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_mpl2p_wp018

Request ID: cder_mpl2p_wp018_nsdp_v01

Request Description: In this request we performed comparative risk assessments of severe uterine bleed (SUB) among users of oral anticoagulants (rivaroxaban, dabigatran, apixaban, and warfarin) in the Sentinel Distributed Database (SDD). This analysis is an update to a previous analysis (cder_mpl2p_wp007).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) and Propensity Score Analysis (PSA) modules in Sentinel Routine Querying System version 8.1.0, with ad hoc programming

Data Source: We distributed this request on December 30, 2019 and queried data from October 19, 2010 through September 30, 2015 in 5 Data Partners contributing to the SDD. See Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: Retrospective cohort study - we followed incident users of oral anticoagulants (rivaroxaban, dabigatran, apixaban, and warfarin) on their exposed time until the earliest occurrence of SUB or until censoring criteria are met. We defined sixteen cohorts, or eight pair-wise comparisons, to estimate the comparative risks for both the overall populations and subgroups by the following characteristics: age groups (18-50 vs. 50+ years of age), baseline gynecological disorder (uterine myoma, endometrial hyperplasia, endometriosis, ovarian cyst, uterine or cervical polyp, adenomyosis, or uterine cancer/ovarian cancer/cervical cancer), baseline atrial fibrillation or atrial flutter (AF), baseline deep vein thrombosis or pulmonary embolism (DVT/PE), and in applicable comparisons, dose of index-defining novel oral anticoagulants (NOACs). High or low dose definition of the index-defining NOAC are:

High dose:
- Dabigatran: 150mg; rivaroxaban: 15, 20mg; apixaban: 5mg

Low dose:
- Dabigatran: 75mg; rivaroxaban: 10mg; apixaban: 2.5mg

Additionally, sensitivity comparisons included cross-stratification subgroups between age groups and the following: baseline AF, baseline DVT/PE, and, when applicable, high/low dose of the index-defining NOAC.

Exposures of Interest: Each comparison paired two of the four exposures of interest per SUB outcome:

1) Rivaroxaban vs. dabigatran
2) Rivaroxaban vs. apixaban
3) Dabigatran vs. apixaban
4) Rivaroxaban vs. warfarin

Please see Appendix B for a list of generic and brand names of medical products used to define exposures in this request.

Outcomes of Interest: SUB is defined as a combination of vaginal bleed and either transfusion or surgical management in non-institutional (non-IS) care settings:

1) Vaginal bleed and transfusion management occurring on the same day (Figure 1 in Appendix M)
2) Vaginal bleed followed by surgical management within 60 days (Figure 2 in Appendix M)

We assigned the date of SUB to the date of transfusion or surgical management. We identified vaginal bleed using International Classification of Diseases, Ninth Revision (ICD-9-CM) diagnosis codes (Appendix E), SUB managements using ICD-9-CM diagnosis and procedure codes, Healthcare Common Procedure Coding System (HCPCS) codes, Current Procedural Terminology, Fourth Edition (CPT-4) codes, and Revenue Center codes (Appendix F).

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Cohort Eligibility Criteria: Members included in the cohorts were required to be continuously enrolled in health plans with medical and drug coverage in the 183 days prior to index oral anticoagulant dispensing date (index date), during which gaps in coverage of up to 45 days were allowed. Members were also required to be 18 years of age or older, female, and have no history of exposure to rivaroxaban, dabigatran, apixaban, warfarin, or edoxaban in the 183 days prior to the index date. We defined exposure incidence using NDCs and days supply information recorded for the outpatient pharmacy dispensings. Please see Appendix B for a list of generic and brand names of medical products used to define cohort eligibility criteria.

Inclusion and Exclusion Criteria: The evaluation window for all inclusion and exclusion conditions was the 183 days prior to and including the index date. We required that members have a baseline condition of AF or DVT/PE. We excluded members with baseline condition(s) of hysterectomy, vaginal bleed, medical managements of SUB, knee/hip joint replacement surgery, or in their respective risk assessments: either surgical managements or same-day transfusion managements. Definition of each SUB management was as follows.

1) Medical management - insertion of intrauterine device, vaginal packing, or initiation of contraception (combined oral contraceptives and progestin-only contraceptives) or an antifibrinolytic drug (tranexamic acid, aminocaproic acid, desmopressin)
2) Transfusion management - red blood cell (RBC)-only transfusion plus outpatient pharmacy dispensing of conjugated equine estrogen
3) Surgical management of SUB - hysteroscopic polypectomy; hysteroscopic, laparoscopic or abdominal myomectomy; dilation and curettage with or without hysteroscopy; hysteroscopy (not otherwise considered by other surgical managements); hysterectomy; thermal, cryo or section endometrial ablation; or uterine artery embolization

Additionally, each cohort within a comparison had an exclusion of any other oral anticoagulants of interest on the index date. For example, when compared to dabigatran, rivaroxaban cohort had no dispensing of dabigatran (implicitly implemented by the PSA module), apixaban, edoxaban, or warfarin on their index date of initiating rivaroxaban.

We defined all inclusion and exclusion criteria using ICD-9-CM diagnosis and procedure codes, HCPCS and CPT-4 procedure codes, and Revenue Center codes. Please refer to Appendix C for a list of diagnosis and procedure codes and Appendix D for generic and brand names of medical products used to define inclusion and exclusion criteria.

Follow-Up Time: We determined follow-up time based on the length of exposure episodes, which was defined using days supply information recorded in the outpatient pharmacy dispensings to create any period of continuous exposure. We considered an exposure episode continuous if gaps in days covered by days supply were less than three days. This query analyzed only the first valid exposure episode per eligible member. Follow-up began on the index date and continued until the last day of supply of the last dispensing plus a three-day extension period, or until the first occurrence of any of the following: 1) disenrollment; 2) death; 3) the end date of the data provided by each Data Partner; 4) the end of the query period (September 30, 2015); 5) occurrence of the outcome of interest; and 6) initiation of any other oral anticoagulants that did not define the index exposure of each respective cohort.

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Covariates: We assessed age (continuous form and in age groups), calendar year, race and, when applicable, high/low dose definition of the index-defining NOAC on the index date, as well as the following covariates during the 183 days prior to and including the index date: from any care setting – comorbidity score (Combined Comorbidity Index)[1], health service and drug utilizations, diabetes, hypertension, renal impairment, obesity, smoking, cardiovascular disease, severe anemia (proxied by RBC transfusion), gynecological disorders, Von Willebrand's disease, AF, and DVT/PE; from outpatient pharmacy dispensings – cardiovascular and antidiabetic agents, medications that increase bleeding risk without interaction with warfarin or NOACs, medications that inhibit metabolism of warfarin or NOACs and increase bleeding risk, medications that induce metabolism of warfarin or NOACs and decrease bleeding risk. Appendix I lists all diagnosis and procedure codes, and Appendix J lists medical product generic and brand names used to define all baseline covariates listed in Appendix J. Appendix L summarizes covariates used to characterize the cohorts only, define analysis subgroups, and/or estimate the propensity score.

Additional reporting 1: Within each cohort, we assessed vaginal bleed beginning on the day after the index date until the end of enrollment. We further assessed subsequent medical managements if a patient was diagnosed with vaginal bleed, overall and separately among patients with SUB events, and among patients without SUB events. The evaluation window started from the day of the first post-index vaginal bleed diagnosis until the earliest of SUB criteria met or censoring. Appendix G lists diagnosis and procedure codes and Appendix H lists medical product generic and brand names used to define medical management.

Additional reporting 2: Additionally, for members who experienced vaginal bleed followed by surgical management within 60 days, we summarized the distribution of each qualifying surgery that contributed to the SUB occurrence.

Analysis: We fitted logistic regression models to estimate an eligible member's propensity score using the following covariates: continuous age, comorbidity score (Combined Comorbidity Index)[1], health service and drug utilizations; presence of diabetes, hypertension, renal impairment, obesity, smoking, cardiovascular disease, severe anemia, gynecological disorders, Von Willebrand's disease, AF, and DVT/PE; any utilization of cardiovascular and antidiabetic agents, medications that increase bleeding risk without interaction with warfarin or NOACs, medications that inhibit metabolism of warfarin or NOACs and increase bleeding risk, medications that induce metabolism of warfarin or NOACs and decrease bleeding risk.

The outcome analysis of each comparison used both propensity score matching and stratification methods. The matching ratio was 1:1 and used the nearest neighbor approach without replacement and a caliper of 0.05 on the probability scale. In subgroup analyses, we allowed patients to be re-matched within the matched population. The stratification sorted patients according to their propensity score deciles (percentile=10). In subgroup analyses, we re-assigned patients to deciles specific to each subgroup level. We created risk sets within each matched set or propensity score decile and within each Data Partner site. We used case-centered logistic regression (mathematically equivalent to Cox proportional hazards regression[2]) models stratified by Data Partner site to estimate the hazard ratio and their 95% confidence intervals. In the conditional analyses, we additionally stratified by the models on the matched set or propensity score decile.

Please see Appendix K for the parameter specifications used in the analyses, Appendix L for the list of covariates considered in this request, and Appendix M for pictorial summaries of the study design, outcome definitions, and additional reporting.

Overview for Request cder_mpl2p_wp018
Limitations: As with all observational studies, this evaluation has limitation in its ability to control for all sources of potential bias. Algorithms used to define exposures, outcomes, inclusion and exclusion criteria, and covariates are subject to misclassifications. Therefore, data should be interpreted with these limitations 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. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse).

[1]Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759

[2]Fireman B, Lee J, Lewis N, Bembom O, van der Laan M, Baxter R. Influenza vaccination and mortality: differentiating vaccine effects from bias. Am J Epidemiol. 2009;170(5):650–656. doi:10.1093/aje/kwp173

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Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module*

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).
Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.
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.
Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.
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.

Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module*

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.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

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

Glossary of Terms for Analyses Using
Propensity Score Analysis (PSA) Tool*

Covariate - requester defined binary variable to include in the propensity score estimation model (e.g., diabetes, heart failure, etc.) during requester-defined lookback period. Requester may also choose to add any of the following categorical, continuous, or count metrics to the propensity score estimation model:

1. Age (continuous)
2. Sex
3. Time period (i.e., monitoring period for sequential analyses)
4. Year of exposure
5. Comorbidity score
6. Medical utilization – number of inpatient stays
7. Medical utilization – number of institutional stays
8. Medical utilization – number of emergency department visits
9. Medical utilization – number of outpatient visits
10. Health care utilization – number of other ambulatory encounters (e.g., telemedicine, email consults)
11. Drug utilization – number of dispensings
12. Drug utilization – number of unique generics dispensed
13. Drug Utilization – number of unique drug classes dispensed

Covariate Evaluation Window - specified number of days relative to index date to evaluate the occurrence of covariates of interest. Note: members are required to have continuous enrollment during the covariate evaluation window, regardless of the value included in the "Continuous enrollment before exposure" field.

Individual Level Data Return - program may return individual-level, de-identified datasets to the Sentinel Operations Center (SOC). While the datasets contain a single row per patient for each specified analysis, patient identifiers such as a patient ID are not included in the output. Individual-level datasets are returned to the SOC, aggregated, and used to calculate effect estimates via Cox (proportional hazards) regression.

Mahalanobis Distance - provides a measure of balance across all variables while accounting for their correlation.

Matching Caliper - maximum allowed difference in propensity scores between treatment and control patients. Requester may select any caliper (e.g., 0.01, 0.025, and 0.05).

Matching Ratio - patients in exposed and comparator groups are nearest neighbor matched by a 1:1 or 1:n (up to 10) matching ratio.

Matched Conditional and Unconditional Analysis - in a conditional matched analysis, a Cox model, stratified by Data Partner site and matched set, is run on the matched population. This can be done for both the both 1:1 and 1:n matched cohorts. In an unconditional analysis, a Cox model, stratified by Data Partner site only, is run on the matched population. This can be done for the 1:1 matched cohort only.

Propensity Score Stratification - option to stratify propensity scores based on requester-defined percentiles in the unmatched population. In a stratified analysis, a Cox model, stratified by Data Partner site, is run on the stratified population. Note that all patients identified in exposure and comparator cohorts are used in the analysis.

PSM Tool - performs effect estimation by comparing exposure propensity-score matched parallel new user cohorts. Propensity score estimation and matching are conducted within each Sentinel Data Partner site via distributed programming code; data are returned to the SOC, aggregated, and used to calculate effect estimates.

Risk-set Level Data Return - alternative to the patient-level data return approach. In this approach, the PSM tool will produce de-identified, risk-set level datasets instead of or in addition to individual-level output. Whereas each observation in the patient-level datasets represents one patient in the cohort, each observation in the risk set dataset represents one event. Risk sets are created at the Data Partner site, returned to the SOC, aggregated, and used to calculate effect estimates via case-centered logistic regression.

Subgroup Analysis - may be conducted using any requester-defined covariates. Subgroup analyses may be performed in the unmatched and the matched population.

Glossary of Terms for Analyses Using
Propensity Score Analysis (PSA) Tool*

Zero Cell Correction - indicator for whether to screen variables with a zero correction added to each cell in the confounder/outcome 2x2 table. Recommended when the number of exposed outcomes is fewer than 150.

*all terms may not be used in this report

Table 1a. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	194,400	100.0%	80,074	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.0	10.9	76.8	9.1	-1.720	-0.171
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,336*	*4.3%*	*1,067*	*1.3%*	*2.956*	*0.180*
51+	*186,064*	*95.7%*	*79,007*	*98.7%*	*-2.956*	*-0.180*
Sex						
Female	*194,400*	*100.0%*	*80,074*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*623*	*0.3%*	*229*	*0.3%*	*0.034*	*0.006*
Asian	*2,185*	*1.1%*	*1,249*	*1.6%*	*-0.436*	*-0.038*
Black or African American	*14,068*	*7.2%*	*4,076*	*5.1%*	*2.146*	*0.089*
Native Hawaiian or Other Pacific Islander	*92*	*0.0%*	*33*	*0.0%*	*0.006*	*0.003*
White	*150,529*	*77.4%*	*64,213*	*80.2%*	*-2.759*	*-0.068*
Unknown	*26,903*	*13.8%*	*10,274*	*12.8%*	*1.008*	*0.030*
Hispanic Origin	*2,894*	*1.5%*	*1,249*	*1.6%*	*-0.071*	*-0.006*
Year						
2010	*0*	*0.0%*	*1,253*	*1.6%*	*-1.565*	-
2011	*278*	*0.1%*	*30,063*	*37.5%*	*-37.401*	*-1.089*
2012	*17,381*	*8.9%*	*22,788*	*28.5%*	*-19.518*	*-0.517*
2013	*53,107*	*27.3%*	*13,042*	*16.3%*	*11.031*	*0.270*
2014	*73,034*	*37.6%*	*8,564*	*10.7%*	*26.874*	*0.662*
2015	*50,600*	*26.0%*	*4,364*	*5.4%*	*20.579*	*0.589*
Presence of Condition in Post-Index Enrollment:						
Vaginal bleed	*6,747*	*3.5%*	*3,538*	*4.4%*	*-0.948*	*-0.049*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.9	2.9	2.6	0.188	0.068
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	9,845	5.1%	2,305	2.9%	2.186	0.112
Cardiovascular disease	88,477	45.5%	40,367	50.4%	-4.899	-0.098
Diabetes	62,499	32.1%	26,912	33.6%	-1.459	-0.031
Hypertension	163,786	84.3%	70,760	88.4%	-4.116	-0.120
Obesity	39,106	20.1%	12,656	15.8%	4.311	0.112
Renal impairment	39,668	20.4%	14,101	17.6%	2.795	0.071
Smoking	40,463	20.8%	12,312	15.4%	5.439	0.142
Von Willebrand disease	48	0.0%	15	0.0%	0.006	0.004
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,643	2.9%	1,416	1.8%	1.134	0.075

Table 1a. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.014*	*0.016*
Endometrial hyperplasia	*118*	*0.1%*	*42*	*0.1%*	*0.008*	*0.003*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.008*	*0.009*
Ovarian cyst	*1,386*	*0.7%*	*366*	*0.5%*	*0.256*	*0.034*
Uterine myoma leiomyoma	*1,196*	*0.6%*	*348*	*0.4%*	*0.181*	*0.025*
Uterine or cervical polyp	*110*	*0.1%*	*44*	*0.1%*	*0.002*	*0.001*
Uterine ovarian or cervical cancer	*3,208*	*1.7%*	*718*	*0.9%*	*0.754*	*0.067*
Atrial Fibrillation (AF) or atrial flutter	133,067	68.5%	77,887	97.3%	-28.819	-0.828
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	78,610	40.4%	7,532	9.4%	31.031	0.769
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*181,691*	*93.5%*	*63,145*	*78.9%*	*14.604*	*0.433*
Cardiovascular and antidiabetic agents	178,761	92.0%	78,138	97.6%	-5.627	-0.255
Medications that increase bleeding risk without interaction	107,884	55.5%	41,116	51.3%	4.148	0.083
Medications that inhibit metabolism of NOACs and increase bleeding risk	131,138	67.5%	56,748	70.9%	-3.412	-0.074
Medications that induce metabolism of NOACs and reduce bleeding risk	55,866	28.7%	22,030	27.5%	1.226	0.027
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.7	12.3	8.6	0.832	0.091
Mean number of emergency room encounters	0.6	1.3	0.5	1.0	0.178	0.156
Mean number of inpatient hospital encounters	0.9	1.0	0.7	0.9	0.130	0.132
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.6	0.084	0.132
Mean number of other ambulatory encounters	7.4	10.8	5.7	8.7	1.628	0.166
Mean number of unique drug classes	10.4	5.0	10.1	4.7	0.220	0.045
Mean number of generics	11.1	5.7	10.8	5.3	0.279	0.051
Mean number of filled prescriptions	26.1	20.2	26.2	19.2	-0.106	-0.005

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1.

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1b. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	80,042	41.2%	80,042	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	76.8	9.1	76.8	9.1	-0.016	-0.002
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,019*	*1.3%*	*1,067*	*1.3%*	*-0.060*	*-0.005*
51+	*79,023*	*98.7%*	*78,975*	*98.7%*	*0.060*	*0.005*
Sex						
Female	*80,042*	*100.0%*	*80,042*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*260*	*0.3%*	*229*	*0.3%*	*0.039*	*0.007*
Asian	*1,193*	*1.5%*	*1,249*	*1.6%*	*-0.070*	*-0.006*
Black or African American	*4,107*	*5.1%*	*4,076*	*5.1%*	*0.039*	*0.002*
Native Hawaiian or Other Pacific Islander	*34*	*0.0%*	*33*	*0.0%*	*0.001*	*0.001*
White	*64,444*	*80.5%*	*64,212*	*80.2%*	*0.290*	*0.007*
Unknown	*10,004*	*12.5%*	*10,243*	*12.8%*	*-0.299*	*-0.009*
Hispanic Origin	*1,106*	*1.4%*	*1,249*	*1.6%*	*-0.179*	*-0.015*
Year						
2010	*0*	*0.0%*	*1,250*	*1.6%*	*-1.562*	-
2011	*138*	*0.2%*	*30,047*	*37.5%*	*-37.367*	*-1.087*
2012	*10,149*	*12.7%*	*22,779*	*28.5%*	*-15.779*	*-0.398*
2013	*23,473*	*29.3%*	*13,039*	*16.3%*	*13.036*	*0.314*
2014	*28,233*	*35.3%*	*8,563*	*10.7%*	*24.575*	*0.611*
2015	*18,049*	*22.5%*	*4,364*	*5.5%*	*17.097*	*0.508*
Presence of Condition in Post-Index Enrollment:						
Vaginal bleed	*2,557*	*3.2%*	*3,537*	*4.4%*	*-1.224*	*-0.064*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	2.9	2.6	3.0	2.6	-0.001	-0.000
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,328	2.9%	2,304	2.9%	0.030	0.002
Cardiovascular disease	40,447	50.5%	40,343	50.4%	0.130	0.003
Diabetes	26,907	33.6%	26,898	33.6%	0.011	0.000
Hypertension	70,807	88.5%	70,731	88.4%	0.095	0.003
Obesity	12,614	15.8%	12,655	15.8%	-0.051	-0.001
Renal impairment	14,129	17.7%	14,100	17.6%	0.036	0.001
Smoking	12,184	15.2%	12,312	15.4%	-0.160	-0.004
Von Willebrand disease	17	0.0%	14	0.0%	0.004	0.003
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,374	1.7%	1,414	1.8%	-0.050	-0.004

Table 1b. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0.004*	*0.007*
Endometrial hyperplasia	*43*	*0.1%*	*42*	*0.1%*	*0.001*	*0.001*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.000*	*0.000*
Ovarian cyst	*352*	*0.4%*	*365*	*0.5%*	*-0.016*	*-0.002*
Uterine myoma leiomyoma	*343*	*0.4%*	*347*	*0.4%*	*-0.005*	*-0.001*
Uterine or cervical polyp	*40*	*0.0%*	*44*	*0.1%*	*-0.005*	*-0.002*
Uterine ovarian or cervical cancer	*689*	*0.9%*	*718*	*0.9%*	*-0.036*	*-0.004*
Atrial Fibrillation (AF) or atrial flutter	77,855	97.3%	77,855	97.3%	0.000	0.000
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	7,506	9.4%	7,532	9.4%	-0.032	-0.001
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*75,003*	*93.7%*	*63,118*	*78.9%*	*14.848*	*0.442*
Cardiovascular and antidiabetic agents	78,115	97.6%	78,106	97.6%	0.011	0.001
Medications that increase bleeding risk without interaction	41,143	51.4%	41,096	51.3%	0.059	0.001
Medications that inhibit metabolism of NOACs and increase bleeding risk	56,759	70.9%	56,723	70.9%	0.045	0.001
Medications that induce metabolism of NOACs and reduce bleeding risk	22,056	27.6%	22,027	27.5%	0.036	0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.2	8.6	12.3	8.6	-0.024	-0.003
Mean number of emergency room encounters	0.5	0.9	0.5	1.0	-0.000	-0.000
Mean number of inpatient hospital encounters	0.7	0.9	0.7	0.9	-0.002	-0.002
Mean number of non-acute institutional encounters	0.2	0.5	0.2	0.6	0.001	0.003
Mean number of other ambulatory encounters	5.8	8.5	5.7	8.7	0.050	0.006
Mean number of unique drug classes	10.1	4.8	10.1	4.7	-0.001	-0.000
Mean number of generics	10.8	5.4	10.8	5.3	0.003	0.000
Mean number of filled prescriptions	26.1	20.3	26.2	19.1	-0.051	-0.003

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1c. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	194,400	100.0%	80,074	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.5	19.8	75.9	93.2	-0.443	-0.007
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*6,792*	*3.5%*	*2,613*	*3.3%*	*0.231*	*0.013*
51+	*187,608*	*96.5%*	*77,461*	*96.7%*	*-0.231*	*-0.013*
Sex						
Female	*194,400*	*100.0%*	*80,074*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*612*	*0.3%*	*274*	*0.3%*	*-0.027*	*-0.005*
Asian	*2,370*	*1.2%*	*1,064*	*1.3%*	*-0.110*	*-0.010*
Black or African American	*12,952*	*6.7%*	*4,076*	*6.4%*	*0.269*	*0.011*
Native Hawaiian or Other Pacific Islander	*92*	*0.0%*	*35*	*0.0%*	*0.004*	*0.002*
White	*151,547*	*78.0%*	*63,153*	*78.9%*	*-0.912*	*-0.022*
Unknown	*26,826*	*13.8%*	*10,429*	*13.0%*	*0.775*	*0.023*
Hispanic Origin	*2,851*	*1.5%*	*1,402*	*1.8%*	*-0.284*	*-0.023*
Year						
2010	*0*	*0.0%*	*1,231*	*1.5%*	*-1.537*	-
2011	*303*	*0.2%*	*27,703*	*34.6%*	*-34.440*	*-1.020*
2012	*19,443*	*10.0%*	*20,699*	*25.8%*	*-15.848*	*-0.422*
2013	*54,090*	*27.8%*	*12,638*	*15.8%*	*12.041*	*0.295*
2014	*71,847*	*37.0%*	*11,043*	*13.8%*	*23.167*	*0.552*
2015	*48,716*	*25.1%*	*6,761*	*8.4%*	*16.616*	*0.456*
Presence of Condition in Post-Index Enrollment:						
Vaginal bleed	*6,563*	*3.4%*	*3,598*	*4.5%*	*-1.118*	*-0.058*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.8	3.2	7.0	-0.116	-0.022
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	8,597	4.4%	3,683	4.6%	-0.178	-0.009
Cardiovascular disease	91,255	46.9%	38,970	48.7%	-1.726	-0.035
Diabetes	63,366	32.6%	26,501	33.1%	-0.500	-0.011
Hypertension	165,958	85.4%	68,823	85.9%	-0.580	-0.017
Obesity	36,573	18.8%	14,980	18.7%	0.106	0.003
Renal impairment	38,010	19.6%	16,563	20.7%	-1.133	-0.028
Smoking	37,215	19.1%	15,389	19.2%	-0.075	-0.002
Von Willebrand disease	45	0.0%	29	0.0%	-0.013	-0.008
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,001	2.6%	2,056	2.6%	0.004	0.000

Table 1c. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0.011*	*0.014*
Endometrial hyperplasia	*111*	*0.1%*	*53*	*0.1%*	*-0.009*	*-0.004*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.007*	*0.009*
Ovarian cyst	*1,237*	*0.6%*	*489*	*0.6%*	*0.026*	*0.003*
Uterine myoma leiomyoma	*1,092*	*0.6%*	*404*	*0.5%*	*0.057*	*0.008*
Uterine or cervical polyp	*107*	*0.1%*	*63*	*0.1%*	*-0.023*	*-0.009*
Uterine ovarian or cervical cancer	*2,782*	*1.4%*	*1,183*	*1.5%*	*-0.046*	*-0.004*
Atrial Fibrillation (AF) or atrial flutter	148,771	76.5%	62,613	78.2%	-1.666	-0.040
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	61,281	31.5%	24,678	30.8%	0.705	0.015
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*181,858*	*93.5%*	*62,536*	*78.1%*	*15.451*	*0.454*
Cardiovascular and antidiabetic agents	181,874	93.6%	75,297	94.0%	-0.477	-0.020
Medications that increase bleeding risk without interaction	105,580	54.3%	44,576	55.7%	-1.358	-0.027
Medications that inhibit metabolism of NOACs and increase bleeding risk	133,033	68.4%	55,350	69.1%	-0.691	-0.015
Medications that induce metabolism of NOACs and reduce bleeding risk	55,183	28.4%	23,379	29.2%	-0.810	-0.018
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.9	9.5	12.9	25.6	0.000	0.000
Mean number of emergency room encounters	0.6	1.1	0.6	4.5	-0.013	-0.004
Mean number of inpatient hospital encounters	0.8	1.0	0.8	2.4	-0.013	-0.007
Mean number of non-acute institutional encounters	0.2	0.6	0.2	1.6	-0.014	-0.012
Mean number of other ambulatory encounters	6.9	9.6	7.3	26.6	-0.401	-0.020
Mean number of unique drug classes	10.3	5.3	10.5	16.8	-0.165	-0.013
Mean number of generics	11.0	5.9	11.2	18.6	-0.190	-0.014
Mean number of filled prescriptions	26.1	21.7	26.5	48.1	-0.381	-0.010

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1d. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	196,090	100.0%	97,784	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.1	10.9	77.9	9.4	-2.879	-0.283
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,361*	*4.3%*	*1,227*	*1.3%*	*3.009*	*0.184*
51+	*187,729*	*95.7%*	*96,557*	*98.7%*	*-3.009*	*-0.184*
Sex						
Female	*196,090*	*100.0%*	*97,784*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*631*	*0.3%*	*220*	*0.2%*	*0.097*	*0.019*
Asian	*2,227*	*1.1%*	*1,164*	*1.2%*	*-0.055*	*-0.005*
Black or African American	*14,152*	*7.2%*	*4,076*	*6.0%*	*1.206*	*0.049*
Native Hawaiian or Other Pacific Islander	*94*	*0.0%*	*62*	*0.1%*	*-0.015*	*-0.007*
White	*151,887*	*77.5%*	*80,294*	*82.1%*	*-4.656*	*-0.116*
Unknown	*27,099*	*13.8%*	*10,166*	*10.4%*	*3.423*	*0.105*
Hispanic Origin	*2,918*	*1.5%*	*1,168*	*1.2%*	*0.294*	*0.026*
Year						
2010	*0*	*0.0%*	*0*	*0.0%*	*0.000*	-
2011	*279*	*0.1%*	*0*	*0.0%*	*0.142*	-
2012	*17,591*	*9.0%*	*0*	*0.0%*	*8.971*	-
2013	*53,707*	*27.4%*	*9,225*	*9.4%*	*17.955*	*0.476*
2014	*73,634*	*37.6%*	*36,251*	*37.1%*	*0.479*	*0.010*
2015	*50,879*	*25.9%*	*52,308*	*53.5%*	*-27.547*	*-0.587*
Presence of Condition in Post-Index Enrollment:						
Vaginal bleed	*6,799*	*3.5%*	*1,514*	*1.5%*	*1.919*	*0.123*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.9	3.4	2.8	-0.215	-0.075
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	9,881	5.0%	3,460	3.5%	1.501	0.074
Cardiovascular disease	89,291	45.5%	52,425	53.6%	-8.077	-0.162
Diabetes	63,009	32.1%	32,633	33.4%	-1.240	-0.026
Hypertension	165,282	84.3%	87,228	89.2%	-4.916	-0.145
Obesity	39,383	20.1%	18,886	19.3%	0.770	0.019
Renal impairment	39,978	20.4%	25,123	25.7%	-5.305	-0.126
Smoking	40,715	20.8%	19,856	20.3%	0.457	0.011
Von Willebrand disease	48	0.0%	20	0.0%	0.004	0.003
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,676	2.9%	1,858	1.9%	0.994	0.065

Table 1d. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.009*	*0.009*
Endometrial hyperplasia	*119*	*0.1%*	*47*	*0.0%*	*0.013*	*0.005*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.009*	*0.010*
Ovarian cyst	*1,396*	*0.7%*	*479*	*0.5%*	*0.222*	*0.029*
Uterine myoma leiomyoma	*1,206*	*0.6%*	*419*	*0.4%*	*0.187*	*0.026*
Uterine or cervical polyp	*112*	*0.1%*	*39*	*0.0%*	*0.017*	*0.008*
Uterine ovarian or cervical cancer	*3,220*	*1.6%*	*974*	*1.0%*	*0.646*	*0.057*
Atrial Fibrillation (AF) or atrial flutter	134,717	68.7%	89,314	91.3%	-22.636	-0.590
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	78,809	40.2%	16,196	16.6%	23.627	0.543
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*183,254*	*93.5%*	*66,066*	*67.6%*	*25.891*	*0.692*
Cardiovascular and antidiabetic agents	180,407	92.0%	95,083	97.2%	-5.236	-0.234
Medications that increase bleeding risk without interaction	108,696	55.4%	51,812	53.0%	2.446	0.049
Medications that inhibit metabolism of NOACs and increase bleeding risk	132,299	67.5%	70,791	72.4%	-4.927	-0.108
Medications that induce metabolism of NOACs and reduce bleeding risk	56,349	28.7%	27,627	28.3%	0.483	0.011
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.7	13.0	8.8	0.135	0.015
Mean number of emergency room encounters	0.6	1.3	0.6	1.0	0.088	0.075
Mean number of inpatient hospital encounters	0.9	1.0	0.8	1.0	0.053	0.052
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.7	0.022	0.032
Mean number of other ambulatory encounters	7.3	10.8	6.9	10.4	0.407	0.038
Mean number of unique drug classes	10.4	5.0	10.5	4.8	-0.119	-0.024
Mean number of generics	11.1	5.7	11.2	5.4	-0.064	-0.012
Mean number of filled prescriptions	26.1	20.2	25.8	19.2	0.236	0.012

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1e. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	97,466	49.7%	97,466	99.7%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	77.8	9.1	77.9	9.4	-0.081	-0.009
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,124*	*1.2%*	*1,227*	*1.3%*	*-0.106*	*-0.010*
51+	*96,342*	*98.8%*	*96,239*	*98.7%*	*0.106*	*0.010*
Sex						
Female	*97,466*	*100.0%*	*97,466*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*292*	*0.3%*	*220*	*0.2%*	*0.074*	*0.014*
Asian	*1,318*	*1.4%*	*1,163*	*1.2%*	*0.159*	*0.014*
Black or African American	*5,727*	*5.9%*	*4,076*	*6.0%*	*-0.144*	*-0.006*
Native Hawaiian or Other Pacific Islander	*48*	*0.0%*	*62*	*0.1%*	*-0.014*	*-0.006*
White	*79,834*	*81.9%*	*80,039*	*82.1%*	*-0.210*	*-0.005*
Unknown	*10,247*	*10.5%*	*10,115*	*10.4%*	*0.135*	*0.004*
Hispanic Origin	*1,401*	*1.4%*	*1,165*	*1.2%*	*0.242*	*0.021*
Year						
2010	*0*	*0.0%*	*0*	*0.0%*	*0.000*	-
2011	*175*	*0.2%*	*0*	*0.0%*	*0.180*	-
2012	*11,075*	*11.4%*	*0*	*0.0%*	*11.363*	-
2013	*27,720*	*28.4%*	*9,199*	*9.4%*	*19.003*	*0.500*
2014	*35,241*	*36.2%*	*36,131*	*37.1%*	*-0.913*	*-0.019*
2015	*23,255*	*23.9%*	*52,136*	*53.5%*	*-29.632*	*-0.639*
Presence of Condition in Post-Index Enrollment:						
Vaginal bleed	*2,964*	*3.0%*	*1,509*	*1.5%*	*1.493*	*0.100*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.3	2.8	3.3	2.8	-0.009	-0.003
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	3,569	3.7%	3,458	3.5%	0.114	0.006
Cardiovascular disease	52,007	53.4%	52,115	53.5%	-0.111	-0.002
Diabetes	32,553	33.4%	32,531	33.4%	0.023	0.000
Hypertension	86,844	89.1%	86,922	89.2%	-0.080	-0.003
Obesity	18,803	19.3%	18,810	19.3%	-0.007	-0.000
Renal impairment	24,958	25.6%	24,811	25.5%	0.151	0.003
Smoking	19,672	20.2%	19,740	20.3%	-0.070	-0.002
Von Willebrand disease	19	0.0%	18	0.0%	0.001	0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,882	1.9%	1,855	1.9%	0.028	0.002

Table 1e. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.001*	*-0.001*
Endometrial hyperplasia	*53*	*0.1%*	*47*	*0.0%*	*0.006*	*0.003*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.003*	*0.005*
Ovarian cyst	*461*	*0.5%*	*478*	*0.5%*	*-0.017*	*-0.003*
Uterine myoma leiomyoma	*438*	*0.4%*	*419*	*0.4%*	*0.019*	*0.003*
Uterine or cervical polyp	*46*	*0.0%*	*39*	*0.0%*	*0.007*	*0.003*
Uterine ovarian or cervical cancer	*1,010*	*1.0%*	*972*	*1.0%*	*0.039*	*0.004*
Atrial Fibrillation (AF) or atrial flutter	89,087	91.4%	88,996	91.3%	0.093	0.003
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	16,092	16.5%	16,196	16.6%	-0.107	-0.003
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*90,994*	*93.4%*	*65,966*	*67.7%*	*25.679*	*0.685*
Cardiovascular and antidiabetic agents	94,761	97.2%	94,765	97.2%	-0.004	-0.000
Medications that increase bleeding risk without interaction	51,572	52.9%	51,643	53.0%	-0.073	-0.001
Medications that inhibit metabolism of NOACs and increase bleeding risk	70,283	72.1%	70,512	72.3%	-0.235	-0.005
Medications that induce metabolism of NOACs and reduce bleeding risk	27,458	28.2%	27,549	28.3%	-0.093	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.9	9.1	12.9	8.8	-0.057	-0.006
Mean number of emergency room encounters	0.6	1.1	0.6	1.0	-0.003	-0.002
Mean number of inpatient hospital encounters	0.8	1.0	0.8	1.0	0.002	0.002
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.7	0.001	0.001
Mean number of other ambulatory encounters	6.9	10.1	6.9	10.3	-0.011	-0.001
Mean number of unique drug classes	10.5	4.8	10.5	4.8	-0.021	-0.004
Mean number of generics	11.2	5.4	11.2	5.4	-0.022	-0.004
Mean number of filled prescriptions	25.8	19.1	25.8	19.2	-0.037	-0.002

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1f. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	196,090	100.0%	97,784	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.8	20.2	76.4	39.2	-0.578	-0.019
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*6,755*	*3.4%*	*2,844*	*2.9%*	*0.537*	*0.031*
51+	*189,335*	*96.6%*	*94,940*	*97.1%*	*-0.537*	*-0.031*
Sex						
Female	*196,090*	*100.0%*	*97,784*	*100.0%*	*-0.000*	*-0.000*
Race						
American Indian or Alaska Native	*612*	*0.3%*	*241*	*0.2%*	*0.065*	*0.012*
Asian	*2,342*	*1.2%*	*1,116*	*1.1%*	*0.053*	*0.005*
Black or African American	*13,166*	*6.7%*	*7,064*	*7.2%*	*-0.510*	*-0.020*
Native Hawaiian or Other Pacific Islander	*95*	*0.0%*	*61*	*0.1%*	*-0.014*	*-0.006*
White	*152,999*	*78.0%*	*78,901*	*80.7%*	*-2.665*	*-0.066*
Unknown	*26,876*	*13.7%*	*10,400*	*10.6%*	*3.070*	*0.094*
Hispanic Origin	*2,862*	*1.5%*	*1,237*	*1.3%*	*0.194*	*0.017*
Year						
2010	*0*	*0.0%*	*0*	*0.0%*	*0.000*	-
2011	*293*	*0.1%*	*0*	*0.0%*	*0.149*	-
2012	*19,135*	*9.8%*	*0*	*0.0%*	*9.759*	-
2013	*54,400*	*27.7%*	*7,925*	*8.1%*	*19.638*	*0.530*
2014	*72,728*	*37.1%*	*33,243*	*34.0%*	*3.093*	*0.065*
2015	*49,533*	*25.3%*	*56,616*	*57.9%*	*-32.639*	*-0.702*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,556*	*3.3%*	*1,551*	*1.6%*	*1.757*	*0.114*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.2	3.0	3.3	3.8	-0.087	-0.025
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	8,884	4.5%	4,641	4.7%	-0.216	-0.010
Cardiovascular disease	93,873	47.9%	48,383	49.5%	-1.607	-0.032
Diabetes	63,538	32.4%	32,442	33.2%	-0.775	-0.017
Hypertension	167,908	85.6%	84,863	86.8%	-1.158	-0.034
Obesity	38,884	19.8%	19,614	20.1%	-0.229	-0.006
Renal impairment	43,227	22.0%	22,590	23.1%	-1.057	-0.025
Smoking	40,115	20.5%	20,482	20.9%	-0.488	-0.012
Von Willebrand disease	45	0.0%	21	0.0%	0.002	0.001
Gynecological disorders of interest	5,065	2.6%	2,435	2.5%	0.093	0.006
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0.007*	*0.007*
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Endometrial hyperplasia	*111*	*0.1%*	*59*	*0.1%*	*-0.004*	*-0.002*

Table 1f. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.006*	*0.007*
Ovarian cyst	*1,258*	*0.6%*	*658*	*0.7%*	*-0.031*	*-0.004*
Uterine myoma leiomyoma	*1,099*	*0.6%*	*495*	*0.5%*	*0.054*	*0.007*
Uterine or cervical polyp	*104*	*0.1%*	*50*	*0.1%*	*0.001*	*0.001*
Uterine ovarian or cervical cancer	*2,826*	*1.4%*	*1,313*	*1.3%*	*0.099*	*0.008*
Atrial Fibrillation (AF) or atrial flutter	148,728	75.8%	75,438	77.1%	-1.301	-0.031
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	63,851	32.6%	31,066	31.8%	0.792	0.017
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*183,236*	*93.4%*	*69,849*	*71.4%*	*22.013*	*0.604*
Cardiovascular and antidiabetic agents	183,399	93.5%	92,126	94.2%	-0.685	-0.029
Medications that increase bleeding risk without interaction	106,948	54.5%	53,465	54.7%	-0.137	-0.003
Medications that inhibit metabolism of NOACs and increase bleeding risk	135,064	68.9%	68,176	69.7%	-0.842	-0.018
Medications that induce metabolism of NOACs and reduce bleeding risk	55,737	28.4%	28,192	28.8%	-0.406	-0.009
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.0	9.8	13.0	13.3	0.012	0.001
Mean number of emergency room encounters	0.6	1.2	0.6	1.5	0.028	0.021
Mean number of inpatient hospital encounters	0.8	1.0	0.9	1.5	-0.024	-0.019
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.9	-0.009	-0.011
Mean number of other ambulatory encounters	7.1	10.4	7.4	14.8	-0.265	-0.021
Mean number of unique drug classes	10.4	5.3	10.5	8.4	-0.097	-0.014
Mean number of generics	11.1	6.0	11.2	9.4	-0.103	-0.013
Mean number of filled prescriptions	25.9	20.2	26.2	30.2	-0.343	-0.013

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1g. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	80,179	100.0%	97,670	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	76.8	9.1	77.9	9.4	-1.169	-0.126
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,070*	*1.3%*	*1,232*	*1.3%*	*0.073*	*0.006*
51+	*79,109*	*98.7%*	*96,438*	*98.7%*	*-0.073*	*-0.006*
Sex						
Female	*80,179*	*100.0%*	*97,670*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*229*	*0.3%*	*223*	*0.2%*	*0.057*	*0.011*
Asian	*1,248*	*1.6%*	*1,168*	*1.2%*	*0.361*	*0.031*
Black or African American	*4,081*	*5.1%*	*5,899*	*6.0%*	*-0.950*	*-0.041*
Native Hawaiian or Other Pacific Islander	*32*	*0.0%*	*60*	*0.1%*	*-0.022*	*-0.010*
White	*64,299*	*80.2%*	*80,159*	*82.1%*	*-1.877*	*-0.048*
Unknown	*10,290*	*12.8%*	*10,161*	*10.4%*	*2.430*	*0.076*
Hispanic Origin	*1,251*	*1.6%*	*1,168*	*1.2%*	*0.364*	*0.031*
Year						
2010	*1,253*	*1.6%*	*0*	*0.0%*	*1.563*	-
2011	*30,063*	*37.5%*	*0*	*0.0%*	*37.495*	-
2012	*22,790*	*28.4%*	*0*	*0.0%*	*28.424*	-
2013	*13,062*	*16.3%*	*9,103*	*9.3%*	*6.971*	*0.210*
2014	*8,600*	*10.7%*	*36,080*	*36.9%*	*-26.215*	*-0.647*
2015	*4,411*	*5.5%*	*52,487*	*53.7%*	*-48.238*	*-1.244*
Presence of condition in post-index enrollment:						
Vaginal bleed	*3,538*	*4.4%*	*1,508*	*1.5%*	*2.869*	*0.169*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.0	2.6	3.4	2.8	-0.404	-0.149
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,307	2.9%	3,466	3.5%	-0.671	-0.038
Cardiovascular disease	40,417	50.4%	52,389	53.6%	-3.230	-0.065
Diabetes	26,943	33.6%	32,612	33.4%	0.214	0.005
Hypertension	70,853	88.4%	87,151	89.2%	-0.862	-0.027
Obesity	12,669	15.8%	18,910	19.4%	-3.560	-0.094
Renal impairment	14,123	17.6%	25,097	25.7%	-8.081	-0.197
Smoking	12,329	15.4%	19,857	20.3%	-4.954	-0.130
Von Willebrand disease	16	0.0%	20	0.0%	-0.001	-0.000
Gynecological disorders of interest	1,417	1.8%	1,849	1.9%	-0.126	-0.009
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.005*	*-0.008*
Endometrial hyperplasia	*42*	*0.1%*	*44*	*0.0%*	*0.007*	*0.003*

