



Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

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

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

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

If you are using a web page screen reader and are unable to access this document, please contact the Mini-Sentinel Operations Center for assistance at info@mini-sentinel.org.

Overview

Request Description

FDA's Center for Drug Evaluation and Research requested execution of Modular Program #3 (MP3), version 5.0, to investigate kidney stones following new use of anti-epileptic medications among all exposed patients and among those with a pre-existing condition of epilepsy and those with an exclusion of pre-existing anti-diabetic agent exposure. This involved two runs of MP3. This report contains the results from the first run-- kidney stones following new use of anti-epileptic medications among all exposed patients in the Mini-Sentinel Distributed Database. A second report (msy4_mpr55_v1, Report 2 of 2) contains results from the second run-- kidney stones following new use of anti-epileptic medications among patients with a pre-existing condition of epilepsy or with an exclusion of pre-existing anti-diabetic agent use. Please see the Specifications tab for details into the exact parameters used in this request.

The query was run against the Mini-Sentinel Distributed Database (MSDD) for a time period of January 1, 2004 – December 31, 2012. The package was distributed to 18 Data Partners on August 15, 2013.

Request ID

msy4_mpr55_v1, Report 1 of 2

Specifications

Program parameter inputs and scenarios

Glossary

List of terms found in this report and their definitions

Table 1

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, New Events, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Events per 10,000 Years at Risk by Drug Product and Blackout Period - January 1, 2004 to December 31, 2012

Table 2

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, New Events, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Events per 10,000 Years at Risk by Drug Product, Blackout Period, and Age Group - January 1, 2004 to December 31, 2012

Table 3

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, New Events, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Events per 10,000 Years at Risk by Drug Product, Blackout Period, and Sex - January 1, 2004 to December 31, 2012

Table 4

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Years at Risk, New Events, Eligible Members, Member-Years, New Users per 1,000 Eligible Members, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Events per 10,000 Years at Risk by Drug Product, Blackout Period, and Year - January 1, 2004 to December 31, 2012

Appendix A

Table displaying a list of kidney stone codes included in this request

Notes:

Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Modular Program Specifications MSY4_MPR55_v1

Modular Program #3, version 5.0, was used to investigate kidney stones following new use of anti-epileptic drugs (AEDs) among all patients and among those with a pre-existing condition of epilepsy and those with an exclusion of pre-existing anti-diabetic agent use. The query period was from January 2004-December 2012, and the enrollment gap was set at 45 days. Age groups were split as follows: 0-9, 10-16, 17-64, and 65+ years. In total, 31 different scenarios were examined in this request with differing exposures of interest, blackout periods, and inclusion/exclusion criteria. This report contains information from Scenarios 1 through 22 outlined below. A second report (msy4_mpr55_v1, Report 2 of 2) contains results from Scenarios 23 through 31. See below for a description of each of these scenarios.

Enrollment Gap 45 Days
Age Groups 0-9, 10-16, 17-64, 65+
Query Period January 1, 2004 - December 31, 2012

Scenario	Drug/Exposure								Pre-Existing Condition					Event/Outcome						
	Incident exposure	Incident w/ respect to:	Washout (days)	Incidence Type*	Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Pre-Existing Condition	Include or Exclude	Look back Start	Look back End	Care Setting	Event/Outcome	Care Setting	Incident w/ respect to:	Incident Only Care Setting	Washout (days)	Incidence Type**	Blackout Period
1	Topiramate	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
2	Gabapentin	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
3	Zonisamide	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
4	Topiramate	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	90
5	Gabapentin	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	90
6	Zonisamide	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	90
7	Topiramate	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	183
8	Gabapentin	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	183
9	Zonisamide	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	183
10	Topiramate	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	365
11	Gabapentin	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	365
12	Zonisamide	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	365
13	Topiramate	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	730

Scenario	Drug/Exposure								Pre-Existing Condition					Event/Outcome						
	Incident exposure	Incident w/ respect to:	Washout (days)	Incidence Type*	Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Pre-Existing Condition	Include or Exclude	Look back Start	Look back End	Care Setting	Event/Outcome	Care Setting	Incident w/ respect to:	Incident Only Care Setting	Washout (days)	Incidence Type**	Blackout Period
14	Gabapentin	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	730
15	Zonisamide	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	730
16	All AEDs	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
17	All AEDs minus topiramate, gabapentin, and zonisamide	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
18	Lamotrigine, levetiracetam, carbamazepine, oxcarbazepine, phenytoin, or valproic acid	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
19	Lamotrigine, levetiracetam, carbamazepine, oxcarbazepine, phenytoin, or valproic acid	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	90
20	Lamotrigine, levetiracetam, carbamazepine, oxcarbazepine, phenytoin, or valproic acid	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	183
21	Lamotrigine, levetiracetam, carbamazepine, oxcarbazepine, phenytoin, or valproic acid	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	365

Scenario	Drug/Exposure								Pre-Existing Condition					Event/Outcome						
	Incident exposure	Incident w/ respect to:	Washout (days)	Incidence Type*	Episode Gap	Exposure Extension Period	Min Episode Duration	Min Days Supplied	Pre-Existing Condition	Include or Exclude	Look back Start	Look back End	Care Setting	Event/Outcome	Care Setting	Incident w/ respect to:	Incident Only Care Setting	Washout (days)	Incidence Type**	Blackout Period
22	Lamotrigine, levetiracetam, carbamazepine, oxcarbazepine, phenytoin, or valproic acid	All AEDs	183	SING	10	10	0	0	NA	NA	NA	NA	NA	Kidney Stones	Any	Kidney Stones	Any	183	MULT	730
23	Topiramate	All AEDs	183	SING	10	10	0	0	Epilepsy	Include	-183	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
24	Gabapentin	All AEDs	183	SING	10	10	0	0	Epilepsy	Include	-183	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
25	Zonisamide	All AEDs	183	SING	10	10	0	0	Epilepsy	Include	-183	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
26	Topiramate	All AEDs	183	SING	10	10	0	0	Epilepsy	Include	-365	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
27	Gabapentin	All AEDs	183	SING	10	10	0	0	Epilepsy	Include	-365	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
28	Zonisamide	All AEDs	183	SING	10	10	0	0	Epilepsy	Include	-365	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
29	Topiramate	All AEDs	183	SING	10	10	0	0	Any Anti-Diabetic Agent	Exclude	-183	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
30	Gabapentin	All AEDs	183	SING	10	10	0	0	Any Anti-Diabetic Agent	Exclude	-183	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0
31	Zonisamide	All AEDs	183	SING	10	10	0	0	Any Anti-Diabetic Agent	Exclude	-183	-1	Any	Kidney Stones	Any	Kidney Stones	Any	183	MULT	0

NDC codes checked against First Data Bank's "National Drug Data File (NDDF®) Plus"
 ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight
 HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight
 CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

*Single incidence type for the exposure will only consider the first incident episode for each user during the query period that satisfies the Washout Period criteria (183 or 365 days). There can be at most one episode per user.

**Mult incidence type for the event will only consider the first event for each episode that satisfies the Washout Period criteria of 183 days. There can be at most one event per episode and consequently, one event per user.

Glossary of Terms in Modular Program 3*

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).

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

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.

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

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

Incidence Type (drug/exposure)- *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Single* and *Multiple incidence types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.

Incidence Type (event/outcome)- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

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

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.

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

New Users - number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

Principal Diagnosis - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal.

