Disclaimer

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

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

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

The following report contains a description of the request, request specifications, and results from the modular

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Overview for Request MSY4_MPR32_v1
Request ID: MSY4_MPR32_v1 **Request Description:** This report investigates the frequency of international normalized ratio (INR) laboratory results that occur within 30 days of incident and prevalent warfarin use. The query was run using the Mini-Sentinel Distributed Database (MSDD). **Modular Program Tool Used:** Modular Program #6 (MP6) **Data Source:** Data from October 1, 2010 - December 31, 2012 from 11 Data Partners contributing to the MSDD were included in this report. This request was distributed to Data Partners on May 3, 2013. This report contains data from 11 Data Partners. See Appendix A for dates of available data for each Data Partner. **Study Design:** This request was designed to investigate the frequency of INR laboratory results that occur within 30 days of incident and prevalent warfarin use. Results provide counts of warfarin users stratified by number of results available in the MSDD for INR tests. Warfarin use was considered new if the member did not have any warfarin use in the prior 183 or 365 days, depending on the specified washout period. Laboratory results were considered new if the member did not have an INR in the previous day. See Appendix B for a list of generic and brand names used to define warfarin use in this report. **Cohort Eligibility Criteria:** Patients were required to be continuously enrolled in plans for either 183 days or 365 days prior to their dispensing date, depending on each scenario, during which gaps in coverage of up to 45 days were allowed. **Limitations:** Algorithms to define exposures are imperfect and, therefore, they may be misclassified. **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.

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Glossary of Terms in Modular Program 6*

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).

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

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

Incidence Type (event)- *Minimum incidence type* will consider the first exposure/lookup period in the query period as long as it is the first exposure/lookup period in the user's entire available history. *Single* and *Multiple incidence types* will use the washout period to

Incidence Type (post-event treatment)- *Minimum incidence type* considers the first event within the lookup period as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying events within the lookup period.

Inclusion/Exclusion Indicator - indicates whether condition(s) of interest are used for inclusion or exclusion criteria. A value of 1 instructs the program that members must have the condition of interest (inclusion criteria); a value of 0 instructs the program that members must not have the condition of interest (exclusion criteria).

Lookback Period Start and End - range of days relative to index that the program looks for inclusion/exclusion conditions of interest. For example, if the Inclusion/Exclusion Indicator =1, Lookback Period Start = -183 and Lookback Period End = 0, the cohort will only include members with the condition of interest present in the 183 days prior to and including the index date (the index date is day 0).

Lookup Period - fixed period of time following an incident exposure that the MP6 program searches for events of interest.

Member-Days - sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such a incidence, pre-existing condition, and enrollment requirements).

Minimum Lookup Period Duration - minimum number of enrollment days required after an incident exposure/lookup period start. For example, if the minimum duration =10, a member must have 10 or more days of continuous enrollment in drug and medical benefit coverage following the exposure/lookup period start in order for the lookup period to be included in output metrics.

New Users - number of members with incident exposure/lookup period during the query period. A user may only be counted once in a query period.

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

Query Period - period in which the modular program evaluates exposures of interest.

Washout Period (event) - 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 exposure/lookup period.

Washout Period (post-event treatment) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis/lab result) and continuous drug and medical coverage prior to an incident exposure/lookup period.

*all terms may not be used in this report

Table 1. Summary of Incident Warfarin Use and Subsequent International Normalized Ratio (INR) Lab Results in the Mini-Sentinel Distributed Database (MSDD) between October 1, 2010 and December 31, 2012 by Incidence Criteria and Washout Period