Table 1g. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.001*	*0.001*
Ovarian cyst	*366*	*0.5%*	*483*	*0.5%*	*-0.038*	*-0.006*
Uterine myoma leiomyoma	*348*	*0.4%*	*416*	*0.4%*	*0.008*	*0.001*
Uterine or cervical polyp	*44*	*0.1%*	*38*	*0.0%*	*0.016*	*0.007*
Uterine ovarian or cervical cancer	*719*	*0.9%*	*968*	*1.0%*	*-0.094*	*-0.010*
Atrial Fibrillation (AF) or atrial flutter	77,983	97.3%	89,148	91.3%	5.986	0.260
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	7,556	9.4%	16,264	16.7%	-7.228	-0.216
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*63,215*	*78.8%*	*66,001*	*67.6%*	*11.267*	*0.256*
Cardiovascular and antidiabetic agents	78,238	97.6%	94,961	97.2%	0.353	0.022
Medications that increase bleeding risk without interaction	41,169	51.3%	51,812	53.0%	-1.702	-0.034
Medications that inhibit metabolism of NOACs and increase bleeding risk	56,813	70.9%	70,681	72.4%	-1.509	-0.033
Medications that induce metabolism of NOACs and reduce bleeding risk	22,062	27.5%	27,627	28.3%	-0.770	-0.017
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.3	8.6	13.0	8.8	-0.701	-0.081
Mean number of emergency room encounters	0.5	1.0	0.6	1.0	-0.091	-0.091
Mean number of inpatient hospital encounters	0.7	0.9	0.8	1.0	-0.075	-0.078
Mean number of non-acute institutional encounters	0.2	0.5	0.2	0.7	-0.061	-0.098
Mean number of other ambulatory encounters	5.7	8.7	6.9	10.4	-1.216	-0.127
Mean number of unique drug classes	10.1	4.7	10.5	4.8	-0.344	-0.072
Mean number of generics	10.8	5.4	11.2	5.4	-0.349	-0.065
Mean number of filled prescriptions	26.2	19.2	25.8	19.2	0.326	0.017

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1h. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	73,880	92.1%	73,880	75.6%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	77.4	8.9	77.3	9.1	0.042	0.005
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*794*	*1.1%*	*832*	*1.1%*	*-0.051*	*-0.005*
51+	*73,086*	*98.9%*	*73,048*	*98.9%*	*0.051*	*0.005*
Sex						
Female	*73,880*	*100.0%*	*73,880*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*208*	*0.3%*	*172*	*0.2%*	*0.049*	*0.010*
Asian	*1,133*	*1.5%*	*953*	*1.3%*	*0.244*	*0.021*
Black or African American	*3,776*	*5.1%*	*3,886*	*5.3%*	*-0.149*	*-0.007*
Native Hawaiian or Other Pacific Islander	*31*	*0.0%*	*50*	*0.1%*	*-0.026*	*-0.011*
White	*60,323*	*81.6%*	*60,667*	*82.1%*	*-0.466*	*-0.012*
Unknown	*8,409*	*11.4%*	*8,152*	*11.0%*	*0.348*	*0.011*
Hispanic Origin	*1,150*	*1.6%*	*856*	*1.2%*	*0.398*	*0.034*
Year						
2010	*1,124*	*1.5%*	*0*	*0.0%*	*1.521*	-
2011	*27,563*	*37.3%*	*0*	*0.0%*	*37.308*	-
2012	*20,923*	*28.3%*	*0*	*0.0%*	*28.320*	-
2013	*12,113*	*16.4%*	*7,598*	*10.3%*	*6.111*	*0.180*
2014	*8,027*	*10.9%*	*28,335*	*38.4%*	*-27.488*	*-0.673*
2015	*4,130*	*5.6%*	*37,947*	*51.4%*	*-45.773*	*-1.177*
Presence of condition in post-index enrollment:						
Vaginal bleed	*3,201*	*4.3%*	*1,178*	*1.6%*	*2.738*	*0.162*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.0	2.6	3.0	2.6	0.015	0.006
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,164	2.9%	2,144	2.9%	0.027	0.002
Cardiovascular disease	37,875	51.3%	37,668	51.0%	0.280	0.006
Diabetes	24,428	33.1%	24,396	33.0%	0.043	0.001
Hypertension	65,551	88.7%	65,489	88.6%	0.084	0.003
Obesity	12,208	16.5%	12,072	16.3%	0.184	0.005
Renal impairment	13,956	18.9%	13,721	18.6%	0.318	0.008
Smoking	12,018	16.3%	11,870	16.1%	0.200	0.005
Von Willebrand disease	13	0.0%	16	0.0%	-0.004	-0.003
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,285	1.7%	1,310	1.8%	-0.034	-0.003

Table 1h. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.005*	*-0.008*
Endometrial hyperplasia	*35*	*0.0%*	*30*	*0.0%*	*0.007*	*0.003*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.001*	*0.002*
Ovarian cyst	*336*	*0.5%*	*326*	*0.4%*	*0.014*	*0.002*
Uterine myoma leiomyoma	*313*	*0.4%*	*308*	*0.4%*	*0.007*	*0.001*
Uterine or cervical polyp	*35*	*0.0%*	*30*	*0.0%*	*0.007*	*0.003*
Uterine ovarian or cervical cancer	*660*	*0.9%*	*680*	*0.9%*	*-0.027*	*-0.003*
Atrial Fibrillation (AF) or atrial flutter	71,686	97.0%	71,557	96.9%	0.175	0.010
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	7,355	10.0%	7,481	10.1%	-0.171	-0.006
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*57,551*	*77.9%*	*51,503*	*69.7%*	*8.186*	*0.187*
Cardiovascular and antidiabetic agents	72,161	97.7%	72,130	97.6%	0.042	0.003
Medications that increase bleeding risk without interaction	38,073	51.5%	38,161	51.7%	-0.119	-0.002
Medications that inhibit metabolism of NOACs and increase bleeding risk	52,726	71.4%	52,745	71.4%	-0.026	-0.001
Medications that induce metabolism of NOACs and reduce bleeding risk	20,371	27.6%	20,441	27.7%	-0.095	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.4	8.6	12.4	8.4	0.001	0.000
Mean number of emergency room encounters	0.5	1.0	0.5	0.9	-0.004	-0.005
Mean number of inpatient hospital encounters	0.7	0.9	0.7	0.9	0.005	0.005
Mean number of non-acute institutional encounters	0.2	0.6	0.2	0.6	-0.000	-0.001
Mean number of other ambulatory encounters	5.9	8.9	5.9	8.9	0.012	0.001
Mean number of unique drug classes	10.2	4.7	10.2	4.7	0.003	0.001
Mean number of generics	10.9	5.3	10.9	5.3	0.007	0.001
Mean number of filled prescriptions	25.8	18.6	25.7	19.7	0.098	0.005

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1i. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	80,179	100.0%	97,670	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	77.3	24.0	77.5	14.1	-0.242	-0.012
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,116*	*1.4%*	*1,183*	*1.2%*	*0.181*	*0.016*
51+	*79,063*	*98.6%*	*96,487*	*98.8%*	*-0.181*	*-0.016*
Sex						
Female	*80,179*	*100.0%*	*97,670*	*100.0%*	*0.000*	*0.000*
Race						
American Indian or Alaska Native	*230*	*0.3%*	*223*	*0.2%*	*0.058*	*0.012*
Asian	*1,182*	*1.5%*	*1,214*	*1.2%*	*0.231*	*0.020*
Black or African American	*4,226*	*5.3%*	*5,637*	*5.8%*	*-0.501*	*-0.022*
Native Hawaiian or Other Pacific Islander	*30*	*0.0%*	*62*	*0.1%*	*-0.025*	*-0.011*
White	*64,275*	*80.2%*	*80,306*	*82.2%*	*-2.057*	*-0.053*
Unknown	*10,235*	*12.8%*	*10,228*	*10.5%*	*2.293*	*0.072*
Hispanic Origin	*1,268*	*1.6%*	*1,158*	*1.2%*	*0.396*	*0.034*
Year						
2010	*1,220*	*1.5%*	*0*	*0.0%*	*1.521*	-
2011	*29,488*	*36.8%*	*0*	*0.0%*	*36.778*	-
2012	*22,469*	*28.0%*	*0*	*0.0%*	*28.024*	-
2013	*13,106*	*16.3%*	*9,535*	*9.8%*	*6.584*	*0.196*
2014	*9,076*	*11.3%*	*36,748*	*37.6%*	*-26.306*	*-0.643*
2015	*4,820*	*6.0%*	*51,387*	*52.6%*	*-46.601*	*-1.192*
Presence of condition in post-index enrollment:						
Vaginal bleed	*3,463*	*4.3%*	*1,531*	*1.6%*	*2.752*	*0.163*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.2	3.4	3.2	2.6	-0.000	-0.000
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,596	3.2%	3,194	3.3%	-0.033	-0.002
Cardiovascular disease	41,913	52.3%	51,076	52.3%	-0.020	-0.000
Diabetes	26,764	33.4%	32,764	33.5%	-0.165	-0.004
Hypertension	71,073	88.6%	86,886	89.0%	-0.316	-0.010
Obesity	14,255	17.8%	17,316	17.7%	0.049	0.001
Renal impairment	17,750	22.1%	21,619	22.1%	0.003	0.000
Smoking	14,514	18.1%	17,698	18.1%	-0.018	-0.000
Von Willebrand disease	18	0.0%	21	0.0%	0.001	0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,467	1.8%	1,787	1.8%	-0.000	-0.000

Table 1i. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.004*	*-0.006*
Endometrial hyperplasia	*41*	*0.1%*	*43*	*0.0%*	*0.007*	*0.003*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.001*	*0.001*
Ovarian cyst	*377*	*0.5%*	*463*	*0.5%*	*-0.004*	*-0.001*
Uterine myoma leiomyoma	*345*	*0.4%*	*409*	*0.4%*	*0.012*	*0.002*
Uterine or cervical polyp	*43*	*0.1%*	*38*	*0.0%*	*0.014*	*0.006*
Uterine ovarian or cervical cancer	*764*	*1.0%*	*928*	*1.0%*	*0.003*	*0.000*
Atrial Fibrillation (AF) or atrial flutter	76,083	94.9%	91,509	93.7%	1.200	0.052
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	10,186	12.7%	13,327	13.6%	-0.941	-0.028
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*61,620*	*76.9%*	*67,445*	*69.1%*	*7.799*	*0.176*
Cardiovascular and antidiabetic agents	78,087	97.4%	95,160	97.4%	-0.039	-0.002
Medications that increase bleeding risk without interaction	42,020	52.4%	51,182	52.4%	0.005	0.000
Medications that inhibit metabolism of NOACs and increase bleeding risk	57,418	71.6%	70,072	71.7%	-0.132	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	22,465	28.0%	27,464	28.1%	-0.100	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.6	10.7	12.7	8.4	-0.019	-0.002
Mean number of emergency room encounters	0.5	1.4	0.5	0.9	0.015	0.013
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.0	-0.004	-0.004
Mean number of non-acute institutional encounters	0.2	0.8	0.2	0.6	-0.006	-0.009
Mean number of other ambulatory encounters	6.4	12.2	6.5	9.0	-0.046	-0.004
Mean number of unique drug classes	10.4	6.3	10.3	4.9	0.011	0.002
Mean number of generics	11.1	7.0	11.1	5.6	0.014	0.002
Mean number of filled prescriptions	26.1	20.3	26.0	21.7	0.093	0.004

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1j. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	189,015	100.0%	722,772	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.1	10.9	75.4	11.9	-0.366	-0.032
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*7,997*	*4.2%*	*36,406*	*5.0%*	*-0.806*	*-0.038*
51+	*181,018*	*95.8%*	*686,366*	*95.0%*	*0.806*	*0.038*
Sex						
Female	*189,015*	*100.0%*	*722,772*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*600*	*0.3%*	*2,781*	*0.4%*	*-0.067*	*-0.011*
Asian	*2,142*	*1.1%*	*6,863*	*0.9%*	*0.184*	*0.018*
Black or African American	*13,452*	*7.1%*	*71,569*	*9.9%*	*-2.785*	*-0.100*
Native Hawaiian or Other Pacific Islander	*88*	*0.0%*	*233*	*0.0%*	*0.014*	*0.007*
White	*146,493*	*77.5%*	*552,603*	*76.5%*	*1.047*	*0.025*
Unknown	*26,240*	*13.9%*	*88,723*	*12.3%*	*1.607*	*0.048*
Hispanic Origin	*2,764*	*1.5%*	*11,759*	*1.6%*	*-0.165*	*-0.013*
Year						
2010	*0*	*0.0%*	*38,359*	*5.3%*	*-5.307*	-
2011	*276*	*0.1%*	*173,959*	*24.1%*	*-23.922*	*-0.788*
2012	*17,180*	*9.1%*	*166,624*	*23.1%*	*-13.964*	*-0.387*
2013	*51,793*	*27.4%*	*145,057*	*20.1%*	*7.332*	*0.173*
2014	*70,802*	*37.5%*	*120,345*	*16.7%*	*20.808*	*0.482*
2015	*48,964*	*25.9%*	*78,428*	*10.9%*	*15.054*	*0.396*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,570*	*3.5%*	*33,030*	*4.6%*	*-1.094*	*-0.056*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Comorbidity Score	3.1	2.9	3.9	3.2	-0.780	-0.256
Severe anemia	9,497	5.0%	70,155	9.7%	-4.682	-0.180
Cardiovascular disease	85,698	45.3%	387,988	53.7%	-8.341	-0.167
Diabetes	60,512	32.0%	269,309	37.3%	-5.246	-0.110
Hypertension	159,325	84.3%	618,984	85.6%	-1.348	-0.038
Obesity	37,884	20.0%	142,085	19.7%	0.385	0.010
Renal impairment	38,219	20.2%	215,402	29.8%	-9.582	-0.223
Smoking	39,283	20.8%	147,651	20.4%	0.355	0.009
Von Willebrand disease	47	0.0%	260	0.0%	-0.011	-0.006
Gynecological disorders of interest	5,491	2.9%	21,335	3.0%	-0.047	-0.003
Adenomyosis	*30*	*0.0%*	*109*	*0.0%*	*0.001*	*0.001*
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Endometrial hyperplasia	*118*	*0.1%*	*387*	*0.1%*	*0.009*	*0.004*

Table 1j. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Endometriosis	*24*	*0.0%*	*118*	*0.0%*	*-0.004*	*-0.003*
Ovarian cyst	*1,356*	*0.7%*	*5,439*	*0.8%*	*-0.035*	*-0.004*
Uterine myoma leiomyoma	*1,168*	*0.6%*	*4,754*	*0.7%*	*-0.040*	*-0.005*
Uterine or cervical polyp	*109*	*0.1%*	*318*	*0.0%*	*0.014*	*0.006*
Uterine ovarian or cervical cancer	*3,107*	*1.6%*	*11,844*	*1.6%*	*0.005*	*0.000*
Atrial Fibrillation (AF) or atrial flutter	130,094	68.8%	433,481	60.0%	8.853	0.186
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	75,195	39.8%	384,804	53.2%	-13.457	-0.272
History of Use:						
Cardiovascular and antidiabetic agents	173,901	92.0%	662,579	91.7%	0.332	0.012
Medications that increase bleeding risk without interaction	104,625	55.4%	447,759	62.0%	-6.597	-0.134
Medications that inhibit metabolism of Novel Oral Anticoagulants (NOACs) and increase bleeding risk	127,487	67.4%	491,050	67.9%	-0.492	-0.011
Medications that induce metabolism of NOACs and reduce bleeding risk	54,046	28.6%	223,694	30.9%	-2.356	-0.052
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.6	13.8	10.1	-0.712	-0.072
Mean number of emergency room encounters	0.6	1.3	0.7	1.4	-0.021	-0.016
Mean number of inpatient hospital encounters	0.9	1.0	1.1	1.2	-0.283	-0.253
Mean number of non-acute institutional encounters	0.2	0.7	0.4	0.9	-0.137	-0.173
Mean number of other ambulatory encounters	7.3	10.7	11.0	14.3	-3.658	-0.289
Mean number of unique drug classes	10.3	5.0	10.7	5.0	-0.399	-0.080
Mean number of generics	11.1	5.6	11.6	5.7	-0.467	-0.082
Mean number of filled prescriptions	25.9	20.1	27.3	20.2	-1.408	-0.070

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1k. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	188,984	100.0%	188,984	26.1%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.1	10.9	75.1	11.6	-0.006	-0.001
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*7,987*	*4.2%*	*9,632*	*5.1%*	*-0.870*	*-0.041*
51+	*180,997*	*95.8%*	*179,352*	*94.9%*	*0.870*	*0.041*
Sex						
Female	*188,984*	*100.0%*	*188,984*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*600*	*0.3%*	*680*	*0.4%*	*-0.042*	*-0.007*
Asian	*2,142*	*1.1%*	*1,699*	*0.9%*	*0.234*	*0.023*
Black or African American	*13,450*	*7.1%*	*14,936*	*7.9%*	*-0.786*	*-0.030*
Native Hawaiian or Other Pacific Islander	*88*	*0.0%*	*68*	*0.0%*	*0.011*	*0.005*
White	*146,480*	*77.5%*	*145,486*	*77.0%*	*0.526*	*0.013*
Unknown	*26,224*	*13.9%*	*26,115*	*13.8%*	*0.058*	*0.002*
Hispanic Origin	*2,764*	*1.5%*	*2,759*	*1.5%*	*0.003*	*0.000*
Year						
2010	*0*	*0.0%*	*10,027*	*5.3%*	*-5.306*	-
2011	*275*	*0.1%*	*45,424*	*24.0%*	*-23.890*	*-0.788*
2012	*17,179*	*9.1%*	*43,307*	*22.9%*	*-13.826*	*-0.384*
2013	*51,784*	*27.4%*	*38,030*	*20.1%*	*7.278*	*0.172*
2014	*70,791*	*37.5%*	*31,473*	*16.7%*	*20.805*	*0.482*
2015	*48,955*	*25.9%*	*20,723*	*11.0%*	*14.939*	*0.393*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,566*	*3.5%*	*8,447*	*4.5%*	*-0.995*	*-0.051*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Comorbidity Score	3.1	2.9	3.1	2.8	-0.017	-0.006
Severe anemia	9,497	5.0%	10,048	5.3%	-0.292	-0.013
Cardiovascular disease	85,696	45.3%	85,415	45.2%	0.149	0.003
Diabetes	60,508	32.0%	60,578	32.1%	-0.037	-0.001
Hypertension	159,302	84.3%	159,320	84.3%	-0.010	-0.000
Obesity	37,866	20.0%	38,179	20.2%	-0.166	-0.004
Renal impairment	38,219	20.2%	38,369	20.3%	-0.079	-0.002
Smoking	39,268	20.8%	39,425	20.9%	-0.083	-0.002
Von Willebrand disease	47	0.0%	46	0.0%	0.001	0.000
Gynecological disorders of interest	5,491	2.9%	5,555	2.9%	-0.034	-0.002
Adenomyosis	*30*	*0.0%*	*31*	*0.0%*	*-0.001*	*-0.000*
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Endometrial hyperplasia	*118*	*0.1%*	*107*	*0.1%*	*0.006*	*0.002*

Table 1k. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Endometriosis	*24*	*0.0%*	*38*	*0.0%*	*-0.007*	*-0.006*
Ovarian cyst	*1,356*	*0.7%*	*1,552*	*0.8%*	*-0.104*	*-0.012*
Uterine myoma leiomyoma	*1,168*	*0.6%*	*1,247*	*0.7%*	*-0.042*	*-0.005*
Uterine or cervical polyp	*109*	*0.1%*	*108*	*0.1%*	*0.001*	*0.000*
Uterine ovarian or cervical cancer	*3,107*	*1.6%*	*2,932*	*1.6%*	*0.093*	*0.007*
Atrial Fibrillation (AF) or atrial flutter	130,068	68.8%	130,465	69.0%	-0.210	-0.005
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	75,190	39.8%	74,713	39.5%	0.252	0.005
History of Use:						
Cardiovascular and antidiabetic agents	173,875	92.0%	174,030	92.1%	-0.082	-0.003
Medications that increase bleeding risk without interaction	104,621	55.4%	103,537	54.8%	0.574	0.012
Medications that inhibit metabolism of Novel Oral Anticoagulants (NOACs) and increase bleeding risk	127,473	67.5%	127,889	67.7%	-0.220	-0.005
Medications that induce metabolism of NOACs and reduce bleeding risk	54,037	28.6%	53,784	28.5%	0.134	0.003
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.6	13.1	9.5	-0.048	-0.005
Mean number of emergency room encounters	0.6	1.3	0.6	1.4	-0.001	-0.001
Mean number of inpatient hospital encounters	0.9	1.0	0.9	1.0	-0.006	-0.006
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.7	-0.006	-0.009
Mean number of other ambulatory encounters	7.3	10.7	7.4	10.4	-0.153	-0.014
Mean number of unique drug classes	10.3	5.0	10.4	4.9	-0.025	-0.005
Mean number of generics	11.1	5.6	11.1	5.6	-0.027	-0.005
Mean number of filled prescriptions	25.9	20.1	26.0	19.2	-0.038	-0.002

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1l. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	189,015	100.0%	722,772	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.3	31.8	75.4	13.7	-0.105	-0.004
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,134*	*4.3%*	*35,912*	*5.0%*	*-0.665*	*-0.032*
51+	*180,881*	*95.7%*	*686,860*	*95.0%*	*0.665*	*0.032*
Sex						
Female	*189,015*	*100.0%*	*722,772*	*100.0%*	*0.000*	*0.000*
Race						
American Indian or Alaska Native	*610*	*0.3%*	*2,769*	*0.4%*	*-0.060*	*-0.010*
Asian	*2,076*	*1.1%*	*6,830*	*0.9%*	*0.153*	*0.015*
Black or African American	*15,444*	*8.2%*	*68,836*	*9.5%*	*-1.353*	*-0.048*
Native Hawaiian or Other Pacific Islander	*95*	*0.1%*	*234*	*0.0%*	*0.018*	*0.009*
White	*144,314*	*76.4%*	*555,731*	*76.9%*	*-0.538*	*-0.013*
Unknown	*26,476*	*14.0%*	*88,373*	*12.2%*	*1.780*	*0.053*
Hispanic Origin	*3,058*	*1.6%*	*11,485*	*1.6%*	*0.029*	*0.002*
Year						
2010	*0*	*0.0%*	*38,471*	*5.3%*	*-5.323*	-
2011	*264*	*0.1%*	*173,882*	*24.1%*	*-23.918*	*-0.788*
2012	*15,288*	*8.1%*	*166,466*	*23.0%*	*-14.943*	*-0.421*
2013	*51,480*	*27.2%*	*145,112*	*20.1%*	*7.159*	*0.169*
2014	*72,094*	*38.1%*	*120,306*	*16.6%*	*21.497*	*0.497*
2015	*49,889*	*26.4%*	*78,535*	*10.9%*	*15.529*	*0.407*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,565*	*3.5%*	*33,002*	*4.6%*	*-1.092*	*-0.056*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Comorbidity Score	3.7	4.7	3.8	2.9	-0.054	-0.014
Severe anemia	15,656	8.3%	63,864	8.8%	-0.553	-0.020
Cardiovascular disease	97,483	51.6%	376,602	52.1%	-0.531	-0.011
Diabetes	67,524	35.7%	262,173	36.3%	-0.549	-0.011
Hypertension	160,195	84.8%	617,768	85.5%	-0.720	-0.020
Obesity	37,032	19.6%	142,521	19.7%	-0.127	-0.003
Renal impairment	51,245	27.1%	201,771	27.9%	-0.805	-0.018
Smoking	38,326	20.3%	148,350	20.5%	-0.248	-0.006
Von Willebrand disease	63	0.0%	244	0.0%	-0.000	-0.000
Gynecological disorders of interest	5,708	3.0%	21,214	2.9%	0.085	0.005
Adenomyosis	*31*	*0.0%*	*110*	*0.0%*	*0.001*	*0.001*
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Endometrial hyperplasia	*113*	*0.1%*	*395*	*0.1%*	*0.005*	*0.002*

Table 1l. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Surgical Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Endometriosis	*25*	*0.0%*	*120*	*0.0%*	*-0.003*	*-0.003*
Ovarian cyst	*1,346*	*0.7%*	*5,481*	*0.8%*	*-0.046*	*-0.005*
Uterine myoma leiomyoma	*1,153*	*0.6%*	*4,719*	*0.7%*	*-0.043*	*-0.005*
Uterine or cervical polyp	*93*	*0.0%*	*327*	*0.0%*	*0.004*	*0.002*
Uterine ovarian or cervical cancer	*3,392*	*1.8%*	*11,690*	*1.6%*	*0.177*	*0.014*
Atrial Fibrillation (AF) or atrial flutter	115,741	61.2%	447,824	62.0%	-0.725	-0.015
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	95,878	50.7%	363,928	50.4%	0.373	0.007
History of Use:						
Cardiovascular and antidiabetic agents	172,726	91.4%	663,744	91.8%	-0.451	-0.016
Medications that increase bleeding risk without interaction	114,383	60.5%	437,459	60.5%	-0.010	-0.000
Medications that inhibit metabolism of Novel Oral Anticoagulants (NOACs) and increase bleeding risk	128,078	67.8%	490,908	67.9%	-0.159	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	56,761	30.0%	220,596	30.5%	-0.491	-0.011
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.7	13.8	13.6	9.7	0.093	0.008
Mean number of emergency room encounters	0.7	1.4	0.7	1.4	0.014	0.010
Mean number of inpatient hospital encounters	1.1	1.7	1.1	1.1	-0.024	-0.017
Mean number of non-acute institutional encounters	0.3	1.1	0.3	0.8	-0.004	-0.004
Mean number of other ambulatory encounters	9.7	20.1	10.3	12.8	-0.587	-0.035
Mean number of unique drug classes	10.7	7.5	10.7	4.9	-0.005	-0.001
Mean number of generics	11.5	8.4	11.5	5.6	-0.005	-0.001
Mean number of filled prescriptions	27.1	27.3	27.1	19.8	0.032	0.001

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1m. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	194,409	100.0%	80,065	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.0	10.9	76.8	9.1	-1.722	-0.171
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,348*	*4.3%*	*1,068*	*1.3%*	*2.960*	*0.180*
51+	*186,061*	*95.7%*	*78,997*	*98.7%*	*-2.960*	*-0.180*
Sex						
Female	*194,409*	*100.0%*	*80,065*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*623*	*0.3%*	*229*	*0.3%*	*0.034*	*0.006*
Asian	*2,186*	*1.1%*	*1,249*	*1.6%*	*-0.436*	*-0.038*
Black or African American	*14,073*	*7.2%*	*4,077*	*5.1%*	*2.147*	*0.089*
Native Hawaiian or Other Pacific Islander	*92*	*0.0%*	*33*	*0.0%*	*0.006*	*0.003*
White	*150,514*	*77.4%*	*64,200*	*80.2%*	*-2.764*	*-0.068*
Unknown	*26,921*	*13.8%*	*10,277*	*12.8%*	*1.012*	*0.030*
Hispanic Origin	*2,894*	*1.5%*	*1,248*	*1.6%*	*-0.070*	*-0.006*
Year						
2010	*0*	*0.0%*	*1,252*	*1.6%*	*-1.564*	-
2011	*277*	*0.1%*	*30,057*	*37.5%*	*-37.398*	*-1.089*
2012	*17,380*	*8.9%*	*22,789*	*28.5%*	*-19.523*	*-0.517*
2013	*53,100*	*27.3%*	*13,041*	*16.3%*	*11.026*	*0.269*
2014	*73,038*	*37.6%*	*8,562*	*10.7%*	*26.875*	*0.662*
2015	*50,614*	*26.0%*	*4,364*	*5.5%*	*20.584*	*0.589*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,762*	*3.5%*	*3,542*	*4.4%*	*-0.946*	*-0.049*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.9	2.9	2.6	0.188	0.069
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	9,790	5.0%	2,282	2.9%	2.186	0.112
Cardiovascular disease	88,466	45.5%	40,361	50.4%	-4.905	-0.098
Diabetes	62,495	32.1%	26,908	33.6%	-1.462	-0.031
Hypertension	163,776	84.2%	70,748	88.4%	-4.120	-0.120
Obesity	39,118	20.1%	12,656	15.8%	4.314	0.113
Renal impairment	39,648	20.4%	14,090	17.6%	2.796	0.071
Smoking	40,458	20.8%	12,308	15.4%	5.438	0.142
Von Willebrand disease	48	0.0%	15	0.0%	0.006	0.004
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,713	2.9%	1,432	1.8%	1.150	0.076

Table 1m. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.014*	*0.014*
Endometrial hyperplasia	*138*	*0.1%*	*48*	*0.1%*	*0.011*	*0.004*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.010*	*0.010*
Ovarian cyst	*1,404*	*0.7%*	*368*	*0.5%*	*0.263*	*0.034*
Uterine myoma leiomyoma	*1,221*	*0.6%*	*355*	*0.4%*	*0.185*	*0.025*
Uterine or cervical polyp	*148*	*0.1%*	*55*	*0.1%*	*0.007*	*0.003*
Uterine ovarian or cervical cancer	*3,218*	*1.7%*	*722*	*0.9%*	*0.754*	*0.067*
Atrial Fibrillation (AF) or atrial flutter	133,056	68.4%	77,879	97.3%	-28.828	-0.828
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	78,626	40.4%	7,531	9.4%	31.037	0.769
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*181,708*	*93.5%*	*63,141*	*78.9%*	*14.605*	*0.433*
Cardiovascular and antidiabetic agents	178,757	91.9%	78,128	97.6%	-5.632	-0.255
Medications that increase bleeding risk without interaction	107,861	55.5%	41,112	51.3%	4.133	0.083
Medications that inhibit metabolism of NOACs and increase bleeding risk	131,137	67.5%	56,737	70.9%	-3.409	-0.074
Medications that induce metabolism of NOACs and reduce bleeding risk	55,849	28.7%	22,021	27.5%	1.224	0.027
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.7	12.3	8.6	0.831	0.091
Mean number of emergency room encounters	0.6	1.3	0.5	1.0	0.178	0.156
Mean number of inpatient hospital encounters	0.9	1.0	0.7	0.9	0.130	0.132
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.6	0.084	0.132
Mean number of other ambulatory encounters	7.3	10.8	5.7	8.7	1.626	0.166
Mean number of unique drug classes	10.4	5.0	10.1	4.7	0.218	0.045
Mean number of generics	11.1	5.7	10.8	5.3	0.277	0.050
Mean number of filled prescriptions	26.1	20.2	26.2	19.2	-0.111	-0.006

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1n. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	80,033	41.2%	80,033	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	76.7	9.1	76.8	9.1	-0.039	-0.004
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,062*	*1.3%*	*1,068*	*1.3%*	*-0.007*	*-0.001*
51+	*78,971*	*98.7%*	*78,965*	*98.7%*	*0.007*	*0.001*
Sex						
Female	*80,033*	*100.0%*	*80,033*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*250*	*0.3%*	*229*	*0.3%*	*0.026*	*0.005*
Asian	*1,162*	*1.5%*	*1,249*	*1.6%*	*-0.109*	*-0.009*
Black or African American	*4,195*	*5.2%*	*4,077*	*5.1%*	*0.147*	*0.007*
Native Hawaiian or Other Pacific Islander	*37*	*0.0%*	*33*	*0.0%*	*0.005*	*0.002*
White	*64,349*	*80.4%*	*64,199*	*80.2%*	*0.187*	*0.005*
Unknown	*10,040*	*12.5%*	*10,246*	*12.8%*	*-0.257*	*-0.008*
Hispanic Origin	*1,145*	*1.4%*	*1,248*	*1.6%*	*-0.129*	*-0.011*
Year						
2010	*0*	*0.0%*	*1,250*	*1.6%*	*-1.562*	-
2011	*149*	*0.2%*	*30,045*	*37.5%*	*-37.355*	*-1.087*
2012	*10,162*	*12.7%*	*22,780*	*28.5%*	*-15.766*	*-0.398*
2013	*23,365*	*29.2%*	*13,033*	*16.3%*	*12.910*	*0.312*
2014	*28,249*	*35.3%*	*8,561*	*10.7%*	*24.600*	*0.611*
2015	*18,108*	*22.6%*	*4,364*	*5.5%*	*17.173*	*0.510*
Presence of condition in post-index enrollment:						
Vaginal bleed	*2,484*	*3.1%*	*3,540*	*4.4%*	*-1.319*	*-0.069*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.0	2.6	2.9	2.6	0.011	0.004
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,338	2.9%	2,282	2.9%	0.070	0.004
Cardiovascular disease	40,802	51.0%	40,341	50.4%	0.576	0.012
Diabetes	26,960	33.7%	26,895	33.6%	0.081	0.002
Hypertension	70,799	88.5%	70,721	88.4%	0.097	0.003
Obesity	12,655	15.8%	12,655	15.8%	0.000	0.000
Renal impairment	14,110	17.6%	14,090	17.6%	0.025	0.001
Smoking	12,310	15.4%	12,308	15.4%	0.002	0.000
Von Willebrand disease	13	0.0%	14	0.0%	-0.001	-0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,472	1.8%	1,429	1.8%	0.054	0.004

Table 1n. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.005*	*0.007*
Endometrial hyperplasia	*51*	*0.1%*	*48*	*0.1%*	*0.004*	*0.002*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.000*	*0.000*
Ovarian cyst	*365*	*0.5%*	*366*	*0.5%*	*-0.001*	*-0.000*
Uterine myoma leiomyoma	*373*	*0.5%*	*354*	*0.4%*	*0.024*	*0.004*
Uterine or cervical polyp	*57*	*0.1%*	*54*	*0.1%*	*0.004*	*0.001*
Uterine ovarian or cervical cancer	*728*	*0.9%*	*722*	*0.9%*	*0.007*	*0.001*
Atrial Fibrillation (AF) or atrial flutter	77,848	97.3%	77,847	97.3%	0.001	0.000
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	7,542	9.4%	7,531	9.4%	0.014	0.000
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*75,021*	*93.7%*	*63,114*	*78.9%*	*14.878*	*0.443*
Cardiovascular and antidiabetic agents	78,147	97.6%	78,096	97.6%	0.064	0.004
Medications that increase bleeding risk without interaction	41,192	51.5%	41,091	51.3%	0.126	0.003
Medications that inhibit metabolism of NOACs and increase bleeding risk	56,784	71.0%	56,712	70.9%	0.090	0.002
Medications that induce metabolism of NOACs and reduce bleeding risk	22,132	27.7%	22,017	27.5%	0.144	0.003
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.3	8.6	12.3	8.6	0.032	0.004
Mean number of emergency room encounters	0.5	0.9	0.5	1.0	0.004	0.004
Mean number of inpatient hospital encounters	0.7	0.9	0.7	0.9	0.007	0.008
Mean number of non-acute institutional encounters	0.2	0.5	0.2	0.6	0.001	0.002
Mean number of other ambulatory encounters	5.8	8.6	5.7	8.7	0.058	0.007
Mean number of unique drug classes	10.2	4.8	10.1	4.7	0.018	0.004
Mean number of generics	10.9	5.4	10.8	5.3	0.021	0.004
Mean number of filled prescriptions	26.1	20.2	26.2	19.1	-0.026	-0.001

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1o. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	194,409	100.0%	80,065	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.5	19.8	75.9	93.2	-0.438	-0.007
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*6,801*	*3.5%*	*2,629*	*3.3%*	*0.214*	*0.012*
51+	*187,608*	*96.5%*	*77,436*	*96.7%*	*-0.214*	*-0.012*
Sex						
Female	*194,409*	*100.0%*	*80,065*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*612*	*0.3%*	*274*	*0.3%*	*-0.027*	*-0.005*
Asian	*2,371*	*1.2%*	*1,071*	*1.3%*	*-0.117*	*-0.010*
Black or African American	*12,958*	*6.7%*	*5,124*	*6.4%*	*0.266*	*0.011*
Native Hawaiian or Other Pacific Islander	*92*	*0.0%*	*34*	*0.0%*	*0.004*	*0.002*
White	*151,533*	*77.9%*	*63,134*	*78.9%*	*-0.909*	*-0.022*
Unknown	*26,843*	*13.8%*	*10,429*	*13.0%*	*0.782*	*0.023*
Hispanic Origin	*2,852*	*1.5%*	*1,400*	*1.7%*	*-0.282*	*-0.022*
Year						
2010	*0*	*0.0%*	*1,231*	*1.5%*	*-1.537*	-
2011	*302*	*0.2%*	*27,693*	*34.6%*	*-34.433*	*-1.020*
2012	*19,442*	*10.0%*	*20,700*	*25.9%*	*-15.853*	*-0.422*
2013	*54,084*	*27.8%*	*12,653*	*15.8%*	*12.017*	*0.294*
2014	*71,851*	*37.0%*	*11,021*	*13.8%*	*23.193*	*0.553*
2015	*48,730*	*25.1%*	*6,767*	*8.5%*	*16.614*	*0.456*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,576*	*3.4%*	*3,603*	*4.5%*	*-1.118*	*-0.057*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.8	3.2	7.0	-0.116	-0.022
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	8,542	4.4%	3,667	4.6%	-0.186	-0.009
Cardiovascular disease	91,246	46.9%	38,969	48.7%	-1.737	-0.035
Diabetes	63,363	32.6%	26,509	33.1%	-0.516	-0.011
Hypertension	165,951	85.4%	68,813	85.9%	-0.585	-0.017
Obesity	36,579	18.8%	14,994	18.7%	0.089	0.002
Renal impairment	37,989	19.5%	16,556	20.7%	-1.137	-0.028
Smoking	37,208	19.1%	15,388	19.2%	-0.081	-0.002
Von Willebrand disease	45	0.0%	29	0.0%	-0.013	-0.008
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,063	2.6%	2,067	2.6%	0.022	0.001

Table 1o. Baseline Characteristics of Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.012*	*0.013*
Endometrial hyperplasia	*130*	*0.1%*	*58*	*0.1%*	*-0.006*	*-0.002*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.008*	*0.010*
Ovarian cyst	*1,251*	*0.6%*	*491*	*0.6%*	*0.030*	*0.004*
Uterine myoma leiomyoma	*1,115*	*0.6%*	*418*	*0.5%*	*0.052*	*0.007*
Uterine or cervical polyp	*140*	*0.1%*	*68*	*0.1%*	*-0.013*	*-0.005*
Uterine ovarian or cervical cancer	*2,790*	*1.4%*	*1,188*	*1.5%*	*-0.048*	*-0.004*
Atrial Fibrillation (AF) or atrial flutter	148,765	76.5%	62,600	78.2%	-1.664	-0.040
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	61,295	31.5%	24,678	30.8%	0.706	0.015
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*181,876*	*93.6%*	*62,524*	*78.1%*	*15.462*	*0.455*
Cardiovascular and antidiabetic agents	181,875	93.6%	75,290	94.0%	-0.484	-0.020
Medications that increase bleeding risk without interaction	105,566	54.3%	44,559	55.7%	-1.353	-0.027
Medications that inhibit metabolism of NOACs and increase bleeding risk	133,031	68.4%	55,332	69.1%	-0.680	-0.015
Medications that induce metabolism of NOACs and reduce bleeding risk	55,168	28.4%	23,357	29.2%	-0.795	-0.018
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.9	9.5	12.9	25.8	-0.005	-0.000
Mean number of emergency room encounters	0.6	1.1	0.6	4.5	-0.013	-0.004
Mean number of inpatient hospital encounters	0.8	1.0	0.8	2.4	-0.013	-0.007
Mean number of non-acute institutional encounters	0.2	0.6	0.2	1.6	-0.015	-0.012
Mean number of other ambulatory encounters	6.9	9.6	7.3	26.6	-0.404	-0.020
Mean number of unique drug classes	10.3	5.3	10.5	16.8	-0.165	-0.013
Mean number of generics	11.0	5.9	11.2	18.6	-0.190	-0.014
Mean number of filled prescriptions	26.1	21.7	26.5	48.0	-0.375	-0.010

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1p. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	196,100	100.0%	97,792	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.1	10.9	77.9	9.4	-2.880	-0.283
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,373*	*4.3%*	*1,229*	*1.3%*	*3.013*	*0.185*
51+	*187,727*	*95.7%*	*96,563*	*98.7%*	*-3.013*	*-0.185*
Sex						
Female	*196,100*	*100.0%*	*97,792*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*631*	*0.3%*	*220*	*0.2%*	*0.097*	*0.019*
Asian	*2,228*	*1.1%*	*1,164*	*1.2%*	*-0.054*	*-0.005*
Black or African American	*14,157*	*7.2%*	*5,879*	*6.0%*	*1.208*	*0.049*
Native Hawaiian or Other Pacific Islander	*94*	*0.0%*	*62*	*0.1%*	*-0.015*	*-0.007*
White	*151,873*	*77.4%*	*80,301*	*82.1%*	*-4.667*	*-0.116*
Unknown	*27,117*	*13.8%*	*10,166*	*10.4%*	*3.433*	*0.105*
Hispanic Origin	*2,918*	*1.5%*	*1,168*	*1.2%*	*0.294*	*0.026*
Year						
2010	*0*	*0.0%*	*0*	*0.0%*	*0.000*	-
2011	*278*	*0.1%*	*0*	*0.0%*	*0.142*	-
2012	*17,590*	*9.0%*	*0*	*0.0%*	*8.970*	-
2013	*53,701*	*27.4%*	*9,222*	*9.4%*	*17.954*	*0.476*
2014	*73,638*	*37.6%*	*36,255*	*37.1%*	*0.478*	*0.010*
2015	*50,893*	*26.0%*	*52,315*	*53.5%*	*-27.544*	*-0.587*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,814*	*3.5%*	*1,515*	*1.5%*	*1.926*	*0.123*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.9	3.4	2.8	-0.215	-0.075
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	9,826	5.0%	3,443	3.5%	1.490	0.074
Cardiovascular disease	89,281	45.5%	52,420	53.6%	-8.075	-0.162
Diabetes	63,005	32.1%	32,633	33.4%	-1.241	-0.026
Hypertension	165,273	84.3%	87,230	89.2%	-4.920	-0.145
Obesity	39,395	20.1%	18,890	19.3%	0.773	0.019
Renal impairment	39,959	20.4%	25,114	25.7%	-5.304	-0.126
Smoking	40,710	20.8%	19,854	20.3%	0.458	0.011
Von Willebrand disease	48	0.0%	20	0.0%	0.004	0.003
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,747	2.9%	1,881	1.9%	1.007	0.065

Table 1p. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0.008*	*0.007*
Endometrial hyperplasia	*140*	*0.1%*	*56*	*0.1%*	*0.014*	*0.006*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.009*	*0.010*
Ovarian cyst	*1,414*	*0.7%*	*485*	*0.5%*	*0.225*	*0.029*
Uterine myoma leiomyoma	*1,231*	*0.6%*	*424*	*0.4%*	*0.194*	*0.027*
Uterine or cervical polyp	*151*	*0.1%*	*50*	*0.1%*	*0.026*	*0.010*
Uterine ovarian or cervical cancer	*3,231*	*1.6%*	*978*	*1.0%*	*0.648*	*0.057*
Atrial Fibrillation (AF) or atrial flutter	134,707	68.7%	89,322	91.3%	-22.646	-0.590
embolism (PE)	78,825	40.2%	16,196	16.6%	23.635	0.543
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*183,272*	*93.5%*	*66,075*	*67.6%*	*25.892*	*0.692*
Cardiovascular and antidiabetic agents	180,404	92.0%	95,088	97.2%	-5.239	-0.234
Medications that increase bleeding risk without interaction	108,673	55.4%	51,812	53.0%	2.435	0.049
Medications that inhibit metabolism of NOACs and increase bleeding risk	132,298	67.5%	70,797	72.4%	-4.931	-0.108
Medications that induce metabolism of NOACs and reduce bleeding risk	56,333	28.7%	27,629	28.3%	0.474	0.010
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.7	13.0	8.8	0.134	0.014
Mean number of emergency room encounters	0.6	1.3	0.6	1.0	0.088	0.075
Mean number of inpatient hospital encounters	0.9	1.0	0.8	1.0	0.053	0.052
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.7	0.022	0.032
Mean number of other ambulatory encounters	7.3	10.8	6.9	10.4	0.405	0.038
Mean number of unique drug classes	10.4	5.0	10.5	4.8	-0.120	-0.025
Mean number of generics	11.1	5.7	11.2	5.4	-0.066	-0.012
Mean number of filled prescriptions	26.1	20.2	25.8	19.2	0.231	0.012

