Disclaimer

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

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

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

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

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Overview for Request cder_mpl1r_wp119 (Report 2 of 2)

Request ID: cder_mpl1r_wp119

Request Description: The goal of this query was to compare risk of stroke and bleeding associated with use of non-vitamin K antagonist oral anticoagulants (NOACs) (including dabigatran, rivaroxaban, and apixaban) in those between the ages of 21 to 64 years in the Sentinel Distributed Database (SDD). This is report 2 of 2. This report assesses follow-up time among new NOAC initiators. Report 1 examines characteristics and utilization among NOAC initiators.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 7.0.1

Data Source: The study period spanned from October 19, 2010 to September 30, 2015 and included data from 16 Data Partners contributing to the SDD. This request was distributed on January 11, 2019. See Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: The request was designed to identify new users with exposures of interest and assess follow-up time available in the SDD. The number of qualifying patients with the exposures of interest was calculated overall and by age group.

Exposures of Interest: The exposures of interest were apixaban 2.5 mg, apixaban 5 mg, dabigatran 75 mg, dabigatran 150 mg, rivaroxaban 10 mg, rivaroxaban 15 mg, and rivaroxaban 20 mg. All exposures were defined using National Drug Codes (NDCs). Please see Appendix B for a list of generic and brand names of medical products used to define exposures in this request.

Cohort Eligibility Criteria: Cohort members were required to be continuously enrolled in plans with medical and drug coverage for at least 183 days prior to their index dispensing date, during which gaps in coverage of up to 45 days were allowed. Members were required to have no evidence of apixaban, dabigatran, rivaroxaban, or warfarin use in the 183 days preceding their index date. Finally, members were required to be between the ages of 21 and 64 years. There were five sensitivity analyses for apixaban 2.5 and rivaroxaban 10 mg exposure groups:

1) Require evidence of an atrial fibrillation diagnosis on index date or up to 183 days prior to index.
2) Require evidence of an atrial fibrillation diagnosis and no evidence of a pulmonary embolism or deep vein thrombosis diagnosis on index date or up to 183 days prior to index.
3) Require no evidence of an atrial fibrillation diagnosis and evidence of a pulmonary embolism or deep vein thrombosis diagnosis on index date or up to 183 days prior to index.
4) Require no evidence of an atrial fibrillation, pulmonary embolism, or deep vein thrombosis diagnosis on index date or up to 183 days prior to index.
5) Require evidence of hip, knee, or spinal surgery on index date or up to 183 days prior to index.

Only a member's first qualifying dispensing that occurred between October 19, 2010 to September 3, 2015 was included.

Follow-Up Time: Follow-up began on the day of the first exposure of interest and continued until the first occurrence of any of the following: 1) disenrollment; 2) end of query period; 3) Data Partner end date; or 4) death.

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

Limitations: Algorithms used to define exposures are imperfect; 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 (info@sentinelsystem.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.

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). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

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

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

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

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

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 Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (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 Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

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

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

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. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

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.

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

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.
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

Table 1. Summary of Follow-Up Time for Users of Apixaban, Dabigatran, and Rivaroxaban in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015

