Disclaimer

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

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

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

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Overview for Request: cder_mpl1r_wp017, Report 3 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 Brilinta users that have a subsequent Brintellix dispensing and numbers of Brintellix users that have a subsequent Brilinta dispensing. This is report 3 of 3. Report 1 contains estimates of Brintellix and Brilinta users with on-label indications for each drug. Report 2 contains estimates of Brintellix and Brilinta users with on- or off-label indications for each drug.

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 identify exposures and follow-up time. The exposure of interest and the occurrence of the other look-a-like/sound-a-like dispensing during exposed time were identified. The number of exposure episodes, number of individuals, number of events, and days at-risk in the SDD 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 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 the exposure of interest in the 6 months (183 days) prior to the exposure of interest. The following age groups were included in the cohort: 0-17, 18-44, 45-64, and 65+ years.

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 include:

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

For Brintellix users, specific inclusion/exclusion groups include:

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

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 3 of 3, continued

Follow-Up Time: Follow-up time for the look-a-like/sound-a-like dispensing was determined by the length of the exposure episodes. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supply were less than ten days. The end date of each exposure episode was extended by ten additional days. Follow-up began on the day on which the first exposure of interest was dispensed and continued until the first occurrence of any of the following: 1) the look-a-like/sound-a-like dispensing of interest; 2) disenrollment; 3) the study end date (September 30, 2015); 4) the end date of the data provided by each Data Partner; or 5) the end of the exposure episode. All qualifying incident exposure episodes that occur between September 30, 2013 and September 30, 2015 were examined.

Events of Interest:

1) For Brilinta exposure episodes, the event of interest was a dispensing of Brintellix. In order to be included, the Brintellix dispensing must have been the first in the prior 6 months (183 days).
2) For Brintellix exposure episodes, the event of interest was a dispensing of Brilinta. In order to be included, the Brilinta dispensing must have been the first in the prior 6 months (183 days).

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@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

Sentinel

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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 Users with an Incident Dispensing of Brintellix in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brilinta Users	23,098	23,257	92,597	3,151,494	6,270,899	9,252.5	7	59,037,520	68,624,955.2	0.39	136.44	4.01	34.03	7.57
Brilinta Users with an Indication for Brilinta	18,653	18,732	76,399	2,591,217	5,158,397	7,596.2	3	1,234,609	803,346.7	15.11	138.92	4.10	33.92	3.95
Brilinta Users with an Indication for Brilinta and No Indication for Brintellix	16,230	16,274	67,930	2,307,526	4,595,452	6,750.9	0	1,105,148	650,128.5	14.69	142.18	4.19	33.97	0.00

Table 1b. Summary of Brintellix Users with an Incident Dispensing of Brilinta in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member-Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brintellix Users	22,017	22,158	66,531	2,117,549	2,174,329	6,413.3	5	59,041,375	68,632,895.7	0.37	96.18	3.02	31.83	7.80
Brintellix Users with an Indication for Brintellix	14,243	14,307	43,695	1,389,430	1,430,267	4,197.3	4	5,133,185	3,615,697.3	2.77	97.55	3.07	31.80	9.53
Brintellix Users with an Indication for Brintellix and No Indication for Brilinta	14,031	14,095	43,086	1,369,762	1,409,841	4,138.2	2	4,976,937	3,341,809.0	2.82	97.62	3.07	31.79	4.83