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1q. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	97,474	49.7%	97,474	99.7%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	77.8	9.1	77.9	9.4	-0.059	-0.006
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,168*	*1.2%*	*1,229*	*1.3%*	*-0.063*	*-0.006*
51+	*96,306*	*98.8%*	*96,245*	*98.7%*	*0.063*	*0.006*
Sex						
Female	*97,474*	*100.0%*	*97,474*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*296*	*0.3%*	*220*	*0.2%*	*0.078*	*0.015*
Asian	*1,315*	*1.3%*	*1,162*	*1.2%*	*0.157*	*0.014*
Black or African American	*5,833*	*6.0%*	*5,866*	*6.0%*	*-0.034*	*-0.001*
Native Hawaiian or Other Pacific Islander	*53*	*0.1%*	*62*	*0.1%*	*-0.009*	*-0.004*
White	*79,755*	*81.8%*	*80,050*	*82.1%*	*-0.303*	*-0.008*
Unknown	*10,222*	*10.5%*	*10,114*	*10.4%*	*0.111*	*0.004*
Hispanic Origin	*1,377*	*1.4%*	*1,165*	*1.2%*	*0.217*	*0.019*
Year						
2010	*0*	*0.0%*	*0*	*0.0%*	*0.000*	-
2011	*149*	*0.2%*	*0*	*0.0%*	*0.153*	-
2012	*11,146*	*11.4%*	*0*	*0.0%*	*11.435*	-
2013	*27,870*	*28.6%*	*9,198*	*9.4%*	*19.156*	*0.503*
2014	*35,119*	*36.0%*	*36,144*	*37.1%*	*-1.052*	*-0.022*
2015	*23,190*	*23.8%*	*52,132*	*53.5%*	*-29.692*	*-0.640*
Presence of condition in post-index enrollment:						
Vaginal bleed	*2,919*	*3.0%*	*1,509*	*1.5%*	*1.447*	*0.097*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.3	2.8	3.3	2.8	-0.001	-0.000
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	3,523	3.6%	3,442	3.5%	0.083	0.004
Cardiovascular disease	52,064	53.4%	52,109	53.5%	-0.046	-0.001
Diabetes	32,404	33.2%	32,525	33.4%	-0.124	-0.003
Hypertension	86,911	89.2%	86,922	89.2%	-0.011	-0.000
Obesity	18,744	19.2%	18,795	19.3%	-0.052	-0.001
Renal impairment	24,869	25.5%	24,804	25.4%	0.067	0.002
Smoking	19,739	20.3%	19,731	20.2%	0.008	0.000
Von Willebrand disease	19	0.0%	18	0.0%	0.001	0.001
Gynecological disorders of interest	1,884	1.9%	1,877	1.9%	0.007	0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.001*	*-0.001*
Endometrial hyperplasia	*54*	*0.1%*	*56*	*0.1%*	*-0.002*	*-0.001*

Table 1q. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.006*	*0.007*
Ovarian cyst	*463*	*0.5%*	*484*	*0.5%*	*-0.022*	*-0.003*
Uterine myoma leiomyoma	*425*	*0.4%*	*424*	*0.4%*	*0.001*	*0.000*
Uterine or cervical polyp	*60*	*0.1%*	*50*	*0.1%*	*0.010*	*0.004*
Uterine ovarian or cervical cancer	*1,006*	*1.0%*	*975*	*1.0%*	*0.032*	*0.003*
Atrial Fibrillation (AF) or atrial flutter	89,077	91.4%	89,004	91.3%	0.075	0.003
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	16,162	16.6%	16,196	16.6%	-0.035	-0.001
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*91,002*	*93.4%*	*65,981*	*67.7%*	*25.669*	*0.685*
Cardiovascular and antidiabetic agents	94,664	97.1%	94,770	97.2%	-0.109	-0.007
Medications that increase bleeding risk without interaction	51,654	53.0%	51,646	53.0%	0.008	0.000
Medications that inhibit metabolism of NOACs and increase bleeding risk	70,432	72.3%	70,524	72.4%	-0.094	-0.002
Medications that induce metabolism of NOACs and reduce bleeding risk	27,604	28.3%	27,538	28.3%	0.068	0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.9	9.1	12.9	8.8	0.000	0.000
Mean number of emergency room encounters	0.6	1.0	0.6	1.0	-0.002	-0.002
Mean number of inpatient hospital encounters	0.8	1.0	0.8	1.0	0.004	0.004
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.7	0.002	0.002
Mean number of other ambulatory encounters	6.9	10.1	6.9	10.3	0.003	0.000
Mean number of unique drug classes	10.5	4.8	10.5	4.8	-0.008	-0.002
Mean number of generics	11.2	5.4	11.2	5.4	-0.007	-0.001
Mean number of filled prescriptions	25.8	19.0	25.8	19.2	-0.049	-0.003

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1r. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	196,100	100.0%	97,792	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.8	20.2	76.4	39.2	-0.577	-0.019
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*6,764*	*3.4%*	*2,857*	*2.9%*	*0.528*	*0.030*
51+	*189,336*	*96.6%*	*94,935*	*97.1%*	*-0.528*	*-0.030*
Sex						
Female	*196,100*	*100.0%*	*97,792*	*100.0%*	*0.000*	*0.000*
Race						
American Indian or Alaska Native	*612*	*0.3%*	*241*	*0.2%*	*0.066*	*0.012*
Asian	*2,343*	*1.2%*	*1,116*	*1.1%*	*0.054*	*0.005*
Black or African American	*13,170*	*6.7%*	*7,067*	*7.2%*	*-0.511*	*-0.020*
Native Hawaiian or Other Pacific Islander	*95*	*0.0%*	*62*	*0.1%*	*-0.015*	*-0.006*
White	*152,988*	*78.0%*	*78,904*	*80.7%*	*-2.671*	*-0.066*
Unknown	*26,892*	*13.7%*	*10,402*	*10.6%*	*3.077*	*0.094*
Hispanic Origin	*2,862*	*1.5%*	*1,237*	*1.3%*	*0.194*	*0.017*
Year						
2010	*0*	*0.0%*	*0*	*0.0%*	*0.000*	-
2011	*292*	*0.1%*	*0*	*0.0%*	*0.149*	-
2012	*19,136*	*9.8%*	*0*	*0.0%*	*9.758*	-
2013	*54,396*	*27.7%*	*7,922*	*8.1%*	*19.639*	*0.530*
2014	*72,730*	*37.1%*	*33,249*	*34.0%*	*3.088*	*0.065*
2015	*49,546*	*25.3%*	*56,621*	*57.9%*	*-32.634*	*-0.702*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,569*	*3.3%*	*1,557*	*1.6%*	*1.758*	*0.113*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.2	3.0	3.3	3.8	-0.087	-0.025
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	8,835	4.5%	4,616	4.7%	-0.215	-0.010
Cardiovascular disease	93,857	47.9%	48,381	49.5%	-1.611	-0.032
Diabetes	63,531	32.4%	32,439	33.2%	-0.774	-0.016
Hypertension	167,900	85.6%	84,858	86.8%	-1.154	-0.033
Obesity	38,893	19.8%	19,620	20.1%	-0.230	-0.006
Renal impairment	43,199	22.0%	22,585	23.1%	-1.065	-0.025
Smoking	40,108	20.5%	20,486	20.9%	-0.495	-0.012
Von Willebrand disease	45	0.0%	21	0.0%	0.002	0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,128	2.6%	2,462	2.5%	0.097	0.006

Table 1r. Baseline Characteristics of Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.006*	*0.006*
Endometrial hyperplasia	*132*	*0.1%*	*67*	*0.1%*	*-0.002*	*-0.001*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.006*	*0.007*
Ovarian cyst	*1,273*	*0.6%*	*666*	*0.7%*	*-0.032*	*-0.004*
Uterine myoma leiomyoma	*1,122*	*0.6%*	*506*	*0.5%*	*0.054*	*0.007*
Uterine or cervical polyp	*139*	*0.1%*	*60*	*0.1%*	*0.009*	*0.004*
Uterine ovarian or cervical cancer	*2,836*	*1.4%*	*1,318*	*1.3%*	*0.098*	*0.008*
Atrial Fibrillation (AF) or atrial flutter	148,726	75.8%	75,439	77.1%	-1.301	-0.031
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	63,854	32.6%	31,078	31.8%	0.782	0.017
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*183,253*	*93.4%*	*69,857*	*71.4%*	*22.014*	*0.604*
Cardiovascular and antidiabetic agents	183,399	93.5%	92,123	94.2%	-0.680	-0.028
Medications that increase bleeding risk without interaction	106,929	54.5%	53,457	54.7%	-0.137	-0.003
Medications that inhibit metabolism of NOACs and increase bleeding risk	135,064	68.9%	68,174	69.7%	-0.838	-0.018
Medications that induce metabolism of NOACs and reduce bleeding risk	55,726	28.4%	28,185	28.8%	-0.404	-0.009
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.0	9.8	13.0	13.3	0.014	0.001
Mean number of emergency room encounters	0.6	1.2	0.6	1.5	0.028	0.021
Mean number of inpatient hospital encounters	0.8	1.0	0.9	1.5	-0.024	-0.019
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.9	-0.009	-0.011
Mean number of other ambulatory encounters	7.1	10.4	7.4	14.8	-0.266	-0.021
Mean number of unique drug classes	10.4	5.3	10.5	8.4	-0.097	-0.014
Mean number of generics	11.1	6.0	11.2	9.4	-0.103	-0.013
Mean number of filled prescriptions	25.9	20.2	26.2	30.2	-0.341	-0.013

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1s. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	80,171	100.0%	97,678	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	76.8	9.1	77.9	9.4	-1.169	-0.126
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,071*	*1.3%*	*1,234*	*1.3%*	*0.073*	*0.006*
51+	*79,100*	*98.7%*	*96,444*	*98.7%*	*-0.073*	*-0.006*
Sex						
Female	*80,171*	*100.0%*	*97,678*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*229*	*0.3%*	*223*	*0.2%*	*0.057*	*0.011*
Asian	*1,248*	*1.6%*	*1,168*	*1.2%*	*0.361*	*0.031*
Black or African American	*4,082*	*5.1%*	*5,900*	*6.0%*	*-0.949*	*-0.041*
Native Hawaiian or Other Pacific Islander	*32*	*0.0%*	*60*	*0.1%*	*-0.022*	*-0.010*
White	*64,287*	*80.2%*	*80,168*	*82.1%*	*-1.886*	*-0.048*
Unknown	*10,293*	*12.8%*	*10,159*	*10.4%*	*2.438*	*0.076*
Hispanic Origin	*1,250*	*1.6%*	*1,168*	*1.2%*	*0.363*	*0.031*
Year						
2010	*1,252*	*1.6%*	*0*	*0.0%*	*1.562*	-
2011	*30,057*	*37.5%*	*0*	*0.0%*	*37.491*	-
2012	*22,791*	*28.4%*	*0*	*0.0%*	*28.428*	-
2013	*13,061*	*16.3%*	*9,100*	*9.3%*	*6.975*	*0.210*
2014	*8,599*	*10.7%*	*36,086*	*36.9%*	*-26.218*	*-0.647*
2015	*4,411*	*5.5%*	*52,492*	*53.7%*	*-48.238*	*-1.244*
Presence of condition in post-index enrollment:						
Vaginal bleed	*3,542*	*4.4%*	*1,509*	*1.5%*	*2.873*	*0.170*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	2.9	2.6	3.4	2.8	-0.404	-0.149
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,284	2.8%	3,449	3.5%	-0.682	-0.039
Cardiovascular disease	40,411	50.4%	52,384	53.6%	-3.223	-0.065
Diabetes	26,939	33.6%	32,613	33.4%	0.214	0.005
Hypertension	70,841	88.4%	87,154	89.2%	-0.863	-0.027
Obesity	12,669	15.8%	18,914	19.4%	-3.561	-0.094
Renal impairment	14,112	17.6%	25,088	25.7%	-8.082	-0.197
Smoking	12,325	15.4%	19,857	20.3%	-4.956	-0.130
Von Willebrand disease	16	0.0%	20	0.0%	-0.001	-0.000
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,434	1.8%	1,872	1.9%	-0.128	-0.009

Table 1s. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.006*	*-0.008*
Endometrial hyperplasia	*48*	*0.1%*	*53*	*0.1%*	*0.006*	*0.002*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*-0.000*	*-0.001*
Ovarian cyst	*368*	*0.5%*	*489*	*0.5%*	*-0.042*	*-0.006*
Uterine myoma leiomyoma	*356*	*0.4%*	*421*	*0.4%*	*0.013*	*0.002*
Uterine or cervical polyp	*56*	*0.1%*	*49*	*0.1%*	*0.020*	*0.008*
Uterine ovarian or cervical cancer	*723*	*0.9%*	*972*	*1.0%*	*-0.093*	*-0.010*
Atrial Fibrillation (AF) or atrial flutter	77,976	97.3%	89,156	91.3%	5.987	0.260
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	7,556	9.4%	16,265	16.7%	-7.227	-0.216
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*63,211*	*78.8%*	*66,009*	*67.6%*	*11.267*	*0.257*
Cardiovascular and antidiabetic agents	78,229	97.6%	94,966	97.2%	0.354	0.022
Medications that increase bleeding risk without interaction	41,166	51.3%	51,815	53.0%	-1.699	-0.034
Medications that inhibit metabolism of NOACs and increase bleeding risk	56,803	70.9%	70,688	72.4%	-1.516	-0.034
Medications that induce metabolism of NOACs and reduce bleeding risk	22,053	27.5%	27,630	28.3%	-0.779	-0.017
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.3	8.6	13.0	8.8	-0.700	-0.080
Mean number of emergency room encounters	0.5	1.0	0.6	1.0	-0.090	-0.091
Mean number of inpatient hospital encounters	0.7	0.9	0.8	1.0	-0.076	-0.078
Mean number of non-acute institutional encounters	0.2	0.5	0.2	0.7	-0.061	-0.098
Mean number of other ambulatory encounters	5.7	8.7	6.9	10.4	-1.217	-0.127
Mean number of unique drug classes	10.1	4.7	10.5	4.8	-0.343	-0.072
Mean number of generics	10.8	5.4	11.2	5.4	-0.349	-0.065
Mean number of filled prescriptions	26.2	19.2	25.8	19.2	0.326	0.017

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1t. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	73,887	92.2%	73,887	75.6%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	77.4	8.9	77.3	9.1	0.023	0.003
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*782*	*1.1%*	*835*	*1.1%*	*-0.072*	*-0.007*
51+	*73,105*	*98.9%*	*73,052*	*98.9%*	*0.072*	*0.007*
Sex						
Female	*73,887*	*100.0%*	*73,887*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*208*	*0.3%*	*164*	*0.2%*	*0.060*	*0.012*
Asian	*1,129*	*1.5%*	*945*	*1.3%*	*0.249*	*0.021*
Black or African American	*3,775*	*5.1%*	*3,876*	*5.2%*	*-0.137*	*-0.006*
Native Hawaiian or Other Pacific Islander	*30*	*0.0%*	*40*	*0.1%*	*-0.014*	*-0.006*
White	*60,357*	*81.7%*	*60,718*	*82.2%*	*-0.489*	*-0.013*
Unknown	*8,388*	*11.4%*	*8,144*	*11.0%*	*0.330*	*0.010*
Hispanic Origin	*1,152*	*1.6%*	*874*	*1.2%*	*0.376*	*0.032*
Year						
2010	*1,115*	*1.5%*	*0*	*0.0%*	*1.509*	-
2011	*27,451*	*37.2%*	*0*	*0.0%*	*37.153*	-
2012	*20,957*	*28.4%*	*0*	*0.0%*	*28.364*	-
2013	*12,155*	*16.5%*	*7,514*	*10.2%*	*6.281*	*0.186*
2014	*8,067*	*10.9%*	*28,400*	*38.4%*	*-27.519*	*-0.674*
2015	*4,142*	*5.6%*	*37,973*	*51.4%*	*-45.787*	*-1.177*
Presence of condition in post-index enrollment:						
Vaginal bleed	*3,217*	*4.4%*	*1,158*	*1.6%*	*2.787*	*0.165*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.0	2.6	3.0	2.6	0.005	0.002
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,145	2.9%	2,149	2.9%	-0.005	-0.000
Cardiovascular disease	37,775	51.1%	37,744	51.1%	0.042	0.001
Diabetes	24,360	33.0%	24,307	32.9%	0.072	0.002
Hypertension	65,567	88.7%	65,526	88.7%	0.055	0.002
Obesity	12,180	16.5%	12,182	16.5%	-0.003	-0.000
Renal impairment	13,954	18.9%	13,720	18.6%	0.317	0.008
Smoking	12,012	16.3%	11,938	16.2%	0.100	0.003
Von Willebrand disease	13	0.0%	14	0.0%	-0.001	-0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,307	1.8%	1,302	1.8%	0.007	0.001

Table 1t. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.007*	*-0.009*
Endometrial hyperplasia	*40*	*0.1%*	*37*	*0.1%*	*0.004*	*0.002*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.000*	*0.000*
Ovarian cyst	*346*	*0.5%*	*339*	*0.5%*	*0.009*	*0.001*
Uterine myoma leiomyoma	*313*	*0.4%*	*303*	*0.4%*	*0.014*	*0.002*
Uterine or cervical polyp	*46*	*0.1%*	*39*	*0.1%*	*0.009*	*0.004*
Uterine ovarian or cervical cancer	*668*	*0.9%*	*662*	*0.9%*	*0.008*	*0.001*
Atrial Fibrillation (AF) or atrial flutter	71,693	97.0%	71,616	96.9%	0.104	0.006
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	7,359	10.0%	7,447	10.1%	-0.119	-0.004
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*57,564*	*77.9%*	*51,550*	*69.8%*	*8.139*	*0.186*
Cardiovascular and antidiabetic agents	72,157	97.7%	72,141	97.6%	0.022	0.001
Medications that increase bleeding risk without interaction	38,005	51.4%	38,043	51.5%	-0.051	-0.001
Medications that inhibit metabolism of NOACs and increase bleeding risk	52,686	71.3%	52,643	71.2%	0.058	0.001
Medications that induce metabolism of NOACs and reduce bleeding risk	20,347	27.5%	20,421	27.6%	-0.100	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.4	8.6	12.4	8.4	0.002	0.000
Mean number of emergency room encounters	0.5	1.0	0.5	0.9	-0.002	-0.002
Mean number of inpatient hospital encounters	0.7	0.9	0.7	0.9	0.002	0.003
Mean number of non-acute institutional encounters	0.2	0.6	0.2	0.6	-0.002	-0.003
Mean number of other ambulatory encounters	5.9	8.9	5.9	8.9	-0.014	-0.002
Mean number of unique drug classes	10.2	4.7	10.2	4.7	0.002	0.000
Mean number of generics	10.9	5.3	10.9	5.3	0.003	0.001
Mean number of filled prescriptions	25.8	18.5	25.7	19.7	0.085	0.004

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1u. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	80,171	100.0%	97,678	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	77.3	24.0	77.5	14.1	-0.243	-0.012
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*1,117*	*1.4%*	*1,184*	*1.2%*	*0.181*	*0.016*
51+	*79,054*	*98.6%*	*96,494*	*98.8%*	*-0.181*	*-0.016*
Sex						
Female	*80,171*	*100.0%*	*97,678*	*100.0%*	*-0.000*	*-0.000*
Race						
American Indian or Alaska Native	*230*	*0.3%*	*223*	*0.2%*	*0.058*	*0.012*
Asian	*1,182*	*1.5%*	*1,214*	*1.2%*	*0.232*	*0.020*
Black or African American	*4,226*	*5.3%*	*5,638*	*5.8%*	*-0.501*	*-0.022*
Native Hawaiian or Other Pacific Islander	*30*	*0.0%*	*62*	*0.1%*	*-0.025*	*-0.011*
White	*64,263*	*80.2%*	*80,315*	*82.2%*	*-2.067*	*-0.053*
Unknown	*10,239*	*12.8%*	*10,226*	*10.5%*	*2.303*	*0.072*
Hispanic Origin	*1,268*	*1.6%*	*1,158*	*1.2%*	*0.396*	*0.034*
Year						
2010	*1,218*	*1.5%*	*0*	*0.0%*	*1.520*	-
2011	*29,484*	*36.8%*	*0*	*0.0%*	*36.777*	-
2012	*22,469*	*28.0%*	*0*	*0.0%*	*28.026*	-
2013	*13,106*	*16.3%*	*9,532*	*9.8%*	*6.589*	*0.197*
2014	*9,074*	*11.3%*	*36,755*	*37.6%*	*-26.311*	*-0.643*
2015	*4,820*	*6.0%*	*51,391*	*52.6%*	*-46.600*	*-1.192*
Presence of condition in post-index enrollment:						
Vaginal bleed	*3,468*	*4.3%*	*1,531*	*1.6%*	*2.758*	*0.164*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.2	3.4	3.2	2.6	-0.000	-0.000
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	2,578	3.2%	3,174	3.2%	-0.034	-0.002
Cardiovascular disease	41,902	52.3%	51,074	52.3%	-0.022	-0.000
Diabetes	26,761	33.4%	32,765	33.5%	-0.164	-0.003
Hypertension	71,062	88.6%	86,889	89.0%	-0.317	-0.010
Obesity	14,258	17.8%	17,318	17.7%	0.055	0.001
Renal impairment	17,736	22.1%	21,611	22.1%	-0.002	-0.000
Smoking	14,512	18.1%	17,698	18.1%	-0.017	-0.000
Von Willebrand disease	18	0.0%	21	0.0%	0.001	0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	1,487	1.9%	1,810	1.9%	0.002	0.000

Table 1u. Baseline Characteristics of Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Dabigatran		Apixaban			
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.005*	*-0.007*
Endometrial hyperplasia	*48*	*0.1%*	*52*	*0.1%*	*0.007*	*0.003*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*-0.001*	*-0.001*
Ovarian cyst	*378*	*0.5%*	*468*	*0.5%*	*-0.008*	*-0.001*
Uterine myoma leiomyoma	*354*	*0.4%*	*412*	*0.4%*	*0.020*	*0.003*
Uterine or cervical polyp	*55*	*0.1%*	*50*	*0.1%*	*0.017*	*0.007*
Uterine ovarian or cervical cancer	*771*	*1.0%*	*932*	*1.0%*	*0.007*	*0.001*
Atrial Fibrillation (AF) or atrial flutter	76,075	94.9%	91,517	93.7%	1.198	0.052
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	10,186	12.7%	13,329	13.6%	-0.941	-0.028
History of Use:						
High dose of index-defining Novel Oral Anticoagulant (NOAC)	*61,616*	*76.9%*	*67,454*	*69.1%*	*7.798*	*0.176*
Cardiovascular and antidiabetic agents	78,079	97.4%	95,166	97.4%	-0.038	-0.002
Medications that increase bleeding risk without interaction	42,017	52.4%	51,187	52.4%	0.006	0.000
Medications that inhibit metabolism of NOACs and increase bleeding risk	57,411	71.6%	70,078	71.7%	-0.133	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	22,458	28.0%	27,464	28.1%	-0.104	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	12.6	10.7	12.7	8.4	-0.019	-0.002
Mean number of emergency room encounters	0.5	1.4	0.5	0.9	0.016	0.013
Mean number of inpatient hospital encounters	0.8	1.1	0.8	1.0	-0.004	-0.004
Mean number of non-acute institutional encounters	0.2	0.8	0.2	0.6	-0.006	-0.009
Mean number of other ambulatory encounters	6.4	12.2	6.5	9.0	-0.047	-0.004
Mean number of unique drug classes	10.4	6.3	10.3	4.9	0.011	0.002
Mean number of generics	11.1	7.0	11.1	5.6	0.014	0.002
Mean number of filled prescriptions	26.1	20.3	26.0	21.7	0.090	0.004

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1v. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	189,030	100.0%	722,539	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.0	10.9	75.4	11.9	-0.368	-0.032
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,011*	*4.2%*	*36,457*	*5.0%*	*-0.808*	*-0.038*
51+	*181,019*	*95.8%*	*686,082*	*95.0%*	*0.808*	*0.038*
Sex						
Female	*189,030*	*100.0%*	*722,539*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*600*	*0.3%*	*2,778*	*0.4%*	*-0.067*	*-0.011*
Asian	*2,143*	*1.1%*	*6,862*	*0.9%*	*0.184*	*0.018*
Black or African American	*13,459*	*7.1%*	*71,572*	*9.9%*	*-2.786*	*-0.100*
Native Hawaiian or Other Pacific Islander	*88*	*0.0%*	*233*	*0.0%*	*0.014*	*0.007*
White	*146,481*	*77.5%*	*552,339*	*76.4%*	*1.047*	*0.025*
Unknown	*26,259*	*13.9%*	*88,755*	*12.3%*	*1.608*	*0.048*
Hispanic Origin	*2,764*	*1.5%*	*11,755*	*1.6%*	*-0.165*	*-0.013*
Year						
2010	*0*	*0.0%*	*38,333*	*5.3%*	*-5.305*	-
2011	*275*	*0.1%*	*173,848*	*24.1%*	*-23.915*	*-0.788*
2012	*17,179*	*9.1%*	*166,558*	*23.1%*	*-13.964*	*-0.387*
2013	*51,790*	*27.4%*	*145,023*	*20.1%*	*7.326*	*0.173*
2014	*70,809*	*37.5%*	*120,338*	*16.7%*	*20.804*	*0.482*
2015	*48,977*	*25.9%*	*78,439*	*10.9%*	*15.054*	*0.396*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,585*	*3.5%*	*33,071*	*4.6%*	*-1.093*	*-0.056*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.9	3.9	3.2	-0.779	-0.256
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	9,444	5.0%	69,696	9.6%	-4.650	-0.179
Cardiovascular disease	85,689	45.3%	387,770	53.7%	-8.337	-0.167
Diabetes	60,512	32.0%	269,216	37.3%	-5.248	-0.110
Hypertension	159,318	84.3%	618,707	85.6%	-1.348	-0.038
Obesity	37,897	20.0%	142,077	19.7%	0.385	0.010
Renal impairment	38,201	20.2%	215,253	29.8%	-9.582	-0.223
Smoking	39,279	20.8%	147,529	20.4%	0.361	0.009
Von Willebrand disease	47	0.0%	260	0.0%	-0.011	-0.006
Gynecological disorders of interest	5,562	2.9%	21,574	3.0%	-0.043	-0.003
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Adenomyosis	*32*	*0.0%*	*112*	*0.0%*	*0.001*	*0.001*
Endometrial hyperplasia	*139*	*0.1%*	*454*	*0.1%*	*0.011*	*0.004*

Table 1v. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Crude, Aggregated)

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Endometriosis	*27*	*0.0%*	*122*	*0.0%*	*-0.003*	*-0.002*
Ovarian cyst	*1,374*	*0.7%*	*5,491*	*0.8%*	*-0.033*	*-0.004*
Uterine myoma leiomyoma	*1,193*	*0.6%*	*4,843*	*0.7%*	*-0.039*	*-0.005*
Uterine or cervical polyp	*148*	*0.1%*	*443*	*0.1%*	*0.017*	*0.006*
Uterine ovarian or cervical cancer	*3,118*	*1.6%*	*11,901*	*1.6%*	*0.002*	*0.000*
Atrial Fibrillation (AF) or atrial flutter	130,085	68.8%	433,326	60.0%	8.844	0.186
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	75,216	39.8%	384,673	53.2%	-13.449	-0.272
History of Use:						
Cardiovascular and antidiabetic agents	173,904	92.0%	662,300	91.7%	0.335	0.012
Medications that increase bleeding risk without interaction	104,605	55.3%	447,555	61.9%	-6.604	-0.134
Medications that inhibit metabolism of Novel Oral Anticoagulants (NOACs) and increase bleeding risk	127,490	67.4%	490,826	67.9%	-0.486	-0.010
Medications that induce metabolism of NOACs and reduce bleeding risk	54,034	28.6%	223,518	30.9%	-2.350	-0.051
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.6	13.8	10.1	-0.711	-0.072
Mean number of emergency room encounters	0.6	1.3	0.7	1.4	-0.020	-0.015
Mean number of inpatient hospital encounters	0.9	1.0	1.1	1.2	-0.283	-0.253
Mean number of non-acute institutional encounters	0.2	0.7	0.4	0.9	-0.136	-0.173
Mean number of other ambulatory encounters	7.3	10.7	10.9	14.3	-3.655	-0.289
Mean number of unique drug classes	10.3	5.0	10.7	5.0	-0.397	-0.080
Mean number of generics	11.1	5.6	11.6	5.7	-0.465	-0.082
Mean number of filled prescriptions	25.9	20.1	27.3	20.2	-1.402	-0.069

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1w. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	188,995	100.0%	188,995	26.2%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.1	10.9	75.1	11.6	-0.019	-0.002
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,004*	*4.2%*	*9,656*	*5.1%*	*-0.874*	*-0.041*
51+	*180,991*	*95.8%*	*179,339*	*94.9%*	*0.874*	*0.041*
Sex						
Female	*188,995*	*100.0%*	*188,995*	*100.0%*	*0.000*	-
Race						
American Indian or Alaska Native	*600*	*0.3%*	*688*	*0.4%*	*-0.047*	*-0.008*
Asian	*2,143*	*1.1%*	*1,655*	*0.9%*	*0.258*	*0.026*
Black or African American	*13,455*	*7.1%*	*14,919*	*7.9%*	*-0.775*	*-0.029*
Native Hawaiian or Other Pacific Islander	*88*	*0.0%*	*81*	*0.0%*	*0.004*	*0.002*
White	*146,465*	*77.5%*	*145,643*	*77.1%*	*0.435*	*0.010*
Unknown	*26,244*	*13.9%*	*26,009*	*13.8%*	*0.124*	*0.004*
Hispanic Origin	*2,764*	*1.5%*	*2,640*	*1.4%*	*0.066*	*0.006*
Year						
2010	*0*	*0.0%*	*10,198*	*5.4%*	*-5.396*	-
2011	*274*	*0.1%*	*45,563*	*24.1%*	*-23.963*	*-0.789*
2012	*17,176*	*9.1%*	*43,081*	*22.8%*	*-13.707*	*-0.381*
2013	*51,781*	*27.4%*	*38,097*	*20.2%*	*7.240*	*0.171*
2014	*70,798*	*37.5%*	*31,444*	*16.6%*	*20.823*	*0.482*
2015	*48,966*	*25.9%*	*20,612*	*10.9%*	*15.003*	*0.395*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,583*	*3.5%*	*8,719*	*4.6%*	*-1.130*	*-0.057*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.1	2.9	3.1	2.8	-0.016	-0.006
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	9,444	5.0%	9,845	5.2%	-0.212	-0.010
Cardiovascular disease	85,685	45.3%	85,738	45.4%	-0.028	-0.001
Diabetes	60,504	32.0%	60,547	32.0%	-0.023	-0.000
Hypertension	159,288	84.3%	159,202	84.2%	0.046	0.001
Obesity	37,874	20.0%	37,985	20.1%	-0.059	-0.001
Renal impairment	38,201	20.2%	38,288	20.3%	-0.046	-0.001
Smoking	39,265	20.8%	39,226	20.8%	0.021	0.001
Von Willebrand disease	47	0.0%	51	0.0%	-0.002	-0.001
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,562	2.9%	5,642	3.0%	-0.042	-0.002

Table 1w. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Adenomyosis	*32*	*0.0%*	*38*	*0.0%*	*-0.003*	*-0.002*
Endometrial hyperplasia	*139*	*0.1%*	*122*	*0.1%*	*0.009*	*0.003*
Endometriosis	*27*	*0.0%*	*48*	*0.0%*	*-0.011*	*-0.008*
Ovarian cyst	*1,374*	*0.7%*	*1,533*	*0.8%*	*-0.084*	*-0.010*
Uterine myoma leiomyoma	*1,193*	*0.6%*	*1,255*	*0.7%*	*-0.033*	*-0.004*
Uterine or cervical polyp	*148*	*0.1%*	*139*	*0.1%*	*0.005*	*0.002*
Uterine ovarian or cervical cancer	*3,118*	*1.6%*	*2,997*	*1.6%*	*0.064*	*0.005*
Atrial Fibrillation (AF) or atrial flutter	130,055	68.8%	130,937	69.3%	-0.467	-0.010
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	75,211	39.8%	74,265	39.3%	0.501	0.010
History of Use:						
Cardiovascular and antidiabetic agents	173,875	92.0%	173,956	92.0%	-0.043	-0.002
Medications that increase bleeding risk without interaction	104,599	55.3%	103,794	54.9%	0.426	0.009
Medications that inhibit metabolism of Novel Oral Anticoagulants (NOACs) and increase bleeding risk	127,470	67.4%	127,746	67.6%	-0.146	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	54,024	28.6%	54,040	28.6%	-0.008	-0.000
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.1	9.6	13.1	9.5	-0.061	-0.006
Mean number of emergency room encounters	0.6	1.3	0.6	1.4	0.002	0.002
Mean number of inpatient hospital encounters	0.9	1.0	0.9	1.0	-0.004	-0.004
Mean number of non-acute institutional encounters	0.2	0.7	0.2	0.7	-0.007	-0.009
Mean number of other ambulatory encounters	7.3	10.7	7.4	10.4	-0.153	-0.015
Mean number of unique drug classes	10.3	5.0	10.4	4.9	-0.020	-0.004
Mean number of generics	11.1	5.6	11.1	5.6	-0.022	-0.004
Mean number of filled prescriptions	25.9	20.1	26.0	19.3	-0.074	-0.004

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1x. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Characteristic[1,2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Number of patients	189,030	100.0%	722,539	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean age (years)	75.3	31.8	75.4	13.7	-0.106	-0.004
	Number	**Percent**	**Number**	**Percent**		
Age (years)						
18-50	*8,148*	*4.3%*	*35,964*	*5.0%*	*-0.667*	*-0.032*
51+	*180,882*	*95.7%*	*686,575*	*95.0%*	*0.667*	*0.032*
Sex						
Female	*189,030*	*100.0%*	*722,539*	*100.0%*	*-0.000*	-
Race						
American Indian or Alaska Native	*610*	*0.3%*	*2,766*	*0.4%*	*-0.060*	*-0.010*
Asian	*2,078*	*1.1%*	*6,829*	*0.9%*	*0.154*	*0.015*
Black or African American	*15,451*	*8.2%*	*68,838*	*9.5%*	*-1.353*	*-0.048*
Native Hawaiian or Other Pacific Islander	*95*	*0.1%*	*234*	*0.0%*	*0.018*	*0.009*
White	*144,301*	*76.3%*	*555,468*	*76.9%*	*-0.539*	*-0.013*
Unknown	*26,495*	*14.0%*	*88,405*	*12.2%*	*1.781*	*0.053*
Hispanic Origin	*3,059*	*1.6%*	*11,481*	*1.6%*	*0.029*	*0.002*
Year						
2010	*0*	*0.0%*	*38,446*	*5.3%*	*-5.321*	-
2011	*263*	*0.1%*	*173,777*	*24.1%*	*-23.912*	*-0.788*
2012	*15,285*	*8.1%*	*166,402*	*23.0%*	*-14.944*	*-0.421*
2013	*51,479*	*27.2%*	*145,077*	*20.1%*	*7.154*	*0.169*
2014	*72,106*	*38.1%*	*120,294*	*16.6%*	*21.497*	*0.497*
2015	*49,898*	*26.4%*	*78,543*	*10.9%*	*15.526*	*0.407*
Presence of condition in post-index enrollment:						
Vaginal bleed	*6,580*	*3.5%*	*33,044*	*4.6%*	*-1.093*	*-0.056*
Recorded History of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Charlson/Elixhauser Combined Comorbidity Score	3.7	4.7	3.8	2.9	-0.054	-0.014
	Number	**Percent**	**Number**	**Percent**		
Severe anemia	15,564	8.2%	63,446	8.8%	-0.547	-0.020
Cardiovascular disease	97,471	51.6%	376,393	52.1%	-0.529	-0.011
Diabetes	67,533	35.7%	262,076	36.3%	-0.545	-0.011
Hypertension	160,190	84.7%	617,494	85.5%	-0.718	-0.020
Obesity	37,044	19.6%	142,514	19.7%	-0.127	-0.003
Renal impairment	51,228	27.1%	201,618	27.9%	-0.804	-0.018
Smoking	38,319	20.3%	148,239	20.5%	-0.245	-0.006
Von Willebrand disease	63	0.0%	243	0.0%	-0.000	-0.000
Recorded History of:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Gynecological disorders of interest	5,781	3.1%	21,456	3.0%	0.089	0.005

Table 1x. Baseline Characteristics of Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 in Risk Assessment for Transfusion Management Definition of Severe Uterine Bleed (Propensity Score Percentiles Weighted, Aggregated), Percentiles: 10

	Medical Product				Covariate Balance	
	Rivaroxaban		Warfarin			
Adenomyosis	*33*	*0.0%*	*113*	*0.0%*	*0.002*	*0.001*
Endometrial hyperplasia	*131*	*0.1%*	*463*	*0.1%*	*0.005*	*0.002*
Endometriosis	*28*	*0.0%*	*124*	*0.0%*	*-0.003*	*-0.002*
Ovarian cyst	*1,365*	*0.7%*	*5,534*	*0.8%*	*-0.044*	*-0.005*
Uterine myoma leiomyoma	*1,180*	*0.6%*	*4,808*	*0.7%*	*-0.041*	*-0.005*
Uterine or cervical polyp	*130*	*0.1%*	*457*	*0.1%*	*0.005*	*0.002*
Uterine ovarian or cervical cancer	*3,406*	*1.8%*	*11,745*	*1.6%*	*0.176*	*0.014*
Atrial Fibrillation (AF) or atrial flutter	115,743	61.2%	447,660	62.0%	-0.727	-0.015
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	95,890	50.7%	363,809	50.4%	0.376	0.008
History of Use:						
Cardiovascular and antidiabetic agents	172,728	91.4%	663,471	91.8%	-0.449	-0.016
Medications that increase bleeding risk without interaction	114,374	60.5%	437,242	60.5%	-0.009	-0.000
Medications that inhibit metabolism of Novel Oral Anticoagulants (NOACs) and increase bleeding risk	128,073	67.8%	490,693	67.9%	-0.160	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	56,741	30.0%	220,428	30.5%	-0.490	-0.011
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**		
Mean number of ambulatory encounters	13.7	13.8	13.6	9.7	0.093	0.008
Mean number of emergency room encounters	0.7	1.4	0.7	1.4	0.014	0.010
Mean number of inpatient hospital encounters	1.1	1.7	1.1	1.1	-0.024	-0.017
Mean number of non-acute institutional encounters	0.3	1.1	0.3	0.8	-0.004	-0.004
Mean number of other ambulatory encounters	9.7	20.1	10.3	12.8	-0.584	-0.035
Mean number of unique drug classes	10.7	7.5	10.7	4.9	-0.005	-0.001
Mean number of generics	11.5	8.4	11.5	5.6	-0.004	-0.001
Mean number of filled prescriptions	27.1	27.3	27.1	19.8	0.034	0.001

[1]Covariates in italics were not included in the propensity score logistic regression model.

[2]Covariates in blue show an absolute standardized difference greater than 0.1

[3]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 2a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Rivaroxaban	194,400	147,257.09	276.68	0.76	786	5.34	4.04	1.73	0.23	1.38 (1.21, 1.59)	<0.001
Dabigatran	80,074	84,595.46	385.87	1.06	305	3.61	3.81				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Rivaroxaban	80,042	33,818.95	154.32	0.42	171	5.06	2.14	1.54	0.65	1.44 (1.14, 1.82)	0.002
Dabigatran	80,042	33,818.95	154.32	0.42	119	3.52	1.49				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	80,042	69,558.41	317.41	0.87	316	4.54	3.95	0.95	0.15	1.22 (1.03, 1.43)	0.018
Dabigatran	80,042	84,568.88	385.91	1.06	304	3.59	3.8				
Predefined Percentile Analysis; Percentile = 10[1]											
Rivaroxaban	194,400	147,202.77	276.57	0.76	784	5.33	4.03	1.72	0.31	1.19 (1.03, 1.38)	0.018
Dabigatran	80,074	82,629.19	376.91	1.03	298	3.61	3.72				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Rivaroxaban	196,090	148,630.34	276.85	0.76	790	5.32	4.03	1.73	2.29	1.49 (1.26, 1.76)	<0.001
Apixaban	97,784	47,399.02	177.05	0.48	170	3.59	1.74				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Rivaroxaban	97,466	28,731.40	107.67	0.29	130	4.52	1.33	1.5	0.44	1.49 (1.14, 1.96)	0.004
Apixaban	97,466	28,731.40	107.67	0.29	87	3.03	0.89				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	97,466	80,343.54	301.08	0.82	335	4.17	3.44	0.57	1.69	1.21 (1.00, 1.46)	0.049
Apixaban	97,466	47,274.54	177.16	0.49	170	3.6	1.74				
Predefined Percentile Analysis; Percentile = 10[1]											
Rivaroxaban	196,090	144,586.66	269.32	0.74	769	5.32	3.92	1.73	2.18	1.23 (1.04, 1.47)	0.018
Apixaban	97,784	47,399.02	177.05	0.48	170	3.59	1.74				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Dabigatran	80,179	84,635.50	385.55	1.06	305	3.6	3.8	0	2.06	0.98 (0.80, 1.20)	0.869
Apixaban	97,670	47,199.86	176.51	0.48	170	3.6	1.74				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Dabigatran	73,880	22,515.16	111.31	0.3	76	3.38	1.03	0.4	0.12	1.13 (0.82, 1.58)	0.452
Apixaban	73,880	22,515.16	111.31	0.3	67	2.98	0.91				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	73,880	77,406.86	382.69	1.05	274	3.54	3.71	-0.05	1.87	0.97 (0.78, 1.21)	0.775
Apixaban	73,880	37,917.91	187.46	0.51	136	3.59	1.84				
Predefined Percentile Analysis; Percentile = 10[1]											
Dabigatran	80,179	72,355.75	329.61	0.9	264	3.65	3.29	0.05	1.55	0.97 (0.79, 1.19)	0.769
Apixaban	97,670	47,199.86	176.51	0.48	170	3.6	1.74				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Rivaroxaban	189,015	143,740.13	277.76	0.76	773	5.38	4.09	1.66	2.23	1.38 (1.26, 1.51)	<0.001
Warfarin	722,772	361,794.23	182.83	0.5	1,344	3.71	1.86				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Rivaroxaban	188,984	48,433.32	93.61	0.26	292	6.03	1.55	2.31	0.59	1.62 (1.35, 1.95)	<0.001
Warfarin	188,984	48,433.32	93.61	0.26	180	3.72	0.95				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	188,984	143,723.48	277.77	0.76	771	5.36	4.08	1.66	2.23	1.42 (1.25, 1.62)	<0.001
Warfarin	188,984	94,600.68	182.84	0.5	350	3.7	1.85				
Predefined Percentile Analysis; Percentile = 10[1]											
Rivaroxaban	189,015	143,740.13	277.76	0.76	773	5.38	4.09	1.66	2.25	1.34 (1.22, 1.47)	<0.001
Warfarin	722,772	357,988.04	180.91	0.5	1,331	3.72	1.84				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Rivaroxaban	194,409	147,730.95	277.55	0.76	194	1.31	1	0.81	0.46	2.24 (1.59, 3.16)	<0.001
Dabigatran	80,065	84,924.06	387.42	1.06	43	0.51	0.54				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Rivaroxaban	80,033	33,851.43	154.49	0.42	33	0.97	0.41	0.27	0.11	1.37 (0.81, 2.33)	0.235
Dabigatran	80,033	33,851.43	154.49	0.42	24	0.71	0.3				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	80,033	69,579.53	317.54	0.87	53	0.76	0.66	0.26	0.12	1.43 (0.95, 2.17)	0.09
Dabigatran	80,033	84,895.94	387.44	1.06	43	0.51	0.54				
Predefined Percentile Analysis; Percentile = 10[1]											
Rivaroxaban	194,409	147,696.69	277.49	0.76	194	1.31	1	0.82	0.49	1.49 (1.03, 2.17)	0.035
Dabigatran	80,065	82,925.01	378.3	1.04	41	0.49	0.51				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Rivaroxaban	196,100	149,111.17	277.73	0.76	194	1.3	0.99	0.61	0.65	2.22 (1.53, 3.22)	<0.001
Apixaban	97,792	47,477.64	177.33	0.49	33	0.7	0.34				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Rivaroxaban	97,474	28,805.30	107.94	0.3	35	1.22	0.36	0.28	0.08	1.30 (0.78, 2.14)	0.311
Apixaban	97,474	28,805.30	107.94	0.3	27	0.94	0.28				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	97,474	80,800.16	302.77	0.83	59	0.73	0.61	0.03	0.27	1.37 (0.89, 2.11)	0.149
Apixaban	97,474	47,362.71	177.48	0.49	33	0.7	0.34				
Predefined Percentile Analysis; Percentile = 10[1]											
Rivaroxaban	196,100	145,014.69	270.1	0.74	193	1.33	0.98	0.64	0.65	1.43 (0.97, 2.12)	0.069
Apixaban	97,792	47,477.64	177.33	0.49	33	0.7	0.34				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Dabigatran	80,171	84,964.36	387.09	1.06	43	0.51	0.54	-0.19	0.2	0.94 (0.58, 1.53)	0.808
Apixaban	97,678	47,278.02	176.79	0.48	33	0.7	0.34				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Dabigatran	73,887	22,584.70	111.64	0.31	15	0.66	0.2	-0.09	-0.03	0.88 (0.44, 1.77)	0.724
Apixaban	73,887	22,584.70	111.64	0.31	17	0.75	0.23				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	73,887	77,676.31	383.98	1.05	40	0.51	0.54	-0.09	0.23	1.09 (0.63, 1.87)	0.768
Apixaban	73,887	37,949.64	187.6	0.51	23	0.61	0.31				
Predefined Percentile Analysis; Percentile = 10[1]											
Dabigatran	80,171	72,559.11	330.57	0.91	37	0.51	0.46	-0.19	0.12	1.03 (0.62, 1.70)	0.915
Apixaban	97,678	47,278.02	176.79	0.48	33	0.7	0.34				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 2h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Crude Analysis (Site-adjusted only)											
Rivaroxaban	189,030	144,213.26	278.65	0.76	191	1.32	1.01	-0.36	0.16	0.86 (0.73, 1.01)	0.065
Warfarin	722,539	362,420.10	183.21	0.5	611	1.69	0.85				
1:1 Matched Conditional Analysis; Caliper= 0.05[1]											
Rivaroxaban	188,995	48,636.11	93.99	0.26	95	1.95	0.5	0.41	0.11	1.27 (0.94, 1.71)	0.126
Warfarin	188,995	48,636.11	93.99	0.26	75	1.54	0.4				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	188,995	144,192.89	278.67	0.76	191	1.32	1.01	0.12	0.41	1.23 (0.98, 1.56)	0.079
Warfarin	188,995	94,662.57	182.94	0.5	114	1.2	0.6				
Predefined Percentile Analysis; Percentile = 10[1]											
Rivaroxaban	189,030	144,213.26	278.65	0.76	191	1.32	1.01	-0.37	0.17	1.12 (0.95, 1.33)	0.181
Warfarin	722,539	358,546.64	181.25	0.5	608	1.7	0.84				

[1]Matched conditional and percentile analyses include informative events and person-time.