	All Data Partners	Claims-Based Data Partners (N=2)	Integrated Delivery System Data Partners (N=9)
Warfarin, Incident with Respect to Warfarin (183-Day Washout Period)			
Eligible members*	24,800,881	18,248,500	6,552,381
Member-days**	10,970,550,474	7,479,952,354	3,490,598,120
Members with incident warfarin use:	219,672 (100%)	185,938 (100%)	33,734 (100%)
with no INR results	171,889 (78.2%)	165,765 (89.2%)	6,124 (18.2%)
with 1 INR result	10,642 (4.8%)	7,517 (4.0%)	3,125 (9.3%)
with 2-3 INR results	11,738 (5.3%)	7,371 (4.0%)	4,367 (12.9%)
with ≥4 INR results	25,403 (11.6%)	5,285 (2.8%)	20,118 (59.6%)
Warfarin, Incident with Respect to Warfarin (365-Day Washout Period)			
Eligible members*	20,685,241	14,705,337	5,979,904
Member-days**	9,523,490,121	6,304,152,408	3,219,337,713
Members with incident warfarin use:	175,701 (100%)	146,696 (100%)	29,005 (100%)
with no INR results	134,709 (76.7%)	129,765 (88.5%)	4,944 (17.0%)
with 1 INR result	7,760 (4.4%)	5,951 (4.1%)	1,809 (6.2%)
with 2-3 INR results	9,636 (5.5%)	6,300 (4.3%)	3,336 (11.5%)
with ≥4 INR results	23,596 (13.4%)	4,680 (3.2%)	18,916 (65.2%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (183-Day Washout Period)			
Eligible members*	24,783,893	18,231,772	6,552,121
Member-days**	10,960,672,637	7,470,310,256	3,490,362,381
Members with incident warfarin use:	216,042 (100%)	182,412 (100%)	33,630 (100%)
with no INR results	168,699 (78.1%)	162,609 (89.1%)	6,090 (18.1%)
with 1 INR result	10,494 (4.9%)	7,374 (4.0%)	3,120 (9.3%)
with 2-3 INR results	11,575 (5.4%)	7,219 (4.0%)	4,356 (13.0%)
with ≥4 INR results	25,274 (11.7%)	5,210 (2.9%)	20,064 (59.7%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (365-Day Washout Period)			
Eligible members*	20,673,352	14,693,622	5,979,730
Member-days**	9,515,629,755	6,296,504,028	3,219,125,727
Members with incident warfarin use:	172,945 (100%)	144,027 (100%)	28,918 (100%)
with no INR results	132,314 (76.5%)	127,397 (88.5%)	4,917 (17.0%)
with 1 INR result	7,644 (4.4%)	5,840 (4.1%)	1,804 (6.2%)
with 2-3 INR results	9,505 (5.5%)	6,178 (4.3%)	3,327 (11.5%)
with ≥4 INR results	23,482 (13.6%)	4,612 (3.2%)	18,870 (65.3%)

*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.

**Sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such a incidence, pre-existing condition, and enrollment requirements).

Table 2. Summary of Incident Warfarin Use and Subsequent International Normalized Ratio (INR) Lab Results in the Mini-Sentinel Distributed Database (MSDD) between October 1, 2010 and December 31, 2012 by Incidence Criteria, Washout Period, and Age Group