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

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

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.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

Table 1: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product and Blackout Period

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
All Anti-Epileptic Drugs (Blackout Period = 0 Days)	6,363,331	6,363,331	13,355,135	364,168,529	1,091,230	26,870	86,091,158	189,113,864	73.91	57.23	2.10	27.27	246.24
All Anti-Epileptic Drugs minus Topiramate, Gabapentin, and Zonisamide (Blackout Period = 0 Days)	4,923,229	4,923,229	8,983,990	212,819,476	678,229	16,455	86,091,257	190,352,275	57.19	43.23	1.82	23.69	242.62
Gabapentin (Blackout Period = 0 Days)	1,321,443	1,321,443	2,890,043	102,193,336	302,359	7,657	86,091,465	194,879,604	15.35	77.33	2.19	35.36	253.24
Gabapentin (Blackout Period = 90 Days)	311,558	311,558	1,750,367	70,611,578	120,961	2,291	86,091,496	195,801,770	3.62	226.64	5.62	40.34	189.40
Gabapentin (Blackout Period = 183 Days)	122,440	122,440	1,213,653	49,928,708	75,863	1,297	86,091,517	195,949,571	1.42	407.78	9.91	41.14	170.97
Gabapentin (Blackout Period = 365 Days)	46,614	46,614	734,438	31,507,623	39,365	555	86,091,523	195,988,137	0.54	675.93	15.76	42.90	140.99
Gabapentin (Blackout Period = 730 Days)	13,333	13,333	325,463	14,994,692	14,106	174	86,091,523	195,998,642	0.15	1124.63	24.41	46.07	123.35
Topiramate (Blackout Period = 0 Days)	352,850	352,850	881,428	30,155,084	88,655	2,195	86,091,487	195,729,140	4.10	85.46	2.50	34.21	247.59
Topiramate (Blackout Period = 90 Days)	88,883	88,883	576,669	21,188,020	37,651	942	86,091,506	195,948,145	1.03	238.38	6.49	36.74	250.19
Topiramate (Blackout Period = 183 Days)	38,605	38,605	415,736	15,498,625	23,570	577	86,091,523	195,983,444	0.45	401.47	10.77	37.28	244.81
Topiramate (Blackout Period = 365 Days)	14,806	14,806	250,980	9,680,854	11,804	270	86,091,524	195,995,748	0.17	653.85	16.95	38.57	228.75
Topiramate (Blackout Period = 730 Days)	4,013	4,013	107,553	4,372,003	3,935	82	86,091,524	195,999,837	0.05	1089.46	26.80	40.65	208.38
Zonisamide (Blackout Period = 0 Days)	17,992	17,992	46,327	1,501,042	4,396	124	86,091,522	195,984,315	0.21	83.43	2.57	32.40	282.07
Zonisamide (Blackout Period = 90 Days)	4,187	4,187	29,869	1,013,580	1,816	50	86,091,523	195,997,771	0.05	242.08	7.13	33.93	275.39
Zonisamide (Blackout Period = 183 Days)	1,880	1,880	21,748	745,468	1,125	21	86,091,525	195,999,556	0.02	396.53	11.57	34.28	186.60
Zonisamide (Blackout Period = 365 Days)	700	700	12,967	451,478	549	4	86,091,525	196,000,250	0.01	644.97	18.52	34.82	72.82

Table 1: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product and Blackout Period

	New New Users	New Episodes	Total Days Dispensings Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Zonisamide (Blackout Period = 730 Days)	186	186	5,759 204,390	193	0	86,091,525	196,000,510	0.00	1098.87	30.96	35.49	0.00
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 0 Days)	485,987	485,987	1,839,946 64,321,665	176,625	2,231	86,091,480	195,638,706	5.65	132.35	3.79	34.96	126.31
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 90 Days)	173,579	173,579	1,467,467 53,777,875	101,611	966	86,091,502	195,906,026	2.02	309.82	8.45	36.65	95.07
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 183 Days)	89,590	89,590	1,181,445 43,950,025	71,732	599	86,091,517	195,964,679	1.04	490.57	13.19	37.20	83.51
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 365 Days)	41,622	41,622	830,285 31,712,704	41,801	315	86,091,521	195,988,311	0.48	761.92	19.95	38.19	75.36
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 730 Days)	14,255	14,255	439,781 17,523,810	17,108	108	86,091,523	195,997,784	0.17	1229.31	30.85	39.85	63.13

Table 2: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Age Group

	New New Users	New Episodes	Total Days Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
All Anti-Epileptic Drugs (Blackout Period = 0 Days)													
0 to 9 Years	71,745	71,745	305,343	9,058,223	23,093	66	12,448,587	24,465,155	5.76	126.26	4.26	29.67	28.58
10 to 16 Years	172,808	172,808	479,595	13,368,522	38,224	176	10,432,201	19,874,080	16.56	77.36	2.78	27.87	46.04
17 to 64 Years	5,077,113	5,077,113	10,162,139	263,089,455	799,864	20,503	62,024,819	125,895,316	81.86	51.82	2.00	25.89	256.33
65+ Years	1,041,665	1,041,665	2,408,058	78,652,329	230,049	6,125	7,588,468	18,879,314	137.27	75.51	2.31	32.66	266.25
All Anti-Epileptic Drugs minus Topiramate, Gabapentin, and Zonisamide (Blackout Period = 0 Days)													
0 to 9 Years	64,727	64,727	238,273	6,903,595	18,903	34	12,448,587	24,469,038	5.20	106.66	3.68	28.97	17.99
10 to 16 Years	138,309	138,309	360,765	9,540,851	28,195	101	10,434,656	19,896,678	13.25	68.98	2.61	26.45	35.82
17 to 64 Years	4,011,303	4,011,303	6,980,121	156,596,478	509,266	13,017	62,037,677	126,779,038	64.66	39.04	1.74	22.43	255.60
65+ Years	708,890	708,890	1,404,831	39,778,552	121,865	3,303	7,616,515	19,207,521	93.07	56.11	1.98	28.32	271.04
Gabapentin (Blackout Period = 0 Days)													
0 to 9 Years	2,641	2,641	6,952	215,313	640	3	12,448,589	24,518,152	0.21	81.53	2.63	30.97	46.88
10 to 16 Years	10,692	10,692	21,692	672,947	2,062	14	10,452,324	20,016,857	1.02	62.94	2.03	31.02	67.89
17 to 64 Years	933,212	933,212	1,931,028	64,899,666	194,296	4,875	62,088,182	130,497,982	15.03	69.54	2.07	33.61	250.91
65+ Years	374,898	374,898	930,371	36,405,410	105,361	2,765	7,696,693	19,846,613	48.71	97.11	2.48	39.13	262.43
Gabapentin (Blackout Period = 90 Days)													
0 to 9 Years	593	593	4,474	144,880	265	1	12,448,589	24,519,823	0.05	244.32	7.54	32.38	37.78
10 to 16 Years	1,926	1,926	11,266	385,087	627	4	10,453,044	20,023,502	0.18	199.94	5.85	34.18	63.77
17 to 64 Years	190,174	190,174	1,087,953	41,424,749	69,545	1,335	62,091,731	131,138,241	3.06	217.83	5.72	38.08	191.96
65+ Years	118,865	118,865	646,674	28,656,862	50,524	951	7,719,122	20,120,203	15.40	241.09	5.44	44.31	188.23
Gabapentin (Blackout Period = 183 Days)													
0 to 9 Years	275	275	3,363	109,891	170	1	12,448,589	24,520,011	0.02	399.60	12.23	32.68	58.98
10 to 16 Years	667	667	6,970	243,606	348	2	10,453,157	20,024,294	0.06	365.23	10.45	34.95	57.48
17 to 64 Years	71,489	71,489	732,818	28,301,894	42,130	728	62,092,239	131,224,055	1.15	395.89	10.25	38.62	172.80
65+ Years	50,009	50,009	470,502	21,273,317	33,215	566	7,724,338	20,181,211	6.47	425.39	9.41	45.21	170.40
Gabapentin (Blackout Period = 365 Days)													
0 to 9 Years	110	110	2,097	69,994	84	0	12,448,589	24,520,071	0.01	636.31	19.06	33.38	0.00
10 to 16 Years	210	210	3,594	132,165	156	1	10,453,190	20,024,503	0.02	629.36	17.11	36.77	64.02
17 to 64 Years	25,893	25,893	430,348	17,256,281	21,267	292	62,092,390	131,245,912	0.42	666.45	16.62	40.10	137.30
65+ Years	20,401	20,401	298,399	14,049,183	17,857	262	7,725,999	20,197,651	2.64	688.65	14.63	47.08	146.72