Table 3a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	8,336	4,311.25	188.9	0.52	167	38.74	20.03	19.45	6.91	1.84 (1.04, 3.26)	0.035
Dabigatran	1,067	725.94	248.5	0.68	14	19.29	13.12				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	957	255.62	97.56	0.27	12	46.94	12.54	*****	*****	2.00 (0.75, 5.33)	0.166
Dabigatran	957	255.62	97.56	0.27	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	957	550.37	210.05	0.58	24	43.61	25.08	21.59	10.45	1.86 (0.94, 3.65)	0.073
Dabigatran	957	636	242.74	0.66	14	22.01	14.63				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	8,336	3,617.83	158.52	0.43	142	39.25	17.03	20.4	4.85	1.69 (0.90, 3.17)	0.104
Dabigatran	1,067	689.77	236.12	0.65	13	18.85	12.18				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	186,064	142,945.84	280.61	0.77	619	4.33	3.33	0.86	-0.36	1.20 (1.04, 1.38)	0.015
Dabigatran	79,007	83,869.52	387.73	1.06	291	3.47	3.68				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	78,908	33,530.63	155.21	0.42	156	4.65	1.98	1.31	0.56	1.39 (1.09, 1.78)	0.007
Dabigatran	78,908	33,530.63	155.21	0.42	112	3.34	1.42				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	78,908	68,879.48	318.83	0.87	292	4.24	3.7	0.78	0.03	1.18 (1.00, 1.40)	0.047
Dabigatran	78,908	83,798.35	387.89	1.06	290	3.46	3.68				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	186,064	142,918.96	280.55	0.77	617	4.32	3.32	0.84	-0.29	1.15 (0.99, 1.34)	0.063
Dabigatran	79,007	81,916.27	378.7	1.04	285	3.48	3.61				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	8,361	4,323.34	188.87	0.52	167	38.63	19.97	20.87	*****	2.18 (1.07, 4.45)	0.031
Apixaban	1,227	*****	*****	*****	*****	17.76	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,099	234.63	77.98	0.21	*****	*****	*****	12.79	2.73	2.00 (0.50, 8.00)	0.327
Apixaban	1,099	234.63	77.98	0.21	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,099	602.81	200.34	0.55	18	29.86	16.38	*****	*****	1.84 (0.76, 4.44)	0.175
Apixaban	1,099	407.75	135.51	0.37	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	8,361	3,527.63	154.1	0.42	144	40.82	17.22	23.06	*****	2.01 (0.96, 4.20)	0.064
Apixaban	1,227	*****	*****	*****	*****	17.76	*****				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	187,729	144,307.00	280.77	0.77	623	4.32	3.32	0.87	*****	1.27 (1.07, 1.51)	0.007
Apixaban	96,557	*****	*****	*****	*****	3.45	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	96,211	28,455.11	108.03	0.3	127	4.46	1.32	1.48	0.44	1.49 (1.14, 1.97)	0.004
Apixaban	96,211	28,455.11	108.03	0.3	85	2.99	0.88				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	96,211	79,631.37	302.31	0.83	315	3.96	3.27	0.5	1.59	1.18 (0.97, 1.43)	0.093
Apixaban	96,211	46,812.71	177.72	0.49	*****	3.46	1.68				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	187,729	140,443.76	273.25	0.75	607	4.32	3.23	0.87	1.56	1.20 (1.00, 1.44)	0.046
Apixaban	96,557	46,948.61	177.59	0.49	*****	3.45	1.68				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,070	726.7	248.06	0.68	14	19.27	13.08	1.5	*****	1.16 (0.47, 2.91)	0.744
Apixaban	1,232	*****	*****	*****	*****	17.76	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	741	169.07	83.34	0.23	*****	*****	*****	11.83	2.7	2.00 (0.37, 10.92)	0.423
Apixaban	741	169.07	83.34	0.23	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	741	502.29	247.58	0.68	*****	*****	*****	4.97	8.1	1.40 (0.46, 4.25)	0.55
Apixaban	741	295.27	145.54	0.4	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,070	569.13	194.27	0.53	12	21.08	11.21	2.7	*****	1.03 (0.40, 2.67)	0.943
Apixaban	1,232	*****	*****	*****	*****	18.38	*****				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Dabigatran	79,109	83,908.80	387.41	1.06	291	3.47	3.68	0	*****	0.98 (0.80, 1.20)	0.838
Apixaban	96,438	*****	*****	*****	*****	3.47	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	72,997	22,322.00	111.69	0.31	73	3.27	1	0.4	0.12	1.14 (0.82, 1.60)	0.442
Apixaban	72,997	22,322.00	111.69	0.31	64	2.87	0.88				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	72,997	76,779.39	384.18	1.05	263	3.43	3.6	-0.06	1.81	0.95 (0.76, 1.20)	0.687
Apixaban	72,997	37,565.53	187.96	0.51	*****	3.49	1.79				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	79,109	71,848.87	331.73	0.91	251	3.49	3.17	0.03	1.49	0.97 (0.79, 1.20)	0.789
Apixaban	96,438	46,749.51	177.06	0.48	*****	3.47	1.68				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,997	4,136.64	188.93	0.52	163	39.4	20.38	18.12	11.81	1.67 (1.38, 2.03)	<0.001
Warfarin	36,406	14,657.86	147.06	0.4	312	21.29	8.57				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,864	1,574.72	73.14	0.2	60	38.1	7.63	19.05	3.81	2.00 (1.29, 3.10)	0.002
Warfarin	7,864	1,574.72	73.14	0.2	30	19.05	3.81				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,864	4,083.37	189.66	0.52	161	39.43	20.47	18.12	12.21	1.80 (1.34, 2.41)	<0.001
Warfarin	7,864	3,050.30	141.67	0.39	65	21.31	8.27				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,997	4,135.85	188.9	0.52	163	39.41	20.38	18.14	12.14	1.65 (1.35, 2.02)	<0.001
Warfarin	36,406	14,105.34	141.51	0.39	300	21.27	8.24				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	181,018	139,603.49	281.69	0.77	610	4.37	3.37	1.4	1.87	1.43 (1.29, 1.58)	<0.001
Warfarin	686,366	347,136.37	184.73	0.51	1,032	2.97	1.5				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	179,227	46,462.64	94.69	0.26	212	4.56	1.18	1.57	0.41	1.53 (1.23, 1.89)	<0.001
Warfarin	179,227	46,462.64	94.69	0.26	139	2.99	0.78				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	179,227	138,341.62	281.93	0.77	602	4.35	3.36	1.36	1.84	1.43 (1.23, 1.65)	<0.001
Warfarin	179,227	90,784.56	185.01	0.51	272	3	1.52				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	181,018	139,603.49	281.69	0.77	610	4.37	3.37	1.39	1.88	1.36 (1.22, 1.51)	<0.001
Warfarin	686,366	343,439.87	182.76	0.5	1,024	2.98	1.49				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 3e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	8,348	4,370.89	191.24	0.52	79	18.07	9.46	15.35	*****	5.25 (1.29, 21.35)	0.021
Dabigatran	1,068	*****	*****	*****	*****	2.73	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	988	280.24	103.6	0.28	*****	*****	*****	21.41	6.07	4.00 (0.85, 18.84)	0.08
Dabigatran	988	280.24	103.6	0.28	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	988	563.82	208.44	0.57	12	21.28	12.15	*****	*****	5.95 (1.33, 26.60)	0.02
Dabigatran	988	682.57	252.34	0.69	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	8,348	3,666.06	160.4	0.44	72	19.64	8.62	16.76	*****	7.60 (1.79, 32.34)	0.006
Dabigatran	1,068	*****	*****	*****	*****	2.87	*****				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	186,061	143,360.06	281.43	0.77	115	0.8	0.62	0.32	*****	1.50 (1.03, 2.18)	0.033
Dabigatran	78,997	*****	*****	*****	*****	0.49	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	78,888	33,547.66	155.33	0.43	22	0.66	0.28	0	0	1.00 (0.55, 1.81)	1
Dabigatran	78,888	33,547.66	155.33	0.43	22	0.66	0.28				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	78,888	68,904.24	319.03	0.87	40	0.58	0.51	0.09	-0.01	1.15 (0.74, 1.81)	0.531
Dabigatran	78,888	84,094.39	389.36	1.07	41	0.49	0.52				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	186,061	143,343.49	281.39	0.77	115	0.8	0.62	0.33	0.12	1.16 (0.78, 1.73)	0.465
Dabigatran	78,997	82,220.51	380.15	1.04	39	0.47	0.49				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	8,373	4,382.98	191.2	0.52	79	18.02	9.44	2.57	*****	1.40 (0.65, 3.04)	0.392
Apixaban	1,229	*****	*****	*****	*****	15.46	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,117	239.07	78.18	0.21	*****	*****	*****	0	0	1.00 (0.29, 3.45)	1
Apixaban	1,117	239.07	78.18	0.21	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,117	650.27	212.63	0.58	*****	*****	*****	-0.66	2.69	1.18 (0.41, 3.35)	0.758
Apixaban	1,117	413.65	135.26	0.37	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	8,373	3,559.49	155.27	0.43	74	20.79	8.84	5.33	*****	1.55 (0.69, 3.48)	0.283
Apixaban	1,229	*****	*****	*****	*****	15.46	*****				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	187,727	144,728.19	281.59	0.77	115	0.79	0.61	0.24	*****	1.72 (1.12, 2.64)	0.013
Apixaban	96,563	*****	*****	*****	*****	0.55	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	96,194	28,537.84	108.36	0.3	30	1.05	0.31	0.28	0.08	1.36 (0.79, 2.36)	0.269
Apixaban	96,194	28,537.84	108.36	0.3	22	0.77	0.23				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	96,194	80,049.72	303.95	0.83	49	0.61	0.51	0.06	0.24	1.43 (0.88, 2.31)	0.147
Apixaban	96,194	46,893.34	178.05	0.49	26	0.55	0.27				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	187,727	140,819.72	273.99	0.75	114	0.81	0.61	0.26	0.34	1.45 (0.93, 2.26)	0.102
Apixaban	96,563	47,024.75	177.87	0.49	26	0.55	0.27				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,071	*****	*****	*****	*****	2.72	*****	-12.73	-3.81	0.25 (0.05, 1.26)	0.093
Apixaban	1,234	*****	*****	*****	*****	15.46	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	737	165.48	82.01	0.22	*****	*****	*****	-24.17	-5.43	0.20 (0.02, 1.71)	0.142
Apixaban	737	165.48	82.01	0.22	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	737	484.51	240.12	0.66	*****	*****	*****	-14.54	-5.43	0.14 (0.02, 1.27)	0.08
Apixaban	737	301.06	149.2	0.41	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,071	*****	*****	*****	*****	3.46	*****	-12.48	-3.81	0.34 (0.06, 1.82)	0.207
Apixaban	1,234	*****	*****	*****	*****	15.94	*****				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Dabigatran	79,100	*****	*****	*****	*****	0.49	*****	-0.07	0.25	1.15 (0.68, 1.95)	0.597
Apixaban	96,444	*****	*****	*****	*****	0.56	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	73,009	22,400.47	112.07	0.31	14	0.62	0.19	0.09	0.03	1.17 (0.54, 2.52)	0.695
Apixaban	73,009	22,400.47	112.07	0.31	12	0.54	0.16				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	73,009	77,074.30	385.59	1.06	39	0.51	0.53	0.03	0.29	1.36 (0.76, 2.45)	0.305
Apixaban	73,009	37,598.69	188.1	0.51	18	0.48	0.25				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	79,100	72,052.07	332.71	0.91	35	0.49	0.44	-0.07	0.17	1.22 (0.71, 2.09)	0.473
Apixaban	96,444	46,825.18	177.34	0.49	26	0.56	0.27				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Age Group in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	8,011	4,195.53	191.29	0.52	77	18.35	9.61	8.44	5.58	2.09 (1.58, 2.76)	<0.001
Warfarin	36,457	14,831.66	148.59	0.41	147	9.91	4.03				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,850	1,578.37	73.44	0.2	46	29.14	5.86	20.91	4.2	3.54 (1.91, 6.55)	<0.001
Warfarin	7,850	1,578.37	73.44	0.2	13	8.24	1.66				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,850	4,121.61	191.77	0.53	77	18.68	9.81	10.59	6.62	2.54 (1.61, 3.99)	<0.001
Warfarin	7,850	3,088.50	143.7	0.39	25	8.09	3.18				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	8,011	4,194.75	191.25	0.52	77	18.36	9.61	8.1	5.61	2.25 (1.68, 3.01)	<0.001
Warfarin	36,457	14,234.63	142.61	0.39	146	10.26	4				
Age Group: 51 years or more											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	181,019	140,017.72	282.52	0.77	114	0.81	0.63	-0.52	-0.05	0.67 (0.54, 0.82)	<0.001
Warfarin	686,082	347,588.45	185.05	0.51	464	1.33	0.68				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	179,182	46,601.77	94.99	0.26	50	1.07	0.28	-0.13	-0.03	0.89 (0.61, 1.31)	0.56
Warfarin	179,182	46,601.77	94.99	0.26	56	1.2	0.31				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	179,182	138,720.70	282.77	0.77	112	0.81	0.63	-0.11	0.16	0.96 (0.72, 1.28)	0.795
Warfarin	179,182	90,723.24	184.93	0.51	83	0.91	0.46				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	181,019	140,017.72	282.52	0.77	114	0.81	0.63	-0.53	-0.04	0.90 (0.72, 1.11)	0.321
Warfarin	686,082	343,850.51	183.06	0.5	462	1.34	0.67				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 4a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	188,757	143,577.63	277.83	0.76	732	5.1	3.88	1.62	0.2	1.39 (1.20, 1.60)	<0.001
Dabigatran	78,658	83,142.89	386.08	1.06	289	3.48	3.67				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	78,574	33,233.64	154.49	0.42	*****	4.9	2.07	1.62	0.69	1.50 (1.17, 1.91)	0.001
Dabigatran	78,574	33,233.64	154.49	0.42	109	3.28	1.39				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	78,574	68,329.58	317.63	0.87	305	4.46	3.88	1.01	0.23	1.25 (1.06, 1.48)	0.008
Dabigatran	78,574	83,068.79	386.14	1.06	287	3.45	3.65				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	188,757	143,530.70	277.74	0.76	730	5.09	3.87	1.61	0.28	1.22 (1.05, 1.42)	0.01
Dabigatran	78,658	81,206.29	377.08	1.03	282	3.47	3.59				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	5,643	3,679.46	238.16	0.65	54	14.68	9.57	3.66	-1.73	1.01 (0.57, 1.78)	0.985
Dabigatran	1,416	1,452.56	374.68	1.03	16	11.02	11.3				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,320	524.09	145.02	0.4	*****	*****	*****	-9.54	-3.79	0.55 (0.20, 1.47)	0.232
Dabigatran	1,320	524.09	145.02	0.4	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,320	1,115.50	308.66	0.85	*****	*****	*****	*****	*****	0.78 (0.36, 1.72)	0.543
Dabigatran	1,320	1,362.90	377.12	1.03	15	11.01	11.36				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	5,643	3,444.02	222.92	0.61	47	13.65	8.33	2.06	-2.97	0.74 (0.39, 1.42)	0.37
Dabigatran	1,416	1,380.53	356.1	0.97	16	11.59	11.3				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	190,414	144,921.73	277.99	0.76	736	5.08	3.87	1.62	*****	1.47 (1.24, 1.75)	<0.001
Apixaban	95,926	*****	*****	*****	*****	3.46	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	95,541	28,198.12	107.8	0.3	*****	4.5	1.33	1.7	0.5	1.61 (1.21, 2.13)	<0.001
Apixaban	95,541	28,198.12	107.8	0.3	*****	2.8	0.83				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	95,541	78,887.88	301.59	0.83	323	4.09	3.38	0.63	1.7	1.22 (1.01, 1.48)	0.044
Apixaban	95,541	46,436.72	177.53	0.49	*****	3.47	1.69				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	190,414	141,041.14	270.54	0.74	715	5.07	3.75	1.61	2.08	1.25 (1.04, 1.49)	0.016
Apixaban	95,926	46,584.22	177.38	0.49	*****	3.46	1.68				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	5,676	3,708.61	238.65	0.65	54	14.56	9.51	3.51	*****	1.39 (0.68, 2.83)	0.364
Apixaban	1,858	*****	*****	*****	*****	11.05	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,818	481.22	96.68	0.26	*****	*****	*****	2.08	0.55	1.17 (0.39, 3.47)	0.782
Apixaban	1,818	481.22	96.68	0.26	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,818	1,377.89	276.83	0.76	12	8.71	6.6	*****	*****	0.99 (0.42, 2.36)	0.983
Apixaban	1,818	801.06	160.94	0.44	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	5,676	3,184.65	204.93	0.56	43	13.5	7.58	2.46	*****	1.07 (0.50, 2.31)	0.853
Apixaban	1,858	*****	*****	*****	*****	11.05	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Dabigatran	78,762	83,182.77	385.75	1.06	289	3.47	3.67	0	*****	0.96 (0.78, 1.18)	0.685
Apixaban	95,821	*****	*****	*****	*****	3.47	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	72,514	22,127.43	111.45	0.31	*****	3.07	0.94	0.32	0.1	1.11 (0.79, 1.58)	0.538
Apixaban	72,514	22,127.43	111.45	0.31	*****	2.76	0.84				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	72,514	75,991.23	382.76	1.05	260	3.42	3.59	-0.04	1.81	0.94 (0.75, 1.18)	0.609
Apixaban	72,514	37,255.33	187.65	0.51	*****	3.46	1.78				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	78,762	71,107.39	329.75	0.9	249	3.5	3.16	0.03	1.48	0.95 (0.77, 1.17)	0.608
Apixaban	95,821	46,389.06	176.83	0.48	*****	3.47	1.68				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,417	1,452.73	374.46	1.03	16	11.01	11.29	-0.09	*****	1.49 (0.65, 3.42)	0.352
Apixaban	1,849	*****	*****	*****	*****	11.1	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	1,238	362.43	106.93	0.29	*****	*****	*****	11.04	3.23	2.00 (0.60, 6.64)	0.258
Apixaban	1,238	362.43	106.93	0.29	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	1,238	1,302.13	384.17	1.05	13	9.98	10.5	*****	*****	1.56 (0.58, 4.18)	0.376
Apixaban	1,238	610.73	180.19	0.49	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,417	1,116.49	287.79	0.79	15	13.43	10.59	2.29	*****	1.44 (0.61, 3.37)	0.405
Apixaban	1,849	*****	*****	*****	*****	11.15	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	183,524	140,154.43	278.94	0.76	720	5.14	3.92	1.67	2.18	1.41 (1.28, 1.54)	<0.001
Warfarin	701,437	352,448.80	183.53	0.5	1,221	3.46	1.74				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	183,278	47,148.35	93.96	0.26	269	5.71	1.47	2.38	0.61	1.71 (1.41, 2.09)	<0.001
Warfarin	183,278	47,148.35	93.96	0.26	157	3.33	0.86				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	183,278	139,966.75	278.94	0.76	718	5.13	3.92	1.72	2.2	1.47 (1.28, 1.68)	<0.001
Warfarin	183,278	91,963.83	183.27	0.5	314	3.41	1.71				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	183,524	140,154.43	278.94	0.76	720	5.14	3.92	1.67	2.2	1.36 (1.23, 1.50)	<0.001
Warfarin	701,437	348,706.27	181.58	0.5	1,208	3.46	1.72				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	5,491	3,585.70	238.51	0.65	53	14.78	9.65	1.62	3.89	1.08 (0.78, 1.49)	0.652
Warfarin	21,335	9,345.43	159.99	0.44	123	13.16	5.77				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	5,342	1,225.27	83.78	0.23	27	22.04	5.05	1.63	0.37	1.08 (0.63, 1.86)	0.782
Warfarin	5,342	1,225.27	83.78	0.23	25	20.4	4.68				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	5,342	3,514.55	240.3	0.66	52	14.8	9.73	1.87	3.74	1.18 (0.75, 1.83)	0.473
Warfarin	5,342	2,474.80	169.21	0.46	32	12.93	5.99				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	5,491	3,579.05	238.07	0.65	53	14.81	9.65	1.48	3.98	1.09 (0.78, 1.53)	0.602
Warfarin	21,335	9,075.69	155.37	0.43	121	13.33	5.67				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 4e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	188,696	143,980.16	278.7	0.76	163	1.13	0.86	0.62	0.32	1.92 (1.35, 2.73)	<0.001
Dabigatran	78,633	83,446.99	387.61	1.06	43	0.52	0.55				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	78,506	33,280.02	154.84	0.42	*****	0.96	0.41	0.24	0.1	1.33 (0.79, 2.26)	0.287
Dabigatran	78,506	33,280.02	154.84	0.42	24	0.72	0.31				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	78,506	68,318.24	317.85	0.87	*****	0.75	0.65	0.23	0.1	1.38 (0.91, 2.10)	0.133
Dabigatran	78,506	83,355.26	387.81	1.06	43	0.52	0.55				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	188,696	143,951.16	278.64	0.76	163	1.13	0.86	0.63	0.34	1.42 (0.97, 2.07)	0.068
Dabigatran	78,633	81,491.36	378.53	1.04	41	0.5	0.52				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	5,713	3,750.79	239.8	0.66	31	8.26	5.43	8.26	5.43	-	-
Dabigatran	1,432	1,477.07	376.75	1.03	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,376	567.9	150.75	0.41	*****	*****	*****	*****	*****	-	-
Dabigatran	1,376	567.9	150.75	0.41	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,376	1,146.30	304.28	0.83	*****	*****	*****	*****	*****	-	-
Dabigatran	1,376	1,434.32	380.73	1.04	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	5,713	3,507.22	224.23	0.61	26	7.41	4.55	7.41	4.55	-	-
Dabigatran	1,432	1,406.00	358.62	0.98	0	0	0				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	190,353	145,328.80	278.86	0.76	163	1.12	0.86	0.48	*****	2.05 (1.39, 3.04)	<0.001
Apixaban	95,911	*****	*****	*****	*****	0.64	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	95,506	28,257.89	108.07	0.3	*****	1.06	0.31	0.18	0.05	1.20 (0.71, 2.04)	0.501
Apixaban	95,506	28,257.89	108.07	0.3	*****	0.88	0.26				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	95,506	79,238.05	303.04	0.83	*****	0.67	0.55	0.02	0.24	1.34 (0.85, 2.10)	0.208
Apixaban	95,506	46,504.95	177.85	0.49	*****	0.65	0.31				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	190,353	141,374.58	271.27	0.74	162	1.15	0.85	0.5	0.54	1.45 (0.96, 2.18)	0.076
Apixaban	95,911	46,647.99	177.65	0.49	*****	0.64	0.31				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	5,747	3,782.37	240.39	0.66	31	8.2	5.39	4.58	*****	2.71 (0.82, 8.90)	0.1
Apixaban	1,881	*****	*****	*****	*****	3.62	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,802	483.32	97.97	0.27	*****	*****	*****	0	0	1.00 (0.20, 4.95)	1
Apixaban	1,802	483.32	97.97	0.27	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,802	1,418.66	287.55	0.79	*****	*****	*****	0.44	1.66	1.76 (0.44, 7.04)	0.426
Apixaban	1,802	792.44	160.62	0.44	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	5,747	3,259.87	207.18	0.57	26	7.98	4.52	4.36	*****	1.07 (0.31, 3.68)	0.908
Apixaban	1,881	*****	*****	*****	*****	3.62	*****				

[1] Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Dabigatran	78,737	83,486.86	387.28	1.06	43	0.52	0.55	-0.13	*****	1.03 (0.62, 1.69)	0.921
Apixaban	95,806	*****	*****	*****	*****	0.65	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	72,518	22,164.82	111.64	0.31	15	0.68	0.21	0.05	0.01	1.07 (0.52, 2.22)	0.853
Apixaban	72,518	22,164.82	111.64	0.31	*****	0.63	0.19				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	72,518	76,281.65	384.21	1.05	40	0.52	0.55	-0.04	0.26	1.18 (0.68, 2.07)	0.557
Apixaban	72,518	37,278.05	187.76	0.51	*****	0.56	0.29				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	78,737	71,290.67	330.71	0.91	37	0.52	0.47	-0.13	0.16	1.13 (0.67, 1.89)	0.648
Apixaban	95,806	46,452.36	177.09	0.48	*****	0.65	0.31				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,434	1,477.50	376.33	1.03	0	0	0	-3.63	*****	-	-
Apixaban	1,872	*****	*****	*****	*****	3.63	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	1,245	371.15	108.89	0.3	0	0	0	*****	*****	-	-
Apixaban	1,245	371.15	108.89	0.3	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	1,245	1,296.63	380.4	1.04	0	0	0	*****	*****	-	-
Apixaban	1,245	619.93	181.87	0.5	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,434	1,136.47	289.47	0.79	0	0	0	-3.65	*****	-	-
Apixaban	1,872	*****	*****	*****	*****	3.65	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 4h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Gynecological Disorder of Interest in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	183,468	140,553.33	279.82	0.77	160	1.14	0.87	-0.35	0.12	0.82 (0.69, 0.98)	0.031
Warfarin	700,965	352,903.94	183.89	0.5	527	1.49	0.75				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	183,200	47,343.91	94.39	0.26	74	1.56	0.4	0.27	0.07	1.21 (0.86, 1.70)	0.264
Warfarin	183,200	47,343.91	94.39	0.26	61	1.29	0.33				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	183,200	140,341.97	279.8	0.77	159	1.13	0.87	0.08	0.34	1.18 (0.92, 1.53)	0.198
Warfarin	183,200	92,059.18	183.54	0.5	97	1.05	0.53				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	183,468	140,553.33	279.82	0.77	160	1.14	0.87	-0.36	0.12	1.07 (0.89, 1.28)	0.502
Warfarin	700,965	349,112.94	181.91	0.5	524	1.5	0.75				
Presence of any gynecological disorders of interest											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	5,562	3,659.93	240.34	0.66	31	8.47	5.57	-0.36	1.68	1.12 (0.74, 1.70)	0.589
Warfarin	21,574	9,516.16	161.11	0.44	84	8.83	3.89				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	5,411	1,256.04	84.78	0.23	19	15.13	3.51	3.98	0.92	1.36 (0.68, 2.71)	0.386
Warfarin	5,411	1,256.04	84.78	0.23	14	11.15	2.59				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	5,411	3,577.26	241.47	0.66	29	8.11	5.36	1.13	2.22	1.44 (0.79, 2.63)	0.232
Warfarin	5,411	2,438.24	164.58	0.45	17	6.97	3.14				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	5,562	3,654.31	239.97	0.66	31	8.48	5.57	-0.51	1.73	1.46 (0.95, 2.24)	0.083
Warfarin	21,574	9,231.01	156.28	0.43	83	8.99	3.85				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 5a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,709	3,542.83	101.82	0.28	14	3.95	1.1	2.02	0.33	1.79 (0.83, 3.84)	0.138
Dabigatran	16,929	6,722.18	145.03	0.4	13	1.93	0.77				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	5,034	670.5	48.65	0.13	*****	*****	*****	-1.49	-0.2	0.67 (0.11, 3.99)	0.657
Dabigatran	5,034	670.5	48.65	0.13	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	5,034	1,694.97	122.98	0.34	*****	*****	*****	-0.99	-0.6	0.66 (0.21, 2.06)	0.475
Dabigatran	5,034	2,032.81	147.49	0.4	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,709	*****	*****	*****	*****	3.14	*****	1.18	*****	1.04 (0.41, 2.63)	0.939
Dabigatran	16,929	6,614.21	142.7	0.39	13	1.97	0.77				
High dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	181,691	143,714.26	288.91	0.79	772	5.37	4.25	1.62	-0.38	1.33 (1.16, 1.53)	<0.001
Dabigatran	63,145	77,873.28	450.44	1.23	292	3.75	4.62				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	63,112	31,007.04	179.45	0.49	159	5.13	2.52	1.42	0.7	1.38 (1.09, 1.76)	0.008
Dabigatran	63,112	31,007.04	179.45	0.49	*****	3.71	1.82				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	63,112	57,057.53	330.21	0.9	259	4.54	4.1	0.8	-0.51	1.16 (0.97, 1.38)	0.096
Dabigatran	63,112	77,844.25	450.51	1.23	291	3.74	4.61				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	181,691	143,654.26	288.79	0.79	770	5.36	4.24	1.61	-0.28	1.16 (1.00, 1.34)	0.056
Dabigatran	63,145	75,944.49	439.29	1.2	285	3.75	4.51				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,836	3,582.48	101.94	0.28	14	3.91	1.09	1.64	0.4	1.41 (0.69, 2.88)	0.35
Apixaban	31,718	9,691.10	111.6	0.31	22	2.27	0.69				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,472	781.09	44.08	0.12	*****	*****	*****	3.84	0.46	4.00 (0.45, 35.79)	0.215
Apixaban	6,472	781.09	44.08	0.12	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,472	2,068.15	116.72	0.32	*****	*****	*****	0.82	0.31	1.30 (0.40, 4.22)	0.666
Apixaban	6,472	1,951.69	110.14	0.3	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,836	*****	*****	*****	*****	3.22	*****	0.95	*****	0.93 (0.39, 2.22)	0.87
Apixaban	31,718	9,672.69	111.39	0.3	22	2.27	0.69				
High dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	183,254	145,047.86	289.1	0.79	776	5.35	4.23	1.43	1.99	1.40 (1.17, 1.67)	<0.001
Apixaban	66,066	37,707.92	208.47	0.57	148	3.92	2.24				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	65,966	22,928.73	126.96	0.35	100	4.36	1.52	0.87	0.3	1.25 (0.93, 1.68)	0.137
Apixaban	65,966	22,928.73	126.96	0.35	*****	3.49	1.21				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	65,966	56,726.12	314.09	0.86	239	4.21	3.62	0.28	1.38	1.11 (0.90, 1.37)	0.309
Apixaban	65,966	37,657.68	208.51	0.57	148	3.93	2.24				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	183,254	141,124.35	281.28	0.77	756	5.36	4.13	1.43	1.89	1.18 (0.99, 1.42)	0.07
Apixaban	66,066	37,707.92	208.47	0.57	148	3.92	2.24				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	16,964	6,729.33	144.89	0.4	13	1.93	0.77	-0.35	0.07	0.74 (0.35, 1.53)	0.413
Apixaban	31,669	9,660.80	111.42	0.31	22	2.28	0.69				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	16,244	2,389.37	53.73	0.15	*****	*****	*****	*****	*****	-	-
Apixaban	16,244	2,389.37	53.73	0.15	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	16,244	6,415.72	144.26	0.39	13	2.03	0.8	-0.32	0.06	0.71 (0.31, 1.63)	0.418
Apixaban	16,244	5,115.96	115.03	0.31	12	2.35	0.74				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	16,964	6,346.07	136.64	0.37	13	2.05	0.77	-0.23	0.07	0.81 (0.39, 1.68)	0.572
Apixaban	31,669	9,658.67	111.4	0.3	22	2.28	0.69				
High dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	63,215	77,906.17	450.13	1.23	292	3.75	4.62	-0.19	2.38	0.97 (0.78, 1.20)	0.783
Apixaban	66,001	37,539.06	207.74	0.57	148	3.94	2.24				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	51,414	19,530.93	138.75	0.38	*****	3.69	1.4	0.2	0.08	1.06 (0.76, 1.47)	0.735
Apixaban	51,414	19,530.93	138.75	0.38	68	3.48	1.32				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	51,414	63,461.53	450.84	1.23	234	3.69	4.55	-0.31	2.16	0.93 (0.73, 1.17)	0.533
Apixaban	51,414	30,798.94	218.8	0.6	123	3.99	2.39				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	63,215	65,992.40	381.3	1.04	251	3.8	3.97	-0.14	1.73	0.97 (0.78, 1.20)	0.752
Apixaban	66,001	37,539.06	207.74	0.57	148	3.94	2.24				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5d. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,701	*****	*****	*****	*****	1.97	*****	1.08	0.2	2.18 (0.73, 6.52)	0.163
Dabigatran	16,924	*****	*****	*****	*****	0.89	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	5,005	655.08	47.81	0.13	0	0	0	0	0	-	-
Dabigatran	5,005	655.08	47.81	0.13	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	5,005	1,613.11	117.72	0.32	*****	*****	*****	0.74	0.2	2.90 (0.26, 32.12)	0.386
Dabigatran	5,005	2,015.00	147.05	0.4	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,701	*****	*****	*****	*****	2	*****	1.09	0.2	1.55 (0.44, 5.47)	0.496
Dabigatran	16,924	*****	*****	*****	*****	0.91	*****				
High dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	181,708	*****	*****	*****	*****	1.3	*****	0.82	0.44	2.31 (1.59, 3.34)	<0.001
Dabigatran	63,141	*****	*****	*****	*****	0.47	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	63,107	31,022.01	179.55	0.49	30	0.97	0.48	0.32	0.16	1.50 (0.85, 2.64)	0.16
Dabigatran	63,107	31,022.01	179.55	0.49	20	0.64	0.32				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	63,107	57,319.92	331.76	0.91	*****	0.82	0.74	0.35	0.16	1.59 (1.02, 2.49)	0.042
Dabigatran	63,107	78,171.37	452.44	1.24	*****	0.47	0.59				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	181,708	144,142.38	289.74	0.79	*****	1.3	1.03	0.84	0.47	1.54 (1.04, 2.30)	0.032
Dabigatran	63,141	76,239.20	441.02	1.21	*****	0.46	0.55				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,828	*****	*****	*****	*****	1.95	*****	1.23	0.32	3.16 (1.10, 9.04)	0.032
Apixaban	31,717	*****	*****	*****	*****	0.72	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,472	794.64	44.85	0.12	*****	*****	*****	0	0	1.00 (0.14, 7.10)	1
Apixaban	6,472	794.64	44.85	0.12	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,472	2,081.96	117.5	0.32	*****	*****	*****	1.38	0.46	2.70 (0.52, 14.01)	0.237
Apixaban	6,472	1,949.52	110.02	0.3	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,828	*****	*****	*****	*****	2.05	*****	1.32	0.32	2.35 (0.69, 8.04)	0.174
Apixaban	31,717	*****	*****	*****	*****	0.72	*****				
High dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	183,272	*****	*****	*****	*****	1.29	*****	0.6	0.63	2.13 (1.41, 3.22)	<0.001
Apixaban	66,075	*****	*****	*****	*****	0.69	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	65,981	23,003.57	127.34	0.35	*****	1.22	0.42	0.3	0.11	1.33 (0.76, 2.35)	0.319
Apixaban	65,981	23,003.57	127.34	0.35	*****	0.91	0.32				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	65,981	56,957.27	315.3	0.86	43	0.75	0.65	0.07	0.26	1.36 (0.83, 2.22)	0.225
Apixaban	65,981	37,725.16	208.83	0.57	*****	0.69	0.39				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	183,272	141,537.86	282.08	0.77	*****	1.31	1.01	0.63	0.62	1.40 (0.91, 2.14)	0.121
Apixaban	66,075	37,780.17	208.84	0.57	*****	0.69	0.39				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	16,960	*****	*****	*****	*****	0.89	*****	0.17	0.13	1.34 (0.43, 4.23)	0.616
Apixaban	31,669	*****	*****	*****	*****	0.72	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	16,245	2,391.22	53.76	0.15	*****	*****	*****	-0.42	-0.06	0.67 (0.11, 3.99)	0.657
Apixaban	16,245	2,391.22	53.76	0.15	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	16,245	6,414.18	144.22	0.39	*****	*****	*****	0.34	0.18	1.64 (0.39, 6.87)	0.497
Apixaban	16,245	5,077.33	114.16	0.31	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	16,960	*****	*****	*****	*****	0.79	*****	0.06	0.07	1.28 (0.40, 4.09)	0.678
Apixaban	31,669	*****	*****	*****	*****	0.72	*****				
High dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	63,211	*****	*****	*****	*****	0.47	*****	-0.22	0.19	0.87 (0.51, 1.49)	0.604
Apixaban	66,009	*****	*****	*****	*****	0.69	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	51,467	19,597.57	139.08	0.38	*****	*****	*****	0	0	1.00 (0.43, 2.31)	1
Apixaban	51,467	19,597.57	139.08	0.38	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	51,467	63,638.32	451.63	1.24	*****	0.5	0.62	-0.02	0.31	1.17 (0.62, 2.22)	0.629
Apixaban	51,467	30,876.87	219.13	0.6	*****	0.52	0.31				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	63,211	66,178.51	382.4	1.05	*****	0.48	0.51	-0.21	0.11	0.97 (0.56, 1.70)	0.925
Apixaban	66,009	37,610.76	208.11	0.57	*****	0.69	0.39				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	468	*****	*****	*****	*****	58.87	*****	58.87	*****	-	-
Dabigatran	48	15.98	121.56	0.33	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	36	2.75	27.86	0.08	0	0	0	0	0	-	-
Dabigatran	36	2.75	27.86	0.08	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	36	5.96	60.47	0.17	0	0	0	0	0	-	-
Dabigatran	36	8.53	86.5	0.24	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	468	*****	*****	*****	*****	73.96	*****	73.96	*****	-	-
Dabigatran	48	12.74	96.96	0.27	0	0	0				
Age Group: 18-50 years and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,868	4,243.30	196.98	0.54	*****	38.41	20.72	18.69	6.98	1.79 (1.01, 3.17)	0.045
Dabigatran	1,019	709.96	254.48	0.7	14	19.72	13.74				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	899	249.49	101.36	0.28	*****	*****	*****	12.02	3.34	1.37 (0.55, 3.42)	0.493
Dabigatran	899	249.49	101.36	0.28	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	899	541.24	219.9	0.6	24	44.34	26.7	21.56	11.12	1.81 (0.92, 3.57)	0.084
Dabigatran	899	614.39	249.62	0.68	14	22.79	15.57				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,868	3,506.41	162.78	0.45	138	39.36	17.54	20.09	4.78	1.65 (0.88, 3.11)	0.118
Dabigatran	1,019	674.63	241.82	0.66	13	19.27	12.76				

Table 6a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,241	*****	*****	*****	*****	2.88	*****	0.94	*****	1.32 (0.57, 3.05)	0.513
Dabigatran	16,881	6,706.20	145.1	0.4	13	1.94	0.77				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	4,971	666.43	48.97	0.13	*****	*****	*****	-1.5	-0.2	0.67 (0.11, 3.99)	0.657
Dabigatran	4,971	666.43	48.97	0.13	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	4,971	1,682.77	123.64	0.34	*****	*****	*****	-0.51	-0.4	0.81 (0.25, 2.59)	0.72
Dabigatran	4,971	2,013.07	147.91	0.4	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,241	*****	*****	*****	*****	2.61	*****	0.64	*****	1.06 (0.41, 2.71)	0.907
Dabigatran	16,881	6,598.48	142.77	0.39	13	1.97	0.77				
Age Group: 51 years or more and and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	173,823	139,470.96	293.07	0.8	*****	4.37	3.5	0.76	-0.97	1.15 (1.00, 1.34)	0.058
Dabigatran	62,126	77,163.32	453.66	1.24	278	3.6	4.47				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	62,090	30,732.83	180.79	0.49	143	4.65	2.3	1.14	0.56	1.32 (1.03, 1.70)	0.028
Dabigatran	62,090	30,732.83	180.79	0.49	*****	3.51	1.74				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	62,090	56,410.87	331.84	0.91	241	4.27	3.88	0.68	-0.58	1.14 (0.95, 1.36)	0.149
Dabigatran	62,090	77,130.87	453.73	1.24	277	3.59	4.46				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	173,823	139,439.39	293	0.8	*****	4.35	3.49	0.74	-0.89	1.11 (0.96, 1.30)	0.167
Dabigatran	62,126	75,244.47	442.38	1.21	272	3.61	4.38				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	470	*****	*****	*****	*****	58.71	*****	58.71	*****	-	-
Apixaban	134	19.07	51.99	0.14	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	43	3.58	30.42	0.08	*****	*****	*****	*****	*****	-	-
Apixaban	43	3.58	30.42	0.08	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	43	5.46	46.37	0.13	*****	*****	*****	*****	*****	-	-
Apixaban	43	6.27	53.28	0.15	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	470	*****	*****	*****	*****	62.32	*****	62.32	*****	-	-
Apixaban	134	16.32	44.49	0.12	0	0	0				
Age Group: 18-50 years and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,891	4,255.21	196.96	0.54	*****	38.31	20.66	19.76	*****	2.08 (1.02, 4.24)	0.043
Apixaban	1,093	*****	*****	*****	*****	18.55	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,028	238.52	84.75	0.23	*****	*****	*****	-8.39	-1.95	0.50 (0.09, 2.73)	0.423
Apixaban	1,028	238.52	84.75	0.23	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,028	589.13	209.32	0.57	*****	28.86	16.54	*****	*****	1.81 (0.74, 4.41)	0.19
Apixaban	1,028	405.72	144.15	0.39	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,891	3,469.82	160.61	0.44	*****	40.35	17.74	21.8	*****	1.94 (0.93, 4.06)	0.079
Apixaban	1,093	*****	*****	*****	*****	18.55	*****				

Table 6b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,366	*****	*****	*****	*****	2.85	*****	0.57	0.11	1.04 (0.47, 2.32)	0.916
Apixaban	31,584	*****	*****	*****	*****	2.27	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,418	777.22	44.23	0.12	*****	*****	*****	2.57	0.31	3.00 (0.31, 28.84)	0.341
Apixaban	6,418	777.22	44.23	0.12	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,418	2,060.05	117.24	0.32	*****	*****	*****	0.34	0.16	1.07 (0.31, 3.65)	0.913
Apixaban	6,418	1,942.39	110.54	0.3	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,366	*****	*****	*****	*****	2.68	*****	0.4	*****	0.85 (0.34, 2.13)	0.732
Apixaban	31,584	9,655.87	111.66	0.31	22	2.28	0.7				
Age Group: 51 years or more and and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	175,363	140,792.65	293.25	0.8	*****	4.35	3.5	0.6	1.34	1.20 (0.99, 1.44)	0.058
Apixaban	64,973	37,276.58	209.55	0.57	*****	3.76	2.15				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	64,870	22,670.68	127.65	0.35	*****	4.28	1.5	0.79	0.28	1.23 (0.91, 1.65)	0.176
Apixaban	64,870	22,670.68	127.65	0.35	*****	3.48	1.22				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	64,870	56,067.81	315.69	0.86	224	4	3.45	0.23	1.29	1.10 (0.89, 1.37)	0.385
Apixaban	64,870	37,225.24	209.6	0.57	*****	3.76	2.16				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	175,363	136,998.84	285.34	0.78	*****	4.36	3.4	0.6	1.25	1.16 (0.96, 1.40)	0.125
Apixaban	64,973	37,276.58	209.55	0.57	*****	3.76	2.15				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	48	15.98	121.56	0.33	0	0	0	0	0	-	-
Apixaban	136	19.42	52.15	0.14	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	35	2.94	30.71	0.08	0	0	0	0	0	-	-
Apixaban	35	2.94	30.71	0.08	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	35	11.73	122.37	0.34	0	0	0	0	0	-	-
Apixaban	35	5.48	57.2	0.16	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	48	6.45	49.06	0.13	0	0	0	0	0	-	-
Apixaban	136	12.69	34.09	0.09	0	0	0				
Age Group: 18-50 years and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,022	710.72	254	0.7	14	19.7	13.7	1.13	*****	1.15 (0.46, 2.86)	0.771
Apixaban	1,096	*****	*****	*****	*****	18.56	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	682	167.09	89.48	0.24	*****	*****	*****	11.97	2.93	1.67 (0.40, 6.97)	0.484
Apixaban	682	167.09	89.48	0.24	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	682	478.1	256.05	0.7	*****	*****	*****	5.89	8.8	1.47 (0.48, 4.45)	0.499
Apixaban	682	292.05	156.41	0.43	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,022	551.43	197.07	0.54	13	23.58	12.72	4.51	*****	1.23 (0.49, 3.06)	0.661
Apixaban	1,096	*****	*****	*****	*****	19.06	*****				

