.21	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable	ICD-10-CM
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus	ICD-10-CM
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus	ICD-10-CM
G40.3	Generalized idiopathic epilepsy and epileptic syndromes	ICD-10-CM
G40.30	Generalized idiopathic epilepsy and epileptic syndromes, not intractable	ICD-10-CM
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus	ICD-10-CM
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus	ICD-10-CM
G40.31	Generalized idiopathic epilepsy and epileptic syndromes, intractable	ICD-10-CM
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus	ICD-10-CM
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus	ICD-10-CM
G40.4	Other generalized epilepsy and epileptic syndromes	ICD-10-CM
G40.40	Other generalized epilepsy and epileptic syndromes, not intractable	ICD-10-CM
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus	ICD-10-CM
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus	ICD-10-CM

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
G40.41	Other generalized epilepsy and epileptic syndromes, intractable	ICD-10-CM
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus	ICD-10-CM
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus	ICD-10-CM
G40.5	Epileptic seizures related to external causes	ICD-10-CM
G40.50	Epileptic seizures related to external causes, not intractable	ICD-10-CM
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus	ICD-10-CM
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus	ICD-10-CM
G40.8	Other epilepsy and recurrent seizures	ICD-10-CM
G40.80	Other epilepsy	ICD-10-CM
G40.801	Other epilepsy, not intractable, with status epilepticus	ICD-10-CM
G40.802	Other epilepsy, not intractable, without status epilepticus	ICD-10-CM
G40.803	Other epilepsy, intractable, with status epilepticus	ICD-10-CM
G40.804	Other epilepsy, intractable, without status epilepticus	ICD-10-CM
G40.81	Lennox-Gastaut syndrome	ICD-10-CM
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus	ICD-10-CM
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus	ICD-10-CM
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus	ICD-10-CM
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus	ICD-10-CM
G40.82	Epileptic spasms	ICD-10-CM
G40.821	Epileptic spasms, not intractable, with status epilepticus	ICD-10-CM
G40.822	Epileptic spasms, not intractable, without status epilepticus	ICD-10-CM
G40.823	Epileptic spasms, intractable, with status epilepticus	ICD-10-CM
G40.824	Epileptic spasms, intractable, without status epilepticus	ICD-10-CM
G40.89	Other seizures	ICD-10-CM
G40.9	Epilepsy, unspecified	ICD-10-CM
G40.90	Epilepsy, unspecified, not intractable	ICD-10-CM
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus	ICD-10-CM
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus	ICD-10-CM
G40.91	Epilepsy, unspecified, intractable	ICD-10-CM
G40.911	Epilepsy, unspecified, intractable, with status epilepticus	ICD-10-CM
G40.919	Epilepsy, unspecified, intractable, without status epilepticus	ICD-10-CM
G40.A	Absence epileptic syndrome	ICD-10-CM
G40.A0	Absence epileptic syndrome, not intractable	ICD-10-CM
G40.A01	Absence epileptic syndrome, not intractable, with status epilepticus	ICD-10-CM
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus	ICD-10-CM
G40.A1	Absence epileptic syndrome, intractable	ICD-10-CM
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus	ICD-10-CM
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus	ICD-10-CM
G40.B	Juvenile myoclonic epilepsy [impulsive petit mal]	ICD-10-CM
G40.B0	Juvenile myoclonic epilepsy, not intractable	ICD-10-CM
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus	ICD-10-CM
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus	ICD-10-CM
G40.B1	Juvenile myoclonic epilepsy, intractable	ICD-10-CM
G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus	ICD-10-CM

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus	ICD-10-CM
Migraine		
346	Migraine	ICD-9-CM
346.0	Migraine with aura	ICD-9-CM
346.00	Migraine with aura, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.01	Migraine with aura, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.02	Migraine with aura, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.03	Migraine with aura, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.1	Migraine without aura	ICD-9-CM
346.10	Migraine without aura, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.11	Migraine without aura, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.12	Migraine without aura, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.13	Migraine without aura, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.2	Variants of migraine, not elsewhere classified	ICD-9-CM
346.20	Variants of migraine, not elsewhere classified, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.21	Variants of migraine, not elsewhere classified, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.22	Variants of migraine, not elsewhere classified, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.23	Variants of migraine, not elsewhere classified, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.3	Hemiplegic migraine	ICD-9-CM
346.30	Hemiplegic migraine, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.31	Hemiplegic migraine, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.32	Hemiplegic migraine, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.33	Hemiplegic migraine, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.4	Menstrual migraine	ICD-9-CM
346.40	Menstrual migraine, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.41	Menstrual migraine, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.42	Menstrual migraine, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.43	Menstrual migraine, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.5	Persistent migraine aura without cerebral infarction	ICD-9-CM