Table 2a. Summary of Brilinta Users with an Incident Dispensing of Brintellix in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brilinta Users														
0-17 Years	1	1	1	30	60	0.1	0	11,585,165	12,683,655.4	0.00	30.00	1.00	30.00	0.00
18-44 Years	985	987	4,903	155,958	310,955	452.8	5	23,228,168	23,732,639.1	0.04	158.33	4.98	31.81	110.42
45-64 Years	9,811	9,876	44,766	1,455,424	2,898,858	4,252.1	0	17,479,581	20,034,932.8	0.56	148.35	4.56	32.51	0.00
65+ Years	12,305	12,393	42,927	1,540,082	3,061,026	4,547.5	2	9,152,787	12,173,728.0	1.34	125.16	3.49	35.88	4.40
Brilinta Users with an Indication for Brilinta														
0-17 Years	0	0	0	0	0	0.0	0	600	242.4	0.00	---	---	---	---
18-44 Years	866	867	4,461	141,421	282,031	410.1	1	41,971	19,685.0	20.63	163.30	5.15	31.70	24.38
45-64 Years	8,125	8,159	37,886	1,229,891	2,451,015	3,587.3	0	379,107	214,083.3	21.43	151.37	4.66	32.46	0.00
65+ Years	9,666	9,706	34,052	1,219,905	2,425,351	3,598.8	2	833,396	569,335.9	11.60	126.21	3.52	35.82	5.56
Brilinta Users with an Indication for Brilinta and No Indication for Brintellix														
0-17 Years	0	0	0	0	0	0.0	0	562	207.4	0.00	---	---	---	---
18-44 Years	773	774	4,038	128,452	256,093	372.0	0	36,735	15,493.9	21.04	166.17	5.22	31.81	0.00
45-64 Years	7,149	7,167	33,968	1,102,288	2,197,309	3,209.1	0	332,119	166,253.0	21.53	154.19	4.75	32.45	0.00
65+ Years	8,308	8,333	29,924	1,076,786	2,142,050	3,169.8	0	751,419	468,174.3	11.06	129.61	3.60	35.98	0.00

Table 2b. Summary of Brintellix Users with an Incident Dispensing of Brilinta in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Age Group

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brintellix Users														
0-17 Years	280	280	754	23,966	24,638	73.3	0	11,585,142	12,683,559.1	0.02	85.59	2.69	31.79	0.00
18-44 Years	9,415	9,476	26,985	829,252	848,134	2,540.1	1	23,227,229	23,728,790.8	0.41	88.08	2.87	30.73	3.94
45-64 Years	10,270	10,330	32,210	1,042,094	1,070,023	3,138.0	2	17,481,609	20,038,143.1	0.59	101.47	3.14	32.35	6.37
65+ Years	2,055	2,072	6,582	222,237	231,534	661.9	2	9,155,690	12,182,402.8	0.22	108.14	3.20	33.76	30.22
Brintellix Users with an Indication for Brintellix														
0-17 Years	170	170	482	15,632	16,063	47.7	0	264,502	162,639.1	0.64	91.95	2.84	32.43	0.00
18-44 Years	5,713	5,737	16,765	514,025	527,491	1,569.7	0	1,666,198	1,008,481.8	3.43	89.97	2.93	30.66	0.00
45-64 Years	6,813	6,840	21,601	697,686	718,484	2,096.0	2	1,937,482	1,347,563.1	3.52	102.41	3.17	32.30	9.54
65+ Years	1,548	1,560	4,847	162,087	168,230	484.0	2	1,420,326	1,097,013.3	1.09	104.71	3.13	33.44	41.32
Brintellix Users with an Indication for Brintellix and No Indication for Brilinta														
0-17 Years	170	170	482	15,632	16,063	47.7	0	261,428	154,778.8	0.65	91.95	2.84	32.43	0.00
18-44 Years	5,697	5,721	16,728	512,944	526,380	1,566.2	0	1,630,324	949,110.5	3.49	90.04	2.94	30.66	0.00
45-64 Years	6,708	6,735	21,278	686,993	707,727	2,064.0	2	1,881,050	1,252,575.0	3.57	102.41	3.17	32.29	9.69
65+ Years	1,457	1,469	4,598	154,193	159,672	460.4	0	1,347,714	985,344.6	1.08	105.83	3.16	33.53	0.00