Table 6c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	16,916	6,713.35	144.95	0.4	13	1.94	0.77	-0.35	*****	0.74 (0.35, 1.53)	0.414
Apixaban	31,533	*****	*****	*****	*****	2.28	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	16,194	2,388.92	53.88	0.15	*****	*****	*****	*****	*****	-	-
Apixaban	16,194	2,388.92	53.88	0.15	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	16,194	6,401.25	144.38	0.4	13	2.03	0.8	-0.32	0.06	0.71 (0.31, 1.63)	0.418
Apixaban	16,194	5,107.58	115.2	0.32	12	2.35	0.74				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	16,916	6,330.57	136.69	0.37	13	2.05	0.77	-0.23	0.07	0.81 (0.39, 1.68)	0.575
Apixaban	31,533	9,639.72	111.66	0.31	22	2.28	0.7				
Age Group: 51 years or more and and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	62,193	77,195.45	453.36	1.24	278	3.6	4.47	-0.17	2.31	0.97 (0.78, 1.21)	0.779
Apixaban	64,905	37,108.12	208.82	0.57	*****	3.77	2.16				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	50,658	19,362.27	139.6	0.38	*****	3.62	1.38	0.26	0.1	1.08 (0.77, 1.51)	0.667
Apixaban	50,658	19,362.27	139.6	0.38	*****	3.36	1.28				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	50,658	62,966.61	454	1.24	224	3.56	4.42	-0.31	2.09	0.91 (0.72, 1.16)	0.462
Apixaban	50,658	30,478.97	219.76	0.6	*****	3.87	2.33				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	62,193	65,341.90	383.74	1.05	237	3.63	3.81	-0.15	1.65	0.97 (0.77, 1.20)	0.756
Apixaban	64,905	37,108.12	208.82	0.57	*****	3.77	2.16				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6d. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	469	*****	*****	*****	*****	14.44	*****	14.44	*****	-	-
Dabigatran	48	15.98	121.56	0.33	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	42	3.82	33.24	0.09	0	0	0	0	0	-	-
Dabigatran	42	3.82	33.24	0.09	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	42	9.24	80.36	0.22	0	0	0	0	0	-	-
Dabigatran	42	10.77	93.67	0.26	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	469	*****	*****	*****	*****	39.12	*****	39.12	*****	-	-
Dabigatran	48	11	83.67	0.23	0	0	0				
Age Group: 18-50 years and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,879	4,301.64	199.41	0.55	*****	18.13	9.9	15.35	*****	5.14 (1.26, 20.93)	0.022
Dabigatran	1,020	*****	*****	*****	*****	2.79	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	931	275.23	107.98	0.3	*****	*****	*****	25.43	7.52	4.50 (0.97, 20.83)	0.054
Dabigatran	931	275.23	107.98	0.3	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	931	556.7	218.4	0.6	13	23.35	13.96	*****	*****	6.26 (1.41, 27.75)	0.016
Dabigatran	931	647.85	254.16	0.7	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,879	3,577.48	165.84	0.45	72	20.13	9.14	17.18	*****	7.65 (1.80, 32.56)	0.006
Dabigatran	1,020	*****	*****	*****	*****	2.94	*****				

Table 6d. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,232	*****	*****	*****	*****	1.72	*****	0.83	0.13	1.92 (0.62, 5.98)	0.261
Dabigatran	16,876	*****	*****	*****	*****	0.89	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	4,945	648.94	47.93	0.13	0	0	0	0	0	-	-
Dabigatran	4,945	648.94	47.93	0.13	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	4,945	1,601.74	118.31	0.32	*****	*****	*****	0.75	0.2	2.88 (0.26, 31.98)	0.388
Dabigatran	4,945	1,989.16	146.92	0.4	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,232	*****	*****	*****	*****	1.74	*****	0.83	0.13	1.55 (0.43, 5.57)	0.499
Dabigatran	16,876	*****	*****	*****	*****	0.91	*****				
Age Group: 51 years or more and and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	173,829	139,880.77	293.92	0.8	*****	0.78	0.63	0.33	0.06	1.54 (1.03, 2.30)	0.037
Dabigatran	62,121	77,482.37	455.57	1.25	*****	0.45	0.56				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	62,084	30,763.15	180.98	0.5	*****	0.68	0.34	0.03	0.02	1.05 (0.57, 1.94)	0.876
Dabigatran	62,084	30,763.15	180.98	0.5	20	0.65	0.32				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	62,084	56,704.81	333.6	0.91	*****	0.62	0.56	0.17	0	1.28 (0.79, 2.09)	0.314
Dabigatran	62,084	77,448.95	455.64	1.25	*****	0.45	0.56				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	173,829	139,850.10	293.85	0.8	*****	0.78	0.63	0.34	0.1	1.20 (0.78, 1.83)	0.412
Dabigatran	62,121	75,538.02	444.14	1.22	*****	0.44	0.53				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	471	*****	*****	*****	*****	14.4	*****	-38.15	-5.34	0.55 (0.03, 8.88)	0.677
Apixaban	134	*****	*****	*****	*****	52.55	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	59	4.69	29.05	0.08	*****	*****	*****	0	0	1.00 (0.06, 15.99)	1
Apixaban	59	4.69	29.05	0.08	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	59	14.53	89.95	0.25	*****	*****	*****	-55.09	0	1.16 (0.07, 18.61)	0.916
Apixaban	59	8.07	49.98	0.14	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	471	*****	*****	*****	*****	30.33	*****	-30.02	-5.34	0.30 (0.02, 4.93)	0.397
Apixaban	134	*****	*****	*****	*****	60.35	*****				
Age Group: 18-50 years and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,902	4,313.55	199.38	0.55	*****	18.08	9.87	4.25	*****	1.54 (0.67, 3.53)	0.311
Apixaban	1,095	*****	*****	*****	*****	13.83	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,034	243.32	85.95	0.24	*****	*****	*****	4.11	0.97	1.25 (0.34, 4.65)	0.739
Apixaban	1,034	243.32	85.95	0.24	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,034	618.05	218.32	0.6	*****	*****	*****	-0.14	2.9	1.22 (0.43, 3.45)	0.713
Apixaban	1,034	408.05	144.14	0.39	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,902	3,497.91	161.68	0.44	*****	20.87	9.24	7.04	*****	1.78 (0.75, 4.22)	0.19
Apixaban	1,095	*****	*****	*****	*****	13.83	*****				

Table 6e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	12,357	*****	*****	*****	*****	1.71	*****	1.09	0.3	3.26 (1.05, 10.15)	0.041
Apixaban	31,583	*****	*****	*****	*****	0.62	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,397	787.99	44.99	0.12	*****	*****	*****	0	0	1.00 (0.06, 15.99)	1
Apixaban	6,397	787.99	44.99	0.12	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,397	2,063.36	117.81	0.32	*****	*****	*****	1.42	0.47	4.31 (0.48, 38.89)	0.193
Apixaban	6,397	1,938.09	110.66	0.3	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	12,357	*****	*****	*****	*****	1.78	*****	1.16	0.3	3.06 (0.84, 11.12)	0.089
Apixaban	31,583	*****	*****	*****	*****	0.62	*****				
Age Group: 51 years or more and and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	175,370	141,209.43	294.1	0.81	*****	0.77	0.62	0.24	0.31	1.66 (1.03, 2.67)	0.039
Apixaban	64,980	37,346.30	209.92	0.57	*****	0.54	0.31				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	64,873	22,734.65	128	0.35	*****	1.01	0.35	0.26	0.09	1.35 (0.72, 2.53)	0.345
Apixaban	64,873	22,734.65	128	0.35	*****	0.75	0.26				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	64,873	56,231.89	316.6	0.87	*****	0.62	0.54	0.09	0.23	1.43 (0.82, 2.48)	0.209
Apixaban	64,873	37,287.69	209.94	0.57	*****	0.54	0.31				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	175,370	137,371.12	286.11	0.78	*****	0.79	0.62	0.25	0.31	1.37 (0.84, 2.24)	0.209
Apixaban	64,980	37,346.30	209.92	0.57	*****	0.54	0.31				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6f. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	48	15.98	121.56	0.33	0	0	0	-51.63	*****	-	-
Apixaban	136	*****	*****	*****	*****	51.63	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	35	2.81	29.29	0.08	0	0	0	*****	*****	-	-
Apixaban	35	2.81	29.29	0.08	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	35	7.55	78.74	0.22	0	0	0	*****	*****	-	-
Apixaban	35	5.04	52.63	0.14	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	48	6.45	49.06	0.13	0	0	0	-79.05	*****	-	-
Apixaban	136	*****	*****	*****	*****	79.05	*****				
Age Group: 18-50 years and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,023	*****	*****	*****	*****	2.78	*****	-11.06	-3.51	0.27 (0.05, 1.40)	0.119
Apixaban	1,098	*****	*****	*****	*****	13.84	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	679	165.79	89.18	0.24	*****	*****	*****	-18.1	-4.42	0.25 (0.03, 2.24)	0.215
Apixaban	679	165.79	89.18	0.24	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	679	457.84	246.28	0.67	*****	*****	*****	-11.38	-4.42	0.18 (0.02, 1.65)	0.128
Apixaban	679	294.93	158.65	0.43	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,023	*****	*****	*****	*****	3.58	*****	-10.61	-3.51	0.36 (0.07, 1.97)	0.239
Apixaban	1,098	*****	*****	*****	*****	14.2	*****				

Table 6f. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Dosage of Index-Defining Novel Oral Anticoagulant (NOAC) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and and low dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	16,912	*****	*****	*****	*****	0.89	*****	0.27	0.16	1.57 (0.48, 5.14)	0.458
Apixaban	31,533	*****	*****	*****	*****	0.62	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	16,198	2,386.41	53.81	0.15	*****	*****	*****	0	0	1.00 (0.14, 7.10)	1
Apixaban	16,198	2,386.41	53.81	0.15	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	16,198	6,405.80	144.44	0.4	*****	*****	*****	0.54	0.25	2.47 (0.48, 12.71)	0.281
Apixaban	16,198	5,068.87	114.3	0.31	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	16,912	*****	*****	*****	*****	0.79	*****	0.17	0.11	1.42 (0.43, 4.73)	0.564
Apixaban	31,533	*****	*****	*****	*****	0.62	*****				
Age Group: 51 years or more and and high dose of index-defining NOAC											
Crude Analysis (Site-adjusted only)											
Dabigatran	62,188	77,514.51	455.27	1.25	*****	0.45	0.56	-0.09	0.25	1.08 (0.60, 1.93)	0.808
Apixaban	64,911	37,177.29	209.19	0.57	*****	0.54	0.31				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	50,704	19,422.42	139.91	0.38	*****	*****	*****	0.15	0.06	1.43 (0.54, 3.75)	0.469
Apixaban	50,704	19,422.42	139.91	0.38	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	50,704	63,063.94	454.29	1.24	*****	0.49	0.61	0.1	0.37	1.52 (0.75, 3.07)	0.242
Apixaban	50,704	30,554.01	220.1	0.6	*****	0.39	0.24				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	62,188	65,543.01	384.96	1.05	*****	0.46	0.48	-0.08	0.17	1.17 (0.64, 2.14)	0.616
Apixaban	64,911	37,177.29	209.19	0.57	*****	0.54	0.31				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	61,333	34,443.41	205.12	0.56	301	8.74	4.91	3.2	*****	1.58 (0.74, 3.41)	0.24
Dabigatran	2,187	*****	*****	*****	*****	5.53	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	2,183	582.88	97.52	0.27	*****	*****	*****	10.29	2.75	4.00 (0.85, 18.84)	0.08
Dabigatran	2,183	582.88	97.52	0.27	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	2,183	1,293.60	216.44	0.59	14	10.82	6.41	*****	*****	2.07 (0.80, 5.36)	0.132
Dabigatran	2,183	1,263.14	211.34	0.58	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	61,333	34,011.74	202.55	0.55	291	8.56	4.74	2.87	*****	1.55 (0.72, 3.33)	0.261
Dabigatran	2,187	*****	*****	*****	*****	5.69	*****				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	133,067	112,813.68	309.66	0.85	485	4.3	3.64	0.72	*****	1.17 (1.01, 1.35)	0.041
Dabigatran	77,887	*****	*****	*****	*****	3.58	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	77,851	33,234.20	155.92	0.43	163	4.9	2.09	1.41	0.6	1.41 (1.11, 1.78)	0.005
Dabigatran	77,851	33,234.20	155.92	0.43	116	3.49	1.49				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	77,851	68,260.54	320.25	0.88	302	4.42	3.88	0.87	0.08	1.20 (1.02, 1.41)	0.03
Dabigatran	77,851	83,302.60	390.83	1.07	296	3.55	3.8				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	133,067	112,813.68	309.66	0.85	485	4.3	3.64	0.73	-0.08	1.17 (1.01, 1.36)	0.041
Dabigatran	77,887	81,341.78	381.45	1.04	290	3.57	3.72				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	61,373	34,462.85	205.1	0.56	301	8.73	4.9	3.46	3.37	1.53 (0.88, 2.69)	0.133
Apixaban	8,470	2,465.28	106.31	0.29	13	5.27	1.53				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	8,378	1,607.71	70.09	0.19	*****	*****	*****	-1.24	-0.24	0.75 (0.26, 2.16)	0.594
Apixaban	8,378	1,607.71	70.09	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	8,378	4,662.47	203.27	0.56	28	6.01	3.34	0.68	*****	1.23 (0.63, 2.42)	0.541
Apixaban	8,378	2,439.29	106.34	0.29	13	5.33	1.55				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	61,373	32,734.57	194.81	0.53	280	8.55	4.56	3.28	3.03	1.28 (0.73, 2.25)	0.387
Apixaban	8,470	2,465.28	106.31	0.29	13	5.27	1.53				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	134,717	114,167.49	309.54	0.85	489	4.28	3.63	0.79	1.87	1.26 (1.05, 1.51)	0.013
Apixaban	89,314	44,933.74	183.76	0.5	157	3.49	1.76				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	88,995	27,106.51	111.25	0.3	125	4.61	1.4	1.7	0.52	1.58 (1.19, 2.10)	0.001
Apixaban	88,995	27,106.51	111.25	0.3	79	2.91	0.89				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	88,995	75,623.00	310.37	0.85	306	4.05	3.44	0.54	1.67	1.20 (0.98, 1.46)	0.074
Apixaban	88,995	44,809.08	183.9	0.5	157	3.5	1.76				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	134,717	111,020.97	301	0.82	480	4.32	3.56	0.83	1.81	1.23 (1.02, 1.47)	0.03
Apixaban	89,314	44,933.74	183.76	0.5	157	3.49	1.76				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	2,196	*****	*****	*****	*****	5.53	*****	0.28	*****	0.91 (0.31, 2.64)	0.856
Apixaban	8,522	2,477.06	106.17	0.29	13	5.25	1.53				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	2,188	383.83	64.07	0.18	*****	*****	*****	0	0	1.00 (0.06, 15.99)	1
Apixaban	2,188	383.83	64.07	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	2,188	1,262.12	210.69	0.58	*****	*****	*****	3.94	*****	2.53 (0.29, 22.43)	0.404
Apixaban	2,188	623.27	104.04	0.28	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	2,196	*****	*****	*****	*****	3.75	*****	-1.52	*****	0.72 (0.23, 2.26)	0.577
Apixaban	8,522	2,466.13	105.7	0.29	13	5.27	1.53				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	77,983	*****	*****	*****	*****	3.57	*****	0.06	*****	1.00 (0.81, 1.23)	0.987
Apixaban	89,148	44,722.81	183.23	0.5	157	3.51	1.76				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	71,552	22,106.12	112.84	0.31	73	3.3	1.02	0.32	0.1	1.11 (0.79, 1.54)	0.553
Apixaban	71,552	22,106.12	112.84	0.31	66	2.99	0.92				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	71,552	76,068.17	388.3	1.06	266	3.5	3.72	-0.13	1.83	0.95 (0.76, 1.18)	0.632
Apixaban	71,552	37,252.88	190.16	0.52	135	3.62	1.89				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	77,983	71,251.94	333.72	0.91	258	3.62	3.31	0.11	1.55	0.97 (0.79, 1.20)	0.792
Apixaban	89,148	44,722.81	183.23	0.5	157	3.51	1.76				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	58,921	33,014.02	204.65	0.56	294	8.91	4.99	4.09	2.64	1.66 (1.44, 1.91)	<0.001
Warfarin	289,291	141,429.20	178.56	0.49	681	4.82	2.35				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	58,033	13,274.44	83.55	0.23	108	8.14	1.86	2.56	0.59	1.46 (1.09, 1.96)	0.012
Warfarin	58,033	13,274.44	83.55	0.23	74	5.57	1.28				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	58,033	32,579.35	205.05	0.56	286	8.78	4.93	3.35	*****	1.53 (1.25, 1.87)	<0.001
Warfarin	58,033	28,161.21	177.24	0.49	153	5.43	2.64				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	58,921	33,014.02	204.65	0.56	294	8.91	4.99	4.09	2.68	1.46 (1.27, 1.69)	<0.001
Warfarin	289,291	138,673.51	175.08	0.48	668	4.82	2.31				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	130,094	110,726.11	310.87	0.85	479	4.33	3.68	1.32	2.15	1.38 (1.23, 1.56)	<0.001
Warfarin	433,481	220,365.03	185.68	0.51	663	3.01	1.53				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	129,581	34,905.82	98.39	0.27	163	4.67	1.26	1.72	0.46	1.58 (1.24, 2.03)	<0.001
Warfarin	129,581	34,905.82	98.39	0.27	103	2.95	0.79				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	129,581	110,336.57	311.01	0.85	475	4.31	3.67	1.36	2.17	1.43 (1.20, 1.69)	<0.001
Warfarin	129,581	65,838.44	185.58	0.51	194	2.95	1.5				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	130,094	110,726.11	310.87	0.85	479	4.33	3.68	1.31	2.17	1.32 (1.17, 1.50)	<0.001
Warfarin	433,481	217,987.41	183.68	0.5	657	3.01	1.52				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 7e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	61,353	34,573.51	205.82	0.56	109	3.15	1.78	2.37	*****	3.55 (0.50, 25.43)	0.207
Dabigatran	2,186	*****	*****	*****	*****	0.79	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	2,182	550.92	92.22	0.25	*****	*****	*****	5.45	1.37	4.00 (0.45, 35.79)	0.215
Dabigatran	2,182	550.92	92.22	0.25	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	2,182	1,260.07	210.93	0.58	*****	*****	*****	3.18	*****	4.87 (0.57, 41.73)	0.148
Dabigatran	2,182	1,270.78	212.72	0.58	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	61,353	34,051.82	202.72	0.56	107	3.14	1.74	2.33	*****	3.45 (0.48, 24.74)	0.218
Dabigatran	2,186	*****	*****	*****	*****	0.81	*****				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	133,056	113,157.44	310.63	0.85	85	0.75	0.64	0.25	*****	1.41 (0.96, 2.07)	0.08
Dabigatran	77,879	*****	*****	*****	*****	0.5	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	77,844	33,298.77	156.24	0.43	*****	0.87	0.37	0.21	0.09	1.32 (0.76, 2.29)	0.329
Dabigatran	77,844	33,298.77	156.24	0.43	*****	0.66	0.28				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	77,844	68,316.48	320.55	0.88	*****	0.7	0.62	0.21	0.09	1.38 (0.89, 2.12)	0.146
Dabigatran	77,844	83,622.97	392.37	1.07	*****	0.49	0.53				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	133,056	113,157.44	310.63	0.85	85	0.75	0.64	0.26	0.13	1.38 (0.94, 2.03)	0.102
Dabigatran	77,879	81,610.46	382.75	1.05	*****	0.49	0.51				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	61,393	34,592.95	205.81	0.56	109	3.15	1.78	1.13	*****	2.03 (0.82, 4.99)	0.124
Apixaban	8,470	*****	*****	*****	*****	2.03	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	8,393	1,604.28	69.82	0.19	*****	6.23	1.19	*****	*****	2.50 (0.78, 7.97)	0.121
Apixaban	8,393	1,604.28	69.82	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	8,393	4,717.28	205.29	0.56	14	2.97	1.67	*****	*****	2.30 (0.82, 6.46)	0.114
Apixaban	8,393	2,448.93	106.57	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	61,393	32,827.85	195.31	0.53	107	3.26	1.74	1.23	*****	1.64 (0.67, 4.05)	0.281
Apixaban	8,470	*****	*****	*****	*****	2.03	*****				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	134,707	114,518.22	310.51	0.85	85	0.74	0.63	0.12	*****	1.43 (0.93, 2.21)	0.105
Apixaban	89,322	*****	*****	*****	*****	0.62	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	89,000	27,184.81	111.56	0.31	25	0.92	0.28	0.07	0.02	1.09 (0.62, 1.91)	0.773
Apixaban	89,000	27,184.81	111.56	0.31	23	0.85	0.26				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	89,000	76,033.48	312.04	0.85	45	0.59	0.51	-0.03	0.19	1.20 (0.75, 1.94)	0.449
Apixaban	89,000	44,891.20	184.23	0.5	28	0.62	0.31				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	134,707	111,347.13	301.91	0.83	84	0.75	0.62	0.13	0.31	1.37 (0.89, 2.12)	0.153
Apixaban	89,322	45,009.13	184.05	0.5	28	0.62	0.31				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	2,195	*****	*****	*****	*****	0.79	*****	-1.23	-0.13	0.76 (0.09, 6.47)	0.798
Apixaban	8,522	*****	*****	*****	*****	2.02	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	2,177	392.01	65.77	0.18	0	0	0	*****	*****	-	-
Apixaban	2,177	392.01	65.77	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	2,177	1,263.42	211.97	0.58	*****	*****	*****	-3.92	*****	0.33 (0.03, 3.14)	0.333
Apixaban	2,177	636.77	106.84	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	2,195	*****	*****	*****	*****	0.94	*****	-1.09	-0.13	0.65 (0.07, 5.71)	0.7
Apixaban	8,522	*****	*****	*****	*****	2.02	*****				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	77,976	*****	*****	*****	*****	0.5	*****	-0.12	0.22	1.01 (0.60, 1.69)	0.969
Apixaban	89,156	*****	*****	*****	*****	0.63	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	71,600	22,165.68	113.07	0.31	15	0.68	0.21	0.14	0.04	1.25 (0.59, 2.67)	0.565
Apixaban	71,600	22,165.68	113.07	0.31	*****	0.54	0.17				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	71,600	76,338.34	389.42	1.07	*****	0.51	0.54	-0.03	0.27	1.19 (0.67, 2.11)	0.542
Apixaban	71,600	37,276.18	190.16	0.52	*****	0.54	0.28				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	77,976	71,439.78	334.63	0.92	*****	0.5	0.46	-0.12	0.15	1.05 (0.62, 1.77)	0.86
Apixaban	89,156	44,797.74	183.53	0.5	*****	0.63	0.31				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 7h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	58,945	33,144.29	205.38	0.56	107	3.23	1.82	0.73	0.59	1.29 (1.04, 1.60)	0.022
Warfarin	289,213	141,708.59	178.97	0.49	354	2.5	1.22				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	57,687	13,214.47	83.67	0.23	67	5.07	1.16	2.12	0.49	1.72 (1.16, 2.55)	0.007
Warfarin	57,687	13,214.47	83.67	0.23	39	2.95	0.68				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	57,687	32,484.32	205.68	0.56	105	3.23	1.82	1.12	*****	1.51 (1.10, 2.08)	0.011
Warfarin	57,687	27,930.84	176.85	0.48	59	2.11	1.02				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	58,945	33,144.29	205.38	0.56	107	3.23	1.82	0.69	0.6	1.33 (1.07, 1.66)	0.012
Warfarin	289,213	138,912.67	175.43	0.48	352	2.53	1.22				
Presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	130,085	111,068.97	311.86	0.85	84	0.76	0.65	-0.41	0.05	0.70 (0.55, 0.90)	0.005
Warfarin	433,326	220,711.51	186.04	0.51	257	1.16	0.59				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	129,683	34,991.51	98.55	0.27	32	0.91	0.25	-0.29	-0.08	0.76 (0.48, 1.21)	0.246
Warfarin	129,683	34,991.51	98.55	0.27	42	1.2	0.32				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	129,683	110,777.86	312	0.85	84	0.76	0.65	-0.05	0.24	1.05 (0.74, 1.48)	0.795
Warfarin	129,683	65,944.62	185.73	0.51	53	0.8	0.41				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	130,085	111,068.97	311.86	0.85	84	0.76	0.65	-0.41	0.06	0.92 (0.71, 1.20)	0.537
Warfarin	433,326	218,298.90	184	0.5	255	1.17	0.59				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 8a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,020	3,580.39	186.29	0.51	144	40.22	20.51	23.36	*****	2.08 (0.51, 8.41)	0.305
Dabigatran	247	*****	*****	*****	*****	16.86	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	222	51.23	84.29	0.23	*****	*****	*****	*****	*****	-	-
Dabigatran	222	51.23	84.29	0.23	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	222	126.54	208.18	0.57	*****	*****	*****	27.46	18.02	1.86 (0.36, 9.72)	0.46
Dabigatran	222	100.2	164.86	0.45	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,020	2,770.96	144.17	0.39	114	41.14	16.24	23.66	*****	2.18 (0.53, 8.87)	0.278
Dabigatran	247	*****	*****	*****	*****	17.48	*****				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,316	730.86	202.85	0.56	23	31.47	17.48	11.71	2.84	1.38 (0.67, 2.85)	0.378
Dabigatran	820	607.29	270.5	0.74	12	19.76	14.63				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	735	204.25	101.5	0.28	*****	*****	*****	19.58	5.44	1.67 (0.61, 4.59)	0.323
Dabigatran	735	204.25	101.5	0.28	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	735	423.83	210.62	0.58	18	42.47	24.49	20.07	8.16	1.74 (0.82, 3.68)	0.15
Dabigatran	735	535.66	266.19	0.73	12	22.4	16.33				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,316	699.68	194.19	0.53	22	31.44	16.72	11.27	*****	1.53 (0.72, 3.29)	0.271
Dabigatran	820	*****	*****	*****	*****	20.18	*****				

Table 8a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	54,313	30,863.02	207.55	0.57	157	5.09	2.89	0.72	*****	1.24 (0.49, 3.12)	0.655
Dabigatran	1,940	*****	*****	*****	*****	4.36	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,911	508.16	97.13	0.27	*****	*****	*****	3.94	1.05	2.00 (0.37, 10.92)	0.423
Dabigatran	1,911	508.16	97.13	0.27	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,911	1,140.20	217.93	0.6	*****	*****	*****	2.6	1.57	1.59 (0.48, 5.20)	0.445
Dabigatran	1,911	1,131.23	216.21	0.59	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	54,313	30,457.81	204.83	0.56	153	5.02	2.82	0.54	*****	1.21 (0.48, 3.05)	0.691
Dabigatran	1,940	*****	*****	*****	*****	4.49	*****				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	131,751	112,082.82	310.72	0.85	462	4.12	3.51	0.66	-0.2	1.16 (1.00, 1.35)	0.055
Dabigatran	77,067	82,723.47	392.06	1.07	286	3.46	3.71				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	76,993	33,022.03	156.65	0.43	152	4.6	1.97	1.27	0.55	1.38 (1.08, 1.77)	0.01
Dabigatran	76,993	33,022.03	156.65	0.43	110	3.33	1.43				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	76,993	67,737.48	321.34	0.88	284	4.19	3.69	0.76	0	1.18 (1.00, 1.40)	0.054
Dabigatran	76,993	82,665.57	392.16	1.07	284	3.44	3.69				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	131,751	112,082.82	310.72	0.85	462	4.12	3.51	0.67	-0.11	1.16 (0.99, 1.35)	0.063
Dabigatran	77,067	80,736.71	382.64	1.05	279	3.46	3.62				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,030	3,584.45	186.23	0.51	144	40.17	20.48	18.63	*****	1.79 (0.66, 4.84)	0.254
Apixaban	641	*****	*****	*****	*****	21.54	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	564	105.47	68.3	0.19	*****	*****	*****	-9.48	-1.77	0.50 (0.05, 5.51)	0.571
Apixaban	564	105.47	68.3	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	564	298.42	193.26	0.53	*****	*****	*****	9.01	10.64	1.55 (0.48, 5.01)	0.467
Apixaban	564	163.27	105.73	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,030	2,769.76	143.91	0.39	119	42.96	16.93	21.42	*****	1.86 (0.68, 5.07)	0.228
Apixaban	641	*****	*****	*****	*****	21.54	*****				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,331	738.89	202.77	0.56	23	31.13	17.28	16.02	*****	2.10 (0.72, 6.12)	0.174
Apixaban	586	*****	*****	*****	*****	15.11	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	525	127.48	88.69	0.24	*****	*****	*****	23.53	5.71	4.00 (0.45, 35.79)	0.215
Apixaban	525	127.48	88.69	0.24	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	525	301.34	209.65	0.57	*****	*****	*****	14.13	9.52	2.12 (0.56, 8.09)	0.27
Apixaban	525	241.63	168.1	0.46	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,331	637.38	174.91	0.48	21	32.95	15.78	17.64	*****	2.26 (0.74, 6.85)	0.151
Apixaban	586	*****	*****	*****	*****	15.31	*****				

Table 8b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	54,343	30,878.40	207.54	0.57	157	5.08	2.89	1.14	*****	1.29 (0.66, 2.55)	0.459
Apixaban	7,829	*****	*****	*****	*****	3.95	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,731	1,478.38	69.85	0.19	*****	*****	*****	0	0	1.00 (0.32, 3.10)	1
Apixaban	7,731	1,478.38	69.85	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,731	4,313.74	203.8	0.56	17	3.94	2.2	*****	*****	1.05 (0.46, 2.42)	0.905
Apixaban	7,731	2,253.45	106.46	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	54,343	29,320.63	197.07	0.54	146	4.98	2.69	1.03	*****	1.18 (0.60, 2.32)	0.641
Apixaban	7,829	*****	*****	*****	*****	3.95	*****				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	133,386	113,428.59	310.6	0.85	466	4.11	3.49	0.68	1.77	1.23 (1.02, 1.48)	0.029
Apixaban	88,728	44,669.00	183.88	0.5	*****	3.43	1.72				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	88,396	26,962.09	111.41	0.31	122	4.52	1.38	1.63	0.5	1.56 (1.18, 2.08)	0.002
Apixaban	88,396	26,962.09	111.41	0.31	78	2.89	0.88				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	88,396	75,262.98	310.98	0.85	*****	3.95	3.36	0.51	1.63	1.19 (0.97, 1.45)	0.093
Apixaban	88,396	44,536.44	184.02	0.5	*****	3.44	1.73				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	133,386	110,317.34	302.08	0.83	456	4.13	3.42	0.71	1.69	1.21 (1.00, 1.45)	0.049
Apixaban	88,728	44,669.00	183.88	0.5	*****	3.43	1.72				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	250	*****	*****	*****	*****	16.75	*****	-4.66	1.82	0.42 (0.04, 4.02)	0.453
Apixaban	647	*****	*****	*****	*****	21.41	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	235	39.75	61.77	0.17	0	0	0	*****	*****	-	-
Apixaban	235	39.75	61.77	0.17	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	235	115	178.73	0.49	*****	*****	*****	2.12	4.26	0.67 (0.04, 11.05)	0.78
Apixaban	235	65.49	101.79	0.28	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	250	87.47	127.8	0.35	0	0	0	-24.25	*****	-	-
Apixaban	647	*****	*****	*****	*****	24.25	*****				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	820	607.29	270.5	0.74	12	19.76	14.63	4.58	*****	1.47 (0.46, 4.71)	0.52
Apixaban	585	*****	*****	*****	*****	15.18	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	492	123.99	92.04	0.25	*****	*****	*****	24.2	6.1	4.00 (0.45, 35.79)	0.215
Apixaban	492	123.99	92.04	0.25	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	492	380.21	282.26	0.77	*****	*****	*****	5.99	10.16	1.55 (0.45, 5.29)	0.484
Apixaban	492	226.17	167.91	0.46	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	820	*****	*****	*****	*****	24.89	*****	9.2	6.58	1.26 (0.39, 4.06)	0.697
Apixaban	585	*****	*****	*****	*****	15.69	*****				

Table 8c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,946	*****	*****	*****	*****	4.36	*****	0.43	1.43	1.33 (0.41, 4.36)	0.637
Apixaban	7,875	*****	*****	*****	*****	3.93	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	1,930	341.92	64.71	0.18	*****	*****	*****	*****	*****	-	-
Apixaban	1,930	341.92	64.71	0.18	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	1,930	1,141.10	215.95	0.59	*****	*****	*****	*****	*****	-	-
Apixaban	1,930	550.34	104.15	0.29	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,946	*****	*****	*****	*****	4.13	*****	0.18	0.91	1.13 (0.34, 3.77)	0.841
Apixaban	7,875	*****	*****	*****	*****	3.95	*****				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	77,163	82,762.12	391.75	1.07	286	3.46	3.71	0.01	1.98	0.98 (0.79, 1.21)	0.857
Apixaban	88,563	44,459.28	183.36	0.5	*****	3.44	1.73				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	70,969	21,972.96	113.09	0.31	72	3.28	1.01	0.23	0.07	1.07 (0.77, 1.50)	0.672
Apixaban	70,969	21,972.96	113.09	0.31	67	3.05	0.94				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	70,969	75,592.17	389.04	1.07	*****	3.41	3.64	-0.13	1.79	0.94 (0.75, 1.18)	0.575
Apixaban	70,969	36,985.90	190.35	0.52	*****	3.54	1.85				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	77,163	70,707.88	334.69	0.92	*****	3.51	3.21	0.07	1.49	0.96 (0.77, 1.19)	0.697
Apixaban	88,563	44,459.28	183.36	0.5	*****	3.44	1.73				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	6,720	3,420.08	185.89	0.51	142	41.52	21.13	19.68	12.28	1.72 (1.40, 2.12)	<0.001
Warfarin	31,618	12,819.30	148.09	0.41	280	21.84	8.86				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,607	1,347.03	74.47	0.2	59	43.8	8.93	24.5	4.99	2.27 (1.43, 3.60)	<0.001
Warfarin	6,607	1,347.03	74.47	0.2	26	19.3	3.94				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,607	3,368.70	186.23	0.51	140	41.56	21.19	19.44	12.41	1.86 (1.36, 2.55)	<0.001
Warfarin	6,607	2,622.00	144.95	0.4	58	22.12	8.78				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	6,720	3,419.51	185.86	0.51	142	41.53	21.13	19.69	12.62	1.67 (1.35, 2.07)	<0.001
Warfarin	31,618	12,317.32	142.29	0.39	269	21.84	8.51				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,277	716.56	204.95	0.56	21	29.31	16.44	11.9	9.76	1.66 (0.94, 2.95)	0.082
Warfarin	4,788	1,838.57	140.25	0.38	32	17.4	6.68				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,231	230.39	68.36	0.19	*****	*****	*****	13.02	2.44	2.00 (0.50, 8.00)	0.327
Warfarin	1,231	230.39	68.36	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,231	699.82	207.64	0.57	20	28.58	16.25	*****	*****	1.97 (0.79, 4.95)	0.147
Warfarin	1,231	445.72	132.25	0.36	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,277	688.16	196.83	0.54	21	30.52	16.44	12.9	10.18	1.71 (0.92, 3.17)	0.089
Warfarin	4,788	1,702.72	129.89	0.36	30	17.62	6.27				

Table 8d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	52,201	29,593.94	207.07	0.57	152	5.14	2.91	2.02	1.36	1.57 (1.30, 1.90)	<0.001
Warfarin	257,673	128,609.91	182.3	0.5	401	3.12	1.56				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	50,337	11,711.30	84.98	0.23	54	4.61	1.07	1.2	0.28	1.35 (0.90, 2.03)	0.15
Warfarin	50,337	11,711.30	84.98	0.23	40	3.42	0.79				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	50,337	28,593.24	207.48	0.57	148	5.18	2.94	1.75	1.23	1.49 (1.13, 1.95)	0.004
Warfarin	50,337	25,087.56	182.04	0.5	86	3.43	1.71				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	52,201	29,593.94	207.07	0.57	152	5.14	2.91	2.01	1.39	1.47 (1.21, 1.78)	<0.001
Warfarin	257,673	125,797.71	178.32	0.49	393	3.12	1.53				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	128,817	110,009.55	311.92	0.85	458	4.16	3.56	1.28	2.08	1.39 (1.23, 1.57)	<0.001
Warfarin	428,693	218,526.46	186.19	0.51	631	2.89	1.47				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	128,189	34,658.86	98.75	0.27	*****	4.47	1.21	1.76	0.48	1.65 (1.28, 2.13)	<0.001
Warfarin	128,189	34,658.86	98.75	0.27	*****	2.71	0.73				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	128,189	109,534.98	312.1	0.85	454	4.14	3.54	1.33	2.11	1.44 (1.21, 1.71)	<0.001
Warfarin	128,189	65,340.93	186.18	0.51	*****	2.82	1.44				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	128,817	110,009.55	311.92	0.85	458	4.16	3.56	1.27	2.1	1.33 (1.17, 1.51)	<0.001
Warfarin	428,693	216,163.90	184.17	0.5	626	2.9	1.46				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,033	3,634.73	188.77	0.52	63	17.33	8.96	17.33	8.96	-	-
Dabigatran	247	122.12	180.58	0.49	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	218	51.9	86.95	0.24	*****	*****	*****	*****	*****	-	-
Dabigatran	218	51.9	86.95	0.24	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	218	121.63	203.79	0.56	*****	*****	*****	*****	*****	-	-
Dabigatran	218	107.32	179.81	0.49	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,033	2,706.47	140.56	0.38	56	20.69	7.96	20.69	7.96	-	-
Dabigatran	247	115.97	171.49	0.47	0	0	0				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,315	736.16	204.47	0.56	16	21.73	12.17	18.46	*****	5.22 (1.20, 22.74)	0.028
Dabigatran	821	*****	*****	*****	*****	3.27	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	770	228.26	108.27	0.3	*****	*****	*****	13.14	3.9	2.50 (0.49, 12.89)	0.273
Dabigatran	770	228.26	108.27	0.3	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	770	442.19	209.75	0.57	*****	*****	*****	16.88	9.09	4.72 (1.02, 21.84)	0.047
Dabigatran	770	576.13	273.29	0.75	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,315	709.25	197	0.54	16	22.56	12.17	18.93	*****	6.67 (1.51, 29.52)	0.012
Dabigatran	821	*****	*****	*****	*****	3.63	*****				

Table 8e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	54,320	30,938.78	208.03	0.57	46	1.49	0.85	0.62	*****	1.54 (0.21, 11.20)	0.667
Dabigatran	1,939	*****	*****	*****	*****	0.87	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,915	487.98	93.07	0.25	*****	*****	*****	2.05	0.52	2.00 (0.18, 22.06)	0.571
Dabigatran	1,915	487.98	93.07	0.25	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,915	1,111.28	211.96	0.58	*****	*****	*****	0.92	0.52	1.94 (0.18, 21.40)	0.588
Dabigatran	1,915	1,135.45	216.57	0.59	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	54,320	30,581.21	205.63	0.56	46	1.5	0.85	0.61	*****	1.52 (0.21, 11.06)	0.679
Dabigatran	1,939	*****	*****	*****	*****	0.89	*****				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	131,741	112,421.28	311.69	0.85	69	0.61	0.52	0.13	0	1.21 (0.81, 1.82)	0.349
Dabigatran	77,058	83,040.15	393.6	1.08	40	0.48	0.52				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	76,971	33,058.98	156.87	0.43	20	0.6	0.26	0	0	1.00 (0.54, 1.86)	1
Dabigatran	76,971	33,058.98	156.87	0.43	20	0.6	0.26				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	76,971	67,792.52	321.7	0.88	38	0.56	0.49	0.09	-0.01	1.17 (0.73, 1.85)	0.515
Dabigatran	76,971	82,958.57	393.66	1.08	39	0.47	0.51				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	131,741	112,421.28	311.69	0.85	69	0.61	0.52	0.14	0.03	1.15 (0.76, 1.72)	0.514
Dabigatran	77,058	81,003.04	383.95	1.05	38	0.47	0.49				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,043	3,638.79	188.71	0.52	63	17.31	8.95	-9.46	*****	0.95 (0.38, 2.37)	0.908
Apixaban	643	*****	*****	*****	*****	26.78	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	584	106.47	66.59	0.18	*****	*****	*****	9.39	1.71	1.25 (0.34, 4.65)	0.739
Apixaban	584	106.47	66.59	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	584	319.74	199.98	0.55	*****	*****	*****	-1.97	5.14	1.55 (0.45, 5.32)	0.486
Apixaban	584	167.6	104.82	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,043	2,801.52	145.29	0.4	59	21.06	8.38	-5.72	*****	0.93 (0.37, 2.35)	0.874
Apixaban	643	*****	*****	*****	*****	26.78	*****				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,330	744.19	204.37	0.56	16	21.5	12.03	13.99	*****	3.20 (0.73, 13.96)	0.122
Apixaban	586	*****	*****	*****	*****	7.51	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	528	131.17	90.74	0.25	0	0	0	*****	*****	-	-
Apixaban	528	131.17	90.74	0.25	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	528	327.98	226.89	0.62	*****	*****	*****	-2.11	0	0.69 (0.10, 4.96)	0.712
Apixaban	528	243.79	168.64	0.46	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,330	635.16	174.43	0.48	16	25.19	12.03	17.48	*****	3.71 (0.84, 16.46)	0.085
Apixaban	586	*****	*****	*****	*****	7.71	*****				

Table 8f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	54,350	30,954.16	208.02	0.57	46	1.49	0.85	1.49	0.85	-	-
Apixaban	7,827	2,281.78	106.48	0.29	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,722	1,478.75	69.94	0.19	*****	*****	*****	*****	*****	-	-
Apixaban	7,722	1,478.75	69.94	0.19	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,722	4,352.24	205.86	0.56	*****	*****	*****	*****	*****	-	-
Apixaban	7,722	2,254.17	106.62	0.29	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	54,350	29,367.28	197.36	0.54	46	1.57	0.85	1.57	0.85	-	-
Apixaban	7,827	2,281.78	106.48	0.29	0	0	0				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	133,377	113,774.03	311.57	0.85	69	0.61	0.52	0.03	0.22	1.25 (0.79, 1.97)	0.345
Apixaban	88,736	44,742.97	184.17	0.5	26	0.58	0.29				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	88,403	27,048.00	111.75	0.31	25	0.92	0.28	0.11	0.03	1.14 (0.64, 2.02)	0.662
Apixaban	88,403	27,048.00	111.75	0.31	22	0.81	0.25				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	88,403	75,654.51	312.58	0.86	41	0.54	0.46	-0.04	0.17	1.20 (0.73, 1.97)	0.472
Apixaban	88,403	44,621.84	184.36	0.5	26	0.58	0.29				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	133,377	110,617.94	302.92	0.83	68	0.61	0.51	0.03	0.22	1.24 (0.78, 1.97)	0.358
Apixaban	88,736	44,742.97	184.17	0.5	26	0.58	0.29				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	250	122.88	179.52	0.49	0	0	0	-26.61	*****	-	-
Apixaban	649	*****	*****	*****	*****	26.61	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	232	41.88	65.93	0.18	0	0	0	*****	*****	-	-
Apixaban	232	41.88	65.93	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	232	116.54	183.47	0.5	0	0	0	*****	*****	-	-
Apixaban	232	70.46	110.92	0.3	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	250	88.11	128.73	0.35	0	0	0	-30.23	*****	-	-
Apixaban	649	*****	*****	*****	*****	30.23	*****				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	821	*****	*****	*****	*****	3.27	*****	-4.28	-0.98	0.54 (0.07, 3.89)	0.541
Apixaban	585	*****	*****	*****	*****	7.55	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	493	117.9	87.35	0.24	*****	*****	*****	0	0	1.00 (0.06, 15.99)	1
Apixaban	493	117.9	87.35	0.24	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	493	355.87	263.65	0.72	*****	*****	*****	-5.94	-2.03	0.32 (0.03, 3.75)	0.367
Apixaban	493	228.45	169.25	0.46	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	821	*****	*****	*****	*****	4.49	*****	-3.31	-0.98	0.61 (0.08, 4.84)	0.636
Apixaban	585	*****	*****	*****	*****	7.8	*****				