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
346.50	Persistent migraine aura without cerebral infarction, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.51	Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.52	Persistent migraine aura without cerebral infarction, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.53	Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.6	Persistent migraine aura with cerebral infarction	ICD-9-CM
346.60	Persistent migraine aura with cerebral infarction, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.61	Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.62	Persistent migraine aura with cerebral infarction, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.63	Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.7	Chronic migraine without aura	ICD-9-CM
346.70	Chronic migraine without aura, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.71	Chronic migraine without aura, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.72	Chronic migraine without aura, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.73	Chronic migraine without aura, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.8	Other forms of migraine	ICD-9-CM
346.80	Other forms of migraine, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.81	Other forms of migraine, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.82	Other forms of migraine, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.83	Other forms of migraine, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
346.9	Migraine, unspecified	ICD-9-CM
346.90	Migraine, unspecified without mention of intractable migraine without mention of status migrainosus	ICD-9-CM
346.91	Migraine, unspecified, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM
346.92	Migraine, unspecified, without mention of intractable migraine with status migrainosus	ICD-9-CM
346.93	Migraine, unspecified, with intractable migraine, so stated, with status migrainosus	ICD-9-CM
G43	Migraine	ICD-10-CM
G43.0	Migraine without aura	ICD-10-CM
G43.00	Migraine without aura, not intractable	ICD-10-CM

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
G43.001	Migraine without aura, not intractable, with status migrainosus	ICD-10-CM
G43.009	Migraine without aura, not intractable, without status migrainosus	ICD-10-CM
G43.01	Migraine without aura, intractable	ICD-10-CM
G43.011	Migraine without aura, intractable, with status migrainosus	ICD-10-CM
G43.019	Migraine without aura, intractable, without status migrainosus	ICD-10-CM
G43.1	Migraine with aura	ICD-10-CM
G43.10	Migraine with aura, not intractable	ICD-10-CM
G43.101	Migraine with aura, not intractable, with status migrainosus	ICD-10-CM
G43.109	Migraine with aura, not intractable, without status migrainosus	ICD-10-CM
G43.11	Migraine with aura, intractable	ICD-10-CM
G43.111	Migraine with aura, intractable, with status migrainosus	ICD-10-CM
G43.119	Migraine with aura, intractable, without status migrainosus	ICD-10-CM
G43.4	Hemiplegic migraine	ICD-10-CM
G43.40	Hemiplegic migraine, not intractable	ICD-10-CM
G43.401	Hemiplegic migraine, not intractable, with status migrainosus	ICD-10-CM
G43.409	Hemiplegic migraine, not intractable, without status migrainosus	ICD-10-CM
G43.41	Hemiplegic migraine, intractable	ICD-10-CM
G43.411	Hemiplegic migraine, intractable, with status migrainosus	ICD-10-CM
G43.419	Hemiplegic migraine, intractable, without status migrainosus	ICD-10-CM
G43.5	Persistent migraine aura without cerebral infarction	ICD-10-CM
G43.50	Persistent migraine aura without cerebral infarction, not intractable	ICD-10-CM
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus	ICD-10-CM
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus	ICD-10-CM
G43.51	Persistent migraine aura without cerebral infarction, intractable	ICD-10-CM
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus	ICD-10-CM
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus	ICD-10-CM
G43.6	Persistent migraine aura with cerebral infarction	ICD-10-CM
G43.60	Persistent migraine aura with cerebral infarction, not intractable	ICD-10-CM
G43.601	Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus	ICD-10-CM
G43.609	Persistent migraine aura with cerebral infarction, not intractable, without status migrainosus	ICD-10-CM
G43.61	Persistent migraine aura with cerebral infarction, intractable	ICD-10-CM
G43.611	Persistent migraine aura with cerebral infarction, intractable, with status migrainosus	ICD-10-CM
G43.619	Persistent migraine aura with cerebral infarction, intractable, without status migrainosus	ICD-10-CM
G43.7	Chronic migraine without aura	ICD-10-CM
G43.70	Chronic migraine without aura, not intractable	ICD-10-CM
G43.701	Chronic migraine without aura, not intractable, with status migrainosus	ICD-10-CM
G43.709	Chronic migraine without aura, not intractable, without status migrainosus	ICD-10-CM
G43.71	Chronic migraine without aura, intractable	ICD-10-CM
G43.711	Chronic migraine without aura, intractable, with status migrainosus	ICD-10-CM
G43.719	Chronic migraine without aura, intractable, without status migrainosus	ICD-10-CM
G43.8	Other migraine	ICD-10-CM

