Disclaimer

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

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

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

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

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

Overview

Request ID: cder_mpl1r_wp033_nsdp_v01

Report Description: This report contains the estimated rates of seizures among indiviuals exposed to ranolazine alone, as well as individuals with concomitant use of ranolazine and either beta blockers, selected oral calcium channel blockers, or non-injectable nitrates. These analyses were conducted overall, for individuals with a pre-exisitng condition of renal disease, and for individuals with a pre-exisiting condition of liver impairment.

Sentinel Modular Program Tool Used: Modular Program #4, version 5.1

Data Source: The query was run against the Sentinel Distributed Database for the time period of January 1, 2006 to September 30, 2015. The request was distributed to 16 data partners on August 4, 2016. See Appendix A for a list of the latest dates available for each Data Partner.

Study Design: This request was designed to calculate rates of seizures among individuals with exposure(s) to ranolazine and/or beta blockers, selected oral calcium channel blockers, or non-injectable nitrates. The rates of qualifying seizures in the SDD were calculated by strength of ranolazine and concomitant exposure overall and stratified by age and sex.

Cohort of Interest: Individuals who are 18 years and older, overall and stratified by those with a pre-exisitng condition of renal disease and with a pre-existing condition of liver impairment.

Cohort Eligibility Criteria: Individuals included in the cohort were required to be continuously enrolled in plans with both medical and drug coverage for at least 183 days, during which gaps in coverage of up to 45 days were allowed. Seizures were defined using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9 CM) codes. Please see Appendix B for a list of codes. Use of ranozaline, beta blockers, oral calcium channel blockers, and non-injectable nitrates were defined using National Drug Codes (NDCs). Please see Appendix C for a list of drugs. Renal disease and liver impairment were defined using ICD-9 CM codes. Please see Appendix D. The program considered all valid outcomes between January 1, 2006 and September 30, 2015 for each individual. All valid incident seizures that occurred during the study period were included per patient.

Limitations: Algorithms to define exposures and events are imperfect and, therefore, may be misclassified.

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (production@mini-sentinel.org) for questions and to provide comments/suggestions for future enhancements to this document.

Sentinel

Table of Contents

Glossary of Terms in Modular Program 4*

Terms in Tables

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.

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

Dispensings - number of dispensings in qualifying treatment episodes.

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

Amount Supplied - number of units (pills, tablets, vials) dispensed.

Episode Duration - number of days in qualifying treatment episodes.

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

Terms in Specifications

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

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

Age Groups - Age group categories for reporting.

Event - Outcome of interest.

Care Setting - type of medical encounter or facility where the event 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).

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

Incident w/ respect to: - Events that the event of interest is incident with respect to. For example, if an event is diabetes, we could examine diabetes incident with respect to itself (new diabetes patients who do not have a diabetes code in the prior washout period days). Instead, we could examine diabetes incident with respect to both diabetes and AMI (new diabetes patients who do not have a diabetes code or an AMI code in the prior washout period days).

Incident Only Care Setting - type of medical encounter or facility where the event in the "Incident w/ respect to:" column 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).

Incident Only PDX Indicator - event in the "Incident w/ respect to:" column established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal.

Washout Period (event) - 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 concomitant treatment episode.

Incidence Type (event/outcome)- *Minimum incidence type* considers the first event in a valid concomitant episode as long as it is the first event 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 event in the query period whereas *Multiple* will consider all qualifying incident events. The program will always 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.

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.

Exposure - Exposure of interest (either primary or secondary).

Incident w/ respect to: - Exposure that the exposure of interest is incident with respect to. For example, if an exposure is Drug X, we could examine Drug X incident with respect to itself (new Drug X users who do not have a Drug X dispensing in the prior washout period days). Instead, we could examine Drug X incident with respect to both Drug X and Drug Y (new Drug X users who do not have a Drug X or Drug Y dispensing in the prior washout period days).

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.

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.

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

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered.

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

Minimum Follow-up Period - number of days the member must be eligible for pharmacy and/or medical benefits after the exposure index date.

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

Exposure Order Indicator - indicates whether the order of primary and secondary exposure is relevant when creating valid prevalent concomitant treatment episodes. A value of 'Y' instructs the program to always require primary exposure to be initiated before secondary exposure; a value of 'N' will not enforce an order restriction.

Event Washout Extension - indicates whether the event washout period should be extended to include all prior primary or secondary exposure days that were used to create the concomitant episode. This will be set to 'Y' if the requester wants washper days for the event of interest to include all days before the concomitant index date that are exposed to either the primary or secondary exposure used to define the concomitant exposure episode. For example, if a requester specifies a washper of 183 for the event and the event washout extension = 'Y', the program will look back whichever number of days is greater: 183 or the number of days before the concomitant index date that are exposed to the primary or secondary exposure used to define the concomitant exposure.

Number of concomitant episodes - indicates whether one or more than one valid incident concomitant episode should be included in output metrics. A value of 'ONE' will retain and report output metrics for only the first concomitant episode. A value of 'ALL' will retain and report output metrics for all valid concomitant episodes.

Minimum Follow-up Period - minimum number of days the member must be eligible for pharmacy and/or medical benefits after the concomitant episode index date.

Episode Extension Period - number of days post concomitant treatment period in which the events are counted for a treatment episode.

Minimum Episode Duration - specifies a minimum number of days in length of the concomitant episode for it to be considered.

*all terms may not be used in this report

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

Table 1: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine and Concomitant Exposure among All Individuals

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use	49,256	49,256	199,812	7,344,143	15,257,873	7,634,313	20,902	32	15.31
With Concomitant Beta Blocker Use	30,679	30,679	na	na	na	3,698,827	10,127	23	22.71
With Concomitant Calcium Channel Blocker Use	2,476	2,476	na	na	na	268,127	734	1	13.62
With Concomitant Nitrates Use	26,853	26,853	na	na	na	2,569,997	7,036	18	25.58
Ranolazine (1000 mg strength)									
Ranolazine With or Without Concomitant Use	5,618	5,618	16,988	639,582	1,294,857	667,033	1,826	4	21.91
With Concomitant Beta Blocker Use	3,394	3,394	na	na	na	321,790	881	2	22.70
With Concomitant Calcium Channel Blocker Use	233	233	na	na	na	18,781	51	1	196.08
With Concomitant Nitrates Use	2,719	2,719	na	na	na	203,253	556	2	35.97

* Years at Risk stop accumulating when first event during episode is encountered

Table 1: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine and Concomitant Exposure among Individuals with a Pre-Existing Condition of Renal Disease

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use	12,075	12,075	47,188	1,723,686	3,569,605	1,789,394	4,899	15	30.62
With Concomitant Beta Blocker Use	8,526	8,526	na	na	na	990,684	2,712	10	36.87
With Concomitant Calcium Channel Blocker Use	678	678	na	na	na	65,005	178	1	56.18
With Concomitant Nitrates Use	7,655	7,655	na	na	na	774,819	2,121	11	51.86
Ranolazine (1000 mg strength)									
Ranolazine With or Without Concomitant Use	1,141	1,141	2,945	111,161	224,633	116,112	318	1	31.45
With Concomitant Beta Blocker Use	765	765	na	na	na	63,578	174	1	57.47
With Concomitant Calcium Channel Blocker Use	46	46	na	na	na	2,406	7	0	0.00
With Concomitant Nitrates Use	632	632	na	na	na	46,839	128	1	78.13

* Years at Risk stop accumulating when first event during episode is encountered

Table 1: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine and Concomitant Exposure among Individuals with a Pre-Existing Condition of Liver Impairment

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use	3,947	3,947	14,285	496,935	1,031,220	518,636	1,420	4	28.17
With Concomitant Beta Blocker Use	2,763	2,763	na	na	na	287,179	786	2	25.45
With Concomitant Calcium Channel Blocker Use	250	250	na	na	na	23,912	65	0	0.00
With Concomitant Nitrates Use	2,361	2,361	na	na	na	191,188	523	3	57.36
Ranolazine (1000 mg strength)									
Ranolazine With or Without Concomitant Use	385	385	979	34,628	70,104	36,192	99	1	101.01
With Concomitant Beta Blocker Use	251	251	na	na	na	19,122	52	1	192.31
With Concomitant Calcium Channel Blocker Use	23	23	na	na	na	1,254	3	1	3333.33
With Concomitant Nitrates Use	209	209	na	na	na	15,026	41	0	0.00

* Years at Risk stop accumulating when first event during episode is encountered

Table 2: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Age Group among all Individuals