Table 8g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	1,945	*****	*****	*****	*****	0.87	*****	0.87	*****	-	-
Apixaban	7,873	2,292.40	106.35	0.29	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	1,927	350.96	66.52	0.18	0	0	0	0	0	-	-
Apixaban	1,927	350.96	66.52	0.18	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	1,927	1,140.97	216.26	0.59	*****	*****	*****	*****	*****	-	-
Apixaban	1,927	565.2	107.13	0.29	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	1,945	*****	*****	*****	*****	1.03	*****	1.03	*****	-	-
Apixaban	7,873	2,280.49	105.8	0.29	0	0	0				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Dabigatran	77,155	83,079.05	393.29	1.08	*****	0.48	0.52	-0.1	0.22	1.07 (0.63, 1.81)	0.811
Apixaban	88,571	44,532.78	183.64	0.5	26	0.58	0.29				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	71,020	22,047.43	113.39	0.31	14	0.63	0.2	0.09	0.03	1.17 (0.54, 2.52)	0.695
Apixaban	71,020	22,047.43	113.39	0.31	12	0.54	0.17				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	71,020	75,897.18	390.33	1.07	*****	0.5	0.54	0.01	0.28	1.31 (0.73, 2.37)	0.368
Apixaban	71,020	37,010.44	190.34	0.52	18	0.49	0.25				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	77,155	70,900.74	335.64	0.92	*****	0.48	0.44	-0.1	0.15	1.12 (0.65, 1.92)	0.674
Apixaban	88,571	44,532.78	183.64	0.5	26	0.58	0.29				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 8h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	6,735	3,474.83	188.45	0.52	62	17.84	9.21	8.6	5.42	2.17 (1.59, 2.96)	<0.001
Warfarin	31,666	12,987.43	149.8	0.41	120	9.24	3.79				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,594	1,332.48	73.81	0.2	*****	30.02	6.07	19.51	3.94	2.86 (1.55, 5.25)	<0.001
Warfarin	6,594	1,332.48	73.81	0.2	*****	10.51	2.12				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,594	3,413.38	189.07	0.52	62	18.16	9.4	10.52	6.37	2.63 (1.59, 4.36)	<0.001
Warfarin	6,594	2,615.96	144.9	0.4	*****	7.65	3.03				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	6,735	3,474.26	188.41	0.52	62	17.85	9.21	8.29	5.45	2.35 (1.70, 3.23)	<0.001
Warfarin	31,666	12,452.99	143.64	0.39	119	9.56	3.76				
Age Group: 18-50 years and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,276	720.7	206.3	0.56	15	20.81	11.76	6.17	6.12	1.58 (0.82, 3.04)	0.169
Warfarin	4,791	1,844.23	140.6	0.38	27	14.64	5.64				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	1,229	245.33	72.91	0.2	*****	*****	*****	20.38	4.07	6.00 (0.72, 49.84)	0.097
Warfarin	1,229	245.33	72.91	0.2	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	1,229	697.05	207.16	0.57	15	21.52	12.21	*****	*****	11.01 (1.45, 83.80)	0.021
Warfarin	1,229	456.1	135.55	0.37	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,276	692.7	198.28	0.54	14	20.21	10.97	4.97	5.54	2.03 (0.99, 4.20)	0.055
Warfarin	4,791	1,706.44	130.09	0.36	26	15.24	5.43				

Table 8h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Any Atrial Fibrillation or Atrial Flutter (AF) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	52,210	29,669.45	207.56	0.57	45	1.52	0.86	-0.3	-0.05	0.85 (0.62, 1.17)	0.328
Warfarin	257,547	128,721.16	182.55	0.5	234	1.82	0.91				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	49,900	11,657.27	85.33	0.23	*****	2.23	0.52	0.6	0.14	1.37 (0.76, 2.47)	0.299
Warfarin	49,900	11,657.27	85.33	0.23	*****	1.63	0.38				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	49,900	28,394.48	207.84	0.57	42	1.48	0.84	0.15	0.18	1.08 (0.69, 1.71)	0.729
Warfarin	49,900	24,775.83	181.35	0.5	*****	1.33	0.66				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	52,210	29,669.45	207.56	0.57	45	1.52	0.86	-0.32	-0.04	0.94 (0.68, 1.30)	0.705
Warfarin	257,547	125,895.80	178.54	0.49	231	1.83	0.9				
Age Group: 51 years or more and presence of AF											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	128,809	110,348.27	312.9	0.86	69	0.63	0.54	-0.43	0	0.65 (0.49, 0.85)	0.002
Warfarin	428,535	218,867.29	186.55	0.51	230	1.05	0.54				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	128,276	34,709.84	98.83	0.27	*****	0.69	0.19	-0.4	-0.11	0.63 (0.38, 1.05)	0.078
Warfarin	128,276	34,709.84	98.83	0.27	*****	1.09	0.3				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	128,276	109,935.75	313.03	0.86	69	0.63	0.54	-0.12	0.16	0.92 (0.64, 1.34)	0.671
Warfarin	128,276	65,418.79	186.27	0.51	*****	0.75	0.38				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	128,809	110,348.27	312.9	0.86	69	0.63	0.54	-0.43	0	0.86 (0.65, 1.15)	0.308
Warfarin	428,535	216,471.33	184.5	0.51	229	1.06	0.53				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	115,790	100,820.41	318.03	0.87	439	4.35	3.79	0.81	-0.03	1.18 (1.01, 1.38)	0.033
Dabigatran	72,542	78,264.22	394.06	1.08	277	3.54	3.82				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	72,427	31,376.77	158.23	0.43	159	5.07	2.2	1.53	0.66	1.43 (1.12, 1.83)	0.004
Dabigatran	72,427	31,376.77	158.23	0.43	111	3.54	1.53				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	72,427	64,306.54	324.3	0.89	285	4.43	3.93	0.9	0.12	1.20 (1.01, 1.42)	0.034
Dabigatran	72,427	78,182.82	394.28	1.08	276	3.53	3.81				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	115,790	100,820.41	318.03	0.87	439	4.35	3.79	0.82	0.07	1.19 (1.01, 1.39)	0.032
Dabigatran	72,542	76,372.55	384.54	1.05	270	3.54	3.72				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	78,610	46,436.68	215.76	0.59	347	7.47	4.41	3.05	0.7	1.53 (1.01, 2.33)	0.044
Dabigatran	7,532	6,331.23	307.02	0.84	28	4.42	3.72				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,423	2,418.41	119	0.33	15	6.2	2.02	*****	*****	1.50 (0.67, 3.34)	0.321
Dabigatran	7,423	2,418.41	119	0.33	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,423	5,125.39	252.2	0.69	31	6.05	4.18	1.54	0.4	1.40 (0.82, 2.41)	0.22
Dabigatran	7,423	6,216.77	305.9	0.84	28	4.5	3.77				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	78,610	46,123.33	214.31	0.59	340	7.37	4.33	3.14	0.87	1.17 (0.75, 1.82)	0.483
Dabigatran	7,532	6,148.98	298.18	0.82	26	4.23	3.45				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	117,281	102,055.04	317.83	0.87	443	4.34	3.78	0.85	1.99	1.29 (1.06, 1.56)	0.009
Apixaban	81,588	41,837.71	187.3	0.51	146	3.49	1.79				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	81,221	25,302.74	113.79	0.31	117	4.62	1.44	1.58	0.49	1.52 (1.14, 2.03)	0.004
Apixaban	81,221	25,302.74	113.79	0.31	77	3.04	0.95				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	81,221	70,108.78	315.28	0.86	288	4.11	3.55	0.61	1.75	1.23 (1.00, 1.50)	0.048
Apixaban	81,221	41,692.56	187.49	0.51	146	3.5	1.8				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	117,281	99,113.82	308.67	0.85	434	4.38	3.7	0.89	1.91	1.26 (1.04, 1.52)	0.019
Apixaban	81,588	41,837.71	187.3	0.51	146	3.49	1.79				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	78,809	46,575.30	215.86	0.59	347	7.45	4.4	3.13	2.92	1.55 (1.02, 2.36)	0.039
Apixaban	16,196	5,561.31	125.42	0.34	24	4.32	1.48				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	16,041	3,436.16	78.24	0.21	*****	*****	*****	*****	*****	0.71 (0.32, 1.61)	0.416
Apixaban	16,041	3,436.16	78.24	0.21	*****	4.07	0.87				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	16,041	10,077.73	229.47	0.63	46	4.56	2.87	0.21	1.37	1.06 (0.63, 1.76)	0.833
Apixaban	16,041	5,512.95	125.53	0.34	24	4.35	1.5				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	78,809	44,615.88	206.78	0.57	328	7.35	4.16	3.04	2.68	1.16 (0.76, 1.78)	0.484
Apixaban	16,196	5,561.31	125.42	0.34	24	4.32	1.48				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	72,623	78,298.46	393.79	1.08	277	3.54	3.81	0.03	2.02	0.99 (0.80, 1.23)	0.924
Apixaban	81,406	41,634.83	186.81	0.51	146	3.51	1.79				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	66,330	20,791.43	114.49	0.31	65	3.13	0.98	0.14	0.05	1.05 (0.74, 1.48)	0.79
Apixaban	66,330	20,791.43	114.49	0.31	62	2.98	0.93				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	66,330	71,110.86	391.58	1.07	246	3.46	3.71	-0.16	1.79	0.94 (0.75, 1.18)	0.588
Apixaban	66,330	35,061.34	193.07	0.53	127	3.62	1.91				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	72,623	66,899.42	336.46	0.92	241	3.6	3.32	0.1	1.53	0.96 (0.77, 1.19)	0.714
Apixaban	81,406	41,634.83	186.81	0.51	146	3.51	1.79				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	7,556	6,337.04	306.33	0.84	28	4.42	3.71	0.11	2.23	1.01 (0.55, 1.87)	0.969
Apixaban	16,264	5,565.03	124.98	0.34	24	4.31	1.48				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	7,309	1,627.04	81.31	0.22	*****	*****	*****	1.23	0.27	1.33 (0.46, 3.84)	0.594
Apixaban	7,309	1,627.04	81.31	0.22	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	7,309	6,099.23	304.79	0.83	28	4.59	3.83	*****	*****	1.30 (0.59, 2.90)	0.516
Apixaban	7,309	2,760.79	137.96	0.38	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	7,556	5,263.70	254.44	0.7	21	3.99	2.78	-0.32	1.3	1.00 (0.53, 1.89)	0.998
Apixaban	16,264	5,564.68	124.97	0.34	24	4.31	1.48				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	113,820	99,351.50	318.82	0.87	436	4.39	3.83	1.52	2.38	1.47 (1.29, 1.67)	<0.001
Warfarin	337,968	171,053.37	184.86	0.51	490	2.86	1.45				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	113,376	30,857.66	99.41	0.27	145	4.7	1.28	1.69	0.46	1.56 (1.20, 2.02)	<0.001
Warfarin	113,376	30,857.66	99.41	0.27	93	3.01	0.82				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	113,376	99,034.02	319.05	0.87	433	4.37	3.82	1.46	2.35	1.46 (1.22, 1.75)	<0.001
Warfarin	113,376	57,406.98	184.94	0.51	167	2.91	1.47				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	113,820	99,351.50	318.82	0.87	436	4.39	3.83	1.51	2.39	1.38 (1.21, 1.58)	<0.001
Warfarin	337,968	169,110.17	182.76	0.5	486	2.87	1.44				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	75,195	44,388.63	215.61	0.59	337	7.59	4.48	3.11	2.26	1.55 (1.37, 1.77)	<0.001
Warfarin	384,804	190,740.87	181.05	0.5	854	4.48	2.22				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	74,294	17,314.64	85.12	0.23	133	7.68	1.79	2.71	0.63	1.55 (1.18, 2.03)	0.002
Warfarin	74,294	17,314.64	85.12	0.23	86	4.97	1.16				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	74,294	43,882.88	215.74	0.59	328	7.47	4.41	2.51	1.97	1.46 (1.21, 1.75)	<0.001
Warfarin	74,294	36,630.56	180.09	0.49	182	4.97	2.45				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	75,195	44,388.63	215.61	0.59	337	7.59	4.48	3.11	2.29	1.36 (1.20, 1.55)	<0.001
Warfarin	384,804	188,178.46	178.62	0.49	844	4.49	2.19				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 9e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	115,783	101,126.79	319.02	0.87	76	0.75	0.66	0.29	*****	1.54 (1.02, 2.33)	0.039
Dabigatran	72,534	*****	*****	*****	*****	0.46	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	72,410	31,458.34	158.68	0.43	28	0.89	0.39	0.29	0.12	1.47 (0.82, 2.64)	0.192
Dabigatran	72,410	31,458.34	158.68	0.43	19	0.6	0.26				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	72,410	64,471.88	325.21	0.89	44	0.68	0.61	0.22	0.11	1.42 (0.90, 2.25)	0.128
Dabigatran	72,410	78,475.85	395.85	1.08	36	0.46	0.5				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	115,783	101,126.79	319.02	0.87	76	0.75	0.66	0.31	0.19	1.55 (1.03, 2.35)	0.038
Dabigatran	72,534	76,647.81	385.97	1.06	34	0.44	0.47				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	78,626	46,604.16	216.5	0.59	118	2.53	1.5	1.43	*****	1.76 (0.80, 3.91)	0.162
Dabigatran	7,531	*****	*****	*****	*****	1.1	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,451	2,348.36	115.12	0.32	*****	*****	*****	0	0	1.00 (0.25, 4.00)	1
Dabigatran	7,451	2,348.36	115.12	0.32	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,451	4,998.84	245.04	0.67	*****	*****	*****	0.69	0.27	1.49 (0.53, 4.14)	0.448
Dabigatran	7,451	6,275.89	307.65	0.84	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	78,626	46,249.04	214.85	0.59	118	2.55	1.5	1.42	*****	1.14 (0.49, 2.65)	0.754
Dabigatran	7,531	*****	*****	*****	*****	1.13	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	117,275	102,368.40	318.82	0.87	76	0.74	0.65	0.15	*****	1.50 (0.95, 2.38)	0.08
Apixaban	81,596	*****	*****	*****	*****	0.6	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	81,240	25,418.52	114.28	0.31	23	0.9	0.28	0.08	0.02	1.10 (0.61, 1.98)	0.763
Apixaban	81,240	25,418.52	114.28	0.31	21	0.83	0.26				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	81,240	70,600.07	317.41	0.87	41	0.58	0.5	-0.02	0.2	1.24 (0.75, 2.05)	0.405
Apixaban	81,240	41,781.89	187.85	0.51	25	0.6	0.31				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	117,275	99,400.74	309.58	0.85	75	0.75	0.64	0.16	0.33	1.51 (0.95, 2.38)	0.081
Apixaban	81,596	41,911.60	187.61	0.51	25	0.6	0.31				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	78,825	46,742.77	216.59	0.59	118	2.52	1.5	1.09	*****	2.09 (1.02, 4.29)	0.045
Apixaban	16,196	*****	*****	*****	*****	1.44	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	16,124	3,420.70	77.49	0.21	*****	*****	*****	1.17	0.25	1.57 (0.61, 4.05)	0.35
Apixaban	16,124	3,420.70	77.49	0.21	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	16,124	10,109.34	229	0.63	18	1.78	1.12	*****	*****	1.76 (0.76, 4.12)	0.189
Apixaban	16,124	5,541.34	125.53	0.34	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	78,825	44,748.91	207.35	0.57	117	2.61	1.48	1.18	*****	1.38 (0.66, 2.87)	0.388
Apixaban	16,196	*****	*****	*****	*****	1.44	*****				

[1] Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	72,615	*****	*****	*****	*****	0.46	*****	-0.14	0.19	0.94 (0.54, 1.62)	0.819
Apixaban	81,413	*****	*****	*****	*****	0.6	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	66,360	20,859.21	114.81	0.31	12	0.58	0.18	*****	*****	1.09 (0.48, 2.47)	0.835
Apixaban	66,360	20,859.21	114.81	0.31	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	66,360	71,366.29	392.8	1.08	33	0.46	0.5	-0.05	0.23	1.11 (0.60, 2.05)	0.73
Apixaban	66,360	35,099.51	193.19	0.53	18	0.51	0.27				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	72,615	67,089.57	337.46	0.92	31	0.46	0.43	-0.14	0.12	0.96 (0.55, 1.67)	0.88
Apixaban	81,413	41,708.16	187.12	0.51	25	0.6	0.31				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	7,556	*****	*****	*****	*****	1.1	*****	-0.34	0.43	1.27 (0.42, 3.78)	0.673
Apixaban	16,265	*****	*****	*****	*****	1.44	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	7,306	1,665.38	83.26	0.23	*****	*****	*****	-1.8	-0.41	0.40 (0.08, 2.06)	0.273
Apixaban	7,306	1,665.38	83.26	0.23	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	7,306	6,103.20	305.12	0.84	*****	*****	*****	-0.66	0.27	0.96 (0.28, 3.22)	0.942
Apixaban	7,306	2,773.68	138.66	0.38	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	7,556	*****	*****	*****	*****	1.14	*****	-0.3	0.3	1.43 (0.45, 4.51)	0.545
Apixaban	16,265	*****	*****	*****	*****	1.44	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
No presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	113,814	99,656.91	319.82	0.88	75	0.75	0.66	-0.13	0.21	0.93 (0.70, 1.23)	0.611
Warfarin	337,866	171,330.71	185.22	0.51	152	0.89	0.45				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	113,482	31,051.07	99.94	0.27	28	0.9	0.25	-0.23	-0.06	0.80 (0.49, 1.31)	0.379
Warfarin	113,482	31,051.07	99.94	0.27	35	1.13	0.31				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	113,482	99,425.55	320.01	0.88	75	0.75	0.66	0.02	0.29	1.15 (0.79, 1.69)	0.467
Warfarin	113,482	57,575.63	185.31	0.51	42	0.73	0.37				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	113,814	99,656.91	319.82	0.88	75	0.75	0.66	-0.13	0.22	1.10 (0.82, 1.46)	0.54
Warfarin	337,866	169,362.42	183.09	0.5	150	0.89	0.44				
Presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	75,216	44,556.35	216.37	0.59	116	2.6	1.54	0.2	0.35	1.09 (0.89, 1.34)	0.402
Warfarin	384,673	191,089.40	181.44	0.5	459	2.4	1.19				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	73,964	17,222.34	85.05	0.23	65	3.77	0.88	1.16	0.27	1.44 (0.99, 2.11)	0.058
Warfarin	73,964	17,222.34	85.05	0.23	45	2.61	0.61				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	73,964	43,853.92	216.56	0.59	114	2.6	1.54	0.67	0.59	1.36 (1.01, 1.84)	0.042
Warfarin	73,964	36,321.26	179.36	0.49	70	1.93	0.95				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	75,216	44,556.35	216.37	0.59	116	2.6	1.54	0.17	0.35	1.15 (0.93, 1.42)	0.187
Warfarin	384,673	188,507.77	178.99	0.49	458	2.43	1.19				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

Table 10a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,055	599.06	207.4	0.57	21	35.05	19.91	15.78	*****	1.61 (0.75, 3.43)	0.218
Dabigatran	758	*****	*****	*****	*****	19.28	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	669	189.99	103.73	0.28	*****	*****	*****	21.05	5.98	1.67 (0.61, 4.59)	0.323
Dabigatran	669	189.99	103.73	0.28	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	669	387.98	211.82	0.58	17	43.82	25.41	*****	*****	1.82 (0.83, 3.98)	0.135
Dabigatran	669	494.87	270.18	0.74	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,055	573.7	198.62	0.54	20	34.86	18.96	14.98	*****	1.87 (0.84, 4.15)	0.125
Dabigatran	758	*****	*****	*****	*****	19.89	*****				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,281	3,712.19	186.22	0.51	146	39.33	20.05	20.02	*****	1.78 (0.57, 5.59)	0.324
Dabigatran	309	*****	*****	*****	*****	19.31	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	273	63.12	84.44	0.23	*****	*****	*****	*****	*****	-	-
Dabigatran	273	63.12	84.44	0.23	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	273	152.12	203.52	0.56	*****	*****	*****	16.75	10.99	1.57 (0.39, 6.31)	0.529
Dabigatran	273	132.22	176.9	0.48	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,281	2,850.93	143.02	0.39	110	38.58	15.11	18.4	*****	1.92 (0.60, 6.13)	0.268
Dabigatran	309	*****	*****	*****	*****	20.19	*****				

Table 10a. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	114,735	100,221.35	319.05	0.87	418	4.17	3.64	0.75	-0.06	1.17 (1.00, 1.37)	0.048
Dabigatran	71,784	77,693.62	395.32	1.08	266	3.42	3.71				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	71,655	31,186.20	158.97	0.44	148	4.75	2.07	1.38	0.6	1.41 (1.10, 1.81)	0.007
Dabigatran	71,655	31,186.20	158.97	0.44	105	3.37	1.47				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	71,655	63,826.49	325.35	0.89	268	4.2	3.74	0.78	0.04	1.18 (0.99, 1.40)	0.062
Dabigatran	71,655	77,603.37	395.57	1.08	265	3.41	3.7				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	114,735	100,221.35	319.05	0.87	418	4.17	3.64	0.73	0.01	1.16 (0.99, 1.36)	0.061
Dabigatran	71,784	75,805.37	385.71	1.06	261	3.44	3.64				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	71,329	42,724.49	218.78	0.6	201	4.7	2.82	0.66	-0.64	1.17 (0.74, 1.85)	0.497
Dabigatran	7,223	6,175.90	312.3	0.86	*****	4.05	3.46				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,085	2,321.62	119.69	0.33	*****	*****	*****	0.43	0.14	1.11 (0.45, 2.73)	0.819
Dabigatran	7,085	2,321.62	119.69	0.33	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,085	4,933.08	254.31	0.7	*****	4.87	3.39	0.73	-0.14	1.25 (0.69, 2.28)	0.457
Dabigatran	7,085	6,047.36	311.76	0.85	*****	4.13	3.53				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	71,329	42,413.35	217.18	0.59	197	4.64	2.76	0.81	-0.42	1.01 (0.62, 1.64)	0.967
Dabigatran	7,223	5,995.64	303.19	0.83	*****	3.84	3.18				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,068	605.54	207.09	0.57	21	34.68	19.66	18.12	*****	2.09 (0.71, 6.15)	0.179
Apixaban	511	*****	*****	*****	*****	16.56	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	457	109.85	87.79	0.24	*****	*****	*****	9.1	2.19	2.00 (0.18, 22.06)	0.571
Apixaban	457	109.85	87.79	0.24	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	457	256.88	205.31	0.56	*****	*****	*****	13.45	8.75	1.88 (0.48, 7.36)	0.367
Apixaban	457	217.34	173.71	0.48	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,068	519.65	177.72	0.49	17	32.71	15.92	15.8	*****	1.99 (0.63, 6.30)	0.24
Apixaban	511	*****	*****	*****	*****	16.91	*****				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,293	3,717.80	186.2	0.51	146	39.27	20.02	20.12	*****	1.96 (0.72, 5.31)	0.186
Apixaban	716	*****	*****	*****	*****	19.16	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	640	123.59	70.54	0.19	*****	*****	*****	8.09	1.56	1.50 (0.25, 8.98)	0.657
Apixaban	640	123.59	70.54	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	640	343.89	196.26	0.54	*****	*****	*****	10.67	10.94	1.75 (0.55, 5.58)	0.344
Apixaban	640	187.67	107.11	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,293	2,911.81	145.83	0.4	120	41.21	16.45	22.06	*****	1.89 (0.69, 5.15)	0.216
Apixaban	716	*****	*****	*****	*****	19.16	*****				

Table 10b. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	116,213	101,449.50	318.85	0.87	422	4.16	3.63	0.75	1.88	1.26 (1.04, 1.53)	0.019
Apixaban	81,077	41,596.13	187.39	0.51	*****	3.41	1.75				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	80,723	25,181.00	113.94	0.31	114	4.53	1.41	1.55	0.48	1.52 (1.14, 2.03)	0.005
Apixaban	80,723	25,181.00	113.94	0.31	75	2.98	0.93				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	80,723	69,836.11	315.99	0.87	*****	4.02	3.48	0.6	1.72	1.23 (1.00, 1.51)	0.049
Apixaban	80,723	41,457.48	187.58	0.51	*****	3.43	1.76				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	116,213	98,522.14	309.65	0.85	414	4.2	3.56	0.79	1.81	1.23 (1.02, 1.50)	0.033
Apixaban	81,077	41,596.13	187.39	0.51	*****	3.41	1.75				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	71,516	42,857.49	218.88	0.6	201	4.69	2.81	0.95	1.52	1.21 (0.76, 1.93)	0.42
Apixaban	15,480	5,352.48	126.29	0.35	*****	3.74	1.29				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	15,311	3,295.16	78.61	0.22	*****	*****	*****	*****	*****	0.69 (0.30, 1.62)	0.396
Apixaban	15,311	3,295.16	78.61	0.22	13	3.95	0.85				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	15,311	9,673.93	230.78	0.63	34	3.51	2.22	-0.26	0.91	0.88 (0.49, 1.56)	0.657
Apixaban	15,311	5,301.89	126.48	0.35	*****	3.77	1.31				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	71,516	41,305.12	210.96	0.58	190	4.6	2.66	0.86	1.36	1.04 (0.65, 1.68)	0.866
Apixaban	15,480	5,352.48	126.29	0.35	*****	3.74	1.29				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	758	*****	*****	*****	*****	19.28	*****	2.65	6.65	1.29 (0.39, 4.23)	0.672
Apixaban	509	*****	*****	*****	*****	16.63	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	443	113.85	93.86	0.26	*****	*****	*****	17.57	4.51	2.00 (0.37, 10.92)	0.423
Apixaban	443	113.85	93.86	0.26	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	443	344.49	284.03	0.78	*****	*****	*****	4.05	9.03	1.36 (0.39, 4.81)	0.631
Apixaban	443	208.64	172.02	0.47	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	758	*****	*****	*****	*****	24.27	*****	7.18	5.33	1.12 (0.34, 3.70)	0.848
Apixaban	509	*****	*****	*****	*****	17.09	*****				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	312	*****	*****	*****	*****	19.22	*****	0.15	4.08	0.77 (0.13, 4.40)	0.77
Apixaban	723	*****	*****	*****	*****	19.07	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	277	48.91	64.49	0.18	*****	*****	*****	0	0	1.00 (0.06, 15.99)	1
Apixaban	277	48.91	64.49	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	277	142.4	187.77	0.51	*****	*****	*****	8.33	7.22	1.40 (0.13, 15.71)	0.784
Apixaban	277	78.51	103.53	0.28	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	312	*****	*****	*****	*****	8.82	*****	-12.55	-2.33	0.47 (0.05, 4.55)	0.514
Apixaban	723	*****	*****	*****	*****	21.37	*****				

Table 10c. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	71,865	77,727.86	395.05	1.08	266	3.42	3.7	-0.01	1.95	0.97 (0.78, 1.21)	0.806
Apixaban	80,897	41,394.25	186.9	0.51	*****	3.43	1.76				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	65,831	20,678.81	114.73	0.31	61	2.95	0.93	0	0	1.00 (0.70, 1.43)	1
Apixaban	65,831	20,678.81	114.73	0.31	61	2.95	0.93				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	65,831	70,681.07	392.16	1.07	*****	3.37	3.62	-0.16	1.75	0.93 (0.73, 1.17)	0.528
Apixaban	65,831	34,823.92	193.21	0.53	*****	3.53	1.87				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	71,865	66,397.99	337.46	0.92	*****	3.48	3.21	0.05	1.46	0.95 (0.76, 1.18)	0.648
Apixaban	80,897	41,394.25	186.9	0.51	142	3.43	1.76				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	7,244	6,180.94	311.65	0.85	*****	4.04	3.45	0.31	2.16	1.11 (0.57, 2.13)	0.766
Apixaban	15,541	5,355.26	125.86	0.34	*****	3.73	1.29				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	6,999	1,570.43	81.95	0.22	*****	*****	*****	1.91	0.43	1.60 (0.52, 4.89)	0.41
Apixaban	6,999	1,570.43	81.95	0.22	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	6,999	5,932.84	309.61	0.85	*****	4.21	3.57	*****	*****	1.33 (0.57, 3.11)	0.506
Apixaban	6,999	2,666.70	139.16	0.38	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	7,244	5,118.49	258.08	0.71	*****	3.71	2.62	-0.02	1.34	1.10 (0.56, 2.18)	0.781
Apixaban	15,541	5,355.04	125.86	0.34	*****	3.73	1.29				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,042	595.53	208.75	0.57	19	31.9	18.23	13.67	11.17	1.60 (0.85, 3.02)	0.149
Warfarin	3,115	1,206.23	141.44	0.39	22	18.24	7.06				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	992	187.42	69.01	0.19	*****	*****	*****	-5.34	-1.01	0.75 (0.17, 3.35)	0.706
Warfarin	992	187.42	69.01	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	992	578.96	213.17	0.58	18	31.09	18.15	*****	*****	1.46 (0.61, 3.52)	0.4
Warfarin	992	353.87	130.29	0.36	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,042	561.02	196.65	0.54	18	32.08	17.27	15.41	11.5	2.11 (1.04, 4.27)	0.039
Warfarin	3,115	1,079.63	126.59	0.35	18	16.67	5.78				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	6,955	3,541.10	185.97	0.51	144	40.67	20.7	19.11	11.99	1.72 (1.40, 2.11)	<0.001
Warfarin	33,291	13,451.63	147.58	0.4	290	21.56	8.71				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,846	1,391.78	74.25	0.2	*****	40.24	8.18	20.84	4.24	2.07 (1.31, 3.28)	0.002
Warfarin	6,846	1,391.78	74.25	0.2	*****	19.4	3.94				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,846	3,490.40	186.22	0.51	142	40.68	20.74	19.09	12.27	1.87 (1.37, 2.56)	<0.001
Warfarin	6,846	2,685.53	143.28	0.39	*****	21.6	8.47				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	6,955	3,540.70	185.94	0.51	144	40.67	20.7	19.15	12.35	1.66 (1.35, 2.06)	<0.001
Warfarin	33,291	12,918.50	141.73	0.39	278	21.52	8.35				

Table 10d. Effect Estimates for Surgical Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	112,778	98,755.96	319.84	0.88	417	4.22	3.7	1.47	2.3	1.48 (1.29, 1.69)	<0.001
Warfarin	334,853	169,847.14	185.27	0.51	468	2.76	1.4				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	112,196	30,672.48	99.85	0.27	*****	4.4	1.2	1.5	0.41	1.52 (1.16, 1.98)	0.002
Warfarin	112,196	30,672.48	99.85	0.27	*****	2.9	0.79				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	112,196	98,316.43	320.07	0.88	414	4.21	3.69	1.4	2.26	1.46 (1.21, 1.76)	<0.001
Warfarin	112,196	56,968.53	185.46	0.51	*****	2.81	1.43				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	112,778	98,755.96	319.84	0.88	417	4.22	3.7	1.46	2.31	1.39 (1.21, 1.59)	<0.001
Warfarin	334,853	167,920.27	183.16	0.5	464	2.76	1.39				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	68,240	40,847.53	218.63	0.6	193	4.72	2.83	1.54	1.22	1.43 (1.21, 1.69)	<0.001
Warfarin	351,513	177,289.23	184.22	0.5	564	3.18	1.6				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	66,225	15,658.23	86.36	0.24	*****	4.73	1.12	1.53	0.36	1.48 (1.03, 2.12)	0.032
Warfarin	66,225	15,658.23	86.36	0.24	*****	3.19	0.76				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	66,225	39,692.04	218.91	0.6	185	4.66	2.79	1.31	1.1	1.38 (1.09, 1.76)	0.008
Warfarin	66,225	33,441.41	184.44	0.5	112	3.35	1.69				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	68,240	40,847.53	218.63	0.6	193	4.72	2.83	1.53	1.24	1.34 (1.13, 1.58)	<0.001
Warfarin	351,513	174,854.80	181.69	0.5	559	3.2	1.59				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,054	603.87	209.26	0.57	15	24.84	14.23	21.36	*****	5.68 (1.30, 24.87)	0.021
Dabigatran	759	*****	*****	*****	*****	3.48	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	696	208.38	109.35	0.3	*****	*****	*****	14.4	4.31	2.50 (0.49, 12.89)	0.273
Dabigatran	696	208.38	109.35	0.3	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	696	402.51	211.23	0.58	*****	*****	*****	18.59	10.06	4.74 (1.02, 21.97)	0.047
Dabigatran	696	531.03	278.68	0.76	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,054	575.36	199.38	0.55	15	26.07	14.23	22.13	*****	8.69 (1.90, 39.71)	0.005
Dabigatran	759	*****	*****	*****	*****	3.94	*****				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,294	3,767.02	188.63	0.52	64	16.99	8.77	16.99	8.77	-	-
Dabigatran	309	159.62	188.68	0.52	0	0	0				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	276	65.17	86.24	0.24	*****	*****	*****	*****	*****	-	-
Dabigatran	276	65.17	86.24	0.24	0	0	0				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	276	153.17	202.7	0.55	*****	*****	*****	*****	*****	-	-
Dabigatran	276	140.26	185.62	0.51	0	0	0				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,294	2,892.38	144.84	0.4	57	19.71	7.81	19.71	7.81	-	-
Dabigatran	309	151.46	179.03	0.49	0	0	0				

Table 10e. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	114,729	100,522.92	320.02	0.88	61	0.61	0.53	0.17	0.06	1.33 (0.86, 2.05)	0.206
Dabigatran	71,775	77,995.23	396.9	1.09	*****	0.44	0.47				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	71,622	31,238.50	159.31	0.44	*****	0.61	0.27	0.06	0.03	1.12 (0.58, 2.15)	0.739
Dabigatran	71,622	31,238.50	159.31	0.44	*****	0.54	0.24				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	71,622	64,005.27	326.41	0.89	*****	0.53	0.47	0.09	0	1.19 (0.73, 1.94)	0.494
Dabigatran	71,622	77,872.73	397.13	1.09	*****	0.44	0.47				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	114,729	100,522.92	320.02	0.88	61	0.61	0.53	0.19	0.09	1.30 (0.84, 2.01)	0.248
Dabigatran	71,775	76,073.30	387.12	1.06	*****	0.42	0.45				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	71,332	42,837.14	219.34	0.6	54	1.26	0.76	0.13	*****	0.95 (0.41, 2.17)	0.898
Dabigatran	7,222	*****	*****	*****	*****	1.13	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	7,113	2,251.39	115.61	0.32	*****	*****	*****	-0.89	-0.28	0.50 (0.09, 2.73)	0.423
Dabigatran	7,113	2,251.39	115.61	0.32	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	7,113	4,808.10	246.89	0.68	*****	*****	*****	0.1	-0.14	1.02 (0.33, 3.15)	0.972
Dabigatran	7,113	6,091.93	312.82	0.86	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	71,332	42,533.55	217.79	0.6	54	1.27	0.76	0.11	*****	0.70 (0.29, 1.72)	0.436
Dabigatran	7,222	*****	*****	*****	*****	1.16	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,067	610.35	208.93	0.57	15	24.58	14.06	16.35	*****	3.34 (0.76, 14.64)	0.11
Apixaban	511	*****	*****	*****	*****	8.23	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	467	118.13	92.39	0.25	0	0	0	*****	*****	-	-
Apixaban	467	118.13	92.39	0.25	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	467	285.99	223.68	0.61	*****	*****	*****	-1.91	0	0.82 (0.11, 5.89)	0.841
Apixaban	467	224.72	175.76	0.48	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,067	521.01	178.35	0.49	14	26.87	13.12	18.4	*****	3.40 (0.76, 15.27)	0.11
Apixaban	511	*****	*****	*****	*****	8.47	*****				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	7,306	3,772.63	188.61	0.52	64	16.96	8.76	-6.86	*****	1.04 (0.42, 2.59)	0.938
Apixaban	718	*****	*****	*****	*****	23.82	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	642	118.63	67.49	0.18	*****	*****	*****	8.43	1.56	1.25 (0.34, 4.65)	0.739
Apixaban	642	118.63	67.49	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	642	353.3	201	0.55	*****	*****	*****	-1.6	4.67	1.54 (0.45, 5.30)	0.49
Apixaban	642	186.78	106.27	0.29	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	7,306	2,949.32	147.45	0.4	60	20.34	8.21	-3.48	*****	0.99 (0.39, 2.50)	0.984
Apixaban	718	*****	*****	*****	*****	23.82	*****				

Table 10f. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	116,208	101,758.05	319.83	0.88	61	0.6	0.52	0.05	0.24	1.32 (0.81, 2.14)	0.269
Apixaban	81,085	41,668.59	187.7	0.51	*****	0.55	0.28				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	80,742	25,297.43	114.44	0.31	*****	0.91	0.28	0.16	0.05	1.21 (0.66, 2.22)	0.538
Apixaban	80,742	25,297.43	114.44	0.31	*****	0.75	0.24				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	80,742	70,280.28	317.92	0.87	*****	0.54	0.47	-0.01	0.19	1.27 (0.75, 2.14)	0.371
Apixaban	80,742	41,543.61	187.93	0.51	*****	0.55	0.28				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	116,208	98,803.66	310.55	0.85	60	0.61	0.52	0.06	0.23	1.35 (0.83, 2.20)	0.229
Apixaban	81,085	41,668.59	187.7	0.51	23	0.55	0.28				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	71,519	42,970.15	219.45	0.6	54	1.26	0.76	0.7	*****	2.73 (0.85, 8.77)	0.092
Apixaban	15,478	*****	*****	*****	*****	0.56	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	15,375	3,280.82	77.94	0.21	*****	*****	*****	0.91	0.2	2.00 (0.50, 8.00)	0.327
Apixaban	15,375	3,280.82	77.94	0.21	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	15,375	9,696.13	230.34	0.63	*****	*****	*****	0.57	0.52	2.55 (0.69, 9.40)	0.158
Apixaban	15,375	5,321.39	126.42	0.35	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	71,519	41,351.86	211.19	0.58	54	1.31	0.76	0.75	*****	2.19 (0.67, 7.18)	0.195
Apixaban	15,478	*****	*****	*****	*****	0.56	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	759	*****	*****	*****	*****	3.48	*****	-4.78	-1.29	0.54 (0.08, 3.90)	0.544
Apixaban	509	*****	*****	*****	*****	8.26	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	440	110.89	92.05	0.25	*****	*****	*****	0	0	1.00 (0.06, 15.99)	1
Apixaban	440	110.89	92.05	0.25	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	440	330.79	274.59	0.75	*****	*****	*****	-6.39	-2.27	0.34 (0.03, 3.90)	0.388
Apixaban	440	212.41	176.32	0.48	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	759	*****	*****	*****	*****	4.79	*****	-3.72	-1.29	0.71 (0.09, 5.54)	0.747
Apixaban	509	*****	*****	*****	*****	8.51	*****				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	312	160.39	187.76	0.51	0	0	0	-23.72	*****	-	-
Apixaban	725	*****	*****	*****	*****	23.72	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	271	50.06	67.48	0.18	0	0	0	*****	*****	-	-
Apixaban	271	50.06	67.48	0.18	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	271	136.65	184.18	0.5	0	0	0	*****	*****	-	-
Apixaban	271	79.95	107.76	0.3	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	312	115.03	134.66	0.37	0	0	0	-26.33	*****	-	-
Apixaban	725	*****	*****	*****	*****	26.33	*****				

Table 10g. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	71,856	78,029.47	396.63	1.09	*****	0.44	0.47	-0.12	0.19	0.99 (0.56, 1.75)	0.983
Apixaban	80,904	41,466.15	187.2	0.51	*****	0.55	0.28				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	65,868	20,733.04	114.97	0.31	*****	*****	*****	0.05	0.02	1.10 (0.47, 2.59)	0.827
Apixaban	65,868	20,733.04	114.97	0.31	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	65,868	70,997.92	393.7	1.08	*****	0.45	0.49	-0.01	0.24	1.24 (0.65, 2.33)	0.514
Apixaban	65,868	34,860.66	193.31	0.53	*****	0.46	0.24				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	71,856	66,582.18	338.44	0.93	*****	0.44	0.4	-0.12	0.12	1.03 (0.58, 1.83)	0.924
Apixaban	80,904	41,466.15	187.2	0.51	*****	0.55	0.28				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Dabigatran	7,244	*****	*****	*****	*****	1.13	*****	0.57	0.77	3.21 (0.77, 13.31)	0.109
Apixaban	15,540	*****	*****	*****	*****	0.56	*****				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Dabigatran	6,997	1,613.86	84.24	0.23	*****	*****	*****	0	0	1.00 (0.14, 7.10)	1
Apixaban	6,997	1,613.86	84.24	0.23	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	6,997	5,952.31	310.72	0.85	*****	*****	*****	0.43	0.71	2.30 (0.45, 11.69)	0.315
Apixaban	6,997	2,689.92	140.42	0.38	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Dabigatran	7,244	*****	*****	*****	*****	1.17	*****	0.61	0.64	3.24 (0.74, 14.32)	0.12
Apixaban	15,540	*****	*****	*****	*****	0.56	*****				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 10h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 18-50 years and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	1,041	599.19	210.24	0.58	14	23.36	13.45	9.27	8	1.88 (0.90, 3.95)	0.094
Warfarin	3,118	1,206.39	141.32	0.39	17	14.09	5.45				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	990	192.03	70.85	0.19	*****	*****	*****	20.83	4.04	5.00 (0.58, 42.80)	0.142
Warfarin	990	192.03	70.85	0.19	*****	*****	*****				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	990	575.77	212.42	0.58	14	24.32	14.14	*****	*****	4.92 (1.11, 21.80)	0.036
Warfarin	990	354.17	130.67	0.36	*****	*****	*****				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	1,041	566.44	198.74	0.54	13	22.95	12.49	9.22	7.68	2.94 (1.26, 6.87)	0.013
Warfarin	3,118	1,092.25	127.95	0.35	15	13.73	4.81				
Age Group: 18-50 years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	6,970	3,596.34	188.46	0.52	63	17.52	9.04	7.98	5.14	2.06 (1.52, 2.80)	<0.001
Warfarin	33,339	13,625.26	149.27	0.41	130	9.54	3.9				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	6,832	1,388.45	74.23	0.2	*****	30.25	6.15	20.89	4.24	3.23 (1.73, 6.02)	<0.001
Warfarin	6,832	1,388.45	74.23	0.2	*****	9.36	1.9				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	6,832	3,535.03	188.99	0.52	63	17.82	9.22	9.72	6	2.42 (1.49, 3.94)	<0.001
Warfarin	6,832	2,714.44	145.12	0.4	*****	8.1	3.22				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	6,970	3,595.53	188.42	0.52	63	17.52	9.04	7.64	5.17	2.21 (1.61, 3.02)	<0.001
Warfarin	33,339	13,055.64	143.03	0.39	129	9.88	3.87				

Table 10h. Effect Estimates for Transfusion Management Definition of Severe Uterine Bleed by Analysis Type, Age Group, and Presence of Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE) in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin

Medical Product	Number of New Users	Person-Years at Risk	Average Person-Days at Risk	Average Person-Years at Risk	Number of Events	Incidence Rate per 1,000 Person-Years	Risk per 1,000 New Users	Incidence Rate Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users	Hazard Ratio (95% Confidence Interval)	Wald P-Value
Age Group: 51 years or more and no presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	112,773	99,057.71	320.83	0.88	61	0.62	0.54	-0.18	0.14	0.85 (0.63, 1.16)	0.314
Warfarin	334,748	170,124.31	185.63	0.51	135	0.79	0.4				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	112,346	30,848.65	100.29	0.27	*****	0.71	0.2	-0.32	-0.09	0.69 (0.40, 1.18)	0.176
Warfarin	112,346	30,848.65	100.29	0.27	*****	1.04	0.28				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	112,346	98,731.56	320.99	0.88	61	0.62	0.54	-0.06	0.2	1.01 (0.67, 1.51)	0.976
Warfarin	112,346	57,163.03	185.84	0.51	39	0.68	0.35				
*****											
Rivaroxaban	112,773	99,057.71	320.83	0.88	61	0.62	0.54	-0.18	0.14	1.01 (0.74, 1.39)	0.933
Warfarin	334,748	168,172.20	183.5	0.5	134	0.8	0.4				
Age Group: 51 or more years and presence of DVT/PE											
Crude Analysis (Site-adjusted only)											
Rivaroxaban	68,246	40,960.01	219.22	0.6	53	1.29	0.78	-0.56	-0.16	0.72 (0.54, 0.96)	0.025
Warfarin	351,334	177,464.13	184.49	0.51	329	1.85	0.94				
1:1 Matched Conditional Analysis; Caliper= 0.05 [1]											
Rivaroxaban	65,828	15,575.10	86.42	0.24	30	1.93	0.46	0.13	0.03	1.07 (0.64, 1.79)	0.793
Warfarin	65,828	15,575.10	86.42	0.24	28	1.8	0.43				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	65,828	39,544.32	219.41	0.6	51	1.29	0.77	-0.01	0.12	1.00 (0.66, 1.50)	0.994
Warfarin	65,828	33,039.35	183.32	0.5	43	1.3	0.65				
Predefined Percentile Analysis; Percentile = 10 [1]											
Rivaroxaban	68,246	40,960.01	219.22	0.6	53	1.29	0.78	-0.58	-0.16	0.81 (0.60, 1.08)	0.155
Warfarin	351,334	175,017.75	181.95	0.5	328	1.87	0.93				