		Follow-up Time in Days							Exposed Members with Specified Follow-up Time					
Level	Exposed Members	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation	0-90 days		91-180 days		181+ days	
Main analyses									Number	Percent	Number	Percent	Number	Percent
Apixaban, Dabigatran, or Rivaroxaban (any dose)	149,388	1	150	353	659	1,792	449.56	372.69	23,584	16%	20,069	13%	105,735	71%
Apixaban, 2.5 mg	1,806	1	63	142	258	839	176.95	146.68	625	35%	460	25%	721	40%
Apixaban, 5 mg	14,670	1	79	190	354	960	244.90	205.72	4,096	28%	2,923	20%	7,651	52%
Dabigatran, 75 mg	782	1	197	495	993	1,756	611.85	476.18	96	12%	88	11%	598	76%
Dabigatran, 150 mg	22,570	1	269	629	1,115	1,792	711.08	497.37	2,055	9%	1,922	9%	18,593	82%
Rivaroxaban, 10 mg	51,571	1	192	421	733	1,521	496.29	364.65	6,313	12%	5,927	11%	39,331	76%
Rivaroxaban, 15 mg	24,162	1	118	275	489	1,379	328.38	250.47	4,793	20%	3,886	16%	15,483	64%
Rivaroxaban, 20 mg	40,659	1	136	313	560	1,412	378.09	294.32	7,041	17%	5,983	15%	27,635	68%
Apixaban, 2.5 mg sensitivity analyses														
Atrial Fibrillation (AF) inclusion	382	1	78	162	307	839	220.40	188.13	110	29%	94	25%	178	47%
AF inclusion; Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT) exclusion	353	1	83	169	322	839	227.74	190.24	96	27%	88	25%	169	48%
PE/DVT inclusion and AF exclusion	152	1	57	121	217	722	156.23	131.74	59	39%	37	24%	56	37%
AF, PE, and DVT exclusion	1,275	1	62	134	247	763	166.21	130.89	457	36%	331	26%	487	38%
Surgery inclusion	775	1	65	148	260	616	172.28	127.79	252	33%	206	27%	317	41%
Rivaroxaban, 10 mg sensitivity analyses														
AF inclusion	1,486	2	182	391	724	1,519	483.96	366.70	210	14%	158	11%	1,118	75%
AF inclusion; PE and DVT exclusion	1,434	2	184	396	724	1,519	486.86	366.85	200	14%	150	10%	1,084	76%
PE/DVT inclusion and AF exclusion	1,345	1	175	394	675	1,505	459.64	340.29	186	14%	160	12%	999	74%
AF, PE, and DVT exclusion	48,841	1	193	422	734	1,521	497.34	365.08	5,936	12%	5,624	12%	37,281	76%
Surgery inclusion	32,234	1	201	435	761	1,521	512.74	372.59	3,786	12%	3,542	11%	24,906	77%

Table 2. Summary of Follow-up Time for Users of Apixaban, Dabigatran, and Rivaroxaban in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Age Group

		Exposed Members with Specified Follow-up Time					
Level	Exposed Members	0-90 days		91-180 days		181+ days	
Main analyses	**Total**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Apixaban, Dabigatran, or Rivaroxaban (any dose)							
Age (Years)							
21-35	7,987	1,547	19%	1,370	17%	5,070	63%
36-50	33,318	5,563	17%	4,581	14%	23,174	70%
51-64	108,083	16,474	15%	14,118	13%	77,491	72%
Apixaban, 2.5 mg							
Age (Years)							
21-35	73	34	47%	22	30%	17	23%
36-50	349	120	34%	92	26%	137	39%
51-64	1,384	471	34%	346	25%	567	41%
Apixaban, 5 mg							
Age (Years)							
21-35	507	192	38%	126	25%	189	37%
36-50	2,639	817	31%	537	20%	1,285	49%
51-64	11,524	3,087	27%	2,260	20%	6,177	54%
Dabigatran, 75 mg							
Age (Years)							
21-35	16	4	25%	1	6%	11	69%
36-50	129	18	14%	17	13%	94	73%
51-64	637	74	12%	70	11%	493	77%
Dabigatran, 150 mg							
Age (Years)							
21-35	614	65	11%	66	11%	483	79%
36-50	4,234	378	9%	339	8%	3,517	83%
51-64	17,722	1,612	9%	1,517	9%	14,593	82%
Rivaroxaban, 10 mg							
Age (Years)							
21-35	2,058	304	15%	325	16%	1,429	69%
36-50	10,311	1,338	13%	1,194	12%	7,779	75%
51-64	39,202	4,671	12%	4,408	11%	30,123	77%
Rivaroxaban, 15 mg							
Age (Years)							
21-35	2,985	599	20%	544	18%	1,842	62%
36-50	8,244	1,610	20%	1,255	15%	5,379	65%
51-64	12,933	2,584	20%	2,087	16%	8,262	64%
Rivaroxaban, 20 mg							
Age (Years)							
21-35	2,453	497	20%	431	18%	1,525	62%
36-50	9,477	1,733	18%	1,465	15%	6,279	66%
51-64	28,729	4,811	17%	4,087	14%	19,831	69%