Table 2: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Age Group

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Gabapentin (Blackout Period = 730 Days)													
0 to 9 Years	33	33	1,023	33,869	27	0	12,448,589	24,520,087	0.00	1026.33	31.00	33.11	0.00
10 to 16 Years	52	52	1,465	57,203	53	0	10,453,214	20,024,597	0.00	1100.06	28.17	39.05	0.00
17 to 64 Years	7,006	7,006	184,435	7,925,170	7,552	97	62,092,440	131,251,607	0.11	1131.20	26.33	42.97	128.45
65+ Years	6,242	6,242	138,540	6,978,450	6,474	77	7,726,533	20,202,351	0.81	1117.98	22.19	50.37	118.94
Topiramate (Blackout Period = 0 Days)													
0 to 9 Years	4,256	4,256	12,723	407,160	1,201	3	12,448,589	24,518,201	0.34	95.67	2.99	32.00	24.97
10 to 16 Years	25,151	25,151	59,291	1,921,160	5,832	43	10,451,603	20,009,332	2.41	76.39	2.36	32.40	73.73
17 to 64 Years	311,831	311,831	780,725	26,699,594	78,403	2,064	62,083,436	131,010,461	5.02	85.62	2.50	34.20	263.26
65+ Years	11,612	11,612	28,689	1,127,170	3,219	85	7,724,346	20,191,145	1.50	97.07	2.47	39.29	264.04
Topiramate (Blackout Period = 90 Days)													
0 to 9 Years	1,157	1,157	8,986	295,675	556	3	12,448,589	24,519,783	0.09	255.55	7.77	32.90	54.00
10 to 16 Years	5,673	5,673	36,431	1,246,215	2,182	20	10,452,854	20,022,020	0.54	219.67	6.42	34.21	91.67
17 to 64 Years	78,608	78,608	511,916	18,798,309	33,421	879	62,090,541	131,205,800	1.27	239.14	6.51	36.72	263.01
65+ Years	3,445	3,445	19,336	847,821	1,493	40	7,726,053	20,200,541	0.45	246.10	5.61	43.85	267.84
Topiramate (Blackout Period = 183 Days)													
0 to 9 Years	557	557	6,806	226,285	355	2	12,448,589	24,520,001	0.04	406.26	12.22	33.25	56.34
10 to 16 Years	2,338	2,338	25,156	869,966	1,281	14	10,453,072	20,023,798	0.22	372.10	10.76	34.58	109.26
17 to 64 Years	34,209	34,209	369,552	13,768,023	20,959	531	62,091,764	131,237,227	0.55	402.47	10.80	37.26	253.35
65+ Years	1,501	1,501	14,222	634,351	974	30	7,726,462	20,202,418	0.19	422.62	9.48	44.60	307.89
Topiramate (Blackout Period = 365 Days)													
0 to 9 Years	224	224	4,263	144,482	177	1	12,448,589	24,520,068	0.02	645.01	19.03	33.89	56.55
10 to 16 Years	810	810	14,332	500,603	586	6	10,453,181	20,024,413	0.08	618.03	17.69	34.93	102.39
17 to 64 Years	13,166	13,166	223,595	8,625,256	10,530	250	62,092,212	131,248,259	0.21	655.12	16.98	38.58	237.42
65+ Years	606	606	8,790	410,513	511	13	7,726,621	20,203,009	0.08	677.41	14.50	46.70	254.50
Topiramate (Blackout Period = 730 Days)													
0 to 9 Years	62	62	1,810	64,771	54	1	12,448,589	24,520,085	0.00	1044.69	29.19	35.79	185.43
10 to 16 Years	182	182	5,397	196,352	176	3	10,453,214	20,024,602	0.02	1078.86	29.65	36.38	170.91
17 to 64 Years	3,588	3,588	96,223	3,913,410	3,533	72	62,092,401	131,251,939	0.06	1090.69	26.82	40.67	203.82
65+ Years	181	181	4,123	197,470	173	6	7,726,682	20,203,211	0.02	1090.99	22.78	47.89	346.49

Table 2: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Age Group

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Zonisamide (Blackout Period = 0 Days)													
0 to 9 Years	548	548	2,603	85,935	236	3	12,448,589	24,519,838	0.04	156.82	4.75	33.01	127.25
10 to 16 Years	1,202	1,202	4,236	136,305	396	1	10,453,105	20,023,872	0.11	113.40	3.52	32.18	25.22
17 to 64 Years	15,227	15,227	36,233	1,162,515	3,436	108	62,092,000	131,238,333	0.25	76.35	2.38	32.08	314.35
65+ Years	1,015	1,015	3,255	116,287	328	12	7,726,543	20,202,272	0.13	114.57	3.21	35.73	365.54
Zonisamide (Blackout Period = 90 Days)													
0 to 9 Years	185	185	2,189	72,763	153	2	12,448,589	24,520,030	0.01	393.31	11.83	33.24	131.13
10 to 16 Years	335	335	3,165	104,565	211	0	10,453,196	20,024,492	0.03	312.13	9.45	33.04	0.00
17 to 64 Years	3,343	3,343	22,066	744,239	1,277	43	62,092,364	131,250,196	0.05	222.63	6.60	33.73	336.78
65+ Years	324	324	2,449	92,013	175	5	7,726,673	20,203,053	0.04	283.99	7.56	37.57	285.00
Zonisamide (Blackout Period = 183 Days)													
0 to 9 Years	115	115	1,915	63,899	116	2	12,448,589	24,520,059	0.01	555.64	16.65	33.37	171.77
10 to 16 Years	179	179	2,597	86,630	150	0	10,453,205	20,024,558	0.02	483.97	14.51	33.36	0.00
17 to 64 Years	1,436	1,436	15,313	522,532	735	18	62,092,411	131,251,743	0.02	363.88	10.66	34.12	244.84
65+ Years	150	150	1,923	72,407	123	1	7,726,690	20,203,196	0.02	482.71	12.82	37.65	81.10
Zonisamide (Blackout Period = 365 Days)													
0 to 9 Years	68	68	1,501	50,490	72	0	12,448,589	24,520,069	0.01	742.50	22.07	33.64	0.00
10 to 16 Years	86	86	1,884	63,258	89	0	10,453,213	20,024,605	0.01	735.56	21.91	33.58	0.00
17 to 64 Years	484	484	8,287	288,851	316	4	62,092,432	131,252,332	0.01	596.80	17.12	34.86	126.74
65+ Years	62	62	1,295	48,879	73	0	7,726,695	20,203,244	0.01	788.37	20.89	37.74	0.00
Zonisamide (Blackout Period = 730 Days)													
0 to 9 Years	27	27	873	30,999	32	0	12,448,589	24,520,081	0.00	1148.11	32.33	35.51	0.00
10 to 16 Years	32	32	1,051	36,448	37	0	10,453,223	20,024,628	0.00	1139.00	32.84	34.68	0.00
17 to 64 Years	101	101	3,011	105,397	89	0	62,092,446	131,252,544	0.00	1043.53	29.81	35.00	0.00
65+ Years	26	26	824	31,546	35	0	7,726,701	20,203,258	0.00	1213.31	31.69	38.28	0.00
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 0 Days)													
0 to 9 Years	26,624	26,624	155,704	5,139,918	13,889	23	12,448,587	24,506,665	2.14	193.06	5.85	33.01	16.56
10 to 16 Years	48,350	48,350	221,910	7,232,516	20,180	59	10,447,266	19,991,486	4.63	149.59	4.59	32.59	29.24
17 to 64 Years	344,674	344,674	1,209,957	41,973,221	115,733	1,653	62,076,312	130,987,525	5.55	121.78	3.51	34.69	142.83
65+ Years	66,339	66,339	252,375	9,976,010	26,823	496	7,721,939	20,153,031	8.59	150.38	3.80	39.53	184.92

Table 2: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Age Group

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 90 Days)													
0 to 9 Years	11,728	11,728	137,769	4,631,500	9,406	13	12,448,588	24,516,035	0.94	394.91	11.75	33.62	13.82
10 to 16 Years	19,241	19,241	189,217	6,311,936	12,395	32	10,450,980	20,014,572	1.84	328.05	9.83	33.36	25.82
17 to 64 Years	116,272	116,272	936,721	34,223,642	63,402	677	62,086,837	131,186,278	1.87	294.34	8.06	36.54	106.78
65+ Years	26,338	26,338	203,760	8,610,797	16,408	244	7,725,161	20,189,141	3.41	326.93	7.74	42.26	148.70
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 183 Days)													
0 to 9 Years	7,371	7,371	121,284	4,105,344	7,129	12	12,448,589	24,518,135	0.59	556.96	16.45	33.85	16.83
10 to 16 Years	10,727	10,727	158,382	5,333,908	8,911	25	10,451,939	20,020,023	1.03	497.24	14.76	33.68	28.06
17 to 64 Years	57,559	57,559	735,415	27,335,074	43,743	402	62,089,667	131,228,079	0.93	474.91	12.78	37.17	91.90
65+ Years	13,933	13,933	166,364	7,175,699	11,949	160	7,726,056	20,198,441	1.80	515.01	11.94	43.13	133.90
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 365 Days)													
0 to 9 Years	4,092	4,092	95,085	3,258,681	4,439	10	12,448,589	24,519,262	0.33	796.35	23.24	34.27	22.53
10 to 16 Years	5,221	5,221	115,227	3,955,202	5,241	14	10,452,565	20,022,761	0.50	757.56	22.07	34.33	26.71
17 to 64 Years	25,462	25,462	500,502	19,162,046	24,938	202	62,091,242	131,244,721	0.41	752.57	19.66	38.29	81.00
65+ Years	6,847	6,847	119,471	5,336,775	7,183	89	7,726,435	20,201,568	0.89	779.43	17.45	44.67	123.91
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 730 Days)													
0 to 9 Years	1,575	1,575	54,708	1,935,121	1,844	5	12,448,589	24,519,847	0.13	1228.65	34.74	35.37	27.12
10 to 16 Years	1,857	1,857	62,548	2,212,833	2,069	7	10,452,949	20,024,098	0.18	1191.62	33.68	35.38	33.83
17 to 64 Years	8,373	8,373	258,990	10,354,787	10,172	64	62,092,067	131,250,984	0.13	1236.69	30.93	39.98	62.92
65+ Years	2,450	2,450	63,535	3,021,069	3,023	32	7,726,623	20,202,854	0.32	1233.09	25.93	47.55	105.86