Appendix C. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
G43.80	Other migraine, not intractable	ICD-10-CM
G43.801	Other migraine, not intractable, with status migrainosus	ICD-10-CM
G43.809	Other migraine, not intractable, without status migrainosus	ICD-10-CM
G43.81	Other migraine, intractable	ICD-10-CM
G43.811	Other migraine, intractable, with status migrainosus	ICD-10-CM
G43.819	Other migraine, intractable, without status migrainosus	ICD-10-CM
G43.82	Menstrual migraine, not intractable	ICD-10-CM
G43.821	Menstrual migraine, not intractable, with status migrainosus	ICD-10-CM
G43.829	Menstrual migraine, not intractable, without status migrainosus	ICD-10-CM
G43.83	Menstrual migraine, intractable	ICD-10-CM
G43.831	Menstrual migraine, intractable, with status migrainosus	ICD-10-CM
G43.839	Menstrual migraine, intractable, without status migrainosus	ICD-10-CM
G43.9	Migraine, unspecified	ICD-10-CM
G43.90	Migraine, unspecified, not intractable	ICD-10-CM
G43.901	Migraine, unspecified, not intractable, with status migrainosus	ICD-10-CM
G43.909	Migraine, unspecified, not intractable, without status migrainosus	ICD-10-CM
G43.91	Migraine, unspecified, intractable	ICD-10-CM
G43.911	Migraine, unspecified, intractable, with status migrainosus	ICD-10-CM
G43.919	Migraine, unspecified, intractable, without status migrainosus	ICD-10-CM
G43.B	Ophthalmoplegic migraine	ICD-10-CM
G43.B0	Ophthalmoplegic migraine, not intractable	ICD-10-CM
G43.B1	Ophthalmoplegic migraine, intractable	ICD-10-CM
G43.D	Abdominal migraine	ICD-10-CM
G43.D0	Abdominal migraine, not intractable	ICD-10-CM
G43.D1	Abdominal migraine, intractable	ICD-10-CM