	Age Group						
	0-20 years	21-44 years	45-54 years	55-64 years	65-74 years	75-84 years	85+ years
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Warfarin, Incident with Respect to Warfarin (183-Day Washout Period)							
Eligible members*	5,377,469	7,816,516	3,835,030	3,249,398	3,644,150	1,983,018	785,194
Member-days**	2,294,028,650	3,059,509,298	1,572,453,072	1,374,223,559	1,480,807,471	856,146,826	333,381,598
Members with incident warfarin use:	399 (100%)	8832 (100%)	15,207 (100%)	30,131 (100%)	70,941 (100%)	67,652 (100%)	26,510 (100%)
with no INR results	236 (59.1%)	5,592 (63.3%)	10,156 (66.8%)	20,190 (67.0%)	58,169 (82.0%)	55,385 (81.9%)	22,161 (83.6%)
with 1 INR result	30 (7.5%)	659 (7.5%)	1,042 (6.9%)	2,015 (6.7%)	2,920 (4.1%)	2,887 (4.3%)	1,089 (4.1%)
with 2-3 INR results	43 (10.8%)	721 (8.2%)	1,196 (7.9%)	2,332 (7.7%)	3,177 (4.5%)	3,101 (4.6%)	1,168 (4.4%)
with ≥4 INR results	90 (22.6%)	1,860 (21.1%)	2,813 (18.5%)	5,594 (18.6%)	6,675 (9.4%)	6,279 (9.3%)	2,092 (7.9%)
Warfarin, Incident with Respect to Warfarin (365-Day Washout Period)							
Eligible members*	4,497,619	6,370,926	3,288,841	2,828,331	2,958,146	1,728,118	691,426
Member-days**	1,968,878,246	2,551,565,060	1,390,803,482	1,233,992,748	1,277,726,734	789,772,140	310,751,711
Members with incident warfarin use:	325 (100%)	6,684 (100%)	11,944 (100%)	23,914 (100%)	55,600 (100%)	55,417 (100%)	21,817 (100%)
with no INR results	182 (56.0%)	4,027 (60.2%)	7,668 (64.2%)	15,409 (64.4%)	44,574 (80.2%)	44,761 (80.8%)	18,088 (82.9%)
with 1 INR result	23 (7.1%)	484 (7.2%)	757 (6.3%)	1,485 (6.2%)	2,132 (3.8%)	2,096 (3.8%)	783 (3.6%)
with 2-3 INR results	36 (11.1%)	559 (8.4%)	965 (8.1%)	1,919 (8.0%)	2,636 (4.7%)	2,569 (4.6%)	952 (4.4%)
with ≥4 INR results	84 (25.8%)	1,614 (24.1%)	2,554 (21.4%)	5,101 (21.3%)	6,258 (11.3%)	5,991 (10.8%)	1,994 (9.1%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (183-Day Washout Period)							
Eligible members*	5,377,465	7,816,329	3,834,453	3,247,389	3,637,715	1,976,065	782,267
Member-days**	2,294,025,805	3,059,401,292	1,572,078,473	1,373,130,158	1,477,467,321	852,572,671	331,996,917
Members with incident warfarin use:	399 (100%)	8,792 (100%)	15,109 (100%)	29,832 (100%)	69,714 (100%)	66,172 (100%)	26,024 (100%)
with no INR results	236 (59.1%)	5,561 (63.3%)	10,081 (66.7%)	19,959 (66.9%)	57,088 (81.9%)	54,061 (81.7%)	21,713 (83.4%)
with 1 INR result	30 (7.5%)	657 (7.5%)	1,035 (6.9%)	1,994 (6.7%)	2,867 (4.1%)	2,836 (4.3%)	1,075 (4.1%)
with 2-3 INR results	43 (10.8%)	716 (8.1%)	1,186 (7.8%)	2,308 (7.7%)	3,131 (4.5%)	3,035 (4.6%)	1,156 (4.4%)
with ≥4 INR results	90 (22.6%)	1,858 (21.1%)	2,807 (18.6%)	5,571 (18.7%)	6,628 (9.5%)	6,240 (9.4%)	2,080 (8.0%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (365-Day Washout Period)							
Eligible members*	4,497,616	6,370,771	3,288,358	2,826,829	2,953,620	1,723,263	689,278
Member-days**	1,968,875,833	2,551,473,828	1,390,484,501	1,233,129,033	1,275,137,462	786,899,051	309,630,047
Members with incident warfarin use:	325 (100%)	6,651 (100%)	11,860 (100%)	23,689 (100%)	54,697 (100%)	54,280 (100%)	21,443 (100%)
with no INR results	182 (56.0%)	4,003 (60.2%)	7,604 (64.1%)	15,240 (64.3%)	43,792 (80.1%)	43,744 (80.6%)	17,749 (82.8%)
with 1 INR result	23 (7.1%)	482 (7.2%)	750 (6.3%)	1,469 (6.2%)	2,089 (3.8%)	2,060 (3.8%)	771 (3.6%)
with 2-3 INR results	36 (11.1%)	554 (8.3%)	956 (8.1%)	1,900 (8.0%)	2,599 (4.8%)	2,520 (4.6%)	940 (4.4%)
with ≥4 INR results	84 (25.8%)	1,612 (24.2%)	2,550 (21.5%)	5,080 (21.4%)	6,217 (11.4%)	5,956 (11.0%)	1,983 (9.2%)

*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.
**Sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such a incidence, pre-existing condition, and enrollment requirements).

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Table 3. Summary of Incident Warfarin Use and Subsequent International Normalized Ratio (INR) Lab Results in the Mini-Sentinel Distributed Database (MSDD) between October 1, 2010 and December 31, 2012 by Incidence Criteria, Washout Period, and Sex