Table 3: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Sex

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
All Anti-Epileptic Drugs (Blackout Period = 0 Days)													
Female	4,029,638	4,029,638	8,209,378	221,414,170	668,853	13,802	43,604,467	95,417,842	92.41	54.95	2.04	26.97	206.35
Male	2,333,491	2,333,491	5,145,374	142,743,321	422,343	13,067	42,482,817	93,689,585	54.93	61.17	2.21	27.74	309.39
Unknown	202	202	383	11,038	34	1	3,874	6,437	52.14	54.64	1.90	28.82	295.61
All Anti-Epileptic Drugs minus Topiramate, Gabapentin, and Zonisamide (Blackout Period = 0 Days)													
Female	3,118,558	3,118,558	5,409,527	124,619,378	404,444	8,173	43,604,544	96,200,798	71.52	39.96	1.73	23.04	202.08
Male	1,804,518	1,804,518	3,574,160	88,192,588	273,763	8,281	42,482,839	94,145,017	42.48	48.87	1.98	24.68	302.49
Unknown	153	153	303	7,510	23	1	3,874	6,459	39.49	49.08	1.98	24.79	437.74
Gabapentin (Blackout Period = 0 Days)													
Female	792,002	792,002	1,710,481	60,415,053	179,237	3,708	43,604,707	99,167,421	18.16	76.28	2.16	35.32	206.88
Male	529,398	529,398	1,179,488	41,774,756	123,112	3,949	42,482,884	95,705,636	12.46	78.91	2.23	35.42	320.77
Unknown	43	43	74	3,527	10	0	3,874	6,548	11.10	82.02	1.72	47.66	0.00
Gabapentin (Blackout Period = 90 Days)													
Female	183,838	183,838	1,030,935	41,627,520	71,446	1,066	43,604,726	99,728,614	4.22	226.44	5.61	40.38	149.20
Male	127,711	127,711	719,401	28,981,809	49,511	1,225	42,482,896	96,066,595	3.01	226.93	5.63	40.29	247.42
Unknown	9	9	31	2,249	4	0	3,874	6,560	2.32	249.89	3.44	72.55	0.00
Gabapentin (Blackout Period = 183 Days)													
Female	72,105	72,105	717,152	29,459,986	44,961	614	43,604,741	99,816,704	1.65	408.57	9.95	41.08	136.56
Male	50,332	50,332	496,481	20,467,190	30,899	683	42,482,902	96,126,301	1.18	406.64	9.86	41.22	221.04
Unknown	3	3	20	1,532	3	0	3,874	6,565	0.77	510.67	6.67	76.60	0.00
Gabapentin (Blackout Period = 365 Days)													
Female	27,684	27,684	436,009	18,691,433	23,385	254	43,604,744	99,839,076	0.63	675.17	15.75	42.87	108.62
Male	18,928	18,928	298,415	12,814,890	15,979	301	42,482,905	96,142,496	0.45	677.03	15.77	42.94	188.37
Unknown	2	2	14	1,300	2	0	3,874	6,565	0.52	650.00	7.00	92.86	0.00
Gabapentin (Blackout Period = 730 Days)													
Female	7,901	7,901	192,267	8,885,234	8,369	80	43,604,744	99,845,107	0.18	1124.57	24.33	46.21	95.59
Male	5,431	5,431	133,186	6,108,558	5,737	94	42,482,905	96,146,970	0.13	1124.76	24.52	45.86	163.86
Unknown	1	1	10	900	0	0	3,874	6,565	0.26	900.00	10.00	90.00	0.00

Table 3: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Sex

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Topiramate (Blackout Period = 0 Days)													
Female	285,964	285,964	728,518	24,963,334	73,334	1,645	43,604,709	99,630,903	6.56	87.30	2.55	34.27	224.32
Male	66,872	66,872	152,891	5,191,196	15,320	550	42,482,904	96,091,679	1.57	77.63	2.29	33.95	359.01
Unknown	14	14	19	554	2	0	3,874	6,558	3.61	39.57	1.36	29.16	0.00
Topiramate (Blackout Period = 90 Days)													
Female	74,040	74,040	484,449	17,792,274	31,801	717	43,604,727	99,803,601	1.70	240.31	6.54	36.73	225.47
Male	14,842	14,842	92,216	3,395,626	5,851	225	42,482,905	96,137,978	0.35	228.78	6.21	36.82	384.58
Unknown	1	1	4	120	0	0	3,874	6,566	0.26	120.00	4.00	30.00	0.00
Topiramate (Blackout Period = 183 Days)													
Female	32,522	32,522	351,183	13,087,977	19,992	438	43,604,743	99,832,243	0.75	402.43	10.80	37.27	219.09
Male	6,083	6,083	64,553	2,410,648	3,577	139	42,482,906	96,144,636	0.14	396.29	10.61	37.34	388.55
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---
Topiramate (Blackout Period = 365 Days)													
Female	12,564	12,564	212,894	8,219,572	10,051	209	43,604,744	99,842,188	0.29	654.22	16.94	38.61	207.95
Male	2,242	2,242	38,086	1,461,282	1,753	61	42,482,906	96,146,995	0.05	651.78	16.99	38.37	348.02
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---
Topiramate (Blackout Period = 730 Days)													
Female	3,433	3,433	91,494	3,731,505	3,359	60	43,604,744	99,845,604	0.08	1086.95	26.65	40.78	178.62
Male	580	580	16,059	640,498	576	22	42,482,906	96,147,667	0.01	1104.31	27.69	39.88	381.83
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---
Zonisamide (Blackout Period = 0 Days)													
Female	13,243	13,243	32,470	1,051,475	3,101	78	43,604,743	99,834,314	0.30	79.40	2.45	32.38	251.49
Male	4,748	4,748	13,856	449,537	1,295	46	42,482,905	96,143,436	0.11	94.68	2.92	32.44	355.34
Unknown	1	1	1	30	0	0	3,874	6,565	0.26	30.00	1.00	30.00	0.00
Zonisamide (Blackout Period = 90 Days)													
Female	2,980	2,980	20,264	689,995	1,212	31	43,604,744	99,844,209	0.07	231.54	6.80	34.05	255.81
Male	1,207	1,207	9,605	323,585	604	19	42,482,905	96,146,997	0.03	268.09	7.96	33.69	314.69
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---