Appendix D. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type
Myocardial Infarction		
410.00	Acute myocardial infarction of anterolateral wall, episode of care unspecified	ICD-9-CM
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care	ICD-9-CM
410.10	Acute myocardial infarction of other anterior wall, episode of care unspecified	ICD-9-CM
410.11	Acute myocardial infarction of other anterior wall, initial episode of care	ICD-9-CM
410.20	Acute myocardial infarction of inferolateral wall, episode of care unspecified	ICD-9-CM
410.21	Acute myocardial infarction of inferolateral wall, initial episode of care	ICD-9-CM
410.30	Acute myocardial infarction of inferoposterior wall, episode of care unspecified	ICD-9-CM
410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care	ICD-9-CM
410.40	Acute myocardial infarction of other inferior wall, episode of care unspecified	ICD-9-CM
410.41	Acute myocardial infarction of other inferior wall, initial episode of care	ICD-9-CM
410.50	Acute myocardial infarction of other lateral wall, episode of care unspecified	ICD-9-CM
410.51	Acute myocardial infarction of other lateral wall, initial episode of care	ICD-9-CM
410.60	Acute myocardial infarction, true posterior wall infarction, episode of care unspecified	ICD-9-CM
410.61	Acute myocardial infarction, true posterior wall infarction, initial episode of care	ICD-9-CM
410.70	Acute myocardial infarction, subendocardial infarction, episode of care unspecified	ICD-9-CM
410.71	Acute myocardial infarction, subendocardial infarction, initial episode of care	ICD-9-CM
410.80	Acute myocardial infarction of other specified sites, episode of care unspecified	ICD-9-CM
410.81	Acute myocardial infarction of other specified sites, initial episode of care	ICD-9-CM
410.90	Acute myocardial infarction, unspecified site, episode of care unspecified	ICD-9-CM
410.91	Acute myocardial infarction, unspecified site, initial episode of care	ICD-9-CM
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall	ICD-10-CM
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall	ICD-10-CM
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery	ICD-10-CM
I21.29	ST elevation (STEMI) myocardial infarction involving other sites	ICD-10-CM
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	ICD-10-CM
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site	ICD-10-CM
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery	ICD-10-CM
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery	ICD-10-CM
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall	ICD-10-CM
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall	ICD-10-CM
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites	ICD-10-CM
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction	ICD-10-CM
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site	ICD-10-CM
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery	ICD-10-CM
Ischemic Stroke		
433.01	Occlusion and stenosis of basilar artery with cerebral infarction	ICD-9-CM
433.11	Occlusion and stenosis of carotid artery with cerebral infarction	ICD-9-CM
433.21	Occlusion and stenosis of vertebral artery with cerebral infarction	ICD-9-CM
433.31	Occlusion and stenosis of multiple and bilateral precerebral arteries with cerebral infarction	ICD-9-CM
433.81	Occlusion and stenosis of other specified precerebral artery with cerebral infarction	ICD-9-CM
433.91	Occlusion and stenosis of unspecified precerebral artery with cerebral infarction	ICD-9-CM

Appendix D. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type
434.01	Cerebral thrombosis with cerebral infarction	ICD-9-CM
434.11	Cerebral embolism with cerebral infarction	ICD-9-CM
434.91	Unspecified cerebral artery occlusion with cerebral infarction	ICD-9-CM
436	Acute, but ill-defined, cerebrovascular disease	ICD-9-CM
I63.22	Cerebral infarction due to unspecified occlusion or stenosis of basilar arteries	ICD-10-CM
I63.139	Cerebral infarction due to embolism of unspecified carotid artery	ICD-10-CM
I63.239	Cerebral infarction due to unspecified occlusion or stenosis of unspecified carotid arteries	ICD-10-CM
I63.019	Cerebral infarction due to thrombosis of unspecified vertebral artery	ICD-10-CM
I63.119	Cerebral infarction due to embolism of unspecified vertebral artery	ICD-10-CM
I63.219	Cerebral infarction due to unspecified occlusion or stenosis of unspecified vertebral arteries	ICD-10-CM
I63.59	Cerebral infarction due to unspecified occlusion or stenosis of other cerebral artery	ICD-10-CM
I63.20	Cerebral infarction due to unspecified occlusion or stenosis of unspecified precerebral arteries	ICD-10-CM
I63.30	Cerebral infarction due to thrombosis of unspecified cerebral artery	ICD-10-CM
I63.40	Cerebral infarction due to embolism of unspecified cerebral artery	ICD-10-CM
I63.50	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebral artery	ICD-10-CM
I67.89	Other cerebrovascular disease	ICD-10-CM
I63.00	Cerebral infarction due to thrombosis of unspecified precerebral artery	ICD-10-CM
I63.011	Cerebral infarction due to thrombosis of right vertebral artery	ICD-10-CM
I63.012	Cerebral infarction due to thrombosis of left vertebral artery	ICD-10-CM
I63.013	Cerebral infarction due to thrombosis of bilateral vertebral arteries	ICD-10-CM
I63.02	Cerebral infarction due to thrombosis of basilar artery	ICD-10-CM
I63.031	Cerebral infarction due to thrombosis of right carotid artery	ICD-10-CM
I63.032	Cerebral infarction due to thrombosis of left carotid artery	ICD-10-CM
I63.033	Cerebral infarction due to thrombosis of bilateral carotid arteries	ICD-10-CM
I63.039	Cerebral infarction due to thrombosis of unspecified carotid artery	ICD-10-CM
I63.09	Cerebral infarction due to thrombosis of other precerebral artery	ICD-10-CM
I63.10	Cerebral infarction due to embolism of unspecified precerebral artery	ICD-10-CM
I63.111	Cerebral infarction due to embolism of right vertebral artery	ICD-10-CM
I63.112	Cerebral infarction due to embolism of left vertebral artery	ICD-10-CM
I63.113	Cerebral infarction due to embolism of bilateral vertebral arteries	ICD-10-CM
I63.12	Cerebral infarction due to embolism of basilar artery	ICD-10-CM
I63.131	Cerebral infarction due to embolism of right carotid artery	ICD-10-CM
I63.132	Cerebral infarction due to embolism of left carotid artery	ICD-10-CM
I63.133	Cerebral infarction due to embolism of bilateral carotid arteries	ICD-10-CM
I63.19	Cerebral infarction due to embolism of other precerebral artery	ICD-10-CM
I63.211	Cerebral infarction due to unspecified occlusion or stenosis of right vertebral arteries	ICD-10-CM
I63.212	Cerebral infarction due to unspecified occlusion or stenosis of left vertebral arteries	ICD-10-CM
I63.213	Cerebral infarction due to unspecified occlusion or stenosis of bilateral vertebral arteries	ICD-10-CM
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries	ICD-10-CM
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries	ICD-10-CM
I63.233	Cerebral infarction due to unspecified occlusion or stenosis of bilateral carotid arteries	ICD-10-CM
I63.29	Cerebral infarction due to unspecified occlusion or stenosis of other precerebral arteries	ICD-10-CM