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use									
18-44 years	1,669	1,669	4,863	152,740	325,642	161,058	441	2	45.35
45-54 years	6,452	6,452	23,616	801,407	1,698,238	840,437	2,301	3	13.04
55-64 years	13,272	13,272	55,442	1,981,724	4,194,590	2,064,474	5,652	5	8.85
65-74 years	13,398	13,398	54,656	2,099,347	4,351,982	2,178,604	5,965	9	15.09
75+ years	14,465	14,465	61,235	2,308,925	4,687,422	2,389,740	6,543	13	19.87
With Concomitant Beta Blocker Use									
18-44 years	909	909	na	na	na	74,257	203	1	49.26
45-54 years	3,922	3,922	na	na	na	401,370	1,099	1	9.10
55-64 years	8,023	8,023	na	na	na	959,331	2,627	4	15.23
65-74 years	8,368	8,368	na	na	na	1,077,764	2,951	6	20.33
75+ years	9,457	9,457	na	na	na	1,186,105	3,247	11	33.88
With Concomitant Calcium Channel Blocker Use									
18-44 years	105	105	na	na	na	8,746	24	0	0.00
45-54 years	309	309	na	na	na	31,620	87	0	0.00
55-64 years	602	602	na	na	na	64,074	175	0	0.00
65-74 years	660	660	na	na	na	76,020	208	0	0.00
75+ years	800	800	na	na	na	87,667	240	1	41.67
With Concomitant Nitrates Use									
18-44 years	746	746	na	na	na	47,866	131	0	0.00
45-54 years	3,235	3,235	na	na	na	230,752	632	2	31.65
55-64 years	6,875	6,875	na	na	na	608,105	1,665	3	18.02
65-74 years	7,245	7,245	na	na	na	731,789	2,004	6	29.94
75+ years	8,752	8,752	na	na	na	951,485	2,605	7	26.87

Table 2: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Age Group among all Individuals

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (1,000 mg strength)									
Ranolazine With or Without Concomitant Use									
18-44 years	242	242	748	23,440	47,703	25,001	68	0	0.00
45-54 years	921	921	2,871	99,363	202,686	104,212	285	0	0.00
55-64 years	1,758	1,758	5,989	220,106	446,200	229,121	627	1	15.95
65-74 years	1,594	1,594	4,417	179,820	365,434	187,337	513	1	19.49
75+ years	1,103	1,103	2,963	116,853	232,834	121,362	332	2	60.24
With Concomitant Beta Blocker Use									
18-44 years	135	135	na	na	na	12,002	33	0	0.00
45-54 years	549	549	na	na	na	50,229	138	0	0.00
55-64 years	1,070	1,070	na	na	na	108,007	296	0	0.00
65-74 years	945	945	na	na	na	89,356	245	0	0.00
75+ years	695	695	na	na	na	62,196	170	2	117.65
With Concomitant Calcium Channel Blocker Use									
18-44 years	14	14	na	na	na	1,133	3	0	0.00
45-54 years	46	46	na	na	na	3,113	9	0	0.00
55-64 years	59	59	na	na	na	5,766	16	0	0.00
65-74 years	67	67	na	na	na	5,124	14	0	0.00
75+ years	47	47	na	na	na	3,645	10	1	1000.00
With Concomitant Nitrates Use									
18-44 years	109	109	na	na	na	7,930	22	0	0.00
45-54 years	442	442	na	na	na	26,443	72	0	0.00
55-64 years	827	827	na	na	na	64,030	175	0	0.00
65-74 years	746	746	na	na	na	54,984	151	1	66.23
75+ years	595	595	na	na	na	49,866	137	1	72.99

* Years at Risk stop accumulating when first event during episode is encountered

Table 2: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Age Group among Individuals with a Pre-Existing Condition of Renal Disease

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use									
18-44 years	116	116	376	11,923	25,542	12,508	34	0	0.00
45-54 years	583	583	1,969	65,559	137,468	68,723	188	1	53.19
55-64 years	1,987	1,987	7,733	280,851	600,651	292,054	800	2	25.00
65-74 years	3,532	3,532	13,658	508,695	1,059,482	529,105	1,449	5	34.51
75+ years	5,857	5,857	23,452	856,658	1,746,462	887,004	2,428	7	28.83
With Concomitant Beta Blocker Use									
18-44 years	78	78	na	na	na	7,386	20	0	0.00
45-54 years	408	408	na	na	na	37,532	103	0	0.00
55-64 years	1,346	1,346	na	na	na	148,749	407	1	24.57
65-74 years	2,514	2,514	na	na	na	301,968	827	3	36.28
75+ years	4,180	4,180	na	na	na	495,049	1,355	6	44.28
With Concomitant Calcium Channel Blocker Use									
18-44 years	6	6	na	na	na	263	1	0	0.00
45-54 years	38	38	na	na	na	3,818	10	0	0.00
55-64 years	93	93	na	na	na	7,534	21	0	0.00
65-74 years	204	204	na	na	na	22,682	62	0	0.00
75+ years	337	337	na	na	na	30,708	84	1	119.05
With Concomitant Nitrates Use									
18-44 years	70	70	na	na	na	5,175	14	0	0.00
45-54 years	346	346	na	na	na	24,218	66	1	151.52
55-64 years	1,233	1,233	na	na	na	108,087	296	2	67.57
65-74 years	2,137	2,137	na	na	na	220,977	605	4	66.12
75+ years	3,869	3,869	na	na	na	416,362	1,140	4	35.09

Table 2: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Age Group among Individuals with a Pre-Existing Condition of Renal Disease

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (1,000 mg strength)									
Ranolazine With or Without Concomitant Use									
18-44 years	14	14	37	1,070	2,404	1,119	3	0	0.00
45-54 years	82	82	195	6,425	13,416	6,710	18	0	0.00
55-64 years	259	259	735	25,952	53,199	27,245	75	0	0.00
65-74 years	394	394	1,023	40,454	81,720	42,345	116	0	0.00
75+ years	392	392	955	37,260	73,894	38,693	106	1	94.34
With Concomitant Beta Blocker Use									
18-44 years	10	10	na	na	na	950	3	0	0.00
45-54 years	54	54	na	na	na	4,161	11	0	0.00
55-64 years	186	186	na	na	na	15,303	42	0	0.00
65-74 years	254	254	na	na	na	21,989	60	0	0.00
75+ years	261	261	na	na	na	21,175	58	1	172.41
With Concomitant Calcium Channel Blocker Use									
18-44 years	0	0	na	na	na	0	0	0	#DIV/0!
45-54 years	5	5	na	na	na	166	0	0	#DIV/0!
55-64 years	5	5	na	na	na	265	1	0	0.00
65-74 years	18	18	na	na	na	1,041	3	0	0.00
75+ years	18	18	na	na	na	934	3	0	0.00
With Concomitant Nitrates Use									
18-44 years	5	5	na	na	na	266	1	0	0.00
45-54 years	45	45	na	na	na	2,952	8	0	0.00
55-64 years	151	151	na	na	na	9,950	27	0	0.00
65-74 years	209	209	na	na	na	15,037	41	0	0.00
75+ years	222	222	na	na	na	18,634	51	1	196.08

* Years at Risk stop accumulating when first event during episode is encountered

Table 2: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Age Group among Individuals with a Pre-Existing Condition of Liver Impairment

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use									
18-44 years	136	136	408	13,174	27,097	13,958	38	0	0.00
45-54 years	525	525	1,775	61,689	129,554	64,596	177	0	0.00
55-64 years	1,073	1,073	4,004	141,157	298,937	147,510	404	0	0.00
65-74 years	1,056	1,056	3,494	127,140	263,019	132,734	363	2	55.10
75+ years	1,157	1,157	4,604	153,775	312,613	159,838	438	2	45.66
With Concomitant Beta Blocker Use									
18-44 years	85	85	na	na	na	6,395	18	0	0.00
45-54 years	366	366	na	na	na	35,487	97	0	0.00
55-64 years	727	727	na	na	na	77,029	211	0	0.00
65-74 years	718	718	na	na	na	76,319	209	0	0.00
75+ years	867	867	na	na	na	91,949	252	2	79.37
With Concomitant Calcium Channel Blocker Use									
18-44 years	12	12	na	na	na	1,285	4	0	0.00
45-54 years	31	31	na	na	na	3,048	8	0	0.00
55-64 years	58	58	na	na	na	5,827	16	0	0.00
65-74 years	67	67	na	na	na	5,845	16	0	0.00
75+ years	82	82	na	na	na	7,907	22	0	0.00
With Concomitant Nitrates Use									
18-44 years	63	63	na	na	na	3,990	11	0	0.00
45-54 years	286	286	na	na	na	19,017	52	0	0.00
55-64 years	625	625	na	na	na	47,172	129	0	0.00
65-74 years	590	590	na	na	na	49,216	135	2	148.15
75+ years	797	797	na	na	na	71,793	197	1	50.76

Table 2: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Age Group among Individuals with a Pre-Existing Condition of Liver Impairment