Table 2. Summary of Follow-up Time for Users of Apixaban, Dabigatran, and Rivaroxaban in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Age Group

		Exposed Members with Specified Follow-up Time					
Level	Exposed Members	0-90 days		91-180 days		181+ days	
Main analyses	**Total**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Apixaban, 2.5 mg sensitivity analyses							
Atrial fibrillation (AF) inclusion							
Age (Years)							
21-35	3	0	0%	2	67%	1	33%
36-50	41	15	37%	9	22%	17	41%
51-64	338	95	28%	83	25%	160	47%
AF inclusion; Pulmonary embolism (PE) and Deep vein thrombosis (DVT) exclusion							
Age (Years)							
21-35	3	0	0%	2	67%	1	33%
36-50	37	13	35%	9	24%	15	41%
51-64	313	83	27%	77	25%	153	49%
PE/DVT inclusion and AF exclusion							
Age (Years)							
21-35	14	6	43%	3	21%	5	36%
36-50	40	13	33%	9	23%	18	45%
51-64	98	40	41%	25	26%	33	34%
AF, PE, and DVT exclusion							
Age (Years)							
21-35	56	28	50%	17	30%	11	20%
36-50	268	92	34%	74	28%	102	38%
51-64	951	337	35%	240	25%	374	39%
Surgery inclusion							
Age (Years)							
21-35	9	4	44%	3	33%	2	22%
36-50	113	39	35%	30	27%	44	39%
51-64	653	209	32%	173	26%	271	42%
Rivaroxaban, 10 mg sensitivity analyses							
AF inclusion							
Age (Years)							
21-35	18	3	17%	2	11%	13	72%
36-50	187	31	17%	23	12%	133	71%
51-64	1,281	176	14%	133	10%	972	76%
AF inclusion; PE and DVT exclusion							
Age (Years)							
21-35	17	3	18%	2	12%	12	71%
36-50	181	28	15%	22	12%	131	72%
51-64	1,236	169	14%	126	10%	941	76%
PE/DVT inclusion and AF exclusion							
Age (Years)							
21-35	122	21	17%	21	17%	80	66%
36-50	370	54	15%	42	11%	274	74%
51-64	853	111	13%	97	11%	645	76%

Table 2. Summary of Follow-up Time for Users of Apixaban, Dabigatran, and Rivaroxaban in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Age Group

		Exposed Members with Specified Follow-up Time					
Level	Exposed Members	0-90 days		91-180 days		181+ days	
Main analyses	**Total**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
AF, PE, and DVT exclusion							
Age (Years)							
21-35	1,920	281	15%	302	16%	1,337	70%
36-50	9,777	1,261	13%	1,134	12%	7,382	76%
51-64	37,144	4,394	12%	4,188	11%	28,562	77%
Surgery inclusion							
Age (Years)							
21-35	396	58	15%	60	15%	278	70%
36-50	5,252	638	12%	556	11%	4,058	77%
51-64	26,586	3,090	12%	2,926	11%	20,570	77%

Appendix A. Dates of Available Data for Each Data Partner (DP) up to Request End Date (9/30/2015) as of Query Distribution Date

Data Partner ID	Start Date[1]	End Date[1]
DP01	01/01/2000	09/30/2015
DP02	01/01/2000	09/30/2015
DP03	01/01/2004	09/30/2015
DP04	01/01/2008	09/30/2015
DP05	06/01/2007	09/30/2015
DP06	01/01/2000	09/30/2015
DP07	01/01/2006	09/30/2015
DP08	01/01/2000	09/30/2015
DP09	01/01/2000	09/30/2015
DP10	01/01/2000	09/30/2015
DP11	01/01/2005	09/30/2015
DP12	01/01/2000	09/30/2015
DP13	01/01/2000	09/30/2015
DP14	01/01/2008	09/30/2015
DP15	01/01/2000	05/31/2015
DP16	01/01/2012	09/30/2015