	Sex		
	Female	Male	Unkown
	Number (%)	Number (%)	Number (%)
Warfarin, Incident with Respect to Warfarin (183-Day Washout Period)			
Eligible members*	13,049,619	11,744,443	6,819
Member-days**	5,815,934,243	5,151,552,070	3,064,161
Members with incident warfarin use:	115,550 (100%)	104,090 (100%)	32 (100%)
with no INR results	92,291 (79.9%)	79,574 (76.4%)	24 (75.0%)
with 1 INR result	5,046 (4.4%)	5,593 (5.4%)	3 (9.4%)
with 2-3 INR results	5,907 (5.1%)	5,827 (5.6%)	4 (12.5%)
with ≥4 INR results	12,306 (10.6%)	13,096 (12.6%)	1 (3.1%)
Warfarin, Incident with Respect to Warfarin (365-Day Washout Period)			
Eligible members*	10,917,545	9,761,723	5,973
Member-days**	5,067,333,641	4,453,397,575	2,758,905
Members with incident warfarin use:	94,253 (100%)	81,421 (100%)	27 (100%)
with no INR results	74,136 (78.7%)	60,552 (74.4%)	21 (77.8%)
with 1 INR result	3,802 (4.0%)	3,955 (4.9%)	3 (11.1%)
with 2-3 INR results	4,871 (5.2%)	4,763 (5.8%)	2 (7.4%)
with ≥4 INR results	11,444 (12.1%)	12,151 (14.9%)	1 (3.7%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (183-Day Washout Period)			
Eligible members*	13,041,849	11,735,226	6,818
Member-days**	5,811,507,388	5,146,101,843	3,063,406
Members with incident warfarin use:	113,776 (100%)	102,235 (100%)	31 (100%)
with no INR results	90,705 (79.7%)	77,971 (76.3%)	23 (74.2%)
with 1 INR result	4,979 (4.4%)	5,512 (5.4%)	3 (9.7%)
with 2-3 INR results	5,843 (5.1%)	5,728 (5.6%)	4 (12.9%)
with ≥4 INR results	12,249 (10.8%)	13,024 (12.7%)	1 (3.2%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (365-Day Washout Period)			
Eligible members*	10,912,182	9,755,198	5,972
Member-days**	5,063,827,396	4,449,044,184	2,758,175
Members with incident warfarin use:	92,903 (100%)	80,015 (100%)	27 (100%)
with no INR results	72,929 (78.5%)	59,364 (74.2%)	21 (77.8%)
with 1 INR result	3,756 (4.0%)	3,885 (4.9%)	3 (11.1%)
with 2-3 INR results	4,824 (5.2%)	4,679 (5.8%)	2 (7.4%)
with ≥4 INR results	11,394 (12.3%)	12,087 (15.1%)	1 (3.7%)

*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.

**Sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such a incidence, pre-existing condition, and enrollment requirements).

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Table 4. Summary of Incident Warfarin Use and Subsequent International Normalized Ratio (INR) Lab Results in the Mini-Sentinel Distributed Database (MSDD) between October 1, 2010 and December 31, 2012 by Incidence Criteria, Washout Period, and Year

	Year		
	2010	2011	2012
	Number (%)	Number (%)	Number (%)
Warfarin, Incident with Respect to Warfarin (183-Day Washout Period)			
Eligible members*	17,023,125	19,582,046	18,450,051
Member-days**	1,492,603,578	5,706,966,834	3,770,980,062
Members with incident warfarin use:	31,789 (100%)	114,601 (100%)	73,282 (100%)
with no INR results	24,319 (76.5%)	88,669 (77.4%)	58,901 (80.4%)
with 1 INR result	1,576 (5.0%)	5,715 (5.0%)	3,351 (4.6%)
with 2-3 INR results	1,954 (6.1%)	6,182 (5.4%)	3,602 (4.9%)
with ≥4 INR results	3,940 (12.4%)	14,035 (12.2%)	7,428 (10.1%)
Warfarin, Incident with Respect to Warfarin (365-Day Washout Period)			
Eligible members*	14,350,712	15,629,386	15,716,128
Member-days**	1,288,161,333	4,918,294,764	3,317,034,024
Members with incident warfarin use:	25,265 (100%)	89,174 (100%)	61,262 (100%)
with no INR results	19,137 (75.7%)	67,068 (75.2%)	48,504 (79.2%)
with 1 INR result	1,024 (4.1%)	4,085 (4.6%)	2,651 (4.3%)
with 2-3 INR results	1,516 (6.0%)	5,007 (5.6%)	3,113 (5.1%)
with ≥4 INR results	3,588 (14.2%)	13,014 (14.6%)	6,994 (11.4%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (183-Day Washout Period)			
Eligible members*	17,023,110	19,571,704	18,424,250
Member-days**	1,492,578,468	5,703,037,151	3,765,057,018
Members with incident warfarin use:	31,769 (100%)	112,889 (100%)	71,384 (100%)
with no INR results	24,300 (76.5%)	87,167 (77.2%)	57,232 (80.2%)
with 1 INR result	1,575 (5.0%)	5,643 (5.0%)	3,276 (4.6%)
with 2-3 INR results	1,954 (6.2%)	6,107 (5.4%)	3,514 (4.9%)
with ≥4 INR results	3,940 (12.4%)	13,972 (12.4%)	7,362 (10.3%)
Warfarin, Incident with Respect to Dabigatran and Warfarin (365-Day Washout Period)			
Eligible members*	14,350,704	15,626,368	15,693,409
Member-days**	1,288,140,346	4,915,610,303	3,311,879,106
Members with incident warfarin use:	25,245 (100%)	87,991 (100%)	59,709 (100%)
with no INR results	19,118 (75.7%)	66,052 (75.1%)	47,144 (79.0%)
with 1 INR result	1,023 (4.1%)	4,029 (4.6%)	2,592 (4.3%)
with 2-3 INR results	1,516 (6.0%)	4,951 (5.6%)	3,038 (5.1%)
with ≥4 INR results	3,588 (14.2%)	12,959 (14.7%)	6,935 (11.6%)