Table 3: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Sex

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Zonisamide (Blackout Period = 183 Days)													
Female	1,295	1,295	14,371	495,488	728	11	43,604,745	99,845,511	0.03	382.62	11.10	34.48	151.07
Male	585	585	7,377	249,980	397	10	42,482,906	96,147,479	0.01	427.32	12.61	33.89	251.71
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---
Zonisamide (Blackout Period = 365 Days)													
Female	467	467	8,237	290,590	336	2	43,604,745	99,845,981	0.01	622.25	17.64	35.28	59.45
Male	233	233	4,730	160,888	213	2	42,482,906	96,147,704	0.01	690.51	20.30	34.01	93.95
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---
Zonisamide (Blackout Period = 730 Days)													
Female	110	110	3,288	119,252	109	0	43,604,745	99,846,169	0.00	1084.11	29.89	36.27	0.00
Male	76	76	2,471	85,138	84	0	42,482,906	96,147,776	0.00	1120.24	32.51	34.45	0.00
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 0 Days)													
Female	276,065	276,065	993,067	34,559,948	95,338	1,076	43,604,714	99,641,163	6.33	125.19	3.60	34.80	112.86
Male	209,910	209,910	846,836	29,759,971	81,282	1,154	42,482,892	95,990,986	4.94	141.77	4.03	35.14	141.97
Unknown	12	12	43	1,746	5	1	3,874	6,557	3.10	145.50	3.58	40.60	2126.02
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 90 Days)													
Female	95,448	95,448	777,653	28,432,547	53,111	449	43,604,730	99,794,822	2.19	297.89	8.15	36.56	84.54
Male	78,126	78,126	689,780	25,343,963	48,497	517	42,482,898	96,104,639	1.84	324.40	8.83	36.74	106.60
Unknown	5	5	34	1,365	3	0	3,874	6,565	1.29	273.00	6.80	40.15	0.00
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 183 Days)													
Female	48,015	48,015	616,133	22,877,922	36,867	279	43,604,740	99,827,566	1.10	476.47	12.83	37.13	75.68
Male	41,573	41,573	565,286	21,071,043	34,863	320	42,482,903	96,130,547	0.98	506.84	13.60	37.28	91.79
Unknown	2	2	26	1,060	2	0	3,874	6,566	0.52	530.00	13.00	40.77	0.00
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 365 Days)													
Female	21,676	21,676	423,871	16,182,706	21,054	136	43,604,742	99,840,230	0.50	746.57	19.55	38.18	64.60
Male	19,944	19,944	406,388	15,528,938	20,746	179	42,482,905	96,141,516	0.47	778.63	20.38	38.21	86.28
Unknown	2	2	26	1,060	1	0	3,874	6,566	0.52	530.00	13.00	40.77	0.00

Table 3: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Sex

	New New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 730 Days)													
Female	7,176	7,176	217,426	8,696,269	8,362	45	43,604,743	99,844,883	0.16	1211.85	30.30	40.00	53.82
Male	7,079	7,079	222,355	8,827,541	8,747	63	42,482,906	96,146,335	0.17	1247.00	31.41	39.70	72.03
Unknown	0	0	0	0	0	0	3,874	6,566	0.00	---	---	---	---

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
All Anti-Epileptic Drugs (Blackout Period = 0 Days)													
2004	259,980	259,980	694,766	20,280,858	56,958	1,016	8,222,599	6,520,023	31.62	78.01	2.67	29.19	178.38
2005	236,707	236,707	524,089	15,894,149	46,205	807	8,296,185	6,757,379	28.53	67.15	2.21	30.33	174.66
2006	371,354	371,354	872,956	25,953,169	74,668	1,404	18,852,692	11,293,954	19.70	69.89	2.35	29.73	188.03
2007	553,448	553,448	1,324,499	37,801,620	110,585	2,399	22,263,070	15,960,269	24.86	68.30	2.39	28.54	216.94
2008	920,968	920,968	2,022,035	55,217,004	165,448	3,930	42,543,064	26,224,467	21.65	59.96	2.20	27.31	237.54
2009	1,144,774	1,144,774	2,445,910	65,849,725	198,598	4,981	43,961,905	33,512,354	26.04	57.52	2.14	26.92	250.81
2010	1,045,899	1,045,899	2,178,956	58,281,264	177,024	4,633	41,652,823	31,895,470	25.11	55.72	2.08	26.75	261.72
2011	991,468	991,468	1,933,625	50,951,724	156,823	4,395	40,110,788	30,999,693	24.72	51.39	1.95	26.35	280.25
2012	838,733	838,733	1,358,299	33,939,016	104,921	3,305	37,012,274	25,950,255	22.66	40.46	1.62	24.99	315.00
All Anti-Epileptic Drugs minus Topiramate, Gabapentin, and Zonisamide (Blackout Period = 0 Days)													
2004	210,840	210,840	464,714	12,317,658	37,064	628	8,222,600	6,521,382	25.64	58.42	2.20	26.51	169.44
2005	198,806	198,806	378,273	10,133,884	31,365	557	8,324,074	6,774,084	23.88	50.97	1.90	26.79	177.59
2006	305,815	305,815	606,449	15,768,197	48,457	897	18,895,560	11,323,329	16.18	51.56	1.98	26.00	185.11
2007	449,018	449,018	927,355	23,516,158	72,766	1,583	22,338,256	16,012,644	20.10	52.37	2.07	25.36	217.55
2008	729,387	729,387	1,395,635	33,664,427	106,451	2,529	42,673,952	26,318,423	17.09	46.15	1.91	24.12	237.57
2009	883,881	883,881	1,630,929	38,154,848	122,114	3,081	44,187,273	33,671,609	20.00	43.17	1.85	23.39	252.30
2010	797,827	797,827	1,433,034	32,940,016	106,541	2,767	41,990,424	32,139,615	19.00	41.29	1.80	22.99	259.71
2011	744,121	744,121	1,265,632	28,236,282	92,741	2,542	40,538,358	31,316,539	18.36	37.95	1.70	22.31	274.10
2012	603,534	603,534	881,969	18,088,006	60,731	1,871	37,494,871	26,274,649	16.10	29.97	1.46	20.51	308.08
Gabapentin (Blackout Period = 0 Days)													
2004	37,735	37,735	104,774	3,773,816	11,038	201	8,222,602	6,530,635	4.59	100.01	2.78	36.02	182.10
2005	33,371	33,371	82,479	3,396,792	9,867	160	8,444,061	6,860,371	3.95	101.79	2.47	41.18	162.16
2006	54,614	54,614	134,731	5,470,621	15,917	282	19,114,314	11,487,987	2.86	100.17	2.47	40.60	177.17
2007	89,521	89,521	218,706	8,284,206	24,350	503	22,708,834	16,295,756	3.94	92.54	2.44	37.88	206.57
2008	164,508	164,508	382,225	13,566,176	40,333	921	43,248,877	26,759,170	3.80	82.47	2.32	35.49	228.35
2009	227,687	227,687	517,951	18,127,150	54,015	1,335	45,061,277	34,332,579	5.05	79.61	2.27	35.00	247.15
2010	233,056	233,056	525,992	18,188,303	54,251	1,424	43,155,981	33,027,795	5.40	78.04	2.26	34.58	262.48
2011	245,829	245,829	520,862	17,954,737	53,611	1,575	41,892,593	32,357,791	5.87	73.04	2.12	34.47	293.78
2012	235,122	235,122	402,323	13,431,535	38,976	1,256	38,873,630	27,227,520	6.05	57.13	1.71	33.38	322.25