[1]Matched Conditional and Percentile analyses include informative events and person-time.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11a. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Crude)

	Rivaroxaban						Dabigatran						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	194,400		786		193,614		80,074		305		79,769		
Vaginal Bleed	6,747	100.0%	786	100.0%	5,961	100.0%	3,538	100.0%	305	100.0%	3,233	100.0%	-
Patient Count													
Any Medical Management	*****	1.4%	*****	2.8%	73	1.2%	*****	*****	*****	*****	*****	*****	0.140
Antifibrinolytic	*****	*****	*****	*****	*****	*****	*****	0.0%	*****	*****	0	0.0%	0.040
Contraceptive Use	*****	0.4%	*****	*****	21	0.4%	*****	*****	0	0.0%	*****	*****	0.070
Intrauterine Device	*****	1.0%	*****	1.9%	50	0.8%	*****	*****	0	0.0%	*****	*****	0.128
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	*****	*****	0	0.0%	0.001
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2	2.2	1.7	1.2	2.1	2.4	1.7	1.6	1	0	2	0	0.181
Antifibrinolytic	1.3	0.3	1.5	0	1.2	0.4	1	0	1	0	0	-	-
Contraceptive Use	3.6	3.2	2	0	4	3.6	2	0	0	-	2	0	-
Intrauterine Device	1.3	0.5	1.4	0.9	1.2	0.4	2	0	0	-	2	0	-
Vaginal Packing	1	0	0	-	1	0	1	0	1	0	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11b. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Rivaroxaban						Dabigatran						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	80,042		316		79,726		80,042		304		79,738		
Vaginal Bleed	2,557	100.0%	316	100.0%	2,241	100.0%	3,537	100.0%	304	100.0%	3,233	100.0%	-
Patient Count													
Any Medical Management	*****	1.0%	*****	*****	17	0.8%	*****	*****	*****	*****	*****	*****	0.110
Antifibrinolytic	*****	*****	*****	*****	*****	*****	*****	0.0%	*****	*****	0	0.0%	0.057
Contraceptive Use	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.054
Intrauterine Device	*****	0.6%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.094
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	*****	0.3%	0	0.0%	0.006
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.5	0.9	1.8	1.1	1.4	0.8	1.7	1.6	1	0	2	0	-0.099
Antifibrinolytic	1.2	0.4	1	0	1.3	0.4	1	0	1	0	0	-	-
Contraceptive Use	1.6	0.7	1.3	0	1.8	1	2	0	0	-	2	0	-
Intrauterine Device	1.4	0.8	1.7	1.2	1.2	0.4	2	0	0	-	2	0	-
Vaginal Packing	1	0	0	-	1	0	1	0	1	0	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11c. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Crude)

	Rivaroxaban						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	196,090		790		195,300		97,784		170		97,614		
Vaginal Bleed	6,799	100.0%	790	100.0%	6,009	100.0%	1,514	100.0%	170	100.0%	1,344	100.0%	-
Patient Count													
Any Medical Management	*****	1.4%	*****	2.8%	73	1.2%	*****	*****	*****	*****	*****	*****	0.115
Antifibrinolytic	*****	*****	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	0.4%	*****	*****	21	0.3%	*****	*****	0	0.0%	*****	*****	0.049
Intrauterine Device	*****	1.0%	*****	1.9%	50	0.8%	*****	*****	*****	*****	*****	*****	0.089
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2	2.2	1.7	1.2	2.1	2.4	1.8	0	1	0	2	0	-
Antifibrinolytic	1.3	0.3	1.5	0	1.2	0.4	0	-	0	-	0	-	-
Contraceptive Use	3.6	3.2	2	0	4	3.6	2.5	0	0	-	2.5	0	-
Intrauterine Device	1.3	0.5	1.4	0.9	1.2	0.4	1	0	1	0	1	0	-
Vaginal Packing	1	0	0	-	1	0	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11d. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Rivaroxaban						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	97,466		335		97,131		97,466		170		97,296		
Vaginal Bleed	2,964	100.0%	335	100.0%	2,629	100.0%	1,509	100.0%	170	100.0%	1,339	100.0%	-
Patient Count													
Any Medical Management	*****	0.8%	*****	*****	17	0.6%	*****	*****	*****	*****	*****	*****	0.067
Antifibrinolytic	*****	*****	*****	*****	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.017
Intrauterine Device	*****	0.5%	*****	*****	*****	0.4%	*****	*****	*****	*****	*****	*****	0.043
Vaginal Packing	*****	*****	0	0.0%	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.8	1.8	1.8	1.1	1.8	1.9	1.8	0	1	0	2	2.2	-
Antifibrinolytic	1	0	1	0	1	0	0	-	0	-	0	-	-
Contraceptive Use	2.8	2.7	2	0	3	3.1	2.5	0	0	-	2.5	0	-
Intrauterine Device	1.3	0.9	1.8	1.5	1.1	0.3	1	0	1	0	1	0	-
Vaginal Packing	1	0	0	-	1	0	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11e. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Crude)

	Dabigatran						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	80,179		305		79,874		97,670		170		97,500		
Vaginal Bleed	3,538	100.0%	305	100.0%	3,233	100.0%	1,508	100.0%	170	100.0%	1,338	100.0%	-
Patient Count													
Any Medical Management	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	-0.032
Antifibrinolytic	*****	0.0%	*****	*****	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.025
Intrauterine Device	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****	-0.052
Vaginal Packing	*****	0.0%	*****	*****	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.7	0.8	1	0	2	0.7	1.8	1.2	1	0	2	1.5	-0.128
Antifibrinolytic	1	0	1	0	0	-	0	-	0	-	0	-	-
Contraceptive Use	2	0	0	-	2	0	2.5	0.5	0	-	2.5	0.5	-
Intrauterine Device	2	0	0	-	2	0	1	0	1	0	1	0	-
Vaginal Packing	1	0	1	0	0	-	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11f. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Dabigatran						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	73,880		274		73,606		73,880		136		73,744		
Vaginal Bleed	3,201	100.0%	274	100.0%	2,927	100.0%	1,178	100.0%	136	100.0%	1,042	100.0%	-
Patient Count													
Any Medical Management	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	-0.065
Antifibrinolytic	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	0.0%	0	0.0%	*****	0.0%	*****	*****	0	0.0%	*****	*****	-0.044
Intrauterine Device	*****	0.0%	0	0.0%	*****	0.0%	*****	*****	*****	*****	*****	*****	-0.072
Vaginal Packing	*****	0.0%	*****	*****	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2	0	1	0	2.5	0	1.8	1.5	1	0	2	1.5	-
Antifibrinolytic	0	-	0	-	0	-	0	-	0	-	0	-	-
Contraceptive Use	3	0	0	-	3	0	2.5	0.5	0	-	2.5	0.5	-
Intrauterine Device	2	0	0	-	2	0	1	0	1	0	1	0	-
Vaginal Packing	1	0	1	0	0	-	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11g. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Crude)

	Rivaroxaban						Warfarin						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	189,015		773		188,242		722,772		1,344		721,428		
Vaginal Bleed	6,570	100.0%	773	100.0%	5,797	100.0%	33,030	100.0%	1,344	100.0%	31,686	100.0%	-
Patient Count													
Any Medical Management	95	1.4%	22	2.8%	73	1.3%	148	0.4%	27	2.0%	121	0.4%	0.103
Antifibrinolytic	*****	0.2%	*****	*****	*****	*****	*****	0.0%	0	0.0%	*****	0.0%	0.049
Contraceptive Use	*****	0.4%	*****	*****	23	0.4%	*****	0.2%	*****	*****	53	0.2%	0.046
Intrauterine Device	62	0.9%	15	1.9%	47	0.8%	85	0.3%	21	1.6%	64	0.2%	0.089
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	*****	0.1%	*****	0.0%	0.013
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2.1	2.3	1.7	1.2	2.3	2.6	2.4	3.8	1.4	1.1	2.6	4.1	-0.072
Antifibrinolytic	1.3	0.6	1.5	0	1.1	0.3	5.7	10.4	0	-	5.7	8	-0.598
Contraceptive Use	3.8	3.2	2	0	4.2	3.7	3.6	4.7	2.4	1.8	3.7	5	0.054
Intrauterine Device	1.3	0.5	1.4	0.9	1.2	0.4	1.2	0.6	1.1	0.4	1.2	0.7	0.150
Vaginal Packing	1	0	0	-	1	0	1	0	1	0	1	0	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11h. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Surgical Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Rivaroxaban						Warfarin						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	188,984		771		188,213		188,984		350		188,634		
Vaginal Bleed	6,566	100.0%	771	100.0%	5,795	100.0%	8,447	100.0%	350	100.0%	8,097	100.0%	-
Patient Count													
Any Medical Management	95	1.4%	22	2.9%	73	1.3%	*****	0.5%	*****	*****	36	0.4%	0.100
Antifibrinolytic	*****	0.2%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	0.4%	*****	*****	23	0.4%	*****	0.2%	*****	*****	15	0.2%	0.043
Intrauterine Device	*****	0.9%	*****	1.9%	47	0.8%	*****	0.3%	*****	*****	22	0.3%	0.083
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	0	0.0%	*****	0.0%	0.013
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2.1	2.3	1.7	1.2	2.3	2.6	2.3	4.1	1.8	0	2.3	4.4	-0.037
Antifibrinolytic	1.3	0.6	1.5	0	1.1	0.3	0	-	0	-	0	-	-
Contraceptive Use	3.8	3.2	2	0	4.2	3.7	3.6	6	3	0	3.6	6.9	0.054
Intrauterine Device	1.3	0.5	1.4	0.9	1.2	0.4	1.3	0.9	1.3	0	1.3	1	-0.008
Vaginal Packing	1	0	0	-	1	0	1	0	0	-	1	0	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11i. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Crude)

	Total[1]		Rivaroxaban With Event[2]		Without Event[2]		Total[1]		Dabigatran With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	194,409		194		194,215		80,065		43		80,022		
Vaginal Bleed	6,762	100.0%	194	100.0%	6,568	100.0%	3,542	100.0%	43	100.0%	3,499	100.0%	-
Patient Count													
Any Medical Management	*****	1.5%	*****	*****	95	1.4%	*****	*****	0	0.0%	*****	*****	0.141
Antifibrinolytic	*****	0.2%	*****	*****	12	0.2%	*****	0.0%	0	0.0%	*****	0.0%	0.049
Contraceptive Use	*****	0.4%	*****	*****	28	0.4%	*****	*****	0	0.0%	*****	*****	0.076
Intrauterine Device	*****	0.9%	*****	*****	60	0.9%	*****	*****	0	0.0%	*****	*****	0.119
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	0	0.0%	*****	0.0%	0.001
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2.3	2.7	1.2	0.4	2.3	2.8	1.6	1.2	0	-	1.6	1.2	0.331
Antifibrinolytic	2.2	3.9	1	0	2.3	4	1	0	0	-	1	0	-
Contraceptive Use	3.9	3.6	2	0	3.9	3.7	2	0	0	-	2	0	-
Intrauterine Device	1.3	0.6	1	0	1.3	0.6	1.3	0	0	-	1.3	0	-
Vaginal Packing	1	0	0	-	1	0	2	0	0	-	2	0	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11j. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Rivaroxaban						Dabigatran						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	80,033		53		79,980		80,033		43		79,990		
Vaginal Bleed	2,484	100.0%	53	100.0%	2,431	100.0%	3,540	100.0%	43	100.0%	3,497	100.0%	-
Patient Count													
Any Medical Management	*****	1.0%	*****	*****	23	0.9%	*****	*****	0	0.0%	*****	*****	0.108
Antifibrinolytic	*****	*****	*****	*****	*****	*****	*****	0.0%	0	0.0%	*****	0.0%	0.051
Contraceptive Use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	0.061
Intrauterine Device	*****	0.4%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.070
Vaginal Packing	*****	*****	0	0.0%	*****	*****	*****	0.0%	0	0.0%	*****	0.0%	0.022
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.7	1.9	1	0	1.7	1.9	1.6	1.2	0	-	1.6	1.2	0.053
Antifibrinolytic	1	0	1	0	1	0	1	0	0	-	1	0	-
Contraceptive Use	2.8	3	0	-	2.8	3	2	0	0	-	2	0	-
Intrauterine Device	1.3	0.4	1	0	1.3	0.3	1.3	0.8	0	-	1.3	0.8	-0.094
Vaginal Packing	1	0	0	-	1	0	2	0	0	-	2	0	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11k. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Crude)

	Rivaroxaban						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	196,100		194		195,906		97,792		33		97,759		
Vaginal Bleed	6,814	100.0%	194	100.0%	6,620	100.0%	1,515	100.0%	33	100.0%	1,482	100.0%	-
Patient Count													
Any Medical Management	*****	1.5%	*****	*****	95	1.4%	*****	*****	0	0.0%	*****	*****	0.103
Antifibrinolytic	*****	0.2%	*****	*****	12	0.2%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	0.4%	*****	*****	28	0.4%	*****	*****	0	0.0%	*****	*****	0.056
Intrauterine Device	*****	0.9%	*****	*****	60	0.9%	*****	*****	0	0.0%	*****	*****	0.065
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2.3	2.7	1.2	0.4	2.3	2.8	1.7	1.7	0	-	1.7	1.7	0.241
Antifibrinolytic	2.2	3.9	1	0	2.3	4	0	-	0	-	0	-	-
Contraceptive Use	3.9	3.6	2	0	3.9	3.7	2.5	0	0	-	2.5	0	-
Intrauterine Device	1.3	0.6	1	0	1.3	0.6	1.2	0	0	-	1.2	0	-
Vaginal Packing	1	0	0	-	1	0	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11l. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Rivaroxaban						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	97,474		59		97,415		97,474		33		97,441		
Vaginal Bleed	2,919	100.0%	59	100.0%	2,860	100.0%	1,509	100.0%	33	100.0%	1,476	100.0%	-
Patient Count													
Any Medical Management	*****	0.8%	*****	*****	22	0.8%	*****	*****	0	0.0%	*****	*****	0.041
Antifibrinolytic	*****	*****	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	0.010
Intrauterine Device	*****	0.4%	0	0.0%	*****	0.4%	*****	*****	0	0.0%	*****	*****	-0.003
Vaginal Packing	*****	*****	0	0.0%	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.8	1.9	1	0	1.8	2	1.7	1.4	0	-	1.7	1.4	0.041
Antifibrinolytic	1	0	1	0	1	0	0	-	0	-	0	-	-
Contraceptive Use	3.2	2.5	0	-	3.2	2.5	2.5	0.7	0	-	2.5	0.7	0.385
Intrauterine Device	1.5	1	0	-	1.5	1	1.2	0	0	-	1.2	0	-
Vaginal Packing	1	0	0	-	1	0	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11m. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Crude)

	Dabigatran						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	80,171		43		80,128		97,678		33		97,645		
Vaginal Bleed	3,542	100.0%	43	100.0%	3,499	100.0%	1,509	100.0%	33	100.0%	1,476	100.0%	-
Patient Count													
Any Medical Management	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.046
Antifibrinolytic	*****	0.0%	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.025
Intrauterine Device	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.064
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.6	0.7	0	-	1.6	0.7	1.7	1	0	-	1.7	1	-0.167
Antifibrinolytic	1	0	0	-	1	0	0	-	0	-	0	-	-
Contraceptive Use	2	0	0	-	2	0	2.5	0.5	0	-	2.5	0.5	-
Intrauterine Device	1.3	0	0	-	1.3	0	1.2	0	0	-	1.2	0	-
Vaginal Packing	2	0	0	-	2	0	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11n. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Dabigatran						Apixaban						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	73,887		40		73,847		73,887		23		73,864		
Vaginal Bleed	3,217	100.0%	40	100.0%	3,177	100.0%	1,158	100.0%	23	100.0%	1,135	100.0%	-
Patient Count													
Any Medical Management	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.044
Antifibrinolytic	*****	0.0%	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive Use	*****	0.0%	0	0.0%	*****	0.0%	*****	*****	0	0.0%	*****	*****	-0.044
Intrauterine Device	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.054
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	1.7	0.8	0	-	1.7	0.8	2	0.8	0	-	2	0.8	-0.403
Antifibrinolytic	1	0	0	-	1	0	0	-	0	-	0	-	-
Contraceptive Use	3	0	0	-	3	0	2.5	0.5	0	-	2.5	0.5	-
Intrauterine Device	1.3	0	0	-	1.3	0	1.3	0	0	-	1.3	0	-
Vaginal Packing	2	0	0	-	2	0	0	-	0	-	0	-	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11o. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Crude)

	Rivaroxaban						Warfarin						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	189,030		191		188,839		722,539		611		721,928		
Vaginal Bleed	6,585	100.0%	191	100.0%	6,394	100.0%	33,071	100.0%	611	100.0%	32,460	100.0%	-
Patient Count													
Any Medical Management	*****	1.5%	*****	*****	93	1.5%	*****	0.4%	*****	*****	136	0.4%	0.108
Antifibrinolytic	*****	0.2%	*****	*****	*****	0.2%	*****	0.0%	0	0.0%	*****	0.0%	0.052
Contraceptive Use	*****	0.5%	*****	*****	30	0.5%	*****	0.2%	*****	*****	54	0.2%	0.052
Intrauterine Device	*****	0.9%	*****	*****	57	0.9%	*****	0.2%	*****	*****	78	0.2%	0.088
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	*****	*****	*****	0.0%	0.013
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2.4	2.8	1.2	0.4	2.5	2.9	2.5	3.9	1.4	0.5	2.5	4	-0.022
Antifibrinolytic	2.3	3.9	1	0	2.5	4	5.7	10.4	0	-	5.7	10.4	-0.425
Contraceptive Use	4.1	3.6	2	0	4.1	3.7	3.7	4.8	1.5	0.5	3.8	4.9	0.092
Intrauterine Device	1.3	0.6	1	0	1.3	0.6	1.3	0.7	1.3	0	1.3	0.7	0.071
Vaginal Packing	1	0	0	-	1	0	1.5	0	1	0	1.7	0	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 11p. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015 with Transfusion Management Definition of Severe Uterine Bleed (Matched), Ratio: 1:1, Caliper: 0.05

	Rivaroxaban						Warfarin						
	Total[1]		With Event[2]		Without Event[2]		Total[1]		With Event[2]		Without Event[2]		
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized Difference (Total)[3]
Cohort Size	188,995		191		188,804		188,995		114		188,881		
Vaginal Bleed	6,583	100.0%	191	100.0%	6,392	100.0%	8,719	100.0%	114	100.0%	8,605	100.0%	-
Patient Count													
Any Medical Management	*****	1.5%	*****	*****	93	1.5%	*****	0.5%	*****	*****	43	0.5%	0.096
Antifibrinolytic	*****	0.2%	*****	*****	*****	0.2%	*****	0.0%	0	0.0%	*****	0.0%	0.050
Contraceptive Use	*****	0.5%	*****	*****	30	0.5%	*****	0.2%	*****	*****	15	0.2%	0.046
Intrauterine Device	*****	0.9%	*****	*****	57	0.9%	*****	0.3%	0	0.0%	*****	0.3%	0.081
Vaginal Packing	*****	0.0%	0	0.0%	*****	0.0%	*****	0.0%	0	0.0%	*****	0.0%	0.013
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Any Medical Management	2.4	2.8	1.2	0.4	2.5	2.9	1.8	1.5	1.3	0.6	1.9	1.6	0.243
Antifibrinolytic	2.3	3.9	1	0	2.5	4	4	0	0	-	4	0	-
Contraceptive Use	4.1	3.6	2	0	4.1	3.7	2.4	1.3	1.3	0.5	2.7	1.3	0.597
Intrauterine Device	1.3	0.6	1	0	1.3	0.6	1.3	0.6	0	-	1.3	0.6	0.062
Vaginal Packing	1	0	0	-	1	0	1	0	0	-	1	0	-

[1]Total counts included individuals with and without vaginal bleed.

[2]Medical managements were only captured for individuals with vaginal bleed using follow-up time for individuals with and without events.

[3]Managements in blue show an absolute standardized difference greater than 0.1.

[4]Management Count summarized distribution of each medical management count for patients who received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count divided by patient count.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 12a. Distribution of Surgical Managements Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran (Crude)

Exposure	Description	Management Count	Percent of Total Management Count
Rivaroxaban	Dilation and curettage with or without hysteroscopy	117	14.7%
Rivaroxaban	Hysterectomy	173	21.9%
Rivaroxaban	Hysteroscopy (not listed in other surgical managements)	94	11.9%
Rivaroxaban	Hysteroscopic polypectomy	365	46.1%
Rivaroxaban	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	42	5.4%
Dabigatran	Dilation and curettage with or without hysteroscopy	53	17.4%
Dabigatran	Hysterectomy	68	22.3%
Dabigatran	Hysteroscopy (not listed in other surgical managements)	*****	*****
Dabigatran	Hysteroscopic polypectomy	163	53.4%
Dabigatran	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	*****	*****

[1]Surgical managements counted in this table were among the exposed members identified prior to the removal of individuals with same-day exposure to both treatment groups, a standard pre-processing step in propensity score analysis (PSA). Total number of surgical managements may be greater than or equal to the total number of events summarized from the analytic cohort used in the PSA analysis.
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 12b. Distribution of Surgical Managements Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban (Crude)

Exposure	Description	Management Count	Percent of Total Management Count
Rivaroxaban	Dilation and curettage with or without hysteroscopy	117	14.7%
Rivaroxaban	Hysterectomy	173	21.9%
Rivaroxaban	Hysteroscopy (not listed in other surgical managements)	94	11.9%
Rivaroxaban	Hysteroscopic polypectomy	365	46.1%
Rivaroxaban	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	42	5.4%
Apixaban	Dilation and curettage with or without hysteroscopy	29	17.1%
Apixaban	Hysterectomy	44	25.9%
Apixaban	Hysteroscopy (not listed in other surgical managements)	*****	*****
Apixaban	Hysteroscopic polypectomy	80	47.1%
Apixaban	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	*****	*****

[1]Surgical managements counted in this table were among the exposed members identified prior to the removal of individuals with same-day exposure to both treatment groups, a standard pre-processing step in propensity score analysis (PSA). Total number of surgical managements may be greater than or equal to the total number of events summarized from the analytic cohort used in the PSA analysis.
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 12c. Distribution of Surgical Managements Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban (Crude)

Exposure	Description	Management Count	Percent of Total Management Count
Dabigatran	Dilation and curettage with or without hysteroscopy	53	17.4%
Dabigatran	Hysterectomy	68	22.3%
Dabigatran	Hysteroscopy (not listed in other surgical managements)	*****	*****
Dabigatran	Hysteroscopic polypectomy	163	53.4%
Dabigatran	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	*****	*****
Apixaban	Dilation and curettage with or without hysteroscopy	29	17.1%
Apixaban	Hysterectomy	44	25.9%
Apixaban	Hysteroscopy (not listed in other surgical managements)	*****	*****
Apixaban	Hysteroscopic polypectomy	80	47.1%
Apixaban	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	*****	*****

[1]Surgical managements counted in this table were among the exposed members identified prior to the removal of individuals with same-day exposure to both treatment groups, a standard pre-processing step in propensity score analysis (PSA). Total number of surgical managements may be greater than or equal to the total number of events summarized from the analytic cohort used in the PSA analysis.
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 12d. Distribution of Surgical Managements Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) from October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin (Crude)

Exposure	Description	Management Count	Percent of Total Management Count
Rivaroxaban	Dilation and curettage with or without hysteroscopy	108	13.6%
Rivaroxaban	Hysterectomy	178	22.4%
Rivaroxaban	Hysteroscopy (not listed in other surgical managements)	144	18.2%
Rivaroxaban	Hysteroscopic polypectomy	216	27.2%
Rivaroxaban	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	147	18.6%
Warfarin	Dilation and curettage with or without hysteroscopy	240	17.9%
Warfarin	Hysterectomy	345	25.7%
Warfarin	Hysteroscopy (not listed in other surgical managements)	232	17.3%
Warfarin	Hysteroscopic polypectomy	289	21.5%
Warfarin	Others (Thermal, cryo or section endometrial ablation; hysteroscopic, laparoscopic or abdominal myomectomy; uterine artery embolization)	238	17.7%

[1]Surgical managements counted in this table were among the exposed members identified prior to the removal of individuals with same-day exposure to both treatment groups, a standard pre-processing step in propensity score analysis (PSA). Total number of surgical managements may be greater than or equal to the total number of events summarized from the analytic cohort used in the PSA analysis.

Figure 1a. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed Defined by Surgical Management (Crude, Aggregated)

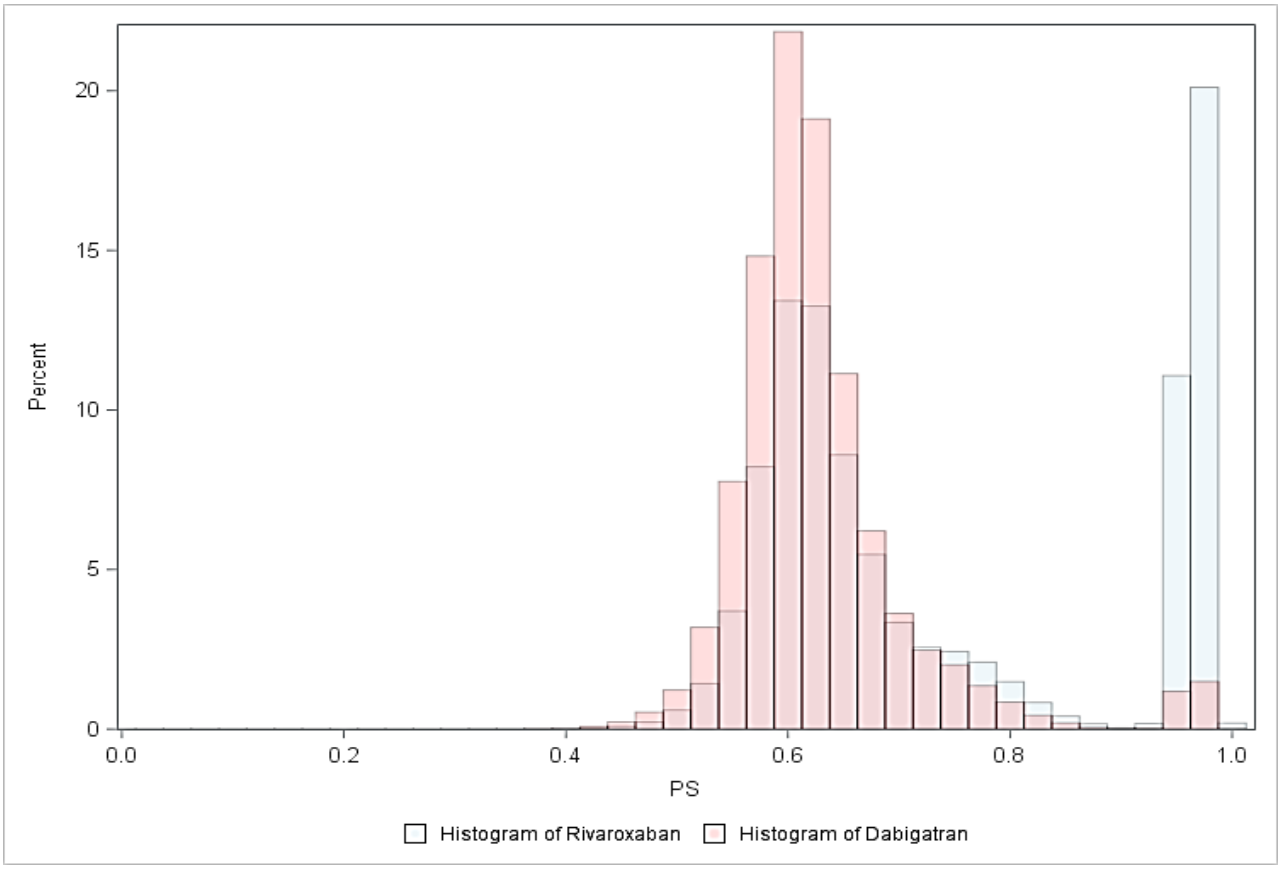


Figure 1b. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed Defined by Surgical Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

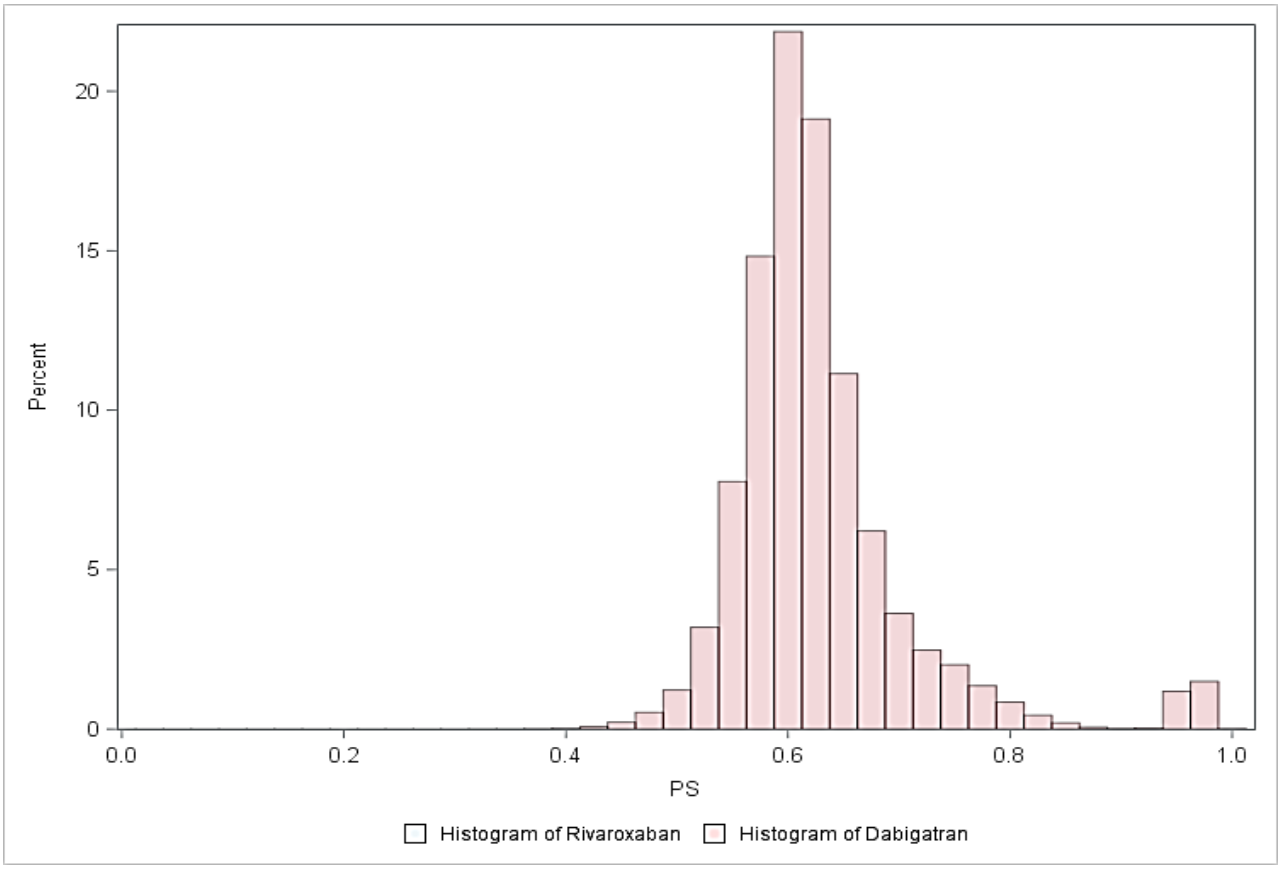


Figure 1c. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed Defined by Surgical Management (Crude, Aggregated)

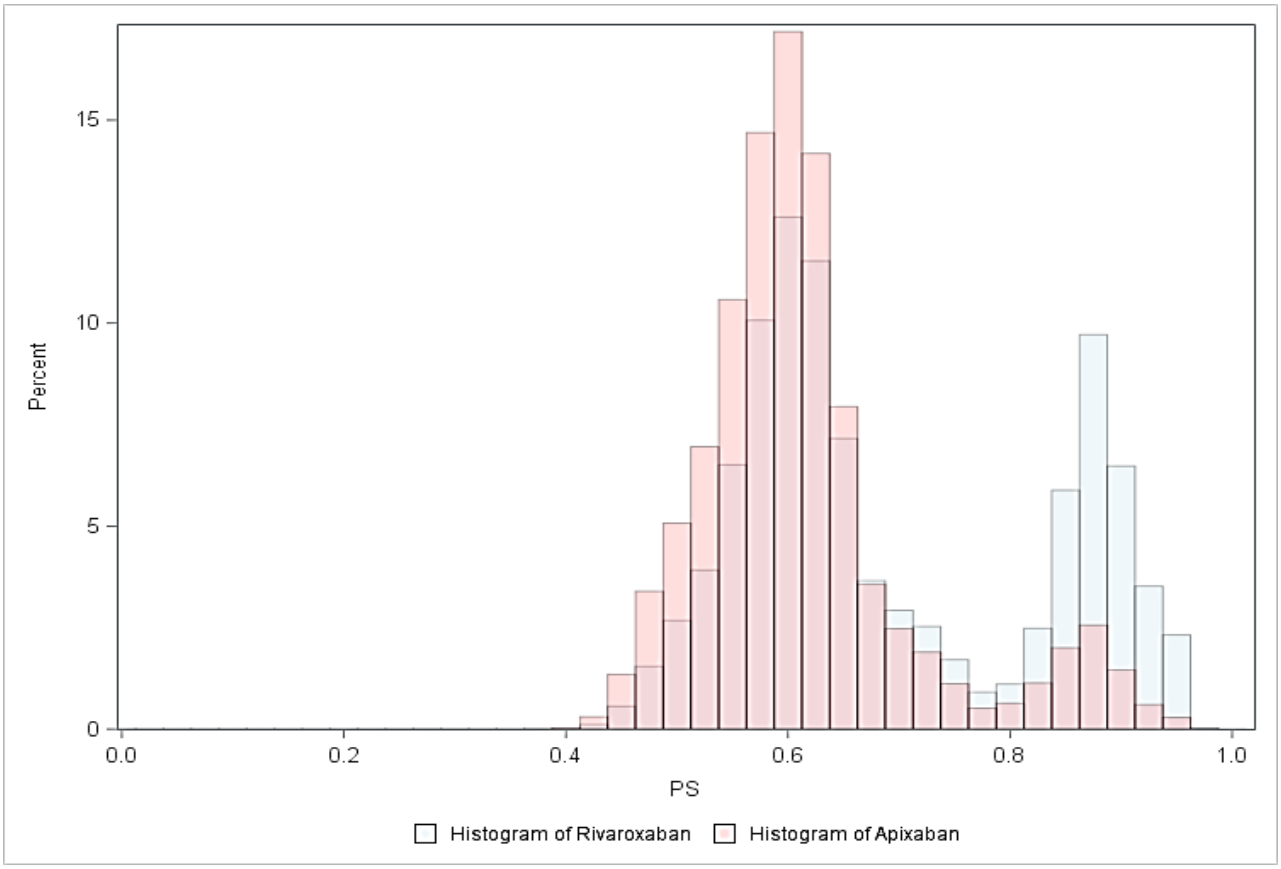


Figure 1d. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed Defined by Surgical Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

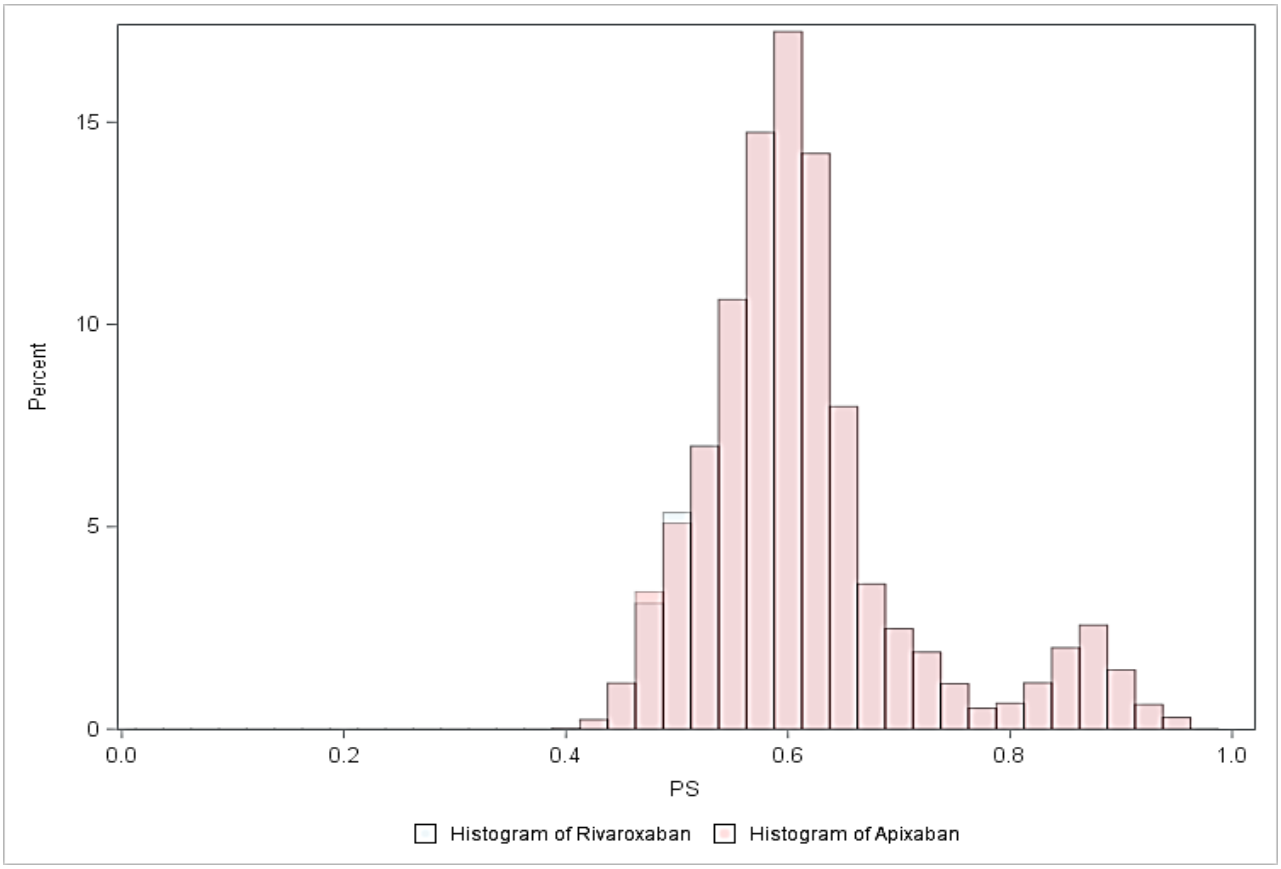


Figure 1e. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed Defined by Surgical Management (Crude, Aggregated)

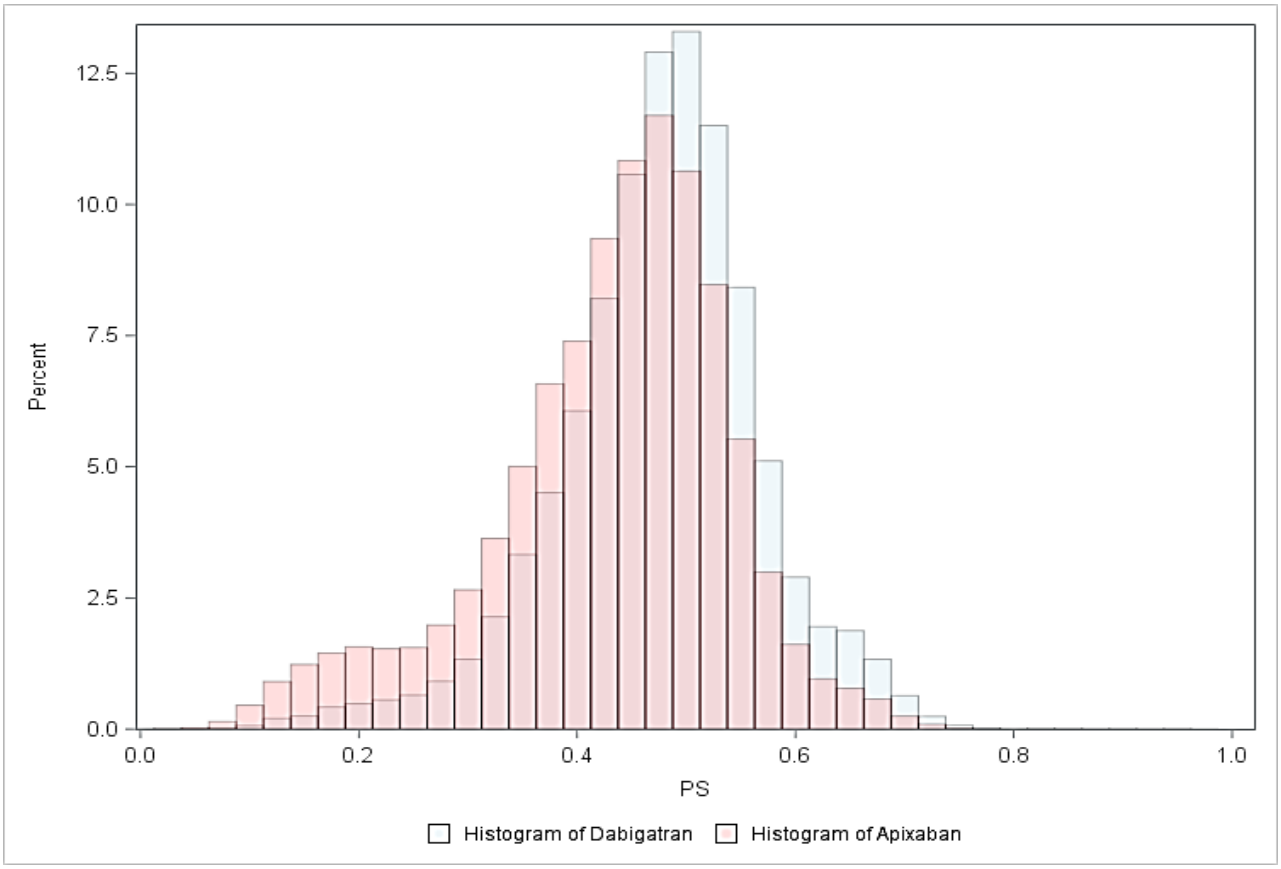


Figure 1f. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed Defined by Surgical Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

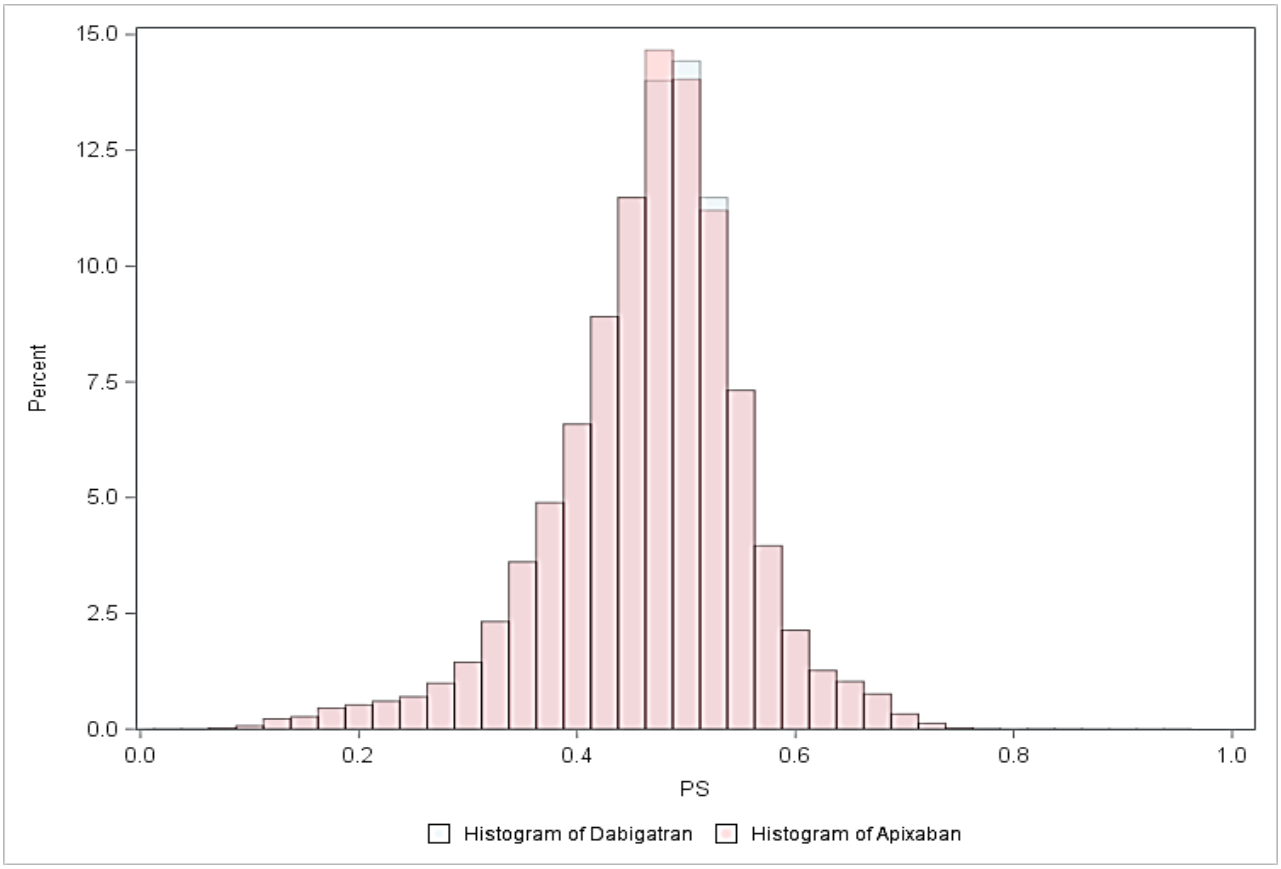


Figure 1g. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed Defined by Surgical Management (Crude, Aggregated)