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (1,000 mg strength)									
Ranolazine With or Without Concomitant Use									
18-44 years	17	17	34	974	1,994	1,098	3	0	0.00
45-54 years	59	59	181	6,965	14,186	7,226	20	0	0.00
55-64 years	133	133	296	9,765	19,850	10,213	28	0	0.00
65-74 years	105	105	269	9,847	19,312	10,355	28	0	0.00
75+ years	71	71	199	7,077	14,762	7,300	20	1	500.00
With Concomitant Beta Blocker Use									
18-44 years	12	12	na	na	na	707	2	0	0.00
45-54 years	38	38	na	na	na	3,309	9	0	0.00
55-64 years	87	87	na	na	na	5,336	15	0	0.00
65-74 years	70	70	na	na	na	5,374	15	0	0.00
75+ years	44	44	na	na	na	4,396	12	1	833.33
With Concomitant Calcium Channel Blocker Use									
18-44 years	2	2	na	na	na	70	0	0	#DIV/0!
45-54 years	4	4	na	na	na	577	2	0	0.00
55-64 years	5	5	na	na	na	253	1	0	0.00
65-74 years	6	6	na	na	na	176	0	0	#DIV/0!
75+ years	6	6	na	na	na	178	0	1	#DIV/0!
With Concomitant Nitrates Use									
18-44 years	10	10	na	na	na	269	1	0	0.00
45-54 years	31	31	na	na	na	2,204	6	0	0.00
55-64 years	70	70	na	na	na	5,223	14	0	0.00
65-74 years	51	51	na	na	na	3,114	9	0	0.00
75+ years	47	47	na	na	na	4,216	12	0	0.00

* Years at Risk stop accumulating when first event during episode is encountered

Table 3: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Sex among all Individuals

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use									
Male	30,615	30,615	126,621	4,734,947	9,890,596	4,918,772	13,467	20	14.85
Female	18,639	18,639	73,185	2,608,926	5,366,731	2,715,265	7,434	12	16.14
Unknown	2	2	6	270	546	276	1	0	0.00
With Concomitant Beta Blocker Use									
Male	19,281	19,281	na	na	na	2,407,619	6,592	16	24.27
Female	11,397	11,397	na	na	na	1,291,137	3,535	7	19.80
Unknown	1	1	na	na	na	71	0	0	0.00
With Concomitant Calcium Channel Blocker Use									
Male	1,233	1,233	na	na	na	133,476	365	1	27.40
Female	1,243	1,243	na	na	na	134,651	369	0	0.00
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Nitrates Use									
Male	16,925	16,925	na	na	na	1,656,937	4,536	9	19.84
Female	9,928	9,928	na	na	na	913,060	2,500	9	36.00
Unknown	0	0	na	na	na	0	0	0	0.00
Ranolazine (1,000 mg strength)									
Ranolazine With or Without Concomitant Use									
Male	3,817	3,817	11,839	450,639	913,399	469,858	1,286	1	7.78
Female	1,799	1,799	5,146	188,693	380,918	196,923	539	3	55.66
Unknown	2	2	3	250	540	252	1	0	0.00
With Concomitant Beta Blocker Use									
Male	2,338	2,338	na	na	na	229,505	628	0	0.00
Female	1,054	1,054	na	na	na	92,058	252	2	79.37
Unknown	2	2	na	na	na	227	1	0	0.00

Table 3: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Sex among all Individuals

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
With Concomitant Calcium Channel Blocker Use									
Male	131	131	na	na	na	11,776	32	0	0.00
Female	102	102	na	na	na	7,005	19	1	526.32
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Nitrates Use									
Male	1,870	1,870	na	na	na	140,860	386	1	25.91
Female	848	848	na	na	na	62,233	170	1	58.82
Unknown	1	1	na	na	na	160	0	0	0.00

* Years at Risk stop accumulating when first event during episode is encountered

Table 3: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Sex among Individuals with a Pre-Existing Condition of Renal Disease

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use									
Male	7,684	7,684	30,516	1,136,088	2,367,254	1,179,501	3,229	7	21.68
Female	4,390	4,390	16,669	587,388	1,201,931	609,681	1,669	8	47.93
Unknown	1	1	3	210	420	212	1	0	0.00
With Concomitant Beta Blocker Use									
Male	5,406	5,406	na	na	na	638,007	1,747	5	28.62
Female	3,120	3,120	na	na	na	352,677	966	5	51.76
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Calcium Channel Blocker Use									
Male	378	378	na	na	na	34,089	93	1	107.53
Female	300	300	na	na	na	30,916	85	0	0.00
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Nitrates Use									
Male	4,887	4,887	na	na	na	508,871	1,393	4	28.72
Female	2,768	2,768	na	na	na	265,948	728	7	96.15
Unknown	0	0	na	na	na	0	0	0	0.00
Ranolazine (1,000 mg strength)									
Ranolazine With or Without Concomitant Use									
Male	805	805	1,983	74,285	150,351	77,909	213	0	0.00
Female	336	336	962	36,876	74,282	38,203	105	1	95.24
Unknown	0	0	0	0	0	0	0	0	0.00
With Concomitant Beta Blocker Use									
Male	550	550	na	na	na	45,559	125	0	0.00
Female	215	215	na	na	na	18,019	49	1	204.08
Unknown	0	0	na	na	na	0	0	0	0.00

Table 3: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Sex among Individuals with a Pre-Existing Condition of Renal Disease

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
With Concomitant Calcium Channel Blocker Use									
Male	26	26	na	na	na	1,516	4	0	0.00
Female	20	20	na	na	na	890	2	0	0.00
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Nitrates Use									
Male	434	434	na	na	na	30,583	84	0	0.00
Female	198	198	na	na	na	16,256	45	1	222.22
Unknown	0	0	na	na	na	0	0	0	0.00

* Years at Risk stop accumulating when first event during episode is encountered

Table 3: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Sex among Individuals with a Pre-Existing Condition of Liver Impairment

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
Ranolazine (500 mg strength)									
Ranolazine With or Without Concomitant Use									
Male	2,374	2,374	8,791	313,779	654,342	327,681	897	2	22.30
Female	1,573	1,573	5,494	183,156	376,879	190,955	523	2	38.24
Unknown	0	0	0	0	0	0	0	0	0.00
With Concomitant Beta Blocker Use									
Male	1,688	1,688	na	na	na	180,489	494	1	20.24
Female	1,075	1,075	na	na	na	106,690	292	1	34.25
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Calcium Channel Blocker Use									
Male	114	114	na	na	na	9,872	27	0	0.00
Female	136	136	na	na	na	14,040	38	0	0.00
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Nitrates Use									
Male	1,436	1,436	na	na	na	123,392	338	1	29.59
Female	925	925	na	na	na	67,796	186	2	107.53
Unknown	0	0	na	na	na	0	0	0	0.00
Ranolazine (1,000 mg strength)									
Ranolazine With or Without Concomitant Use									
Male	244	244	651	23,718	48,586	24,795	68	0	0.00
Female	141	141	328	10,910	21,518	11,397	31	1	322.58
Unknown	0	0	0	0	0	0	0	0	0.00
With Concomitant Beta Blocker Use									
Male	161	161	na	na	na	13,266	36	0	0.00
Female	90	90	na	na	na	5,856	16	1	625.00
Unknown	0	0	na	na	na	0	0	0	0.00

Table 3: Incident Ranolazine Use with Either Concomitant Beta Blocker, Calcium Channel Blocker, or Nitrate Use and Seizures in the Sentinel Distributed Database (SDD) between January 1, 2006 and September 30, 2015, by Strength of Ranolazine, Concomitant Exposure, and Sex among Individuals with a Pre-Existing Condition of Liver Impairment

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Episode Duration	Years at Risk*	Episodes with Events	Episodes with Events per 10K Years at Risk*
With Concomitant Calcium Channel Blocker Use									
Male	11	11	na	na	na	860	2	0	0.00
Female	12	12	na	na	na	394	1	1	10000.00
Unknown	0	0	na	na	na	0	0	0	0.00
With Concomitant Nitrates Use									
Male	137	137	na	na	na	10,529	29	0	0.00
Female	72	72	na	na	na	4,497	12	0	0.00
Unknown	0	0	na	na	na	0	0	0	0.00

* Years at Risk stop accumulating when first event during episode is encountered

Appendix A: Latest Date of Available Data for Each Data Partner up to Request End Date (9/30/2015)

DP ID	End Date
DP0001	9/30/2015
DP0002	9/30/2015
DP0003	6/30/2015
DP0004	9/30/2015
DP0005	9/30/2015
DP0006	9/30/2015
DP0007	6/30/2015
DP0008	9/30/2015
DP0009	9/30/2015
DP0010	9/30/2015
DP0011	5/31/2015
DP0012	2/28/2015
DP0013	12/31/2014
DP0014	9/30/2015
DP0015	9/30/2015
DP0016	6/30/2012

Appendix B. List of Codes Used to Define Events in this Request

Description	Code	Code Type
Seizures		
Epilepsy and recurrent seizures	345	ICD-9-CM Diagnosis
Epilepsy and recurrent seizures	345*	ICD-9-CM Diagnosis
Epilepsy and recurrent seizures	345**	ICD-9-CM Diagnosis
Convulsions	780.3	ICD-9-CM Diagnosis
Convulsions	780.3*	ICD-9-CM Diagnosis
Myoclonus	333.2	ICD-9-CM Diagnosis