*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.

**Sum of all days a member is eligible for an incident exposure/lookup period (i.e., days that the member meets all inclusion criteria such a incidence, pre-existing condition, and enrollment requirements).

Appendix A. List of Dates of Available Data for Each Data Partner as of Request Send Date (May 3, 2013)

DP ID	Start Date	End Date
DP0001	10/1/2010	6/30/2012
DP0002	10/1/2010	12/31/2012
DP0003	10/1/2010	7/31/2012
DP0004	10/1/2010	8/31/2012
DP0005	10/1/2010	12/31/2012
DP0006	10/1/2010	12/31/2012
DP0007	10/1/2010	5/30/2012
DP0008	10/1/2010	6/30/2012
DP0009	10/1/2010	10/31/2012
DP0010	10/1/2010	6/30/2012
DP0011	10/1/2010	12/31/2012

Appendix B. List of Generic and Brand Names Included in this Request

Code Type	Generic Name	Brand Name
National Drug Code	Warfarin Sodium	Warfarin Sodium
National Drug Code	Warfarin Sodium	Athrombin-K
National Drug Code	Warfarin Sodium	Coumadin
National Drug Code	Warfarin Sodium	Panwarfarin
National Drug Code	Warfarin Sodium	Sofarin
National Drug Code	Warfarin Sodium	Coufarin
National Drug Code	Warfarin Sodium	Jantoven

Appendix C. Modular Program 6 Specifications for Request MSY4_MPR32

Modular Program 6 was used to describe the presence of International Normalized Ratio (INR) lab results in a pre-specified period following incident warfarin use. The query period was from October 1, 2010 to December 31, 2012, and the enrollment gap was set at 45 days. Age groups were split as follows: 0 - 20, 21 - 44, 45 - 54, 55 - 64, 65 - 74, 75 - 84, and 85+ years. In total, four different scenarios were examined in this report with differing incidence criteria and washout periods. See below for a description of each of these scenarios.

	Events (Warfarin Use)										Post-Event Treatment (INR Lab result)									
Scenario	Event	Event Principal Diagnosis Indicator	Event Care Setting	Incident with respect to:	Incident only Principal Diagnosis	Incident only Event Care Setting	Washout Type	Washout Period	Lookup Period Duration	Minimum Lookup Period Duration	Treatment	Lab Frequency Categories	Treatment Principal Diagnosis Indicator	Treatment Care Setting	Incident with respect to:	Incident only Principal Diagnosis	Incident only Care Setting	Washout Type	Washout Period	Episode Gap
1	Warfarin	N/A	N/A	Warfarin	N/A	N/A	Single	183 Days	30 days	0 Days	INR Lab Result	0, 1, 2-3, ≥4	NO	Any	INR Lab Result	NO	Any	Multiple	1 Day	0 Days
2	Warfarin	N/A	N/A	Warfarin	N/A	N/A	Single	365 Days	30 days	0 Days	INR Lab Result	0, 1, 2-3, ≥4	NO	Any	INR Lab Result	NO	Any	Multiple	1 Day	0 Days
3	Warfarin	N/A	N/A	Wafarin and dabigatran	N/A	N/A	Single	183 days	30 days	0 days	INR Lab Result	0, 1, 2-3, ≥4	NO	Any	INR Lab Result	NO	Any	Multiple	1 Day	0 Days
4	Warfarin	N/A	N/A	Warfarin and dabigatran	N/A	N/A	Single	365 days	30 days	0 days	INR Lab Result	0, 1, 2-3, ≥4	NO	Any	INR Lab Result	NO	Any	Multiple	1 Day	0 Days

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

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

Healthcare Common Procedure Coding System (HCPCS) codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

Current Procedural Terminology, Fourth Revision (CPT-4) codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight