

## Disclaimer

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

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## Overview for Request: cder\_mpl1r\_wp017, Report 1 of 3

**Request ID:** cder\_mpl1r\_wp017\_nsdp\_v01

**Request Description:** The goal of this request is to identify medication errors due to look-a-like and sound-a-like name confusion of Brintellix and Brilinta. This report contains estimated numbers of Brintellix users and Brilinta users. Users with the appropriate on-label indication were evaluated in addition to users without the appropriate on-label indication and with an on-label indication for the other drug of interest. This is report 1 of 3. Report 2 contains estimates of Brintellix and Brilinta users with on- or off-label indications for each drug. Report 3 contains estimates of Brilinta users that have a subsequent Brintellix dispensing and numbers of Brintellix users that have a subsequent Brilinta dispensing.

**Sentinel Modular Program Tool Used:** Cohort Identification and Descriptive Analysis (CIDA) tool, version 2.0

**Data Source:** Data from September 30, 2013 to September 30, 2015 from 16 Data Partners contributing to the Sentinel Distributed Database (SDD) were included in this report. This request was distributed to Data Partners on August 30, 2016.

**Study Design:** This request was designed to calculate background rates of Brintellix and Brilinta users. The number of qualifying patients with the exposure of interest, number of eligible members, and member days were calculated overall and were stratified by age group, sex, and year.

**Exposure of Interest:** The exposures of interest were Brintellix and Brilinta, which were defined by National Drug Codes (NDCs). Please refer to Appendix A for generic and brand names used to define the drug exposures in this request.

**Cohort Eligibility Criteria:** Those included in the cohort were required to be continuously enrolled in plans with medical and drug coverage for at least 6 months (183 days) prior to their dispensing date, during which gaps in coverage of up to 45 days were allowed, and for at least 30 days after the dispensing date. Members were excluded if they had a prior history of the exposure of interest in the 6 months (183 days) prior to the index-defining dispensing. The following age groups were included in the cohort: 0-17, 18-44, 45-64, and 65+ years. All qualifying incident exposures that occurred between September 30, 2013 and September 30, 2015 were examined.

**Inclusion/Exclusion Criteria:** In addition to all users, users with and without on-label indications for each exposure were evaluated.

For Brilinta users, specific inclusion/exclusion groups included:

- 1) users with an indication for Brilinta
- 2) users with an indication for Brilinta and without an indication for Brintellix
- 3) users with an indication for Brintellix and without an indication for Brilinta

For Brintellix users, specific inclusion/exclusion groups included:

- 1) users with an indication for Brintellix
- 2) users with an indication for Brintellix and without an indication for Brilinta
- 3) users with an indication for Brilinta and without an indication for Brintellix

Inclusion and exclusion criteria were evaluated in the 183 days prior to the dispensing of interest. On-label indications for Brintellix are depression diagnoses, and on-label indications for Brilinta are acute coronary syndrome (ACS) or myocardial infarction (MI) diagnoses. Indications were defined by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes. Please refer to Appendix B for a list of specific ICD-9-CM codes used to define the on-label indications for each cohort.

**Overview for Request: cder\_mpl1r\_wp017, Report 1 of 3, continued**

**Sensitivity Analyses:** A sensitivity analysis examined a longer inclusion/exclusion evaluation period, in which indications were evaluated in the 1 year (365 days) prior to the dispensing of interest. Users were also required to be continuously enrolled in plans with both medical and drug coverage for at least 1 year (365 days) prior to their dispensing date, during which gaps in coverage of up to 45 days were allowed.

**Please see Appendix C for the specifications of parameters used in the analyses for this request.**

**Limitations:** Algorithms to define exposures and indications are imperfect and may not have been validated; thus it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

**Notes:** Please contact the Sentinel Operations Center Query Fulfillment Team ([qf@sentinelssystem.org](mailto:qf@sentinelssystem.org)) for questions and to provide comments/suggestions for future enhancements to this document.

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

**Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the MSCDM.

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

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

**Cohort Definition (drug/exposure)** - indicates how the cohort will be defined: 1: Cohort includes only the first valid incident treatment episode during the query period; 2: Cohort includes all valid incident treatment episodes during the query period; 3: Cohort includes all valid incident treatment episodes during the query period until an event occurs.

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

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

**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"

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

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

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

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

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

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

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

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

**Treatment Episode Truncation Indicator** - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.

**Users** - number of members with 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.

**Washout Period (drug/exposure)\*\*** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

**Washout Period (event/outcome)\*\*** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

**Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

\*all terms may not be used in this report

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



**Table 1a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Inclusion/Exclusion Period**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brilinta Users</b>													
183-Day Inclusion/Exclusion Period	23,102	23,261	92,602	3,151,739	6,271,359	9,253.8	59,037,824	68,628,708.6	0.39	136.43	4.01	34.04	100.0%
365-Day Inclusion/Exclusion Period	19,936	20,075	80,725	2,751,685	5,474,906	8,074.1	46,471,030	58,016,084.4	0.43	138.03	4.05	34.09	100.0%
<b>Brilinta Users with an On-Label Indication for Brilinta</b>													
183-Day Inclusion/Exclusion Period	18,656	18,735	76,403	2,591,432	5,158,827	7,597.2	1,234,622	803,392.5	15.11	138.91	4.10	33.92	80.8%
365-Day Inclusion/Exclusion Period	16,418	16,509	67,757	2,297,172	4,572,135	6,733.3	1,208,884	1,050,137.7	13.58	139.92	4.13	33.90	82.4%
<b>Brilinta Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
183-Day Inclusion/Exclusion Period	16,231	16,275	67,931	2,307,556	4,595,512	6,751.0	1,105,153	650,141.3	14.69	142.17	4.19	33.97	70.3%
365-Day Inclusion/Exclusion Period	13,808	13,857	58,595	1,993,089	3,969,061	5,826.1	1,036,345	818,674.6	13.32	144.34	4.24	34.01	69.3%
<b>Brilinta Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
183-Day Inclusion/Exclusion Period	522	522	1,642	55,385	109,757	166.4	4,978,525	3,349,256.0	0.10	106.10	3.15	33.73	2.3%
365-Day Inclusion/Exclusion Period	499	501	1,575	54,006	106,255	162.4	4,579,085	3,903,294.6	0.11	108.23	3.16	34.29	2.5%



**Table 1b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Inclusion/Exclusion Period**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brintellix Users</b>													
183-Day Inclusion/Exclusion Period	22,019	22,161	66,539	2,117,909	2,174,719	6,415.6	59,042,169	#####	0.37	96.19	3.02	31.83	100.0%
365-Day Inclusion/Exclusion Period	18,793	18,918	57,549	1,834,597	1,884,043	5,551.2	46,474,433	#####	0.40	97.62	3.06	31.88	100.0%
<b>Brintellix Users with an On-Label Indication for Brintellix</b>													
183-Day Inclusion/Exclusion Period	14,245	14,309	43,701	1,389,610	1,430,477	4,199.0	5,133,367	3,616,356.1	2.77	97.55	3.07	31.80	64.7%
365-Day Inclusion/Exclusion Period	13,056	13,127	40,396	1,287,138	1,324,629	3,888.0	4,769,939	4,258,615.5	2.74	98.59	3.09	31.86	69.5%
<b>Brintellix Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
183-Day Inclusion/Exclusion Period	14,033	14,097	43,092	1,369,942	1,410,051	4,139.5	4,977,025	3,341,948.7	2.82	97.62	3.07	31.79	63.7%
365-Day Inclusion/Exclusion Period	12,760	12,830	39,547	1,259,267	1,295,918	3,803.5	4,577,831	3,896,014.6	2.79	98.69	3.10	31.84	67.9%
<b>Brintellix Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
183-Day Inclusion/Exclusion Period	76	76	255	8,092	8,119	24.0	1,111,909	661,748.7	0.07	106.47	3.36	31.73	0.3%
365-Day Inclusion/Exclusion Period	72	72	200	6,648	6,678	20.0	1,041,533	831,393.1	0.07	92.33	2.78	33.24	0.4%



**Table 2a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015 by On-Label Indication, Inclusion/Exclusion Period, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brilinta Users</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	1	1	1	30	60	0.1	11,585,169	12,683,700.2	0.00	30.00	1.00	30.00	100.0%
18-44 Years	986	988	4,904	155,988	311,015	453.3	23,228,280	23,734,081.8	0.04	158.20	4.97	31.81	100.0%
45-64 Years	9,812	9,877	44,767	1,455,454	2,898,888	4,252.2	17,479,775	20,036,780.1	0.56	148.33	4.56	32.51	100.0%
65+ Years	12,307	12,395	42,930	1,540,267	3,061,396	4,548.2	9,152,828	12,174,146.5	1.34	125.15	3.49	35.88	100.0%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	1	1	1	30	60	0.1	9,149,408	10,574,898.7	0.00	30.00	1.00	30.00	100.0%
18-44 Years	784	786	4,085	129,368	257,865	375.2	17,601,263	19,249,717.4	0.04	165.01	5.21	31.67	100.0%
45-64 Years	8,346	8,397	38,684	1,257,801	2,505,553	3,670.7	14,150,653	17,321,492.7	0.59	150.71	4.64	32.51	100.0%
65+ Years	10,809	10,891	37,955	1,364,486	2,711,428	4,028.1	7,630,385	10,869,975.6	1.42	126.24	3.51	35.95	100.0%
<b>Brilinta Users with an On-Label Indication for Brilinta</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	0	0	0	0	0	0.0	600	242.4	0.00	---	---	---	0.0%
18-44 Years	867	868	4,462	141,451	282,091	410.4	41,971	19,687.5	20.66	163.15	5.15	31.70	87.9%
45-64 Years	8,125	8,159	37,886	1,229,891	2,451,015	3,587.3	379,116	214,111.3	21.43	151.37	4.66	32.46	82.8%
65+ Years	9,668	9,708	34,055	1,220,090	2,425,721	3,599.5	833,400	569,351.3	11.60	126.20	3.52	35.83	78.6%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	0	0	0	0	0	0.0	631	338.9	0.00	---	---	---	0.0%
18-44 Years	696	698	3,731	118,003	235,285	341.8	39,666	25,018.9	17.55	169.54	5.36	31.63	88.8%
45-64 Years	7,040	7,075	33,228	1,078,051	2,148,124	3,142.4	366,387	276,338.9	19.21	153.13	4.72	32.44	84.4%
65+ Years	8,686	8,736	30,798	1,101,118	2,188,726	3,249.1	826,734	748,441.0	10.51	126.77	3.55	35.75	80.4%
<b>Brilinta Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	0	0	0	0	0	0.0	562	207.4	0.00	---	---	---	0.0%
18-44 Years	774	775	4,039	128,482	256,153	372.1	36,735	15,495.0	21.07	166.00	5.22	31.81	78.5%
45-64 Years	7,149	7,167	33,968	1,102,288	2,197,309	3,209.1	332,121	166,260.9	21.53	154.19	4.75	32.45	72.9%
65+ Years	8,308	8,333	29,924	1,076,786	2,142,050	3,169.8	751,422	468,178.0	11.06	129.61	3.60	35.98	67.5%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	0	0	0	0	0	0.0	577	285.4	0.00	---	---	---	0.0%
18-44 Years	615	616	3,350	106,345	211,969	307.6	33,312	19,073.3	18.46	172.92	5.45	31.74	78.4%
45-64 Years	6,028	6,045	29,092	944,087	1,881,915	2,745.9	306,106	206,116.6	19.69	156.62	4.83	32.45	72.2%
65+ Years	7,165	7,196	26,153	942,657	1,875,177	2,772.6	714,120	593,199.3	10.03	131.56	3.65	36.04	66.3%