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

Generic Name	Brand Name	Form	Route
1,000 MG Ranolazine			
RANOLAZINE	Ranexa	tablet extended release 12 hr	oral
500 MG Ranolazine			
RANOLAZINE	Ranexa	tablet extended release 12 hr	oral
Beta Blockers			
ACEBUTOLOL HCL	ACEBUTOLOL HCL	CAPSULE	ORAL
ACEBUTOLOL HCL	SECTRAL	CAPSULE	ORAL
ATENOLOL	ATENOLOL	TABLET	ORAL
ATENOLOL	TENORMIN	TABLET	ORAL
ATENOLOL/CHLORTHALIDONE	ATENOLOL-CHLORTHALIDONE	TABLET	ORAL
ATENOLOL/CHLORTHALIDONE	TENORETIC 50	TABLET	ORAL
ATENOLOL/CHLORTHALIDONE	TENORETIC 100	TABLET	ORAL
BETAXOLOL HCL	BETAXOLOL HCL	TABLET	ORAL
BETAXOLOL HCL	KERLONE	TABLET	ORAL
BISOPROLOL FUMARATE	BISOPROLOL FUMARATE	TABLET	ORAL
BISOPROLOL FUMARATE	ZEBETA	TABLET	ORAL
BISOPROLOL FUMARATE/HYDROCHLOROTHIAZIDE	BISOPROLOL-HYDROCHLOROTHIAZIDE	TABLET	ORAL
BISOPROLOL FUMARATE/HYDROCHLOROTHIAZIDE	ZIAC	TABLET	ORAL
BISOPROLOL FUMARATE/HYDROCHLOROTHIAZIDE	BISOPROLOL FUMARATE-HCTZ	TABLET	ORAL
CARVEDILOL	COREG	TABLET	ORAL
CARVEDILOL	CARVEDILOL	TABLET	ORAL
CARVEDILOL PHOSPHATE	COREG CR	CAPSULE,EXTENDED RELEASE MULTIPHASE 24H	ORAL
LABETALOL HCL	LABETALOL HCL	TABLET	ORAL
LABETALOL HCL	TRANDATE	TABLET	ORAL
LABETALOL HCL	NORMODYNE	TABLET	ORAL
METOPROLOL SUCCINATE	METOPROLOL SUCCINATE	TABLET, EXTENDED RELEASE 24 HR	ORAL
METOPROLOL SUCCINATE	TOPROL XL	TABLET, EXTENDED RELEASE 24 HR	ORAL
METOPROLOL SUCCINATE/HYDROCHLOROTHIAZIDE	DUTOPROL	TABLET, EXTENDED RELEASE 24 HR	ORAL
METOPROLOL TARTRATE	METOPROLOL TARTRATE	TABLET	ORAL
METOPROLOL TARTRATE	LOPRESSOR	TABLET	ORAL
METOPROLOL TARTRATE/DIETARY SUPPLEMENT,COMB.10	HYPERTENSOLOL	COMBINATION PACKAGE (EA)	ORAL
METOPROLOL TARTRATE/HYDROCHLOROTHIAZIDE	METOPROLOL-HYDROCHLOROTHIAZIDE	TABLET	ORAL

METOPROLOL TARTRATE/HYDROCHLOROTHIAZIDE	LOPRESSOR HCT	TABLET	ORAL
NADOLOL	NADOLOL	TABLET	ORAL
NADOLOL	CORGARD	TABLET	ORAL
NADOLOL/BENDROFLUMETHIAZIDE	NADOLOL-BENDROFLUMETHIAZIDE	TABLET	ORAL
NADOLOL/BENDROFLUMETHIAZIDE	CORZIDE	TABLET	ORAL
NEBIVOLOL HCL	BYSTOLIC	TABLET	ORAL
PENBUTOLOL SULFATE	LEVATOL	TABLET	ORAL
PINDOLOL	PINDOLOL	TABLET	ORAL
PROPRANOLOL HCL	PROPRANOLOL HCL	SOLUTION, ORAL	ORAL
PROPRANOLOL HCL	PROPRANOLOL HCL ER	CAPSULE, EXTENDED RELEASE 24HR	ORAL
PROPRANOLOL HCL	PROPRANOLOL HCL	TABLET	ORAL
PROPRANOLOL HCL	INNOPRAN XL	CAPSULE, EXT RELEASE 24 HR	ORAL
PROPRANOLOL HCL	INDERAL LA	CAPSULE, EXTENDED RELEASE 24HR	ORAL
PROPRANOLOL HCL	HEMANGEOL	SOLUTION, ORAL	ORAL
PROPRANOLOL HCL	INDERAL XL	CAPSULE, EXT RELEASE 24 HR	ORAL
PROPRANOLOL HCL	INDERAL	TABLET	ORAL
PROPRANOLOL HCL	PROPRANOLOL HCL	CAPSULE, EXTENDED RELEASE 24HR	ORAL
PROPRANOLOL HCL/HYDROCHLOROTHIAZIDE	PROPRANOLOL-HYDROCHLOROTHIAZID	TABLET	ORAL
PROPRANOLOL HCL/HYDROCHLOROTHIAZIDE	PROPRANOLOL HCL W/HCTZ	TABLET	ORAL
PROPRANOLOL HCL/HYDROCHLOROTHIAZIDE	PROPRANOLOL HCL-HCTZ	TABLET	ORAL
PROPRANOLOL HCL/HYDROCHLOROTHIAZIDE	INDERIDE-40/25	TABLET	ORAL
PROPRANOLOL HCL/HYDROCHLOROTHIAZIDE	INDERIDE-80/25	TABLET	ORAL
SOTALOL HCL	SOTALOL	TABLET	ORAL
SOTALOL HCL	SORINE	TABLET	ORAL
SOTALOL HCL	SOTALOL AF	TABLET	ORAL
SOTALOL HCL	SOTYLIZE	SOLUTION, ORAL	ORAL
SOTALOL HCL	BETAPACE	TABLET	ORAL
SOTALOL HCL	BETAPACE AF	TABLET	ORAL
TIMOLOL MALEATE	TIMOLOL MALEATE	TABLET	ORAL
Calcium Channel Blockers			
NICARDIPINE HCL	Cardene SR	capsule, extended release	oral
NICARDIPINE HCL	Cardene	capsule	oral
VERAPAMIL HCL	Calan	tablet	oral
VERAPAMIL HCL	Calan SR	tablet extended release	oral
VERAPAMIL HCL	Covera-HS	tablet extended release 24hr	oral
VERAPAMIL HCL	Isoptin SR	tablet extended release	oral
DILTIAZEM HCL	Cardizem LA	tablet extended release 24 hr	oral
DILTIAZEM HCL	Cardizem	tablet	oral

DILTIAZEM HCL	Cardizem CD	capsule,extended release 24hr	oral
VERAPAMIL HCL	Verelan	capsule,ext rel. pellets 24 hr	oral
VERAPAMIL HCL	Verelan PM	capsule, 24 hr ER pellet CT	oral
DILTIAZEM HCL	diltiazem HCl	tablet	oral
NICARDIPINE HCL	nicardipine	capsule	oral
VERAPAMIL HCL	verapamil	tablet extended release	oral
DILTIAZEM HCL	diltiazem HCl	capsule,extended release 24hr	oral
VERAPAMIL HCL	verapamil	tablet	oral
DILTIAZEM HCL	Tiazac	capsule, extended release	oral
DILTIAZEM HCL	diltiazem HCl	capsule, extended release	oral
DILTIAZEM HCL	diltiazem HCl	capsule,ext release degradable	oral
DILTIAZEM HCL	diltiazem HCl	capsule,extended release 12 hr	oral
VERAPAMIL HCL	verapamil	capsule, 24 hr ER pellet CT	oral
VERAPAMIL HCL	verapamil	capsule,ext rel. pellets 24 hr	oral
DILTIAZEM HCL	Cartia XT	capsule,extended release 24hr	oral
DILTIAZEM HCL	Diltia XT	capsule,ext release degradable	oral
DILTIAZEM HCL	Dilacor XR	capsule,ext release degradable	oral
DILTIAZEM HCL	Matzim LA	tablet extended release 24 hr	oral
DILTIAZEM HCL	DILT-XR	capsule,ext release degradable	oral
DILTIAZEM HCL	DILT-CD	capsule,extended release 24hr	oral
DILTIAZEM HCL	Diltzac ER	capsule, extended release	oral
DILTIAZEM HCL	Taztia XT	capsule, extended release	oral
DILTIAZEM HCL	diltiazem HCl	tablet extended release 24 hr	oral
Nitrates			
AMYL NITRITE	AMYL NITRITE	AMPUL (ML)	INHALATION
AMYL NITRITE	AMYL NITRITE	AMPUL (EA)	INHALATION
GLYCERYL DISTEARATE	GLYCERYL DISTEARATE	POWDER (GRAM)	MISCELLANEOUS
GLYCERYL MONOSTEARATE	GLYCERYL MONOSTEARATE	FLAKES (GRAM)	MISCELLANEOUS
GLYCERYL MONOSTEARATE	GLYCERYL MONOSTEARATE	POWDER (GRAM)	MISCELLANEOUS
GLYCERYL OLEATE	GLYCEROL MONOOLEATE	PASTE (GRAM)	MISCELLANEOUS
ISOSORBIDE	ISOSORBIDE	POWDER (GRAM)	MISCELLANEOUS
ISOSORBIDE DINITRATE	ISORDIL	TABLET, SUBLINGUAL	SUBLINGUAL
ISOSORBIDE DINITRATE	ISORDIL	TABLET	ORAL
ISOSORBIDE DINITRATE	DILATRATE-SR	CAPSULE, EXTENDED RELEASE	ORAL
ISOSORBIDE DINITRATE	ISOSORBIDE DINITRATE	TABLET, SUBLINGUAL	SUBLINGUAL
ISOSORBIDE DINITRATE	ISOSORBIDE DINITRATE	TABLET	ORAL
ISOSORBIDE DINITRATE	ISOSORBIDE DINITRATE	TABLET, EXTENDED RELEASE	ORAL

ISOSORBIDE DINITRATE	ISORDIL TITRADOSE	TABLET	ORAL
ISOSORBIDE DINITRATE	SORBITRATE	TABLET	ORAL
ISOSORBIDE DINITRATE	SORBITRATE	TABLET, CHEWABLE	ORAL
ISOSORBIDE DINITRATE	ISOCHRON	TABLET, EXTENDED RELEASE	ORAL
ISOSORBIDE DINITRATE	ISODITRATE	TABLET, EXTENDED RELEASE	ORAL
ISOSORBIDE DINITRATE/HYDRALAZINE HCL	BIDIL	TABLET	ORAL
ISOSORBIDE MONONITRATE	ISMO	TABLET	ORAL
ISOSORBIDE MONONITRATE	IMDUR	TABLET, EXTENDED RELEASE 24 HR	ORAL
ISOSORBIDE MONONITRATE	MONOKET	TABLET	ORAL
ISOSORBIDE MONONITRATE	ISOSORBIDE MONONITRATE	TABLET	ORAL
ISOSORBIDE MONONITRATE	ISOSORBIDE MONONITRATE ER	TABLET, EXTENDED RELEASE 24 HR	ORAL
ISOSORBIDE MONONITRATE	ISOSORBIDE MONONITRATE	TABLET, EXTENDED RELEASE 24 HR	ORAL
ISOSORBIDE MONONITRATE	ISOTRATE ER	TABLET, EXTENDED RELEASE 24 HR	ORAL
NITROGLYCERIN	NTG	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITROSTAT	TABLET, SUBLINGUAL	SUBLINGUAL
NITROGLYCERIN	TRANSDERM-NITRO	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITRO-DUR	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITRO-BID	OINTMENT (GRAM)	TRANSDERMAL
NITROGLYCERIN	MINITRAN	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITROGLYCERIN PATCH	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	DEPONIT	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITROGLYCERIN	OINTMENT (GRAM)	TRANSDERMAL
NITROGLYCERIN	NITROGLYCERIN	CAPSULE, EXTENDED RELEASE	ORAL
NITROGLYCERIN	NITRO TRANSDERM	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITRO-TRANS SYSTEM	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITROL	OINTMENT (GRAM)	TRANSDERMAL
NITROGLYCERIN	NITROGLYCERIN	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITROGARD	TABLET, BUCCAL SUSTAINED ACTION	BUCCAL
NITROGLYCERIN	NITROCOT	CAPSULE, EXTENDED RELEASE	ORAL
NITROGLYCERIN	NITROGLYN	CAPSULE, EXTENDED RELEASE	ORAL
NITROGLYCERIN	NITROGLYCERIN	TABLET, SUBLINGUAL	SUBLINGUAL
NITROGLYCERIN	NITROLINGUAL	SPRAY, NON-AEROSOL (GRAM)	TRANSLINGUAL
NITROGLYCERIN	NITROMIST	AEROSOL, SPRAY (GRAM)	TRANSLINGUAL
NITROGLYCERIN	RECTIV	OINTMENT (GRAM)	RECTAL
NITROGLYCERIN	NITROGLYCERIN	AEROSOL, SPRAY (GRAM)	TRANSLINGUAL
NITROGLYCERIN	NITROGLYCERIN	SPRAY, NON-AEROSOL (GRAM)	TRANSLINGUAL
NITROGLYCERIN	NITRO-TIME	CAPSULE, EXTENDED RELEASE	ORAL
NITROGLYCERIN	NITROTAB	TABLET, SUBLINGUAL	SUBLINGUAL

NITROGLYCERIN	NITRODISC	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
NITROGLYCERIN	NITROLINGUAL	AEROSOL, SPRAY (GRAM)	TRANSLINGUAL
NITROGLYCERIN	NITROQUICK	TABLET, SUBLINGUAL	SUBLINGUAL
NITROGLYCERIN	NITREK	PATCH, TRANSDERMAL 24 HOURS	TRANSDERMAL
PEG 100 STEARATE/GLYCERYL MONOSTEARATE	ARLACEL 165	FLAKES (GRAM)	MISCELLANEOUS

Appendix D. List of Codes Used to Define Pre-existing Conditions in this Request

Description	Code	Code Type
Renal Disease		
Chronic glomerulonephritis	582	ICD-9-CM Diagnosis
Chronic glomerulonephritis	582*	ICD-9-CM Diagnosis
Chronic glomerulonephritis	582**	ICD-9-CM Diagnosis
Nephritis and nephropathy not specified as acute or chronic	583	ICD-9-CM Diagnosis
Nephritis and nephropathy not specified as acute or chronic	583*	ICD-9-CM Diagnosis
Nephritis and nephropathy not specified as acute or chronic	583**	ICD-9-CM Diagnosis
Chronic kidney disease, Stage I	5851	ICD-9-CM Diagnosis
Chronic kidney disease, Stage I	5851*	ICD-9-CM Diagnosis
Chronic kidney disease, Stage II (mild)	5852	ICD-9-CM Diagnosis
Chronic kidney disease, Stage II (mild)	5852*	ICD-9-CM Diagnosis
Chronic kidney disease, Stage III (moderate)	5853	ICD-9-CM Diagnosis
Chronic kidney disease, Stage III (moderate)	5853*	ICD-9-CM Diagnosis
Chronic kidney disease, Stage IV (severe)	5854	ICD-9-CM Diagnosis
Chronic kidney disease, Stage IV (severe)	5854*	ICD-9-CM Diagnosis
Chronic kidney disease, Stage V	5855	ICD-9-CM Diagnosis
Chronic kidney disease, Stage V	5855*	ICD-9-CM Diagnosis
Chronic kidney disease, unspecified	5859	ICD-9-CM Diagnosis
Chronic kidney disease, unspecified	5859*	ICD-9-CM Diagnosis
Renal failure, unspecified	586	ICD-9-CM Diagnosis
Renal failure, unspecified	586*	ICD-9-CM Diagnosis
Renal failure, unspecified	586**	ICD-9-CM Diagnosis
Disorders resulting from impaired renal function	588	ICD-9-CM Diagnosis
Disorders resulting from impaired renal function	588*	ICD-9-CM Diagnosis
Disorders resulting from impaired renal function	588**	ICD-9-CM Diagnosis
NS W LESION PROLIF GN	5810	ICD-9-CM Diagnosis
EPIMEMBRANOUS NEPHRITIS	5811	ICD-9-CM Diagnosis
MEMBRANOPROLIF NEPHROSIS	5812	ICD-9-CM Diagnosis
MINIMAL CHANGE NEPHROSIS	5813	ICD-9-CM Diagnosis
NEPHROTIC SYND IN DCE	58181	ICD-9-CM Diagnosis

NEPHROTIC SYNDROME NEC	58189	ICD-9-CM Diagnosis
NEPHROTIC SYNDROME NOS	5819	ICD-9-CM Diagnosis
RENAL SCLEROSIS NOS	587	ICD-9-CM Diagnosis
ESRD	5856	ICD-9-CM Diagnosis
CHRONIC KIDNEY DIS NOS	5859	ICD-9-CM Diagnosis
KIDNEY TRANSPLANT STATUS	V420	ICD-9-CM Diagnosis
RENAL DIALYSIS STATUS	V451	ICD-9-CM Diagnosis
DIALYSIS STATUS	V4511	ICD-9-CM Diagnosis
DIALYSIS NONCOMPLIANCE	V4512	ICD-9-CM Diagnosis
RENAL DIALYSIS ENCOUNTER	V560	ICD-9-CM Diagnosis
FIT EXTRACORP RD CATH	V561	ICD-9-CM Diagnosis
FIT PERITONEAL RD CATH	V562	ICD-9-CM Diagnosis
HEMODIALYS ADEQUACY TEST	V5631	ICD-9-CM Diagnosis
PD ADEQUACY TESTING	V5632	ICD-9-CM Diagnosis
DIALYSIS ENCOUNTER NEC	V568	ICD-9-CM Diagnosis
NEPHROPTOSIS	5930	ICD-9-CM Diagnosis
KIDNEY HYPERTROPHY	5931	ICD-9-CM Diagnosis
ACQUIRED KIDNEY CYST	5932	ICD-9-CM Diagnosis
RENAL VASCULAR DISORDER	59381	ICD-9-CM Diagnosis
RENAL/URETER DISORD NEC	59389	ICD-9-CM Diagnosis
RENAL/URETER DISORD NOS	5939	ICD-9-CM Diagnosis
Acute glomerulonephritis	580	ICD-9-CM Diagnosis
Acute glomerulonephritis	580*	ICD-9-CM Diagnosis
Acute glomerulonephritis	580**	ICD-9-CM Diagnosis
Acute kidney failure	584	ICD-9-CM Diagnosis
Acute kidney failure	584*	ICD-9-CM Diagnosis
Unspecified renal disease in pregnancy without mention of hypertens	6462	ICD-9-CM Diagnosis
Unspecified renal disease in pregnancy without mention of hypertens	6462*	ICD-9-CM Diagnosis
VENOUS CATHETERIZATION FOR RENAL DIALYSIS	3895	ICD-9-CM Procedure
ARTERIOVENOSTOMY FOR RENAL DIALYSIS	3927	ICD-9-CM Procedure
REVISION OF ARTERIOVENOUS SHUNT RENAL DIALYSIS	3942	ICD-9-CM Procedure
REMOVAL OF ARTERIOVENOUS SHUNT RENAL DIALYSIS	3943	ICD-9-CM Procedure
HEMODIALYSIS	3995	ICD-9-CM Procedure
PERITONEAL DIALYSIS	5498	ICD-9-CM Procedure

HEMODIALYSIS PLAN OF CARE DOCUMENTED	0505F	CPT Procedure
PERITONEAL DIALYSIS PLAN DOCUMENTED	0507F	CPT Procedure
HEMODIALYSIS VIA FUNCTIONING AVGRAFT	4053F	CPT Procedure
HEMODIALYSIS VIA CATHETER	4054F	CPT Procedure
PATIENT RECEIVING PERITONEAL DIALYSIS	4055F	CPT Procedure
HEPB VACCINE DIALYSIS/IMMUNSUP PAT 3 DOSE IM	90740	CPT Procedure
HEPB VACCINE DIALYSIS/IMMUNSUP PAT 4 DOSE IM	90747	CPT Procedure
HEMODIALYSIS PROCEDURE W/ PHYS/QHP EVALUATION	90935	CPT Procedure
HEMODIALYSIS PX REPEAT EVAL W/WO REVJ DIALYS RX	90937	CPT Procedure
HEMODIALYSIS ACCESS FLOW STUDY	90940	CPT Procedure
DIALYSIS OTHER/THAN HEMODIALYSIS 1 PHYS/QHP EVAL	90945	CPT Procedure
DIALYSIS OTH/THN HEMODIALY REPEAT PHYS/QHP EVALS	90947	CPT Procedure
ESRD SVC HOME DIALYSIS FULL MONTH <2YR OLD	90963	CPT Procedure
ESRD SVC HOME DIALYSIS FULL MONTH 2-11 YR OLD	90964	CPT Procedure
ESRD SVC HOME DIALYSIS FULL MONTH 12-19 YR OLD	90965	CPT Procedure
ESRD SVC HOME DIALYSIS FULL MONTH 20 YR OLD	90966	CPT Procedure
DIALYSIS TRAINING PATIENT COMPLETED COURSE	90989	CPT Procedure
DIALYSIS TRAINING PATIENT PER TRAINING SESSION	90993	CPT Procedure
UNLISTED DIALYSIS PROCEDURE INPATIENT/OUTPATIENT	90999	CPT Procedure
DUPLEX SCAN HEMODIALYSIS ACCESS	93990	CPT Procedure
HOME VISIT HEMODIALYSIS	99512	CPT Procedure
HOME INFUSION OF PERITONEAL DIALYSIS PER VISIT	99559	CPT Procedure
PERITON DIALYSIS CATHETER ANCHR DEVICE BELT EA	A4653	HCPCS Procedure
DISPBL CYCLER SET USED W/CYCLER DIALYSIS MACH EA	A4671	HCPCS Procedure
DRAINAGE EXTENSION LINE STERILE DIALYSIS EACH	A4672	HCPCS Procedure
EXT LINE W/EASY LOCK CONNECTORS USED W/DIALYSIS	A4673	HCPCS Procedure
ACTIVATED CARBON FILTER FOR HEMODIALYSIS EACH	A4680	HCPCS Procedure
DIALYZER ALL TYPES ALL SIZES HEMODIALYSIS EACH	A4690	HCPCS Procedure
TREATED WATER FOR PERITONEAL DIALYSIS PER GALLON	A4714	HCPCS Procedure
Y SET TUBING FOR PERITONEAL DIALYSIS	A4719	HCPCS Procedure
FISTULA CANNULATION SET FOR HEMODIALYSIS EACH	A4730	HCPCS Procedure
TOPICAL ANESTHETIC FOR DIALYSIS PER G	A4736	HCPCS Procedure
INJECTABLE ANESTHETIC FOR DIALYSIS PER 10 ML	A4737	HCPCS Procedure
SHUNT ACCESSORY HEMODIALYSIS ANY TYPE EACH	A4740	HCPCS Procedure

BLOOD TUBING ARTERIAL/VENOUS HEMODIALYSIS EACH	A4750	HCPCS Procedure
BLOOD TUBING ART&VENOUS COMBINED HEMODIALYSIS EA	A4755	HCPCS Procedure
DIALYSATE SOL TST KIT PERITON DIALYSIS TYPE EA	A4760	HCPCS Procedure
DIALYSATE CONC POWDER ADD PERITON DIALYSIS-PCKET	A4765	HCPCS Procedure
DIALYSATE CONC SOL ADD PERITON DIALYSIS-10 ML	A4766	HCPCS Procedure
BLOOD COLLECTION TUBE VACUUM FOR DIALYSIS PER 50	A4770	HCPCS Procedure
SERUM CLOTTING TIME TUBE FOR DIALYSIS PER 50	A4771	HCPCS Procedure
BLOOD GLUCOSE TEST STRIPS FOR DIALYSIS PER 50	A4772	HCPCS Procedure
OCCULT BLOOD TEST STRIPS FOR DIALYSIS PER 50	A4773	HCPCS Procedure
AMMONIA TEST STRIPS FOR DIALYSIS PER 50	A4774	HCPCS Procedure
STERILIZING AGENT DIALYSIS EQUIPMENT PER GALLON	A4780	HCPCS Procedure
HEPARIN ANY TYPE FOR HEMODIALYSIS PER 1000 UNITS	A4801	HCPCS Procedure
PROTAMINE SULFATE FOR HEMODIALYSIS PER 50 MG	A4802	HCPCS Procedure
DISPBL CATHETER TIPS PERITONEAL DIALYSIS PER 10	A4860	HCPCS Procedure
STORAGE TANK W/WATER PURIFY REPLCE DIALYSIS TANK	A4880	HCPCS Procedure
CONT AMB PERITONEAL DIALYSIS SUPPLY KIT	A4900	HCPCS Procedure
CONT CYCLING PERITONEAL DIALYSIS SUPPLY KIT	A4901	HCPCS Procedure
INTERMITTENT PERITONEAL DIALYSIS SUPPLY KIT	A4905	HCPCS Procedure
NON-MEDICAL SUPPLIES DIALYSIS	A4910	HCPCS Procedure
DRAIN BAG/BOTTLE FOR DIALYSIS EACH	A4911	HCPCS Procedure
MISCELLANEOUS DIALYSIS SUPPLIES NOS	A4913	HCPCS Procedure
VENOUS PRESSURE CLAMP FOR HEMODIALYSIS EACH	A4918	HCPCS Procedure
TOURNIQUET FOR DIALYSIS EACH	A4929	HCPCS Procedure
CATH DIALYSIS VAXCEL CHRONIC DIALYSIS CATH	C1037	HCPCS Procedure
ACCESS SYST DIALYSIS LIFESITE ACCESS SYST	C1152	HCPCS Procedure
CATHETER HEMODIALYSIS SHORT-TERM	C1752	HCPCS Procedure
DIALYSIS ACCESS SYSTEM	C1881	HCPCS Procedure
CENTRIFUGE FOR DIALYSIS	E1500	HCPCS Procedure
HEPARIN INFUSION PUMP FOR HEMODIALYSIS	E1520	HCPCS Procedure
AIR BUBBLE DETECTOR HEMODIALYSIS EA REPLACEMENT	E1530	HCPCS Procedure
PRESSURE ALARM FOR HEMODIALYSIS EACH REPLACEMENT	E1540	HCPCS Procedure
BATH CONDUCTIVITY METER FOR HEMODIALYSIS EACH	E1550	HCPCS Procedure
BLOOD LEAK DETECTOR HEMODIALYSIS EA REPLACEMENT	E1560	HCPCS Procedure
UNIPUNCTURE CONTROL SYSTEM FOR HEMODIALYSIS	E1580	HCPCS Procedure