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Gabapentin (Blackout Period = 90 Days)													
2004	10,422	10,422	71,368	2,826,113	5,339	71	8,222,602	6,531,673	1.27	271.17	6.85	39.60	132.99
2005	9,563	9,563	54,662	2,604,888	4,901	59	8,461,943	6,871,822	1.13	272.39	5.72	47.65	120.38
2006	15,123	15,123	89,591	4,153,729	7,863	112	19,141,176	11,507,056	0.79	274.66	5.92	46.36	142.44
2007	22,978	22,978	142,671	6,117,368	11,488	170	22,758,172	16,331,336	1.01	266.23	6.21	42.88	147.98
2008	37,673	37,673	237,429	9,548,864	17,538	328	43,337,931	26,825,098	0.87	253.47	6.30	40.22	187.02
2009	52,068	52,068	319,791	12,688,807	22,824	426	45,221,220	34,448,819	1.15	243.70	6.14	39.68	186.65
2010	55,619	55,619	330,546	12,919,676	22,603	437	43,400,322	33,209,181	1.28	232.29	5.94	39.09	193.33
2011	61,232	61,232	318,801	12,574,060	20,132	468	42,210,211	32,597,722	1.45	205.35	5.21	39.44	232.47
2012	46,880	46,880	185,508	7,178,073	8,273	220	39,241,622	27,479,063	1.19	153.12	3.96	38.69	265.93
Gabapentin (Blackout Period = 183 Days)													
2004	4,791	4,791	54,510	2,184,477	3,615	50	8,222,602	6,531,721	0.58	455.95	11.38	40.07	138.32
2005	3,725	3,725	39,209	1,957,822	3,488	40	8,464,897	6,873,309	0.44	525.59	10.53	49.93	114.67
2006	6,211	6,211	67,883	3,192,122	5,653	71	19,146,927	11,510,612	0.32	513.95	10.93	47.02	125.60
2007	9,536	9,536	108,042	4,664,182	8,086	99	22,768,421	16,337,855	0.42	489.11	11.33	43.17	122.44
2008	15,284	15,284	174,631	7,124,194	12,001	205	43,355,316	26,836,751	0.35	466.12	11.43	40.80	170.82
2009	21,195	21,195	231,821	9,360,768	15,191	256	45,249,324	34,467,318	0.47	441.65	10.94	40.38	168.52
2010	23,143	23,143	236,855	9,446,686	14,438	261	43,441,727	33,237,376	0.53	408.19	10.23	39.88	180.77
2011	25,779	25,779	218,301	8,790,417	11,102	256	42,264,870	32,636,230	0.61	340.99	8.47	40.27	230.60
2012	12,776	12,776	82,401	3,208,040	2,289	59	39,305,811	27,518,398	0.33	251.10	6.45	38.93	257.79
Gabapentin (Blackout Period = 365 Days)													
2004	2,052	2,052	35,625	1,511,634	2,069	23	8,222,602	6,531,721	0.25	736.66	17.36	42.43	111.15
2005	1,538	1,538	26,272	1,420,478	2,332	28	8,465,735	6,873,606	0.18	923.59	17.08	54.07	120.06
2006	2,741	2,741	48,498	2,349,451	3,680	39	19,148,626	11,511,551	0.14	857.15	17.69	48.44	105.98
2007	4,201	4,201	75,892	3,379,018	5,057	54	22,771,207	16,339,521	0.18	804.34	18.07	44.52	106.79
2008	6,677	6,677	120,132	5,069,107	7,190	114	43,360,210	26,839,682	0.15	759.19	17.99	42.20	158.56
2009	9,160	9,160	154,573	6,478,733	8,556	134	45,256,949	34,471,960	0.20	707.29	16.87	41.91	156.61
2010	10,058	10,058	152,867	6,327,738	7,214	106	43,453,215	33,244,513	0.23	629.12	15.20	41.39	146.94
2011	9,692	9,692	116,267	4,785,907	3,241	57	42,280,542	32,646,414	0.23	493.80	12.00	41.16	175.85
2012	495	495	4,312	185,557	26	0	39,324,189	27,529,168	0.01	374.86	8.71	43.03	0.00

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Gabapentin (Blackout Period = 730 Days)													
2004	514	514	14,528	755,466	998	16	8,222,602	6,531,721	0.06	1469.78	28.26	52.00	160.38
2005	660	660	16,794	982,564	1,342	19	8,465,811	6,873,619	0.08	1488.73	25.45	58.51	141.57
2006	1,154	1,154	30,476	1,549,191	1,925	13	19,149,043	11,511,743	0.06	1342.45	26.41	50.83	67.53
2007	1,662	1,662	45,383	2,113,745	2,451	22	22,771,909	16,339,962	0.07	1271.81	27.31	46.58	89.75
2008	2,600	2,600	68,542	3,045,629	3,091	49	43,361,445	26,840,394	0.06	1171.40	26.36	44.43	158.50
2009	3,408	3,408	81,513	3,617,239	3,026	37	45,258,936	34,473,152	0.08	1061.40	23.92	44.38	122.27
2010	3,249	3,249	66,914	2,866,660	1,267	17	43,456,234	33,246,363	0.07	882.32	20.60	42.84	134.21
2011	86	86	1,313	64,198	6	1	42,285,104	32,649,243	0.00	746.49	15.27	48.89	1687.85
2012	0	0	0	0	0	0	39,329,792	27,532,446	0.00	---	---	---	---
Topiramate (Blackout Period = 0 Days)													
2004	9,534	9,534	28,259	1,019,483	2,955	63	8,222,601	6,531,499	1.16	106.93	2.96	36.08	213.23
2005	8,137	8,137	22,331	842,900	2,440	49	8,460,494	6,870,551	0.96	103.59	2.74	37.75	200.79
2006	17,011	17,011	51,601	1,967,273	5,627	145	19,139,802	11,505,483	0.89	115.65	3.03	38.12	257.66
2007	26,888	26,888	80,705	2,903,240	8,441	208	22,754,913	16,328,663	1.18	107.98	3.00	35.97	246.41
2008	46,175	46,175	122,425	4,196,078	12,395	308	43,331,309	26,819,944	1.07	90.87	2.65	34.27	248.48
2009	64,539	64,539	171,727	5,762,136	17,021	408	45,208,114	34,438,901	1.43	89.28	2.66	33.55	239.71
2010	62,736	62,736	160,145	5,371,360	15,909	394	43,379,400	33,193,460	1.45	85.62	2.55	33.54	247.66
2011	59,720	59,720	139,389	4,669,210	13,862	347	42,187,037	32,579,715	1.42	78.19	2.33	33.50	250.32
2012	58,110	58,110	104,846	3,423,404	10,005	273	39,220,489	27,460,923	1.48	58.91	1.80	32.65	272.85
Topiramate (Blackout Period = 90 Days)													
2004	2,766	2,766	19,977	774,320	1,481	30	8,222,602	6,531,712	0.34	279.94	7.22	38.76	202.63
2005	2,120	2,120	14,840	639,042	1,250	20	8,464,778	6,873,197	0.25	301.43	7.00	43.06	160.02
2006	5,012	5,012	37,386	1,521,301	2,973	73	19,147,012	11,510,506	0.26	303.53	7.46	40.69	245.51
2007	7,729	7,729	58,340	2,226,454	4,337	96	22,768,381	16,337,872	0.34	288.06	7.55	38.16	221.33
2008	11,544	11,544	82,363	3,032,783	5,696	146	43,355,010	26,836,513	0.27	262.72	7.13	36.82	256.32
2009	16,419	16,419	115,996	4,146,846	7,651	183	45,248,718	34,466,912	0.36	252.56	7.06	35.75	239.17
2010	16,348	16,348	108,300	3,869,045	6,895	187	43,440,908	33,236,732	0.38	236.67	6.62	35.73	271.22
2011	15,372	15,372	89,309	3,210,734	5,267	145	42,265,008	32,635,993	0.36	208.87	5.81	35.95	275.29
2012	11,573	11,573	50,158	1,767,495	2,101	62	39,307,153	27,518,708	0.29	152.73	4.33	35.24	295.11

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Topiramate (Blackout Period = 183 Days)													
2004	1,352	1,352	15,212	608,266	996	21	8,222,602	6,531,721	0.16	449.90	11.25	39.99	210.79
2005	976	976	11,154	504,202	893	15	8,465,510	6,873,533	0.12	516.60	11.43	45.20	167.97
2006	2,476	2,476	29,726	1,226,563	2,117	47	19,148,361	11,511,367	0.13	495.38	12.01	41.26	221.97
2007	3,774	3,774	45,883	1,770,574	3,014	65	22,770,823	16,339,357	0.17	469.15	12.16	38.59	215.65
2008	5,206	5,206	62,174	2,323,748	3,837	105	43,359,393	26,839,252	0.12	446.36	11.94	37.37	273.63
2009	7,588	7,588	87,528	3,158,306	4,984	115	45,255,674	34,471,239	0.17	416.22	11.54	36.08	230.72
2010	7,334	7,334	79,646	2,870,848	4,293	110	43,451,390	33,243,495	0.17	391.44	10.86	36.05	256.25
2011	6,719	6,719	62,178	2,252,719	2,869	76	42,278,816	32,645,198	0.16	335.28	9.25	36.23	264.90
2012	3,180	3,180	22,235	783,399	565	23	39,322,745	27,528,282	0.08	246.35	6.99	35.23	406.88
Topiramate (Blackout Period = 365 Days)													
2004	549	549	9,325	407,368	567	8	8,222,602	6,531,721	0.07	742.02	16.99	43.69	141.19
2005	442	442	7,777	372,923	573	11	8,465,772	6,873,613	0.05	843.72	17.60	47.95	192.10
2006	1,166	1,166	21,469	902,438	1,291	28	19,148,896	11,511,672	0.06	773.96	18.41	42.03	216.93
2007	1,679	1,679	32,062	1,256,611	1,782	40	22,771,710	16,339,849	0.07	748.43	19.10	39.19	224.49
2008	2,288	2,288	42,081	1,619,207	2,164	54	43,361,068	26,840,195	0.05	707.70	18.39	38.48	249.50
2009	3,149	3,149	56,201	2,077,857	2,587	54	45,258,271	34,472,762	0.07	659.85	17.85	36.97	208.70
2010	3,034	3,034	49,321	1,827,130	1,995	49	43,455,277	33,245,792	0.07	602.22	16.26	37.05	245.67
2011	2,416	2,416	32,004	1,186,310	842	26	42,283,992	32,648,459	0.06	491.02	13.25	37.07	308.96
2012	83	83	740	31,010	4	0	39,328,513	27,531,685	0.00	373.61	8.92	41.91	0.00
Topiramate (Blackout Period = 730 Days)													
2004	160	160	4,131	219,391	280	2	8,222,602	6,531,721	0.02	1371.19	25.82	53.11	71.52
2005	176	176	4,613	240,191	298	7	8,465,811	6,873,619	0.02	1364.72	26.21	52.07	235.00
2006	426	426	12,430	533,737	593	15	19,149,058	11,511,748	0.02	1252.90	29.18	42.94	253.14
2007	611	611	18,072	729,015	778	15	22,771,959	16,339,992	0.03	1193.15	29.58	40.34	192.88
2008	768	768	21,678	876,155	857	27	43,361,552	26,840,460	0.02	1140.83	28.23	40.42	314.90
2009	1,002	1,002	26,954	1,019,611	803	9	45,259,125	34,473,270	0.02	1017.58	26.90	37.83	112.07
2010	845	845	19,217	735,434	325	7	43,456,536	33,246,540	0.02	870.34	22.74	38.27	215.11
2011	25	25	458	18,469	1	0	42,285,777	32,649,586	0.00	738.76	18.32	40.33	0.00
2012	0	0	0	0	0	0	39,330,639	27,532,902	0.00	---	---	---	---

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Zonisamide (Blackout Period = 0 Days)													
2004	1,034	1,034	3,299	99,460	291	5	8,222,602	6,531,693	0.13	96.19	3.19	30.15	171.70
2005	644	644	1,509	48,925	145	4	8,465,250	6,873,299	0.08	75.97	2.34	32.42	276.51
2006	1,018	1,018	3,175	104,924	304	5	19,148,249	11,511,197	0.05	103.07	3.12	33.05	164.31
2007	1,508	1,508	4,401	145,123	427	9	22,770,704	16,339,104	0.07	96.24	2.92	32.98	210.90
2008	2,526	2,526	6,929	225,905	664	16	43,359,555	26,839,056	0.06	89.43	2.74	32.60	241.07
2009	3,303	3,303	8,260	266,474	784	18	45,256,065	34,471,209	0.07	80.68	2.50	32.26	229.64
2010	2,963	2,963	7,804	253,010	741	28	43,452,165	33,243,490	0.07	85.39	2.63	32.42	377.90
2011	2,666	2,666	6,578	216,267	633	23	42,280,649	32,645,899	0.06	81.12	2.47	32.88	363.51
2012	2,330	2,330	4,372	140,954	408	16	39,325,409	27,529,367	0.06	60.50	1.88	32.24	392.11
Zonisamide (Blackout Period = 90 Days)													
2004	290	290	2,353	73,302	136	2	8,222,602	6,531,720	0.04	252.77	8.11	31.15	147.57
2005	114	114	857	29,401	54	1	8,465,704	6,873,574	0.01	257.90	7.52	34.31	184.27
2006	256	256	2,266	77,418	153	2	19,148,902	11,511,645	0.01	302.41	8.85	34.17	130.61
2007	354	354	3,040	104,780	208	5	22,771,751	16,339,850	0.02	295.99	8.59	34.47	240.37
2008	587	587	4,665	159,148	302	8	43,361,241	26,840,252	0.01	271.12	7.95	34.12	265.03
2009	752	752	5,328	179,888	319	10	45,258,713	34,473,010	0.02	239.21	7.09	33.76	313.05
2010	734	734	5,173	174,725	313	9	43,455,930	33,246,148	0.02	238.04	7.05	33.78	287.89
2011	663	663	4,147	144,690	242	8	42,285,087	32,649,095	0.02	218.24	6.25	34.89	330.04
2012	437	437	2,040	70,228	88	5	39,330,026	27,532,475	0.01	160.70	4.67	34.43	565.95
Zonisamide (Blackout Period = 183 Days)													
2004	154	154	1,828	57,478	83	2	8,222,602	6,531,721	0.02	373.23	11.87	31.44	240.10
2005	55	55	621	22,172	35	0	8,465,781	6,873,608	0.01	403.13	11.29	35.70	0.00
2006	122	122	1,802	61,435	109	1	19,148,992	11,511,706	0.01	503.57	14.77	34.09	91.58
2007	159	159	2,365	82,323	149	3	22,771,897	16,339,943	0.01	517.75	14.87	34.81	200.79
2008	283	283	3,642	124,633	203	5	43,361,468	26,840,408	0.01	440.40	12.87	34.22	245.89
2009	327	327	3,835	130,907	196	6	45,259,068	34,473,223	0.01	400.33	11.73	34.13	306.74
2010	324	324	3,706	126,885	191	2	43,456,469	33,246,490	0.01	391.62	11.44	34.24	104.74
2011	321	321	2,959	105,190	131	2	42,285,751	32,649,550	0.01	327.69	9.22	35.55	152.21
2012	135	135	990	34,445	27	0	39,330,713	27,532,908	0.00	255.15	7.33	34.79	0.00

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Zonisamide (Blackout Period = 365 Days)													
2004	64	64	1,133	35,736	35	0	8,222,602	6,531,721	0.01	558.38	17.70	31.54	0.00
2005	18	18	357	13,591	20	0	8,465,809	6,873,619	0.00	755.06	19.83	38.07	0.00
2006	60	60	1,360	46,412	68	0	19,149,035	11,511,736	0.00	773.53	22.67	34.13	0.00
2007	82	82	1,812	63,574	94	2	22,771,957	16,339,979	0.00	775.29	22.10	35.08	212.82
2008	105	105	2,297	79,455	114	2	43,361,569	26,840,465	0.00	756.71	21.88	34.59	175.93
2009	123	123	2,189	77,905	93	0	45,259,207	34,473,301	0.00	633.37	17.80	35.59	0.00
2010	129	129	2,295	78,413	89	0	43,456,683	33,246,620	0.00	607.85	17.79	34.17	0.00
2011	113	113	1,467	54,142	35	0	42,286,009	32,649,724	0.00	479.13	12.98	36.91	0.00
2012	6	6	57	2,250	0	0	39,330,992	27,533,086	0.00	375.00	9.50	39.47	0.00
Zonisamide (Blackout Period = 730 Days)													
2004	11	11	320	11,711	10	0	8,222,602	6,531,721	0.00	1064.64	29.09	36.60	0.00
2005	5	5	168	6,910	9	0	8,465,811	6,873,619	0.00	1382.00	33.60	41.13	0.00
2006	19	19	801	25,911	34	0	19,149,061	11,511,748	0.00	1363.74	42.16	32.35	0.00
2007	38	38	1,178	41,573	39	0	22,771,985	16,340,000	0.00	1094.03	31.00	35.29	0.00
2008	41	41	1,336	48,506	52	0	43,361,603	26,840,490	0.00	1183.07	32.59	36.31	0.00
2009	32	32	927	34,473	31	0	45,259,254	34,473,329	0.00	1077.28	28.97	37.19	0.00
2010	38	38	989	33,806	17	0	43,456,750	33,246,662	0.00	889.63	26.03	34.18	0.00
2011	2	2	40	1,500	0	0	42,286,108	32,649,785	0.00	750.00	20.00	37.50	0.00
2012	0	0	0	0	0	0	39,331,102	27,533,155	0.00	---	---	---	---
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 0 Days)													
2004	22,774	22,774	94,195	3,644,582	9,900	93	8,222,601	6,531,260	2.77	160.03	4.14	38.69	93.94
2005	23,883	23,883	90,626	3,869,959	10,562	102	8,455,285	6,867,418	2.82	162.04	3.79	42.70	96.57
2006	32,024	32,024	143,354	5,435,406	14,727	151	19,129,068	11,498,675	1.67	169.73	4.48	37.92	102.54
2007	41,431	41,431	181,981	6,559,754	17,909	231	22,739,133	16,317,578	1.82	158.33	4.39	36.05	128.99
2008	67,214	67,214	284,079	9,769,916	26,899	312	43,312,263	26,806,161	1.55	145.36	4.23	34.39	115.99
2009	82,441	82,441	335,033	11,314,601	31,218	390	45,186,317	34,423,850	1.82	137.24	4.06	33.77	124.93
2010	76,466	76,466	297,675	10,057,597	27,790	358	43,359,641	33,178,835	1.76	131.53	3.89	33.79	128.82
2011	74,832	74,832	258,352	8,676,410	23,998	351	42,168,519	32,566,028	1.77	115.95	3.45	33.58	146.26
2012	64,922	64,922	154,651	4,993,440	13,621	243	39,204,216	27,448,903	1.66	76.91	2.38	32.29	178.40