**Table 2a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015 by On-Label Indication, Inclusion/Exclusion Period, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>Brilinta Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
<b><i>183-Day Inclusion/Exclusion Period</i></b>													
0-17 Years	0	0	0	0	0	0.0	261,453	154,861.3	0.00	---	---	---	0.0%
18-44 Years	23	23	76	2,605	5,090	7.8	1,631,512	952,275.0	0.01	113.26	3.30	34.28	2.3%
45-64 Years	200	200	625	20,561	40,611	61.9	1,882,005	1,256,295.9	0.11	102.81	3.13	32.90	2.0%
65+ Years	299	299	941	32,219	64,056	96.7	1,347,426	985,823.8	0.22	107.76	3.15	34.24	2.4%
<b><i>365-Day Inclusion/Exclusion Period</i></b>													
0-17 Years	0	0	0	0	0	0.0	247,619	176,713.6	0.00	---	---	---	0.0%
18-44 Years	17	17	63	2,119	4,118	6.3	1,499,917	1,100,052.9	0.01	124.65	3.71	33.63	2.2%
45-64 Years	187	187	637	20,310	40,381	61.2	1,743,144	1,463,356.4	0.11	108.61	3.41	31.88	2.2%
65+ Years	295	297	875	31,577	61,756	95.0	1,247,333	1,163,171.7	0.24	107.04	2.97	36.09	2.7%

**Table 2b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015 by On-Label Indication, Inclusion/Exclusion Period, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brintellix Users</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	280	280	754	23,966	24,638	73.3	11,585,142	12,683,559.2	0.02	85.59	2.69	31.79	100.0%
18-44 Years	9,416	9,478	26,991	829,432	848,344	2,540.8	23,227,285	23,729,085.8	0.41	88.09	2.87	30.73	100.0%
45-64 Years	10,270	10,330	32,210	1,042,094	1,070,023	3,138.6	17,482,068	20,040,947.3	0.59	101.47	3.14	32.35	100.0%
65+ Years	2,056	2,073	6,584	222,417	231,714	662.8	9,156,068	12,185,592.3	0.22	108.18	3.20	33.78	100.0%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	235	235	633	20,358	20,811	62.1	9,149,385	10,574,776.6	0.03	86.63	2.69	32.16	100.0%
18-44 Years	7,822	7,876	22,714	697,449	713,226	2,134.1	17,600,619	19,245,536.0	0.44	89.17	2.90	30.71	100.0%
45-64 Years	8,959	9,011	28,442	922,523	947,519	2,775.8	14,152,692	17,325,022.3	0.63	102.97	3.17	32.44	100.0%
65+ Years	1,779	1,796	5,760	194,267	202,488	579.1	7,632,573	10,880,076.5	0.23	109.20	3.24	33.73	100.0%
<b>Brintellix Users with an On-Label Indication for Brintellix</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	170	170	482	15,632	16,063	47.7	264,502	162,639.1	0.64	91.95	2.84	32.43	60.7%
18-44 Years	5,715	5,739	16,771	514,205	527,701	1,570.3	1,666,213	1,008,511.1	3.43	89.97	2.93	30.66	60.7%
45-64 Years	6,813	6,840	21,601	697,686	718,484	2,096.6	1,937,576	1,347,846.9	3.52	102.41	3.17	32.30	66.3%
65+ Years	1,548	1,560	4,847	162,087	168,230	484.4	1,420,412	1,097,359.1	1.09	104.71	3.13	33.44	75.3%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	154	154	444	14,822	15,154	44.8	250,509	185,268.7	0.61	96.25	2.88	33.38	65.5%
18-44 Years	5,096	5,123	14,931	456,337	468,422	1,394.7	1,533,556	1,162,155.1	3.32	89.55	2.93	30.56	65.1%
45-64 Years	6,365	6,395	20,416	661,888	681,416	1,987.9	1,809,872	1,581,584.1	3.52	103.99	3.21	32.42	71.0%
65+ Years	1,442	1,455	4,605	154,091	159,638	460.6	1,349,266	1,329,607.8	1.07	106.86	3.19	33.46	81.1%
<b>Brintellix Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	170	170	482	15,632	16,063	47.7	261,428	154,778.8	0.65	91.95	2.84	32.43	60.7%
18-44 Years	5,699	5,723	16,734	513,124	526,590	1,566.8	1,630,327	949,116.9	3.50	90.04	2.94	30.66	60.5%
45-64 Years	6,708	6,735	21,278	686,993	707,727	2,064.6	1,881,098	1,252,635.8	3.57	102.41	3.17	32.29	65.3%
65+ Years	1,457	1,469	4,598	154,193	159,672	460.4	1,347,758	985,417.2	1.08	105.83	3.16	33.53	70.9%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	154	154	444	14,822	15,154	44.8	247,599	176,636.4	0.62	96.25	2.88	33.38	65.5%
18-44 Years	5,076	5,103	14,880	454,876	466,931	1,390.1	1,499,069	1,097,016.5	3.39	89.61	2.93	30.57	64.9%
45-64 Years	6,204	6,234	19,927	645,639	665,091	1,939.1	1,742,410	1,459,666.0	3.56	104.07	3.21	32.40	69.2%
65+ Years	1,327	1,339	4,296	143,930	148,743	429.5	1,247,431	1,162,695.7	1.06	108.46	3.24	33.50	74.6%



**Table 2b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015 by On-Label Indication, Inclusion/Exclusion Period, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>Brintellix Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
0-17 Years	0	0	0	0	0	0.0	562	207.4	0.00	---	---	---	0.0%
18-44 Years	11	11	17	490	490	1.6	37,134	16,024.6	0.30	44.55	1.55	28.82	0.1%
45-64 Years	48	48	192	6,187	6,184	18.1	335,533	171,315.3	0.14	128.90	4.00	32.22	0.5%
65+ Years	17	17	46	1,415	1,445	4.3	754,705	474,201.4	0.02	83.24	2.71	30.76	0.8%
<i>365-Day Inclusion/Exclusion Period</i>													
0-17 Years	0	0	0	0	0	0.0	577	285.4	0.00	---	---	---	0.0%
18-44 Years	12	12	20	640	640	2.1	33,637	19,623.8	0.36	53.33	1.67	32.00	0.2%
45-64 Years	44	44	133	4,427	4,427	13.3	308,913	211,737.2	0.14	100.61	3.02	33.29	0.5%
65+ Years	16	16	47	1,581	1,611	4.6	716,498	599,746.7	0.02	98.81	2.94	33.64	0.9%

**Table 3a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brilinta Users</b>													
<i><b>183-Day Inclusion/Exclusion Period</b></i>													
Female	7,367	7,423	27,258	926,227	1,841,122	2,737.8	30,101,758	35,085,871.9	0.24	125.73	3.70	33.98	100.0%
Male	15,733	15,836	65,341	2,225,422	4,430,058	6,515.7	28,933,863	33,540,442.7	0.54	141.45	4.15	34.06	100.0%
Unknown	2	2	3	90	180	0.3	2,203	2,394.0	0.91	45.00	1.50	30.00	100.0%
<i><b>365-Day Inclusion/Exclusion Period</b></i>													
Female	6,383	6,431	23,810	810,771	1,611,500	2,395.5	23,736,300	29,725,880.9	0.27	127.02	3.73	34.05	100.0%
Male	13,551	13,642	56,912	1,940,824	3,863,227	5,678.3	22,733,084	28,288,132.8	0.60	143.22	4.20	34.10	100.0%
Unknown	2	2	3	90	180	0.3	1,646	2,070.8	1.22	45.00	1.50	30.00	100.0%
<b>Brilinta Users with an On-Label Indication for Brilinta</b>													
<i><b>183-Day Inclusion/Exclusion Period</b></i>													
Female	5,825	5,851	21,983	747,768	1,487,643	2,206.7	477,031	302,753.5	12.21	128.37	3.77	34.02	79.1%
Male	12,830	12,883	54,419	1,843,634	3,671,124	5,390.4	757,517	500,591.2	16.94	143.70	4.24	33.88	81.5%
Unknown	1	1	1	30	60	0.1	74	47.8	13.51	30.00	1.00	30.00	50.0%
<i><b>365-Day Inclusion/Exclusion Period</b></i>													
Female	5,160	5,189	19,649	668,204	1,328,828	1,971.9	471,126	399,926.4	10.95	129.50	3.81	34.01	80.8%
Male	11,257	11,319	48,107	1,628,938	3,243,247	4,761.3	737,683	650,143.0	15.26	144.70	4.27	33.86	83.1%
Unknown	1	1	1	30	60	0.1	75	68.3	13.33	30.00	1.00	30.00	50.0%
<b>Brilinta Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
<i><b>183-Day Inclusion/Exclusion Period</b></i>													
Female	4,690	4,703	18,015	614,510	1,223,751	1,809.1	406,593	225,663.3	11.53	131.03	3.84	34.11	63.7%
Male	11,540	11,571	49,915	1,693,016	3,371,701	4,941.8	698,495	424,440.8	16.52	146.71	4.33	33.92	73.3%
Unknown	1	1	1	30	60	0.1	65	37.1	15.38	30.00	1.00	30.00	50.0%
<i><b>365-Day Inclusion/Exclusion Period</b></i>													
Female	3,940	3,954	15,372	526,375	1,047,989	1,548.0	376,742	281,992.0	10.46	133.60	3.90	34.24	61.7%
Male	9,867	9,902	43,222	1,466,684	2,921,012	4,278.0	659,539	536,632.3	14.96	148.65	4.38	33.93	72.8%
Unknown	1	1	1	30	60	0.1	64	50.3	15.63	30.00	1.00	30.00	50.0%

**Table 3a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>Brilinta Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
<b><i>183-Day Inclusion/Exclusion Period</i></b>													
Female	274	274	911	31,025	61,427	92.5	3,384,062	2,320,960.6	0.08	113.23	3.32	34.06	3.7%
Male	248	248	731	24,360	48,330	73.9	1,594,264	1,028,183.6	0.16	98.23	2.95	33.32	1.6%
Unknown	0	0	0	0	0	0.0	199	111.8	0.00	---	---	---	0.0%
<b><i>365-Day Inclusion/Exclusion Period</i></b>													
Female	253	255	858	28,436	56,405	85.1	3,109,622	2,703,998.6	0.08	112.40	3.39	33.14	4.0%
Male	246	246	717	25,570	49,850	77.4	1,469,271	1,199,146.9	0.17	103.94	2.91	35.66	1.8%
Unknown	0	0	0	0	0	0.0	192	149.1	0.00	---	---	---	0.0%