Table 3a. Summary of Brilinta Users with an Incident Dispensing of Brintellix in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brilinta Users														
Female	7,363	7,419	27,253	925,982	1,840,662	2,737.0	1	30,101,545	35,083,343.1	0.24	125.76	3.70	33.98	3.65
Male	15,733	15,836	65,341	2,225,422	4,430,058	6,515.2	6	28,933,772	33,539,218.1	0.54	141.45	4.15	34.06	9.21
Unknown	2	2	3	90	180	0.3	0	2,203	2,394.0	0.91	45.00	1.50	30.00	0.00
Brilinta Users with an Indication for Brilinta														
Female	5,822	5,848	21,979	747,553	1,487,213	2,206.0	0	477,020	302,732.0	12.20	128.40	3.78	34.01	0.00
Male	12,830	12,883	54,419	1,843,634	3,671,124	5,390.1	3	757,515	500,566.8	16.94	143.70	4.24	33.88	5.57
Unknown	1	1	1	30	60	0.1	0	74	47.8	13.51	30.00	1.00	30.00	0.00
Brilinta Users with an Indication for Brilinta and No Indication for Brintellix														
Female	4,689	4,702	18,014	614,480	1,223,691	1,809.0	0	406,590	225,657.1	11.53	131.05	3.84	34.11	0.00
Male	11,540	11,571	49,915	1,693,016	3,371,701	4,941.8	0	698,493	424,434.3	16.52	146.71	4.33	33.92	0.00
Unknown	1	1	1	30	60	0.1	0	65	37.1	15.38	30.00	1.00	30.00	0.00

Table 3b. Summary of Brintellix Users with an Incident Dispensing of Brilinta in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brintellix Users														
Female	14,947	15,040	44,696	1,422,298	1,461,085	4,313.0	4	30,101,582	35,081,926.9	0.50	95.16	2.99	31.82	9.27
Male	7,070	7,118	21,835	695,251	713,244	2,100.3	1	28,937,590	33,548,573.4	0.24	98.34	3.09	31.84	4.76
Unknown	0	0	0	0	0	0.0	0	2,203	2,395.5	0.00	---	---	---	---
Brintellix Users with an Indication for Brintellix														
Female	9,863	9,908	30,001	955,196	984,538	2,887.8	3	3,469,481	2,480,813.4	2.84	96.85	3.04	31.84	10.39
Male	4,380	4,399	13,694	434,234	445,729	1,309.5	1	1,663,493	1,134,754.1	2.63	99.14	3.13	31.71	7.64
Unknown	0	0	0	0	0	0.0	0	211	129.7	0.00	---	---	---	---
Brintellix Users with an Indication for Brintellix and No Indication for Brilinta														
Female	9,763	9,808	29,755	946,843	975,875	2,862.6	1	3,382,741	2,315,650.8	2.89	96.98	3.05	31.82	3.49
Male	4,268	4,287	13,331	422,919	433,966	1,275.7	1	1,593,997	1,026,046.3	2.68	99.09	3.12	31.72	7.84
Unknown	0	0	0	0	0	0.0	0	199	111.8	0.00	---	---	---	---

Table 4a. Summary of Brilinta Users with an Incident Dispensing of Brintellix in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brilinta Users														
2013	2,220	2,220	10,385	369,560	734,703	1,087.6	0	38,417,500	9,047,590.7	0.06	166.47	4.68	35.59	0.00
2014	10,358	10,371	48,369	1,693,083	3,369,417	4,961.6	7	45,067,352	34,708,017.0	0.23	163.46	4.67	35.00	14.11
2015	10,664	10,666	33,843	1,088,851	2,166,779	3,203.3	0	41,499,342	24,869,347.5	0.26	102.11	3.17	32.17	0.00
Brilinta Users with an Indication for Brilinta														
2013	1,782	1,782	8,548	307,640	611,607	903.0	0	518,144	100,016.5	3.44	172.64	4.80	35.99	0.00
2014	8,280	8,288	39,802	1,384,930	2,757,979	4,053.5	3	847,345	395,785.2	9.77	167.26	4.81	34.80	7.40
2015	8,660	8,662	28,049	898,647	1,788,811	2,639.7	0	743,547	307,545.0	11.65	103.77	3.24	32.04	0.00
Brilinta Users with an Indication for Brilinta and No Indication for Brintellix														
2013	1,573	1,573	7,712	277,883	553,139	814.7	0	443,953	81,417.8	3.54	176.66	4.90	36.03	0.00
2014	7,205	7,209	35,650	1,239,422	2,469,413	3,620.5	0	752,668	323,449.7	9.57	172.02	4.95	34.77	0.00
2015	7,492	7,492	24,568	790,221	1,572,900	2,315.8	0	650,811	245,261.0	11.51	105.48	3.28	32.16	0.00

Table 4b. Summary of Brintellix Users with an Incident Dispensing of Brilinta in the Sentinel Distributed Database between September 30, 2013 - September 30, 2015, by On-Label Indication and Year

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes with Events	Eligible Members	Member- Years	New Users per 1,000 Eligible Members	Days Supplied per User	Dispensings per User	Days Supplied per Dispensing	New Episodes with Events per 10,000 Years at Risk
All Brintellix Users														
2013	131	131	402	13,256	15,098	40.2	0	38,423,560	9,049,129.1	0.00	101.19	3.07	32.98	0.00
2014	12,497	12,512	41,278	1,343,401	1,382,563	4,057.7	3	45,072,221	34,712,778.1	0.28	107.50	3.30	32.55	7.39
2015	9,514	9,515	24,851	760,892	776,667	2,315.4	2	41,502,093	24,870,988.6	0.23	79.98	2.61	30.62	8.64
Brintellix Users with an Indication for Brintellix														
2013	84	84	240	8,117	9,708	24.7	0	2,279,958	452,304.3	0.04	96.63	2.86	33.82	0.00
2014	7,966	7,971	26,978	875,563	903,153	2,638.8	2	3,556,842	1,799,866.3	2.24	109.91	3.39	32.45	7.58
2015	6,251	6,252	16,477	505,750	517,406	1,533.8	2	3,125,439	1,363,526.8	2.00	80.91	2.64	30.69	13.04
Brintellix Users with an Indication for Brintellix and No Indication for Brilinta														
2013	84	84	240	8,117	9,708	24.7	0	2,181,594	418,105.1	0.04	96.63	2.86	33.82	0.00
2014	7,860	7,865	26,615	863,862	890,899	2,603.5	2	3,458,684	1,687,162.1	2.27	109.91	3.39	32.46	7.68
2015	6,145	6,146	16,231	497,783	509,234	1,510.0	0	3,030,893	1,236,541.8	2.03	81.01	2.64	30.67	0.00

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

Generic Name	Brand Name
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

Exposure	Code	Description	Code Type
		Depression	
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
		Acute Coronary Syndrome	
Brilinta	411.1	Intermediate coronary syndrome	ICD-9-CM
		Myocardial Infarction	
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

Exposure	Code	Description	Code Type
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, 6 scenarios were examined in this request.

Enrollment Gap: 45 days
Age Groups: 0-17, 18-44, 45-64, 65+
Query Period: September 30, 2013 - September 30, 2015
Coverage Requirement: Drug and Medical
Post-Exposure Enrollment Requirement: 30 days
Pre-Exposure Enrollment Requirement: 183 days

	Drug/Exposure								Inclusion/Exclusion Criteria					Event/Outcome			
Scenario	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	Incident with respect to:	Washout (days)	Blackout Period
1	Brilinta	Brilinta	183	02	10	10	0	0	None	N/A	N/A	N/A	N/A	Brintellix	Brintellix	183 (before event)	0
2	Brilinta	Brilinta	183	02	10	10	0	0	ACS or MI	Any	Include	-183	30	Brintellix	Brintellix	183 (before event)	0
3	Brilinta	Brilinta	183	02	10	10	0	0	ACS or MI Depression	Any Any	Include Exclude	-183 -183	30 30	Brintellix	Brintellix	183 (before event)	0
4	Brintellix	Brintellix	183	02	10	10	0	0	None	N/A	N/A	N/A	N/A	Brilinta	Brilinta	183 (before event)	0
5	Brintellix	Brintellix	183	02	10	10	0	0	Depression	Any	Include	-183	30	Brilinta	Brilinta	183 (before event)	0
6	Brintellix	Brintellix	183	02	10	10	0	0	Depression ACS or MI	Any Any	Include Exclude	-183 -183	30 30	Brilinta	Brilinta	183 (before event)	0