[1]The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
apixaban	Eliquis
dabigatran etexilate mesylate	Pradaxa
rivaroxaban	Xarelto
warfarin sodium	warfarin
warfarin sodium	Jantoven
warfarin sodium	Coumadin
warfarin sodium	warfarin (bulk)

Appendix C. Specifications Defining Parameters in this Request

The goal of this query was to compare risk of stroke and bleeding associated with use of non-vitamin K antagonist oral anticoagulants (NOACs) (including dabigatran, rivaroxaban, and apixaban) in those between the ages of 21 to 64 years in the Sentinel Distributed Database (SDD). This is report 2 of 2. This report assesses follow-up time among new NOAC initiators. Report 1 examines characteristics and utilization among NOAC initiators.

Query period: October 19, 2010 -September 30, 2015
Coverage requirement: Medical and drug coverage
Pre-index enrollment requirement: 183 days
Enrollment gap: 45 days
Age groups: 21-35, 36-50, 51-64 years
Stratifications: Age group
Additional output: Censoring table (0-90, 90-180, 180+ day categories)

	Exposure					Inclusion/Exclusion		
Cohort	Index exposure	Cohort definition	Exposure washout (days)	Incident with respect to:	Censor treatment episode at evidence of:	Include/Exclude	Condition	Evaluation Period (Days)
1	Apixaban, dabigatran, or rivaroxaban (all doses)	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *Data Partner (DP) end date; *Query end date; *Disenrollment;	---	---	---
2	Apixaban, 2.5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---
3	Apixaban, 5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---
4	Dabigatran, 75 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---

Appendix C. Specifications Defining Parameters in this Request

	Exposure					Inclusion/Exclusion		
Cohort	Index exposure	Cohort definition	Exposure washout (days)	Incident with respect to:	Censor treatment episode at evidence of:	Include/Exclude	Condition	Evaluation Period (Days)
5	Dabigatran, 150 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---
6	Rivaroxaban, 10 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---
7	Rivaroxaban, 15 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---
8	Rivaroxaban, 20 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	---	---	---
9	Apixaban, 2.5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	Atrial fibrillation (AF)	-183 to 0
						Exclude		-183 to 0
10	Apixaban, 2.5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	AF	-183 to 0
						Exclude	Pulmonary embolism (PE)/Deep vein thrombosis (DVT)	-183 to 0
11	Apixaban, 2.5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	PE/DVT	-183 to 0
						Exclude	AF	-183 to 0

Appendix C. Specifications Defining Parameters in this Request

	Exposure					Inclusion/Exclusion		
Cohort	Index exposure	Cohort definition	Exposure washout (days)	Incident with respect to:	Censor treatment episode at evidence of:	Include/Exclude	Condition	Evaluation Period (Days)
12	Apixaban, 2.5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	---	-183 to 0
						Exclude	AF, PE, DVT	-183 to 0
13	Apixaban, 2.5 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	Select surgeries	-183 to 0
						Exclude		-183 to 0
14	Rivaroxaban, 20 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	AF	-183 to 0
						Exclude		-183 to 0
15	Rivaroxaban, 20 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	AF	-183 to 0
						Exclude	PE, DVT	-183 to 0
16	Rivaroxaban, 20 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	PE/DVT	-183 to 0
						Exclude	AF	-183 to 0
17	Rivaroxaban, 20 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	---	-183 to 0
						Exclude	AF, PE, DVT	-183 to 0
18	Rivaroxaban, 20 mg	Retain first valid incident exposure episode only	183	Apixaban, dabigatran, rivaroxaban, and warfarin (all doses)	*Death; *DP end date; *Query end date; *Disenrollment;	Include	Select surgeries	-183 to 0
						Exclude		-183 to 0

International Classification of Diseases, Ninth Revision (ICD-9), International Classification of Diseases, Tenth Revision (ICD-10), Healthcare Common Procedure Coding System (HCPCS), and Current Prodecural Technology (CPT) codes are provided by Optum360. National Drug Codes (NDC) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."