**Table 3b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brintellix Users</b>													
<i><b>183-Day Inclusion/Exclusion Period</b></i>													
Female	14,947	15,041	44,697	1,422,328	1,461,145	4,313.9	30,101,809	35,083,769.2	0.50	95.16	2.99	31.82	100.0%
Male	7,072	7,120	21,842	695,581	713,574	2,101.7	28,938,157	33,553,018.8	0.24	98.36	3.09	31.85	100.0%
Unknown	0	0	0	0	0	0.0	2,203	2,396.5	0.00	---	---	---	N/A
<i><b>365-Day Inclusion/Exclusion Period</b></i>													
Female	12,734	12,815	38,386	1,223,177	1,257,365	3,707.9	23,736,512	29,724,250.2	0.54	96.06	3.01	31.87	100.0%
Male	6,059	6,103	19,163	611,420	626,679	1,843.3	22,736,275	28,299,088.0	0.27	100.91	3.16	31.91	100.0%
Unknown	0	0	0	0	0	0.0	1,646	2,073.0	0.00	---	---	---	N/A
<b>Brintellix Users with an On-Label Indication for Brintellix</b>													
<i><b>183-Day Inclusion/Exclusion Period</b></i>													
Female	9,864	9,909	30,002	955,226	984,598	2,888.6	3,469,566	2,481,125.7	2.84	96.84	3.04	31.84	66.0%
Male	4,381	4,400	13,699	434,384	445,879	1,310.4	1,663,590	1,135,100.7	2.63	99.15	3.13	31.71	61.9%
Unknown	0	0	0	0	0	0.0	211	129.7	0.00	---	---	---	N/A
<i><b>365-Day Inclusion/Exclusion Period</b></i>													
Female	9,010	9,055	27,458	875,556	902,282	2,648.0	3,212,224	2,912,539.2	2.80	97.18	3.05	31.89	70.8%
Male	4,046	4,072	12,938	411,582	422,348	1,240.0	1,557,506	1,345,902.3	2.60	101.73	3.20	31.81	66.8%
Unknown	0	0	0	0	0	0.0	209	174.1	0.00	---	---	---	N/A
<b>Brintellix Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
<i><b>183-Day Inclusion/Exclusion Period</b></i>													
Female	9,764	9,809	29,756	946,873	975,935	2,862.9	3,382,786	2,315,721.8	2.89	96.98	3.05	31.82	65.3%
Male	4,269	4,288	13,336	423,069	434,116	1,276.6	1,594,040	1,026,115.1	2.68	99.10	3.12	31.72	60.4%
Unknown	0	0	0	0	0	0.0	199	111.8	0.00	---	---	---	N/A
<i><b>365-Day Inclusion/Exclusion Period</b></i>													
Female	8,859	8,904	27,083	862,470	888,801	2,607.9	3,108,635	2,698,839.4	2.85	97.36	3.06	31.85	69.6%
Male	3,901	3,926	12,464	396,797	407,118	1,195.6	1,469,004	1,197,026.1	2.66	101.72	3.20	31.84	64.4%
Unknown	0	0	0	0	0	0.0	192	149.1	0.00	---	---	---	N/A

**Table 3b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Sex**

	New Users	New Episodes	Days Dispensings Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users	
<b>Brintellix Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
<b>183-Day Inclusion/Exclusion Period</b>													
Female	40	40	102	3,335	3,335	10.1	408,537	229,021.1	0.10	83.38	2.55	32.70	0.3%
Male	36	36	153	4,757	4,784	13.9	703,307	432,689.0	0.05	132.14	4.25	31.09	0.5%
Unknown	0	0	0	0	0	0.0	65	38.5	0.00	---	---	---	N/A
<b>365-Day Inclusion/Exclusion Period</b>													
Female	38	38	90	3,091	3,091	9.4	378,188	285,546.9	0.10	81.34	2.37	34.34	0.3%
Male	34	34	110	3,557	3,587	10.7	663,281	545,794.4	0.05	104.62	3.24	32.34	0.6%
Unknown	0	0	0	0	0	0.0	64	51.8	0.00	---	---	---	N/A

**Table 4a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brilinta Users</b>													
<b>183-Day Inclusion/Exclusion Period</b>													
2013	2,220	2,220	10,385	369,560	734,703	1,087.6	38,417,504	9,047,598.5	0.06	166.47	4.68	35.59	100.0%
2014	10,360	10,373	48,371	1,693,143	3,369,507	4,962.4	45,067,533	34,709,772.9	0.23	163.43	4.67	35.00	100.0%
2015	10,666	10,668	33,846	1,089,036	2,167,149	3,203.8	41,500,076	24,871,337.2	0.26	102.10	3.17	32.18	100.0%
<b>365-Day Inclusion/Exclusion Period</b>													
2013	1,852	1,852	8,822	317,266	630,610	932.2	31,223,586	7,606,795.6	0.06	171.31	4.76	35.96	100.0%
2014	8,717	8,728	41,293	1,446,253	2,878,046	4,236.6	35,081,175	29,185,919.3	0.25	165.91	4.74	35.02	100.0%
2015	9,493	9,495	30,610	988,166	1,966,250	2,905.2	32,938,922	21,223,369.5	0.29	104.09	3.22	32.28	100.0%
<b>Brilinta Users with an On-Label Indication for Brilinta</b>													
<b>183-Day Inclusion/Exclusion Period</b>													
2013	1,782	1,782	8,548	307,640	611,607	903.0	518,145	100,016.7	3.44	172.64	4.80	35.99	80.3%
2014	8,281	8,289	39,803	1,384,960	2,758,039	4,053.9	847,349	395,803.7	9.77	167.25	4.81	34.80	79.9%
2015	8,662	8,664	28,052	898,832	1,789,181	2,640.2	743,568	307,572.0	11.65	103.77	3.24	32.04	81.2%
<b>365-Day Inclusion/Exclusion Period</b>													
2013	1,535	1,535	7,396	269,042	534,538	789.2	579,959	126,083.7	2.65	175.27	4.82	36.38	82.9%
2014	7,112	7,123	34,660	1,201,746	2,392,956	3,517.1	838,990	515,636.7	8.48	168.97	4.87	34.67	81.6%
2015	7,849	7,851	25,701	826,384	1,644,641	2,427.0	787,236	408,417.3	9.97	105.29	3.27	32.15	82.7%
<b>Brilinta Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
<b>183-Day Inclusion/Exclusion Period</b>													
2013	1,573	1,573	7,712	277,883	553,139	814.7	443,953	81,417.8	3.54	176.66	4.90	36.03	70.9%
2014	7,206	7,210	35,651	1,239,452	2,469,473	3,620.6	752,672	323,455.0	9.57	172.00	4.95	34.77	69.6%
2015	7,492	7,492	24,568	790,221	1,572,900	2,315.8	650,819	245,268.5	11.51	105.48	3.28	32.16	70.2%
<b>365-Day Inclusion/Exclusion Period</b>													
2013	1,310	1,310	6,508	237,611	472,813	695.2	475,252	99,161.7	2.76	181.38	4.97	36.51	70.7%
2014	6,020	6,024	30,296	1,052,069	2,096,245	3,071.2	713,857	406,251.3	8.43	174.76	5.03	34.73	69.1%
2015	6,523	6,523	21,791	703,409	1,400,003	2,059.7	653,253	313,261.5	9.99	107.84	3.34	32.28	68.7%

**Table 4a. Summary of Brilinta Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>Brilinta Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
<b><i>183-Day Inclusion/Exclusion Period</i></b>													
2013	47	47	144	5,019	9,618	15.4	2,181,271	418,055.1	0.02	106.79	3.06	34.85	2.1%
2014	252	252	926	32,852	65,584	97.9	3,459,269	1,689,961.1	0.07	130.37	3.67	35.48	2.4%
2015	223	223	572	17,514	34,555	53.1	3,036,039	1,241,239.9	0.07	78.54	2.57	30.62	2.1%
<b><i>365-Day Inclusion/Exclusion Period</i></b>													
2013	39	39	130	4,105	8,148	12.6	2,255,476	482,042.5	0.02	105.26	3.33	31.58	2.1%
2014	252	252	900	33,471	65,564	99.9	3,203,471	1,957,255.3	0.08	132.82	3.57	37.19	2.9%
2015	210	210	545	16,430	32,543	50.0	2,922,318	1,463,996.8	0.07	78.24	2.60	30.15	2.2%

**Table 4b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>All Brintellix Users</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
2013	131	131	402	13,256	15,098	40.2	38,424,566	9,049,679.0	0.00	101.19	3.07	32.98	100.0%
2014	12,500	12,515	41,286	1,343,761	1,382,953	4,059.5	45,072,753	34,715,495.5	0.28	107.50	3.30	32.55	100.0%
2015	9,514	9,515	24,851	760,892	776,667	2,315.8	41,503,340	24,874,010.0	0.23	79.98	2.61	30.62	100.0%
<i>365-Day Inclusion/Exclusion Period</i>													
2013	117	117	360	12,055	13,837	36.5	31,229,457	7,608,555.9	0.00	103.03	3.08	33.49	100.0%
2014	10,570	10,585	35,391	1,153,492	1,186,821	3,481.2	35,085,262	29,190,892.9	0.30	109.13	3.35	32.59	100.0%
2015	8,215	8,216	21,798	669,050	683,385	2,033.4	32,941,436	21,225,962.5	0.25	81.44	2.65	30.69	100.0%
<b>Brintellix Users with an On-Label Indication for Brintellix</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
2013	84	84	240	8,117	9,708	24.7	2,280,095	452,365.7	0.04	96.63	2.86	33.82	64.1%
2014	7,968	7,973	26,984	875,743	903,363	2,640.0	3,557,008	1,800,150.5	2.24	109.91	3.39	32.45	63.7%
2015	6,251	6,252	16,477	505,750	517,406	1,534.2	3,125,625	1,363,840.0	2.00	80.91	2.64	30.69	65.7%
<i>365-Day Inclusion/Exclusion Period</i>													
2013	86	86	231	7,939	9,480	24.3	2,386,054	526,465.1	0.04	92.31	2.69	34.37	73.5%
2014	7,241	7,247	24,815	805,842	830,446	2,427.2	3,321,744	2,107,064.1	2.18	111.29	3.43	32.47	68.5%
2015	5,793	5,794	15,350	473,357	484,704	1,436.5	3,057,827	1,625,086.3	1.89	81.71	2.65	30.84	70.5%
<b>Brintellix Users with an On-Label Indication for Brintellix and No Indication for Brilinta</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
2013	84	84	240	8,117	9,708	24.7	2,181,632	418,116.9	0.04	96.63	2.86	33.82	64.1%
2014	7,862	7,867	26,621	864,042	891,109	2,604.8	3,458,766	1,687,231.1	2.27	109.90	3.39	32.46	62.9%
2015	6,145	6,146	16,231	497,783	509,234	1,510.0	3,030,975	1,236,600.7	2.03	81.01	2.64	30.67	64.6%
<i>365-Day Inclusion/Exclusion Period</i>													
2013	86	86	231	7,939	9,480	24.3	2,255,713	482,086.5	0.04	92.31	2.69	34.37	73.5%
2014	7,092	7,098	24,303	788,990	813,049	2,376.6	3,203,022	1,954,659.9	2.21	111.25	3.43	32.46	67.1%
2015	5,645	5,646	15,013	462,338	473,390	1,402.6	2,918,202	1,459,268.2	1.93	81.90	2.66	30.80	68.7%



**Table 4b. Summary of Brintellix Use in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication, Inclusion/Exclusion Period, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	Percent of Total Users
<b>Brintellix Users with an On-Label Indication for Brilinta and No Indication for Brintellix</b>													
<i>183-Day Inclusion/Exclusion Period</i>													
2013	1	1	2	37	37	0.1	448,053	82,430.6	0.00	37.00	2.00	18.50	0.8%
2014	42	42	159	5,221	5,218	15.5	758,038	328,626.6	0.06	124.31	3.79	32.84	0.3%
2015	33	33	94	2,834	2,864	8.4	658,385	250,691.4	0.05	85.88	2.85	30.15	0.3%
<i>365-Day Inclusion/Exclusion Period</i>													
2013	0	0	0	0	0	0.0	479,151	100,243.2	0.00	---	---	---	0.0%
2014	36	36	115	3,935	3,935	11.9	718,082	411,854.4	0.05	109.31	3.19	34.22	0.3%
2015	36	36	85	2,713	2,743	8.2	659,561	319,295.5	0.05	75.36	2.36	31.92	0.4%

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

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<b>Generic Name</b>	<b>Brand Name</b>
BRILINTA	TICAGRELOR
Brintellix	VORTIOXETINE HYDROBROMIDE

**Appendix B. List of International Classification of Diseases, Ninth Revision (ICD-9-CM) Diagnosis Codes Used to Define On-Label Indications in this Request**

<b>Exposure</b>	<b>Code</b>	<b>Description</b>	<b>Code Type</b>
<b>Depression</b>			
Brintellix	296.2	Major depressive disorder, single episode	ICD-9-CM
Brintellix	296.20	Major depressive disorder, single episode, unspecified	ICD-9-CM
Brintellix	296.21	Major depressive disorder, single episode, mild	ICD-9-CM
Brintellix	296.22	Major depressive disorder, single episode, moderate	ICD-9-CM
Brintellix	296.23	Major depressive disorder, single episode, severe, without mention of psychotic behavior	ICD-9-CM
Brintellix	296.24	Major depressive disorder, single episode, severe, specified as with psychotic behavior	ICD-9-CM
Brintellix	296.25	Major depressive disorder, single episode, in partial or unspecified remission	ICD-9-CM
Brintellix	296.26	Major depressive disorder, single episode in full remission	ICD-9-CM
Brintellix	296.3	Major depressive disorder, recurrent episode	ICD-9-CM
Brintellix	296.30	Major depressive disorder, recurrent episode, unspecified	ICD-9-CM
Brintellix	296.31	Major depressive disorder, recurrent episode, mild	ICD-9-CM
Brintellix	296.32	Major depressive disorder, recurrent episode, moderate	ICD-9-CM
Brintellix	296.33	Major depressive disorder, recurrent episode, severe, without mention of psychotic behavior	ICD-9-CM
Brintellix	296.34	Major depressive disorder, recurrent episode, severe, specified as with psychotic behavior	ICD-9-CM
Brintellix	296.35	Major depressive disorder, recurrent episode, in partial or unspecified remission	ICD-9-CM
Brintellix	296.36	Major depressive disorder, recurrent episode, in full remission	ICD-9-CM
Brintellix	311	Depressive disorder, not elsewhere classified	ICD-9-CM
<b>Acute Coronary Syndrome</b>			
Brilinta	411.1	Intermediate coronary syndrome	ICD-9-CM
<b>Myocardial Infarction</b>			
Brilinta	410	Acute myocardial infarction	ICD-9-CM
Brilinta	410.0	Acute myocardial infarction of anterolateral wall	ICD-9-CM
Brilinta	410.00	Acute myocardial infarction of anterolateral wall, episode of care unspecified	ICD-9-CM
Brilinta	410.01	Acute myocardial infarction of anterolateral wall, initial episode of care	ICD-9-CM
Brilinta	410.02	Acute myocardial infarction of anterolateral wall, subsequent episode of care	ICD-9-CM
Brilinta	410.1	Acute myocardial infarction of other anterior wall	ICD-9-CM
Brilinta	410.10	Acute myocardial infarction of other anterior wall, episode of care unspecified	ICD-9-CM
Brilinta	410.11	Acute myocardial infarction of other anterior wall, initial episode of care	ICD-9-CM
Brilinta	410.12	Acute myocardial infarction of other anterior wall, subsequent episode of care	ICD-9-CM
Brilinta	410.2	Acute myocardial infarction of inferolateral wall	ICD-9-CM
Brilinta	410.20	Acute myocardial infarction of inferolateral wall, episode of care unspecified	ICD-9-CM
Brilinta	410.21	Acute myocardial infarction of inferolateral wall, initial episode of care	ICD-9-CM
Brilinta	410.22	Acute myocardial infarction of inferolateral wall, subsequent episode of care	ICD-9-CM
Brilinta	410.3	Acute myocardial infarction of inferoposterior wall	ICD-9-CM
Brilinta	410.30	Acute myocardial infarction of inferoposterior wall, episode of care unspecified	ICD-9-CM
Brilinta	410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care	ICD-9-CM
Brilinta	410.32	Acute myocardial infarction of inferoposterior wall, subsequent episode of care	ICD-9-CM
Brilinta	410.4	Acute myocardial infarction of other inferior wall	ICD-9-CM
Brilinta	410.40	Acute myocardial infarction of other inferior wall, episode of care unspecified	ICD-9-CM
Brilinta	410.41	Acute myocardial infarction of other inferior wall, initial episode of care	ICD-9-CM
Brilinta	410.42	Acute myocardial infarction of other inferior wall, subsequent episode of care	ICD-9-CM
Brilinta	410.5	Acute myocardial infarction of other lateral wall	ICD-9-CM
Brilinta	410.50	Acute myocardial infarction of other lateral wall, episode of care unspecified	ICD-9-CM
Brilinta	410.51	Acute myocardial infarction of other lateral wall, initial episode of care	ICD-9-CM

**Appendix B. List of International Classification of Diseases, Ninth Revision (ICD-9-CM) Diagnosis Codes Used to Define On-Label Indications in this Request**

<b>Exposure</b>	<b>Code</b>	<b>Description</b>	<b>Code Type</b>
Brilinta	410.52	Acute myocardial infarction of other lateral wall, subsequent episode of care	ICD-9-CM
Brilinta	410.6	Acute myocardial infarction, true posterior wall infarction	ICD-9-CM
Brilinta	410.60	Acute myocardial infarction, true posterior wall infarction, episode of care unspecified	ICD-9-CM
Brilinta	410.61	Acute myocardial infarction, true posterior wall infarction, initial episode of care	ICD-9-CM
Brilinta	410.62	Acute myocardial infarction, true posterior wall infarction, subsequent episode of care	ICD-9-CM
Brilinta	410.7	Acute myocardial infarction, subendocardial infarction	ICD-9-CM
Brilinta	410.70	Acute myocardial infarction, subendocardial infarction, episode of care unspecified	ICD-9-CM
Brilinta	410.71	Acute myocardial infarction, subendocardial infarction, initial episode of care	ICD-9-CM
Brilinta	410.72	Acute myocardial infarction, subendocardial infarction, subsequent episode of care	ICD-9-CM
Brilinta	410.8	Acute myocardial infarction of other specified sites	ICD-9-CM
Brilinta	410.80	Acute myocardial infarction of other specified sites, episode of care unspecified	ICD-9-CM
Brilinta	410.81	Acute myocardial infarction of other specified sites, initial episode of care	ICD-9-CM
Brilinta	410.82	Acute myocardial infarction of other specified sites, subsequent episode of care	ICD-9-CM
Brilinta	410.9	Acute myocardial infarction, unspecified site	ICD-9-CM
Brilinta	410.90	Acute myocardial infarction, unspecified site, episode of care unspecified	ICD-9-CM
Brilinta	410.91	Acute myocardial infarction, unspecified site, initial episode of care	ICD-9-CM
Brilinta	410.92	Acute myocardial infarction, unspecified site, subsequent episode of care	ICD-9-CM
Brilinta	412	Old myocardial infarction	ICD-9-CM

### Appendix C. Specifications for Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool, version 2.0, to investigate the frequency of medication errors due to look-a-like and sound-a-like name confusion in the Sentinel Distributed Database (SDD). Brintellix and Brilinta were used as an example. In total, 16 different scenarios were examined in this report.

**Enrollment Gap:** 45 days

**Age Groups:** 0-17, 18-44, 45-64, 65+ years

**Query Period:** September 30, 2013 - September 30, 2015

**Coverage Requirement:** Drug and Medical

**Post-Exposure Enrollment Requirement:** 30 days

Scenario	Drug/Exposure							Inclusion/Exclusion Criteria						Event/Outcome	
	Pre-Exposure Enrollment Requirement	Incident Exposure	Incident with respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Min Days Supplied	Min Episode Duration	Inclusion/Exclusion Condition	Care Setting	Include or Exclude	Lookback Start	Lookback End	Event
1	183 days	Brilinta	Brilinta	183	02	10	10	0	0	None	N/A	N/A	N/A	N/A	None
2	183 days	Brilinta	Brilinta	183	02	10	10	0	0	ACS or MI	Any	Include	-183	30	None
3	183 days	Brilinta	Brilinta	183	02	10	10	0	0	ACS or MI Depression	Any	Include Exclude	-183	30	None
4	183 days	Brilinta	Brilinta	183	02	10	10	0	0	Depression ACS or MI	Any	Include Exclude	-183	30	None
5	183 days	Brintellix	Brintellix	183	02	10	10	0	0	None	N/A	N/A	N/A	N/A	None
6	183 days	Brintellix	Brintellix	183	02	10	10	0	0	Depression	Any	Include	-183	30	None
7	183 days	Brintellix	Brintellix	183	02	10	10	0	0	Depression ACS or MI	Any	Include Exclude	-183	30	None
8	183 days	Brintellix	Brintellix	183	02	10	10	0	0	ACS or MI Depression	Any	Include Exclude	-183	30	None
9	365 days	Brilinta	Brilinta	183	02	10	10	0	0	None	N/A	N/A	N/A	N/A	None
10	365 days	Brilinta	Brilinta	183	02	10	10	0	0	ACS or MI	Any	Include	-365	30	None
11	365 days	Brilinta	Brilinta	183	02	10	10	0	0	ACS or MI Depression	Any	Include Exclude	-365	30	None
12	365 days	Brilinta	Brilinta	183	02	10	10	0	0	Depression ACS or MI	Any	Include Exclude	-365	30	None
13	365 days	Brintellix	Brintellix	183	02	10	10	0	0	None	N/A	N/A	N/A	N/A	None
14	365 days	Brintellix	Brintellix	183	02	10	10	0	0	Depression	Any	Include	-365	30	None
15	365 days	Brintellix	Brintellix	183	02	10	10	0	0	Depression ACS or MI	Any	Include Exclude	-365	30	None
16	365 days	Brintellix	Brintellix	183	02	10	10	0	0	ACS or MI Depression	Any	Include Exclude	-365	30	None