HEMODIALYSIS MACHINE	E1590	HCPCS Procedure
AUTO INTERMITTENT PERITONEAL DIALYSIS SYSTEM	E1592	HCPCS Procedure
CYCLER DIALYSIS MACHINE FOR PERITONEAL DIALYSIS	E1594	HCPCS Procedure
DEIONIZER WATER PURIFICATION SYSTEM HEMODIALYSIS	E1615	HCPCS Procedure
BLOOD PUMP FOR HEMODIALYSIS REPLACEMENT	E1620	HCPCS Procedure
WATER SOFTENING SYSTEM FOR HEMODIALYSIS	E1625	HCPCS Procedure
RECIPROCATING PERITONEAL DIALYSIS SYSTEM	E1630	HCPCS Procedure
PERITONEAL DIALYSIS CLAMPS EACH	E1634	HCPCS Procedure
SORBENT CARTRIDGES FOR HEMODIALYSIS PER 10	E1636	HCPCS Procedure
HEATING PAD PERITONEAL DIALYSIS ANY SIZE EACH	E1638	HCPCS Procedure
REPLACE COMPONENT HEMO/PERITONEALDIALYSIS PT OWN	E1640	HCPCS Procedure
DIALYSIS EQUIPMENT NOT OTHERWISE SPECIFIED	E1699	HCPCS Procedure
UNSCHD/EMERG DIALYSIS TX ESRD PT HOS OP NOT CERT	G0257	HCPCS Procedure
ESRD REL SRVC HOM DIALYSIS FULL MO; UND 2 YR AGE	G0320	HCPCS Procedure
ESRD REL SRVC HOM DIALYSIS FULL MO; 2-11 YRS AGE	G0321	HCPCS Procedure
ESRD REL SRVC HOM DIALYSIS FULL MO; 12-19 YR AGE	G0322	HCPCS Procedure
ESRD REL SRVC HOM DIALYSIS FULL MO; 20 YRS&OLDER	G0323	HCPCS Procedure
ESRD REL SERVICE HOME DIALYSIS PER DAY; PT <2 YR	G0324	HCPCS Procedure
ESRD REL SERV HOME DIALYSIS PER DAY; PT 2-11 YRS	G0325	HCPCS Procedure
ERSD REL SERV HOME DIALYSIS PER DAY; PT 12-19 YR	G0326	HCPCS Procedure
ESRD REL SERV HOME DIALYSIS PER DAY; PT 20 YR >	G0327	HCPCS Procedure
VESSEL MAPPING OF VESSELS FOR HEMODIALYSIS ACESS	G0365	HCPCS Procedure
ESRD PT W/DOC DIALYSIS DOSE OF URR >/= TO 65%	G8075	HCPCS Procedure
ESRD PT W/DOC DIALYSIS DOSE OF URR < 65%	G8076	HCPCS Procedure
DEVELOPED POSTOP RENAL FAILURE/REQ DIALYSIS	G8575	HCPCS Procedure
NO POSTOP RENAL FAILURE/DIALYSIS NOT REQUIRED	G8576	HCPCS Procedure
HEMODIALYSIS TX PERF EXACTLY 3X PR WEEK >90 DAYS	G8714	HCPCS Procedure
PT RECV MAINT HEMODIALYSIS IN O/P DIALYSIS FAC	G8956	HCPCS Procedure
DOC ESRD DIALYSIS RENAL TRANSPLANT OR PREGNANCY	G9231	HCPCS Procedure
PT DISCONTINUED HEMODIALYSIS/PERITONEAL DIALYSIS	G9523	HCPCS Procedure
INJ DARBEPOETIN ALFA 1 MCG FOR ESRD DIALYSIS	J0882	HCPCS Procedure
INJ EPOETIN ALFA 1000 UNITS FOR ESRD DIALYSIS	J0886	HCPCS Procedure
PERITONEAL DIALYSIS CLAMPS EACH	K0610	HCPCS Procedure
DISPBL CYCLER SET USED W/CYCLER DIALYSIS MACH EA	K0611	HCPCS Procedure

DRAINAGE EXTENSION LINE STERILE DIALYSIS EACH	K0612	HCPCS Procedure
EXT LINE W/EASY LOCK CONNECTORS USED W/DIALYSIS	K0613	HCPCS Procedure
CHEM/ANTISEPTICS SOL CLEAN/STERILZE DIALYSIS EQP	K0614	HCPCS Procedure
INJ DARBEPOETIN ALFA 1 MCG ERSD ON DIALYSIS	Q4054	HCPCS Procedure
INJECTION EPOETIN ALFA 1000 U ERSD ON DIALYSIS	Q4055	HCPCS Procedure
INJ EPOETIN ALFA 100 UNITS FOR ESRD ON DIALYSIS	Q4081	HCPCS Procedure
DIALYSIS/STRESS VITAMIN SUPL ORAL 100 CAPSULES	S0194	HCPCS Procedure
HOME THERAPY; PERITONEAL DIALYSIS PER DIEM	S9339	HCPCS Procedure
Liver Impairment		
Esophageal varices with bleeding	4560	ICD-9-CM Diagnosis
Esophageal varices with bleeding	4560*	ICD-9-CM Diagnosis
Esophageal varices without mention of bleeding	4561	ICD-9-CM Diagnosis
Esophageal varices without mention of bleeding	4561*	ICD-9-CM Diagnosis
Esophageal varices in diseases classified elsewhere	4562	ICD-9-CM Diagnosis
Esophageal varices in diseases classified elsewhere	4562*	ICD-9-CM Diagnosis
Hepatic encephalopathy	5722	ICD-9-CM Diagnosis
Hepatic encephalopathy	5722*	ICD-9-CM Diagnosis
Portal hypertension	5723	ICD-9-CM Diagnosis
Portal hypertension	5723*	ICD-9-CM Diagnosis
Hepatorenal syndrome	5724	ICD-9-CM Diagnosis
Hepatorenal syndrome	5724*	ICD-9-CM Diagnosis
Other sequelae of chronic liver disease	5728	ICD-9-CM Diagnosis
Other sequelae of chronic liver disease	5728*	ICD-9-CM Diagnosis
ALCOHOLIC FATTY LIVER	5710	ICD-9-CM Diagnosis
AC ALCOHOLIC HEPATITIS	5711	ICD-9-CM Diagnosis
ALCOHOL LIVER CIRRHOSIS	5712	ICD-9-CM Diagnosis
ALCOHOL LIVER DAMAGE NOS	5713	ICD-9-CM Diagnosis
LIVER CIRRHOSIS W/O ALC	5715	ICD-9-CM Diagnosis
LIVER ABSCESS	5720	ICD-9-CM Diagnosis
PORTAL PYEMIA	5721	ICD-9-CM Diagnosis
HEPATOPULMONARY SYNDROME	5735	ICD-9-CM Diagnosis
ASCITES	7895	ICD-9-CM Diagnosis
ASCITES NEC	78959	ICD-9-CM Diagnosis

CUTE LIVER NECROSIS	570A	ICD-9-CM Diagnosis
BILIARY CIRRHOSIS	5716	ICD-9-CM Diagnosis
CHRONIC LIVER DIS NEC	5718	ICD-9-CM Diagnosis
CHRONIC LIVER DIS NOS	5719	ICD-9-CM Diagnosis
CHR PASS CONGEST LIVER	5730	ICD-9-CM Diagnosis
HEPATIC INFARCTION	5734	ICD-9-CM Diagnosis
LIVER DISORDERS NEC	5738	ICD-9-CM Diagnosis
LIVER DISORDER NOS	5739	ICD-9-CM Diagnosis
JAUNDICE NOS	7824	ICD-9-CM Diagnosis
HEPATOMEGALY	7891	ICD-9-CM Diagnosis
ELEVAT TRANSAMINASE/LDH	7904	ICD-9-CM Diagnosis
ABN SERUM ENZYME LEV NEC	7905	ICD-9-CM Diagnosis
ABN LIVER FUNCTION STUDY	7948	ICD-9-CM Diagnosis
LIVER TRANSPLANT STATUS	V427	ICD-9-CM Diagnosis
BILIARY & LIVER ANOM NOS	75160	ICD-9-CM Diagnosis
COMP LIVER TRANSPLANT	99682	ICD-9-CM Diagnosis

Appendix E. List of Generic and Brand Names Used to Define Exclusions in this Request

Generic Name	Brand Name	Form	Route
CARBAMAZEPINE	Tegretol XR	tablet extended release 12 hr	oral
CARBAMAZEPINE	carbamazepine	tablet	oral
CARBAMAZEPINE	carbamazepine	tablet,chewable	oral
CARBAMAZEPINE	Equetro	capsule, ER multiphase 12 hr	oral
CARBAMAZEPINE	carbamazepine	tablet extended release 12 hr	oral
CARBAMAZEPINE	carbamazepine	suspension	oral
CARBAMAZEPINE	carbamazepine	capsule, ER multiphase 12 hr	oral
CARBAMAZEPINE	Carbatrol	capsule, ER multiphase 12 hr	oral
CARBAMAZEPINE	Tegretol	suspension	oral
CARBAMAZEPINE	Tegretol	tablet	oral
CARBAMAZEPINE	Tegretol	tablet,chewable	oral
CARBAMAZEPINE	Epitol	tablet	oral
CLOBAZAM	Onfi	suspension	oral
CLOBAZAM	Onfi	tablet	oral
CLONAZEPAM	Klonopin	tablet,disintegrating	oral
CLONAZEPAM	Klonopin	tablet	oral
CLONAZEPAM	clonazepam	tablet,disintegrating	oral
CLONAZEPAM	clonazepam	tablet	oral
DIVALPROEX SODIUM	divalproex	tablet extended release 24 hr	oral
DIVALPROEX SODIUM	divalproex	tablet,delayed release (DR/EC)	oral
DIVALPROEX SODIUM	Depakote	tablet,delayed release (DR/EC)	oral
DIVALPROEX SODIUM	Depakote ER	tablet extended release 24 hr	oral
DIVALPROEX SODIUM	divalproex	capsule, sprinkle	oral
DIVALPROEX SODIUM	Depakote Sprinkles	capsule, sprinkle	oral
ESLICARBAZEPINE ACETATE	Aptiom	tablet	oral
ETHOSUXIMIDE	ethosuximide	solution	oral
ETHOSUXIMIDE	Zarontin	capsule	oral
ETHOSUXIMIDE	ethosuximide	capsule	oral
ETHOSUXIMIDE	Zarontin	solution	oral
ETHOTOIN	Peganone	tablet	oral