Appendix D. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type
163.311	Cerebral infarction due to thrombosis of right middle cerebral artery	ICD-10-CM
163.312	Cerebral infarction due to thrombosis of left middle cerebral artery	ICD-10-CM
163.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries	ICD-10-CM
163.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery	ICD-10-CM
163.321	Cerebral infarction due to thrombosis of right anterior cerebral artery	ICD-10-CM
163.322	Cerebral infarction due to thrombosis of left anterior cerebral artery	ICD-10-CM
163.323	Cerebral infarction due to thrombosis of bilateral anterior arteries	ICD-10-CM
163.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery	ICD-10-CM
163.331	Cerebral infarction due to thrombosis of right posterior cerebral artery	ICD-10-CM
163.332	Cerebral infarction due to thrombosis of left posterior cerebral artery	ICD-10-CM
163.333	Cerebral infarction to thrombosis of bilateral posterior arteries	ICD-10-CM
163.339	Cerebral infarction due to thrombosis of unspecified posterior cerebral artery	ICD-10-CM
163.341	Cerebral infarction due to thrombosis of right cerebellar artery	ICD-10-CM
163.342	Cerebral infarction due to thrombosis of left cerebellar artery	ICD-10-CM
163.343	Cerebral infarction to thrombosis of bilateral cerebellar arteries	ICD-10-CM
163.349	Cerebral infarction due to thrombosis of unspecified cerebellar artery	ICD-10-CM
163.39	Cerebral infarction due to thrombosis of other cerebral artery	ICD-10-CM
163.411	Cerebral infarction due to embolism of right middle cerebral artery	ICD-10-CM
163.412	Cerebral infarction due to embolism of left middle cerebral artery	ICD-10-CM
163.413	Cerebral infarction due to embolism of bilateral middle cerebral arteries	ICD-10-CM
163.419	Cerebral infarction due to embolism of unspecified middle cerebral artery	ICD-10-CM
163.421	Cerebral infarction due to embolism of right anterior cerebral artery	ICD-10-CM
163.422	Cerebral infarction due to embolism of left anterior cerebral artery	ICD-10-CM
163.423	Cerebral infarction due to embolism of bilateral anterior cerebral arteries	ICD-10-CM
163.429	Cerebral infarction due to embolism of unspecified anterior cerebral artery	ICD-10-CM
163.431	Cerebral infarction due to embolism of right posterior cerebral artery	ICD-10-CM
163.432	Cerebral infarction due to embolism of left posterior cerebral artery	ICD-10-CM
163.433	Cerebral infarction due to embolism of bilateral posterior cerebral arteries	ICD-10-CM
163.439	Cerebral infarction due to embolism of unspecified posterior cerebral artery	ICD-10-CM
163.441	Cerebral infarction due to embolism of right cerebellar artery	ICD-10-CM
163.442	Cerebral infarction due to embolism of left cerebellar artery	ICD-10-CM
163.443	Cerebral infarction due to embolism of bilateral cerebellar arteries	ICD-10-CM
163.449	Cerebral infarction due to embolism of unspecified cerebellar artery	ICD-10-CM
163.49	Cerebral infarction due to embolism of other cerebral artery	ICD-10-CM
163.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery	ICD-10-CM
163.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery	ICD-10-CM
163.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle arteries	ICD-10-CM
163.519	Cerebral infarction due to unspecified occlusion or stenosis of unspecified middle cerebral artery	ICD-10-CM
163.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery	ICD-10-CM
163.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery	ICD-10-CM
163.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior arteries	ICD-10-CM