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 90 Days)													
2004	8,090	8,090	75,445	3,090,443	6,202	53	8,222,602	6,531,696	0.98	382.01	9.33	40.96	85.46
2005	9,035	9,035	72,857	3,339,782	6,719	47	8,463,565	6,872,600	1.07	369.65	8.06	45.84	69.96
2006	12,357	12,357	120,629	4,761,532	9,610	82	19,143,695	11,508,689	0.65	385.33	9.76	39.47	85.33
2007	15,481	15,481	151,925	5,690,706	11,412	108	22,763,017	16,334,452	0.68	367.59	9.81	37.46	94.64
2008	24,048	24,048	233,730	8,361,780	16,567	145	43,347,942	26,831,706	0.55	347.71	9.72	35.78	87.52
2009	29,434	29,434	271,738	9,562,755	18,503	177	45,239,274	34,460,746	0.65	324.89	9.23	35.19	95.66
2010	28,195	28,195	241,883	8,522,109	16,033	165	43,429,842	33,229,060	0.65	302.26	8.58	35.23	102.92
2011	28,064	28,064	203,203	7,162,846	12,413	136	42,252,318	32,627,091	0.66	255.23	7.24	35.25	109.56
2012	18,875	18,875	96,057	3,285,922	4,153	53	39,294,091	27,509,985	0.48	174.09	5.09	34.21	127.62
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 183 Days)													
2004	4,341	4,341	63,637	2,639,514	4,743	35	8,222,602	6,531,721	0.53	608.04	14.66	41.48	73.79
2005	4,412	4,412	59,445	2,803,577	5,212	30	8,465,259	6,873,439	0.52	635.44	13.47	47.16	57.56
2006	6,694	6,694	103,218	4,112,358	7,452	60	19,147,356	11,510,900	0.35	614.33	15.42	39.84	80.51
2007	8,379	8,379	128,834	4,874,109	8,715	68	22,768,935	16,338,222	0.37	581.71	15.38	37.83	78.02
2008	12,987	12,987	195,998	7,096,038	12,364	98	43,356,653	26,837,456	0.30	546.40	15.09	36.20	79.26
2009	15,830	15,830	223,997	7,972,700	13,311	118	45,251,641	34,468,740	0.35	503.64	14.15	35.59	88.65
2010	15,347	15,347	197,216	7,042,899	11,079	100	43,446,146	33,239,932	0.35	458.91	12.85	35.71	90.26
2011	15,027	15,027	158,412	5,664,021	7,523	81	42,272,219	32,640,685	0.36	376.92	10.54	35.75	107.67
2012	6,573	6,573	50,688	1,744,809	1,333	9	39,315,655	27,523,584	0.17	265.45	7.71	34.42	67.49
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 365 Days)													
2004	2,246	2,246	48,806	2,098,218	3,209	20	8,222,602	6,531,721	0.27	934.20	21.73	42.99	62.33
2005	2,252	2,252	46,180	2,257,885	3,689	19	8,465,759	6,873,609	0.27	1002.61	20.51	48.89	51.51
2006	3,510	3,510	81,747	3,297,591	5,096	38	19,148,629	11,511,565	0.18	939.48	23.29	40.34	74.58
2007	4,380	4,380	100,635	3,864,471	5,775	45	22,771,078	16,339,481	0.19	882.30	22.98	38.40	77.92
2008	6,689	6,689	149,252	5,516,472	7,856	49	43,360,113	26,839,555	0.15	824.71	22.31	36.96	62.37
2009	7,923	7,923	164,983	5,983,363	7,873	60	45,256,802	34,471,840	0.18	755.19	20.82	36.27	76.21
2010	7,614	7,614	139,676	5,096,625	5,829	53	43,453,213	33,244,419	0.18	669.38	18.34	36.49	90.93
2011	6,695	6,695	95,781	3,474,949	2,460	31	42,281,079	32,646,552	0.16	519.04	14.31	36.28	126.00
2012	313	313	3,225	123,130	16	0	39,325,322	27,529,569	0.01	393.39	10.30	38.18	0.00

Table 4: Summary of Incident Anti-Epileptic Drug Use and Kidney Stones in the MSDD between January 1, 2004 and December 31, 2012, by Drug Product, Blackout Period, and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Years at Risk	New Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Events / 10K Years at Risk
Lamotrigine, Levetiracetam, Carbamazepine, Oxcarbazepine, Phenytoin, Valproic acid (Blackout Period = 730 Days)													
2004	866	866	29,414	1,388,693	1,822	10	8,222,602	6,531,721	0.11	1603.57	33.97	47.21	54.87
2005	1,023	1,023	31,694	1,618,196	2,178	12	8,465,811	6,873,619	0.12	1581.81	30.98	51.06	55.11
2006	1,605	1,605	56,073	2,306,049	2,759	19	19,149,037	11,511,742	0.08	1436.79	34.94	41.13	68.88
2007	1,915	1,915	65,711	2,580,885	2,898	21	22,771,878	16,339,949	0.08	1347.72	34.31	39.28	72.46
2008	2,861	2,861	93,415	3,553,213	3,557	17	43,361,351	26,840,341	0.07	1241.95	32.65	38.04	47.79
2009	3,201	3,201	94,834	3,536,710	2,839	15	45,258,753	34,473,040	0.07	1104.88	29.63	37.29	52.83
2010	2,696	2,696	66,922	2,473,048	1,050	14	43,455,976	33,246,172	0.06	917.30	24.82	36.95	133.32
2011	88	88	1,718	67,016	5	0	42,284,870	32,649,001	0.00	761.55	19.52	39.01	0.00
2012	0	0	0	0	0	0	39,329,539	27,532,198	0.00	---	---	---	---

Appendix A. List of Kidney Stone Codes Included in this Request

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes

592.0	Calculus of kidney
592.1	Calculus of ureter
592.9	Urinary calculus, unspecified
274.11	Uric acid nephrolithiasis
594	Calculus of lower urinary tract

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Procedure Codes

55.04	Percutaneous Nephrostomy With Fragmentation
55.92	Percutaneous aspiration of kidney (pelvis)
56.2	Ureterotomy
59.8	Ureteral Catheterization
59.95	Ultrasonic Fragmentation Of Urinary Stones
98.51	Extracorporeal shockwave lithotripsy of the kidney, ureter and/or bladder
55.04	Percutaneous Nephrostomy With Fragmentation
98.51	Extracorporeal shockwave lithotripsy of the kidney, ureter and/or bladder
59.95	Ultrasonic Fragmentation Of Urinary Stones

Healthcare Common Procedure Coding System (HCPCS)

50060	Removal of Kidney Stone
50065	Incision of Kidney
50070	Incision of Kidney
50075	Removal of Kidney Stone
50080	Removal of Kidney Stone
50081	Removal of Kidney Stone
50130	Removal of Kidney Stone
50590	Fragmenting of Kidney Stone
50610	Removal of Ureter Stone
50620	Removal of Ureter Stone
50630	Removal of Ureter Stone
52320	Cystoscopy and Treatment
52325	Cystoscopy Stone Removal
52330	Cystoscopy and Treatment
52336	Cystourethroscopy with Ureteroscopy; with Remove Calculus
52337	Cystourethroscopy with Ureteroscopy; with Lith
50945	Laparoscopy Ureterolithotomy
50561	Kidney Endoscopy and Treatment
50580	Kidney Endoscopy and Treatment
51060	Removal of Ureter Stone
51065	Remove Ureter Calculus
50080	Removal of Kidney Stone
50081	Removal of Kidney Stone
50060	Removal of Kidney Stone
50070	Incision of Kidney
50075	Removal of Kidney Stone
50610	Removal of Ureter Stone
50620	Removal of Ureter Stone
50630	Removal of Ureter Stone
50590	Fragmenting of Kidney Stone
52320	Cystoscopy and Treatment
52325	Cystoscopy Stone Removal
52352	Cystouretero with Stone Remove
52353	Cystouretero with Lithotripsy