EZOGABINE	Potiga	tablet	oral
FELBAMATE	felbamate	tablet	oral
FELBAMATE	felbamate	suspension	oral
FELBAMATE	Felbatol	tablet	oral
FELBAMATE	Felbatol	suspension	oral
GABAPENTIN	gabapentin	capsule	oral
GABAPENTIN	gabapentin	tablet	oral
GABAPENTIN	Neurontin	capsule	oral
GABAPENTIN	Gabarone	tablet	oral
GABAPENTIN	Neurontin	tablet	oral
GABAPENTIN	Gralise	tablet extended release 24 hr	oral
GABAPENTIN	gabapentin	solution	oral
GABAPENTIN	Gralise 30-Day Starter Pack	tablet extended release 24 hr	oral
GABAPENTIN	Neurontin	solution	oral
GABAPENTIN	Fanatrex	suspension	oral
GABAPENTIN ENACARBIL	Horizant	tablet extended release	oral
GABAPENTIN/DIETARY SUPPLEMENT, MISC COMBO NO.11	Therapentin-60	capsule	oral
GABAPENTIN/DIETARY SUPPLEMENT, MISC COMBO NO.11	Therapentin-90	capsule	oral
LACOSAMIDE	Vimpat	tablet	oral
LACOSAMIDE	Vimpat	tablets,dose pack	oral
LACOSAMIDE	Vimpat	solution	intravenous
LACOSAMIDE	Vimpat	solution	oral
LAMOTRIGINE	lamotrigine	tablet	oral
LAMOTRIGINE	lamotrigine	tablet, chewable dispersible	oral
LAMOTRIGINE	Lamictal	tablet	oral
LAMOTRIGINE	lamotrigine	tablet,disintegrating	oral
LAMOTRIGINE	Lamictal	tablet, chewable dispersible	oral
LAMOTRIGINE	Lamictal XR	tablet extended release 24hr	oral
LAMOTRIGINE	lamotrigine	tablet extended release 24hr	oral
LAMOTRIGINE	Lamictal ODT	tablet,disintegrating	oral
LAMOTRIGINE	lamotrigine	tablets,dose pack	oral
LAMOTRIGINE	Lamictal Starter (Blue) Kit	tablets,dose pack	oral
LAMOTRIGINE	Lamictal Starter (Orange) Kit	tablets,dose pack	oral
LAMOTRIGINE	Lamictal ODT Starter (Orange)	tablet disintegrating, dose pk	oral

LAMOTRIGINE	lamotrigine	tablet disintegrating, dose pk	oral
LAMOTRIGINE	Lamictal ODT Starter (Blue)	tablet disintegrating, dose pk	oral
LAMOTRIGINE	Lamictal Starter (Green) Kit	tablets,dose pack	oral
LAMOTRIGINE	Lamictal XR Starter (Green)	tablet extended rel,dose pack	oral
LAMOTRIGINE	Lamictal XR Starter (Orange)	tablet extended rel,dose pack	oral
LAMOTRIGINE	Lamictal ODT Starter (Green)	tablet disintegrating, dose pk	oral
LAMOTRIGINE	Lamictal XR Starter (Blue)	tablet extended rel,dose pack	oral
LEVETIRACETAM	levetiracetam	tablet	oral
LEVETIRACETAM	levetiracetam	solution	oral
LEVETIRACETAM	levetiracetam	tablet extended release 24 hr	oral
LEVETIRACETAM	levetiracetam	solution	intravenous
LEVETIRACETAM	Keppra	tablet	oral
LEVETIRACETAM	Keppra XR	tablet extended release 24 hr	oral
LEVETIRACETAM	Keppra	solution	intravenous
LEVETIRACETAM	Keppra	solution	oral
LEVETIRACETAM IN SODIUM CHLORIDE, ISO-OSMOTIC	levetiracetam in NaCl (iso-os)	piggyback	intravenous
OXCARBAZEPINE	Trileptal	tablet	oral
OXCARBAZEPINE	oxcarbazepine	tablet	oral
OXCARBAZEPINE	Oxtellar XR	tablet extended release 24 hr	oral
OXCARBAZEPINE	oxcarbazepine	suspension	oral
OXCARBAZEPINE	Trileptal	suspension	oral
PERAMPANEL	Fycompa	tablets,dose pack	oral
PERAMPANEL	Fycompa	tablet	oral
PHENOBARBITAL	phenobarbital	tablet	oral
PHENOBARBITAL	phenobarbital	elixir	oral
PHENOBARBITAL SODIUM	Luminal	syringe	injection
PHENOBARBITAL SODIUM	phenobarbital sodium	syringe	injection
PHENOBARBITAL SODIUM	phenobarbital sodium	solution	injection
PHENOBARBITAL SODIUM IN 0.9 % SODIUM CHLORIDE	phenobarbital in 0.9 % Sod Chl	solution	intravenous
PHENTERMINE HCL/TOPIRAMATE	Qsymia	capsule, ER multiphase 24 hr	oral
PHENYTOIN	phenytoin	suspension	oral
PHENYTOIN	Dilantin Infatabs	tablet,chewable	oral
PHENYTOIN	phenytoin	tablet,chewable	oral
PHENYTOIN	Dilantin-125	suspension	oral

PHENYTOIN	phenytoin	syringe	oral
PHENYTOIN SODIUM	phenytoin sodium	solution	intravenous
PHENYTOIN SODIUM	phenytoin sodium	capsule	oral
PHENYTOIN SODIUM	phenytoin sodium	syringe	intravenous
PHENYTOIN SODIUM EXTENDED	phenytoin sodium extended	capsule	oral
PHENYTOIN SODIUM EXTENDED	Dilantin Kapseal	capsule	oral
PHENYTOIN SODIUM EXTENDED	Phenytek	capsule	oral
PHENYTOIN SODIUM EXTENDED	Dilantin Extended	capsule	oral
PHENYTOIN SODIUM EXTENDED	Dilantin	capsule	oral
PREGABALIN	Lyrica	capsule	oral
PREGABALIN	Lyrica	solution	oral
PRIMIDONE	primidone	tablet	oral
PRIMIDONE	Mysoline	tablet	oral
RUFINAMIDE	Banzel	tablet	oral
RUFINAMIDE	Banzel	suspension	oral
TIAGABINE HCL	Gabitril	tablet	oral
TIAGABINE HCL	tiagabine	tablet	oral
TOPIRAMATE	Topamax	tablet	oral
TOPIRAMATE	topiramate	tablet	oral
TOPIRAMATE	Qudexy XR	capsule,sprinkle,ER 24hr	oral
TOPIRAMATE	topiramate	capsule,sprinkle,ER 24hr	oral
TOPIRAMATE	topiramate	capsule, sprinkle	oral
TOPIRAMATE	Topamax	capsule, sprinkle	oral
TOPIRAMATE	Trokendi XR	capsule,extended release 24hr	oral
TOPIRAMATE	Topiragen	tablet	oral
VALPROIC ACID	valproic acid	capsule	oral
VALPROIC ACID	Stavzor	capsule,delayed release(DR/EC)	oral
VALPROIC ACID	Depakene	capsule	oral
VALPROIC ACID (AS SODIUM SALT) (VALPROATE SODIUM)	valproic acid (as sodium salt)	syringe	oral
VALPROIC ACID (AS SODIUM SALT) (VALPROATE SODIUM)	valproic acid (as sodium salt)	solution	oral
VALPROIC ACID (AS SODIUM SALT) (VALPROATE SODIUM)	valproate sodium	solution	intravenous
VALPROIC ACID (AS SODIUM SALT) (VALPROATE SODIUM)	Depacon	solution	intravenous
VALPROIC ACID (AS SODIUM SALT) (VALPROATE SODIUM)	Depakene	solution	oral
VIGABATRIN	Sabril	tablet	oral

VIGABATRIN	Sabril	powder in packet	oral
ZONISAMIDE	Zonegran	capsule	oral
ZONISAMIDE	zonisamide	capsule	oral
FOSPHENYTOIN SODIUM	Cerebyx	solution	injection
METHSUXIMIDE	Celontin	capsule	oral
FOSPHENYTOIN SODIUM	fosphenytoin	solution	injection