Appendix D. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type
I63.529	Cerebral infarction due to unspecified occlusion or stenosis of unspecified anterior cerebral artery	ICD-10-CM
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery	ICD-10-CM
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery	ICD-10-CM
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of bilateral posterior arteries	ICD-10-CM
I63.539	Cerebral infarction due to unspecified occlusion or stenosis of unspecified posterior cerebral artery	ICD-10-CM
I63.541	Cerebral infarction due to unspecified occlusion or stenosis of right cerebellar artery	ICD-10-CM
I63.542	Cerebral infarction due to unspecified occlusion or stenosis of left cerebellar artery	ICD-10-CM
I63.543	Cerebral infarction due to unspecified occlusion or stenosis of bilateral cerebellar arteries	ICD-10-CM
I63.549	Cerebral infarction due to unspecified occlusion or stenosis of unspecified cerebellar artery	ICD-10-CM
I63.6	Cerebral infarction due to cerebral venous thrombosis, nonpyogenic	ICD-10-CM
I63.8	Other cerebral infarction	ICD-10-CM
I63.9	Cerebral infarction, unspecified	ICD-10-CM

Appendix E. Specifications for Request: cder_mpl1r_wp060_nsdp_v01

This request utilizes the Cohort Identification and Descriptive Analysis (CIDA) tool, version 4.1.3 to calculate background rates of new initiators of Qsymia, phentermine, topiramate, and concomitant phentermine and topiramate (defined as initiation of both components within 14 days of initiation of the other regardless of initiation sequence) in the Sentinel Distributed Database (SDD).

Query Period: September 17, 2012 - April 30, 2017
Enrollment Requirement: 183 Days
Enrollment Gap: 30 Days
Coverage Requirement: Medical and Drug
Age Stratifications: 18-44, 45-64, 65+ years
Results Stratified by: Age, Sex, Calendar Year

	Drug/Exposure					Inclusion/Exclusion Criteria			Baseline Characteristics						
	Incident Exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap (days)	Extension Period (days)	Minimum Episode Duration	Minimum Days Supplied	Maximum Days Supplied	Pre-Existing Condition	Include/Exclude	Lookback Period	Characteristic evaluation window (days)	Care Setting	Characteristics
1	Qsymia	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999				-183, 0	Any	Myocardial infarction, ischemic stroke, both
2	Phentermine	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999				-183, 0	Any	Myocardial infarction, ischemic stroke, both
3	Topiramate	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999				-183, 0	Any	Myocardial infarction, ischemic stroke, both
4	Concomitant topiramate and phentermine (initiated within 14 days)	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999				-183, 0	Any	Myocardial infarction, ischemic stroke, both

5	Qsymia	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
6	Phentermine	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
7	Topiramate	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
8	Concomitant topiramate and phentermine (initiated within 14 days)	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
9	Qsymia	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Migraine	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
10	Phentermine	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Migraine	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
11	Topiramate	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Migraine	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
12	Concomitant topiramate and phentermine (initiated within 14 days)	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Migraine	Include	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both

13	Qsymia	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure or Migraine	Exclude	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
14	Phentermine	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure or Migraine	Exclude	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
15	Topiramate	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure or Migraine	Exclude	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both
16	Concomitant topiramate and phentermine (initiated within 14 days)	Qsymia, phentermine, topiramate	183	Retain all valid incident exposure episodes	30	30	1	1	999	Epilepsy/ Seizure or Migraine	Exclude	-183, 0	-183, 0	Any	Myocardial infarction, ischemic stroke, both

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) codes are provided by Optum360.

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