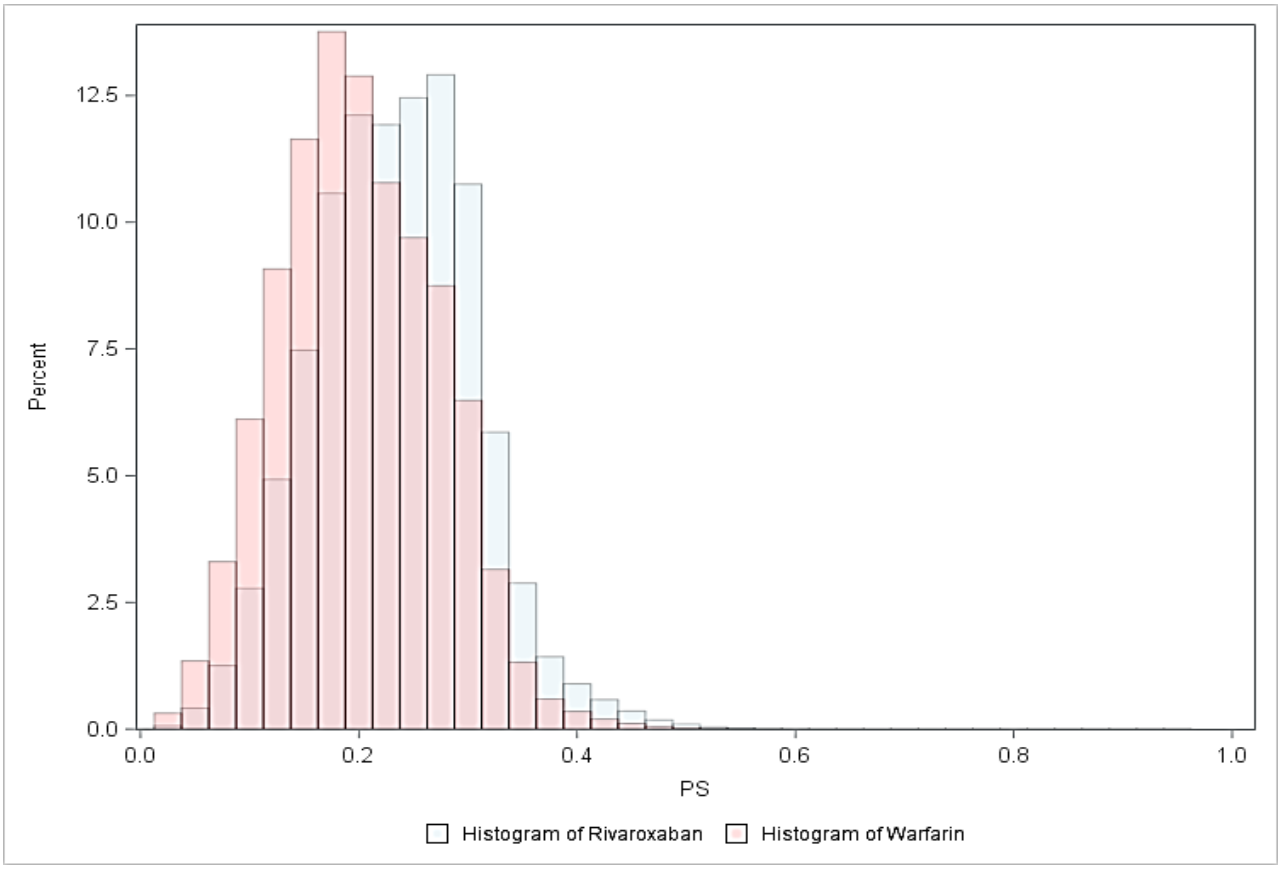


Figure 1h. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed Defined by Surgical Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

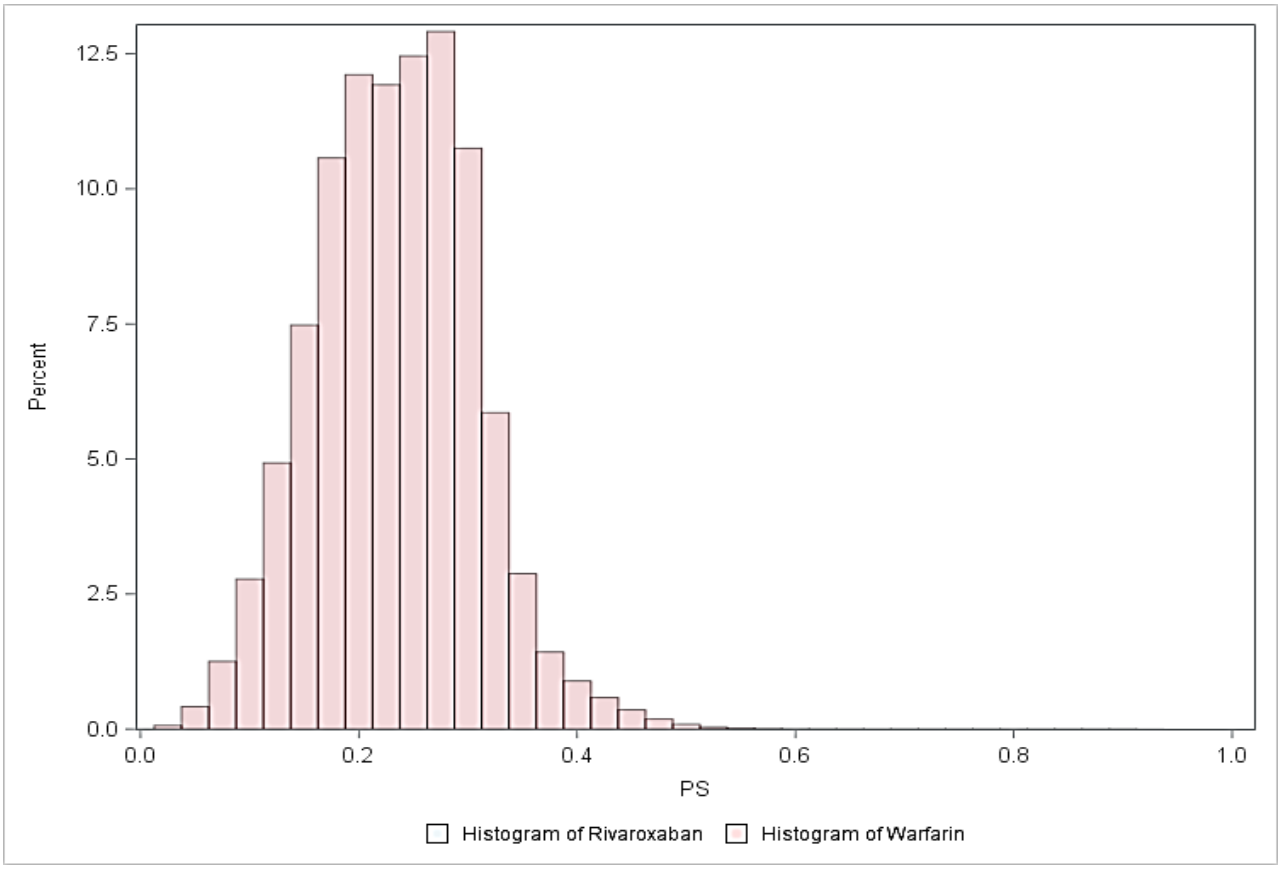


Figure 1i. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed Defined by Transfusion Management (Crude, Aggregated)

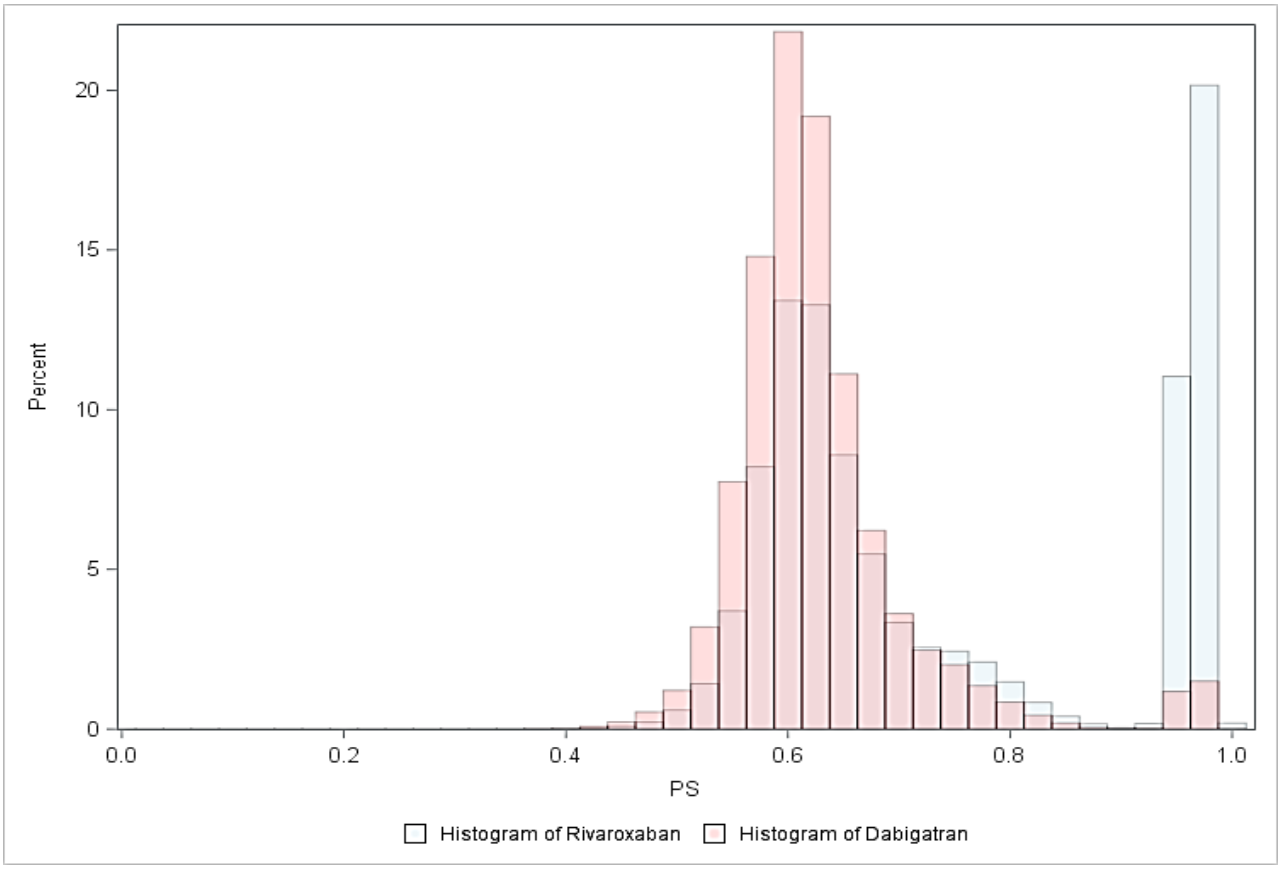


Figure 1j. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed Defined by Transfusion Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

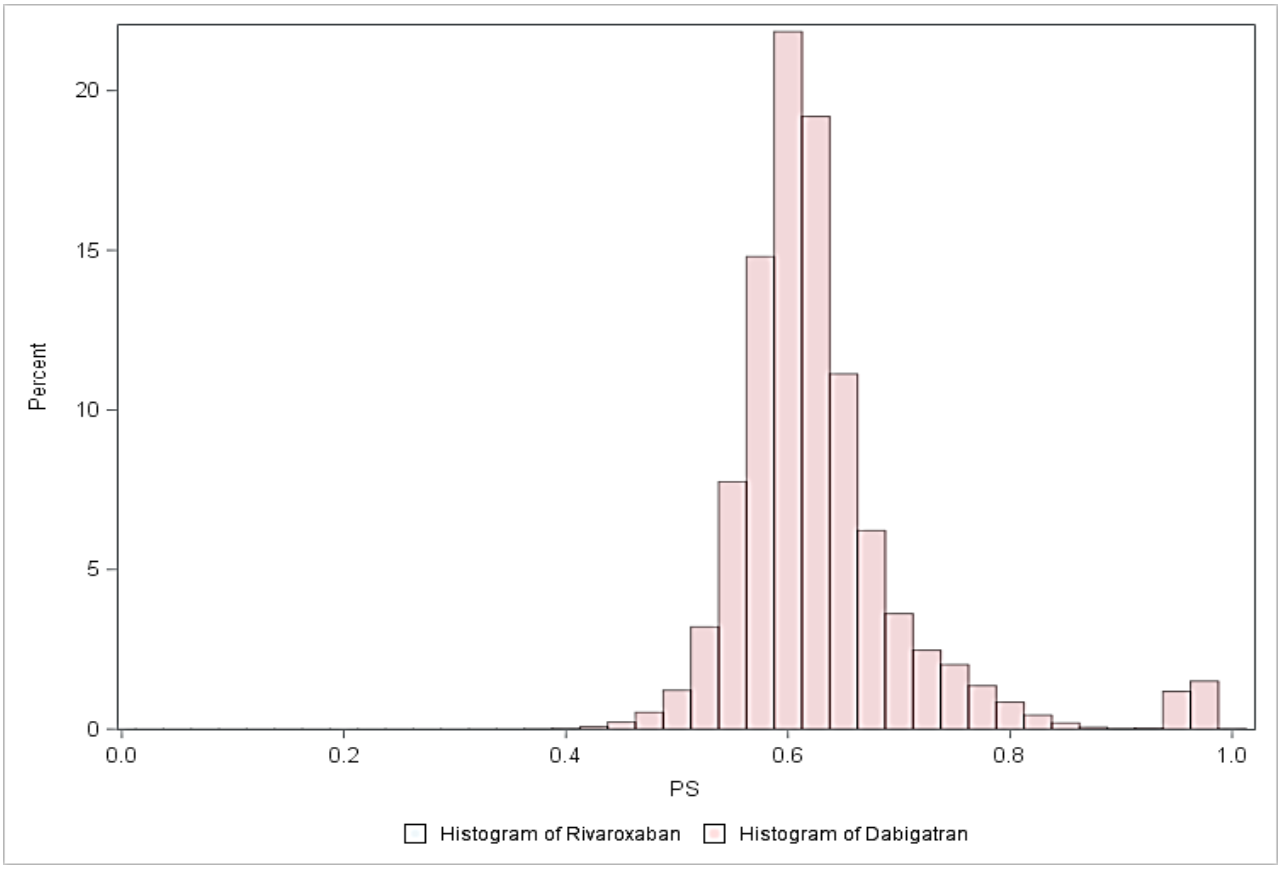


Figure 1k. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed Defined by Transfusion Management (Crude, Aggregated)

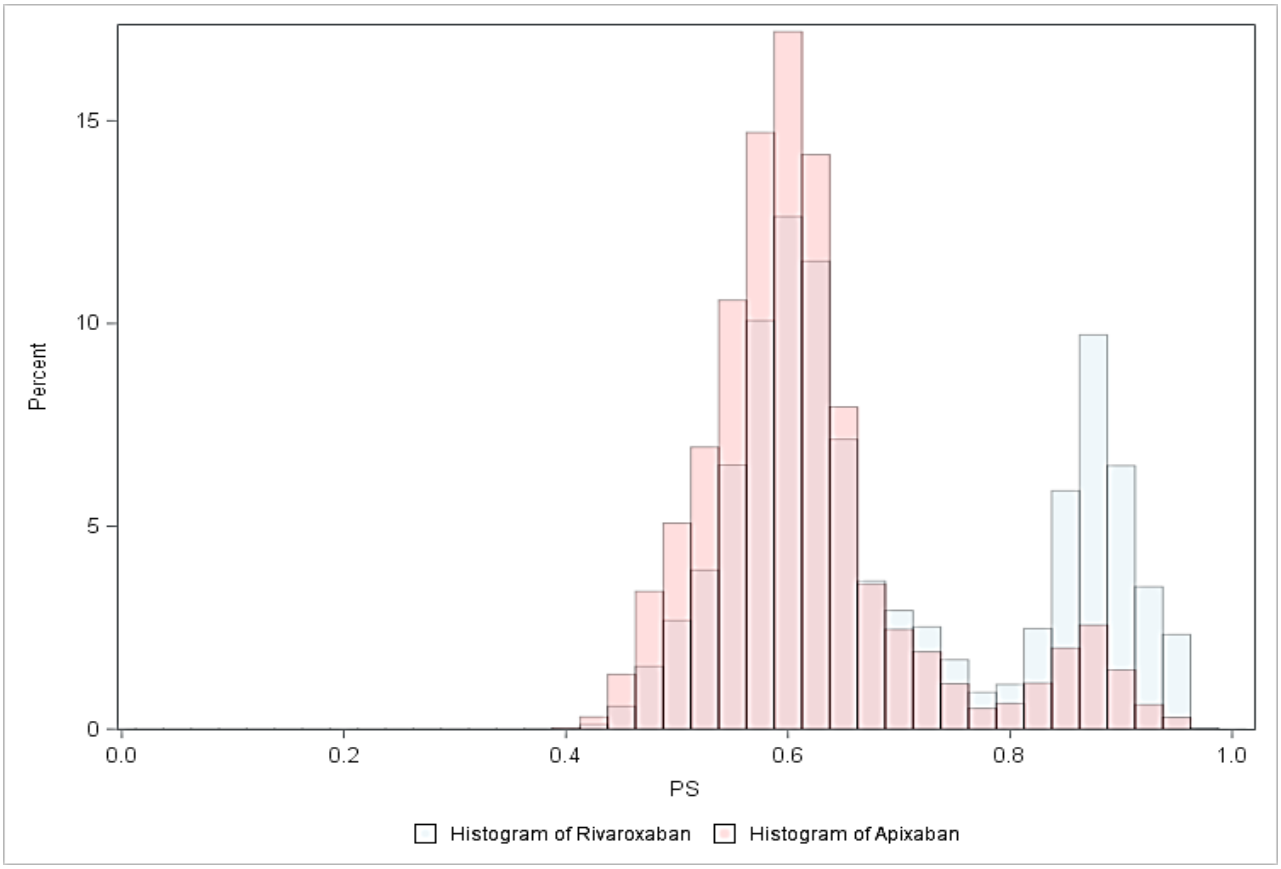


Figure 1l. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed Defined by Transfusion Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

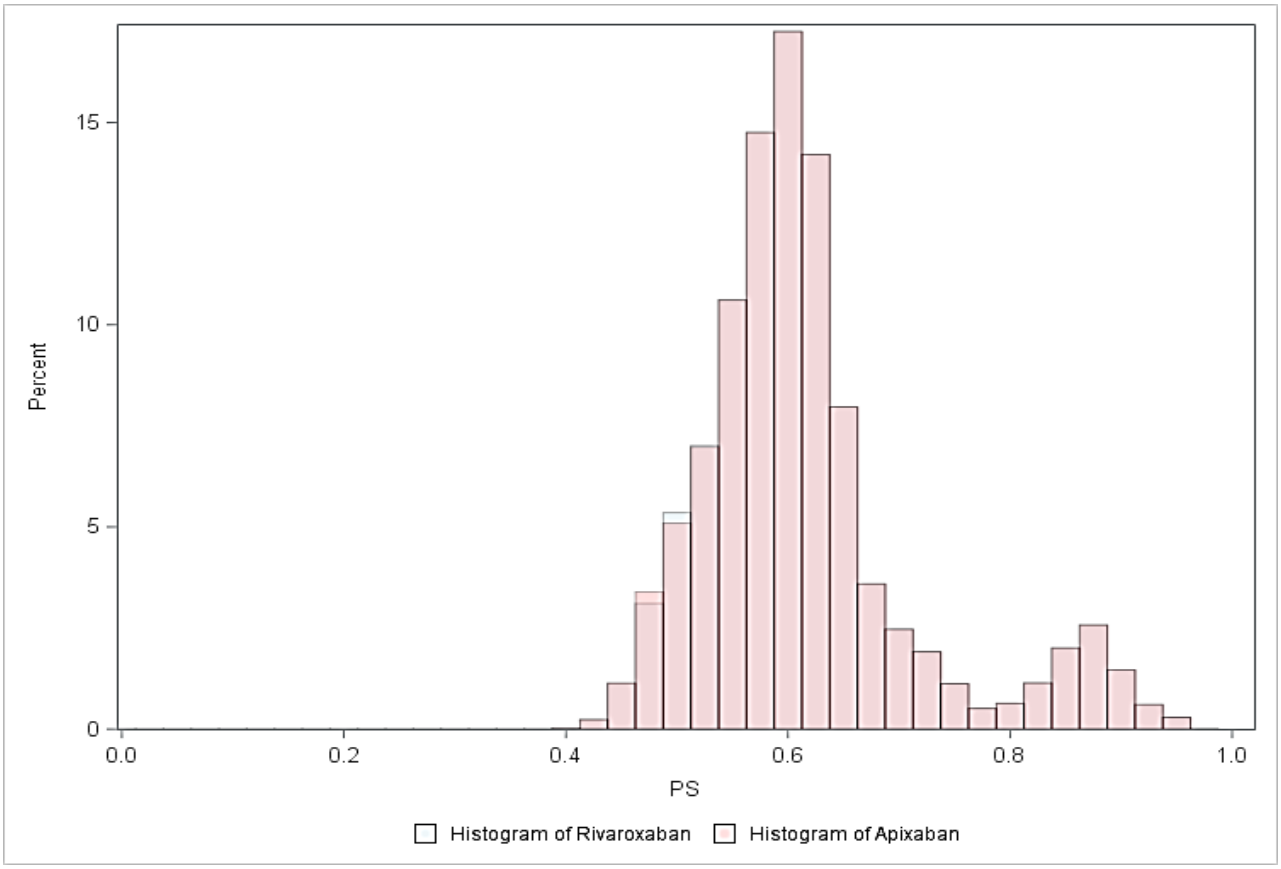


Figure 1m. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed Defined by Transfusion Management (Crude, Aggregated)

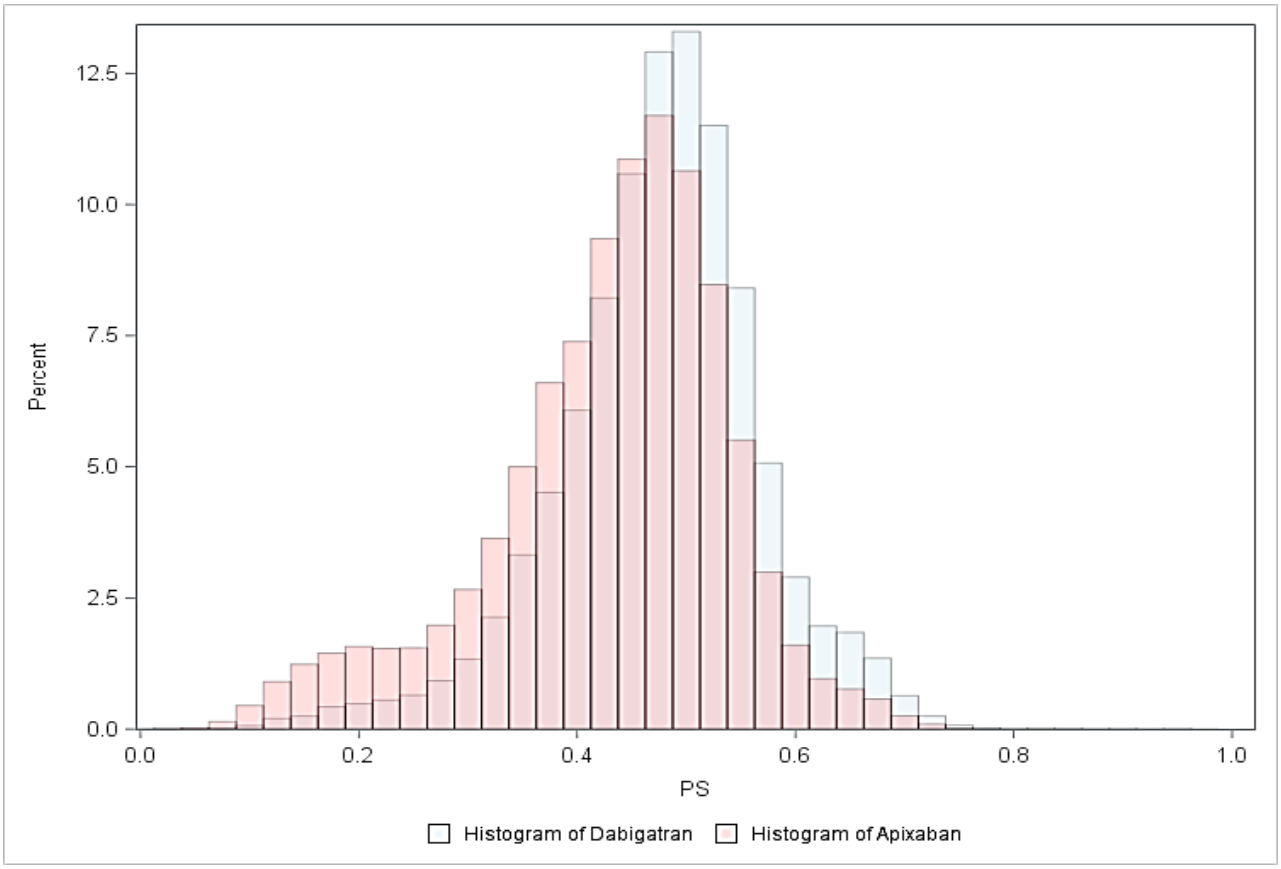


Figure 1n. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed Defined by Transfusion Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

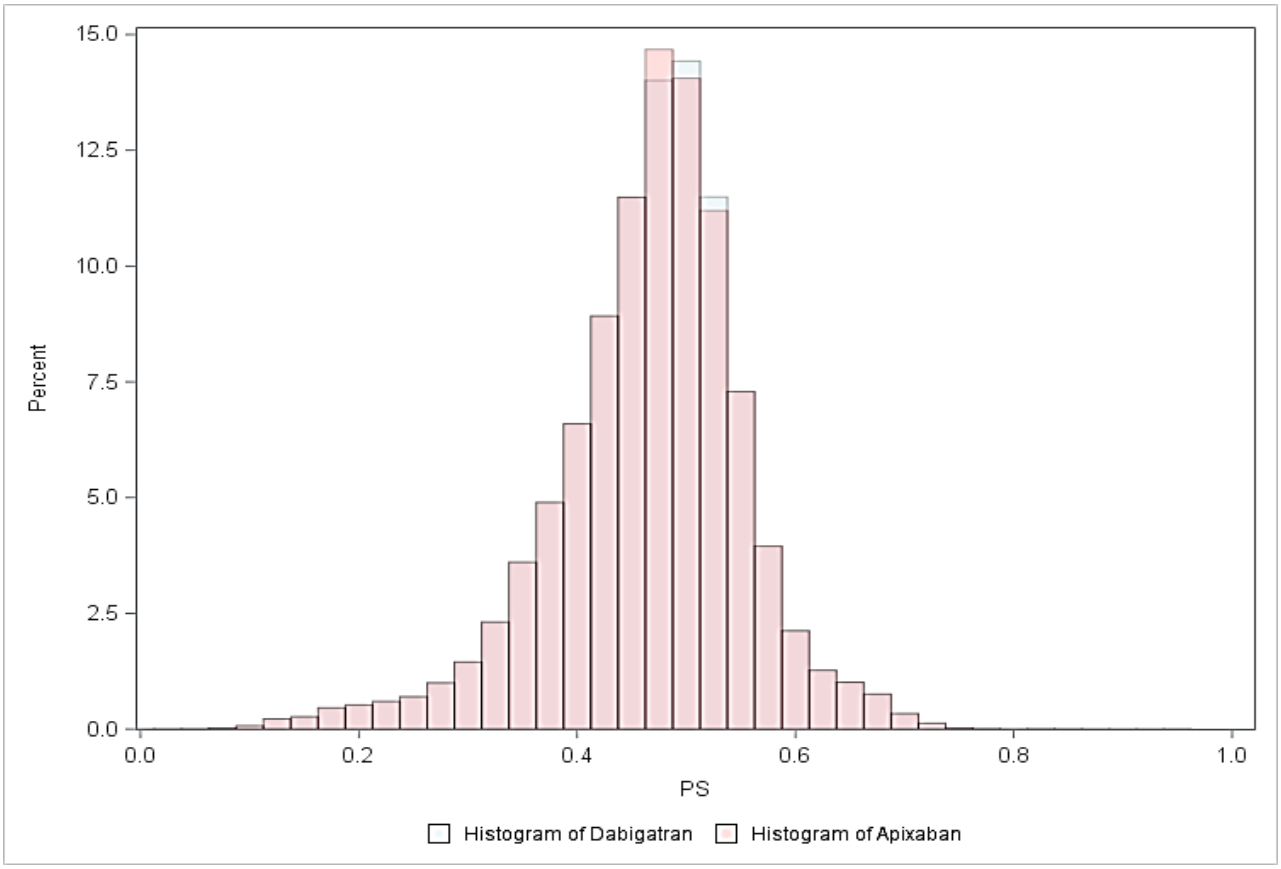


Figure 1o. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed Defined by Transfusion Management (Crude, Aggregated)

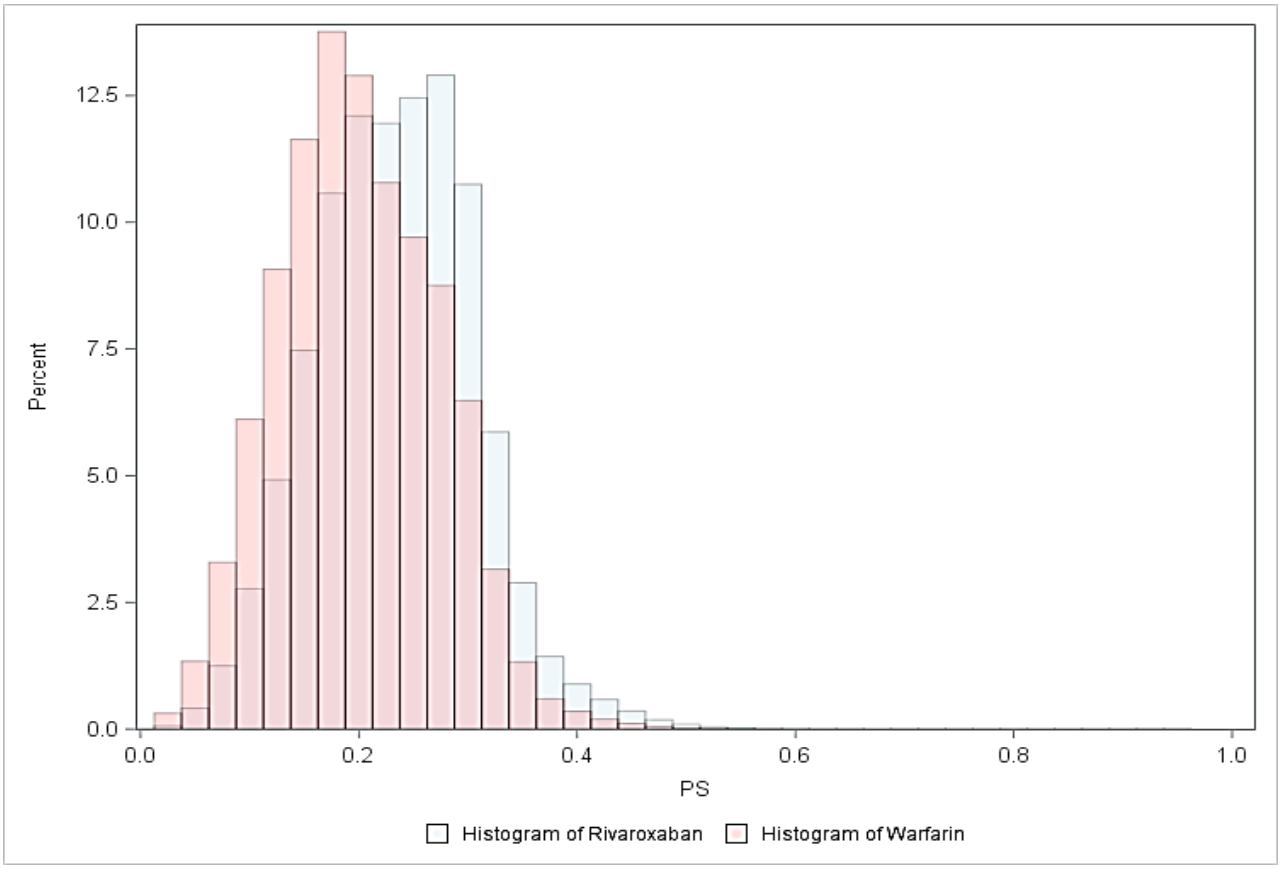


Figure 1p. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed Defined by Transfusion Management (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

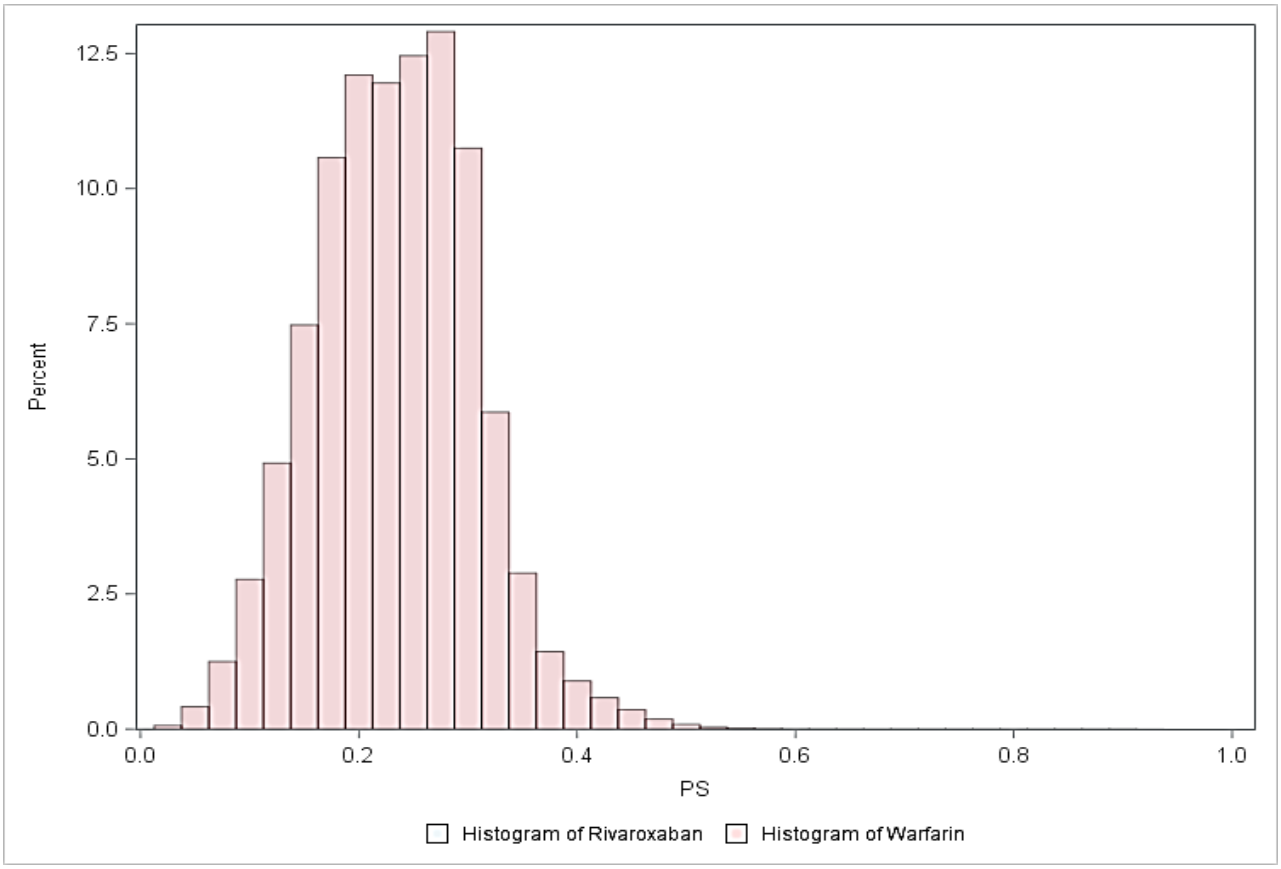
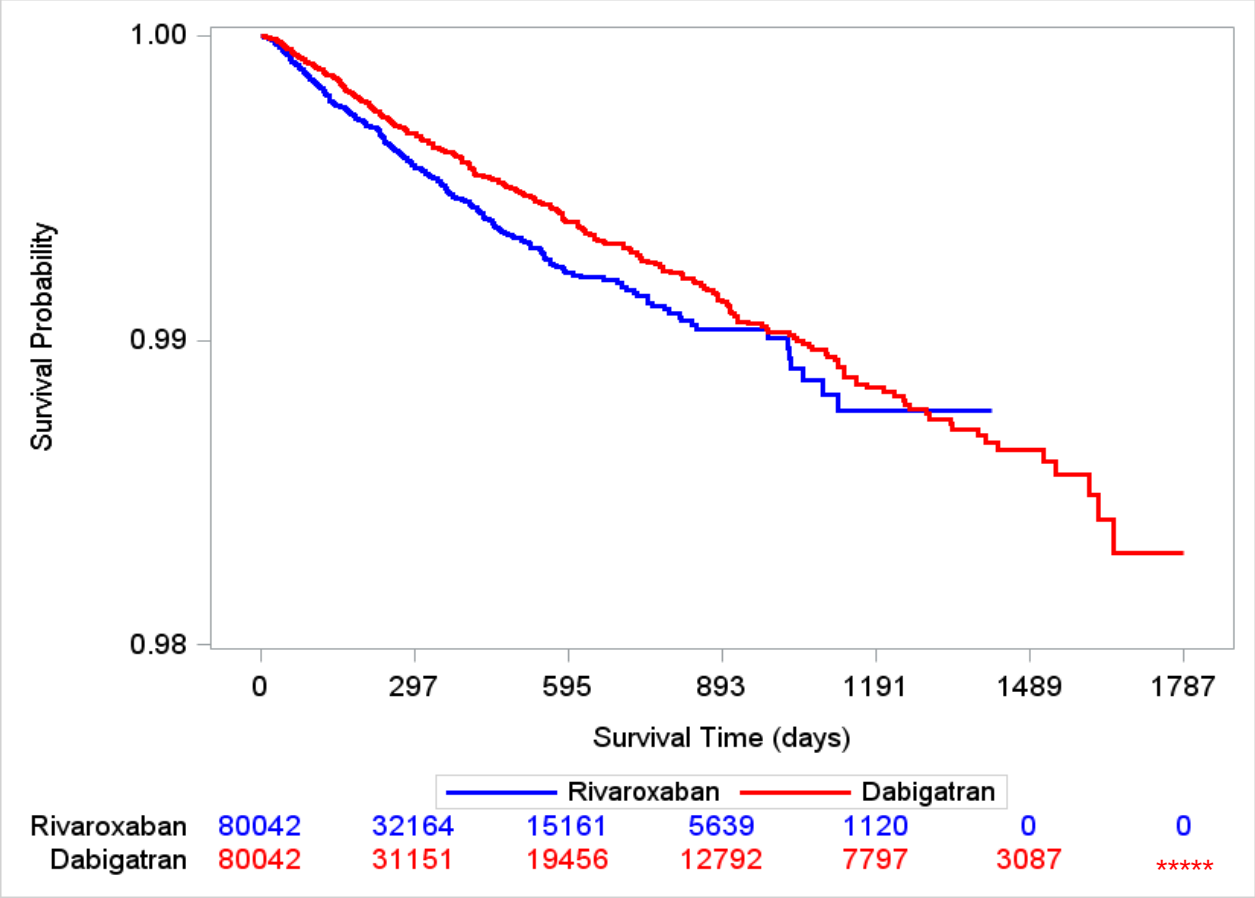
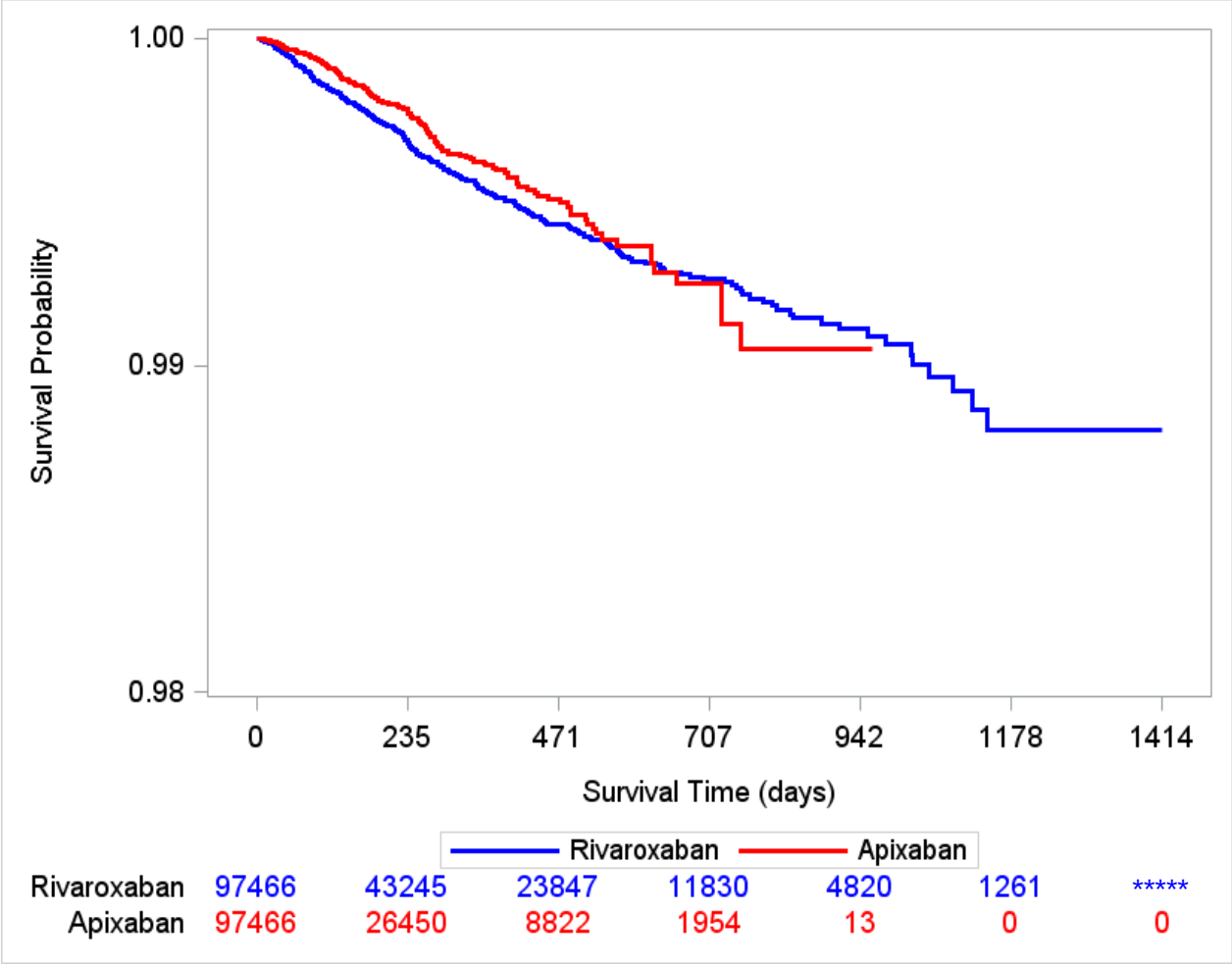


Figure 2a. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Rivaroxaban and Dabigatran, Unconditional Matched Cohort



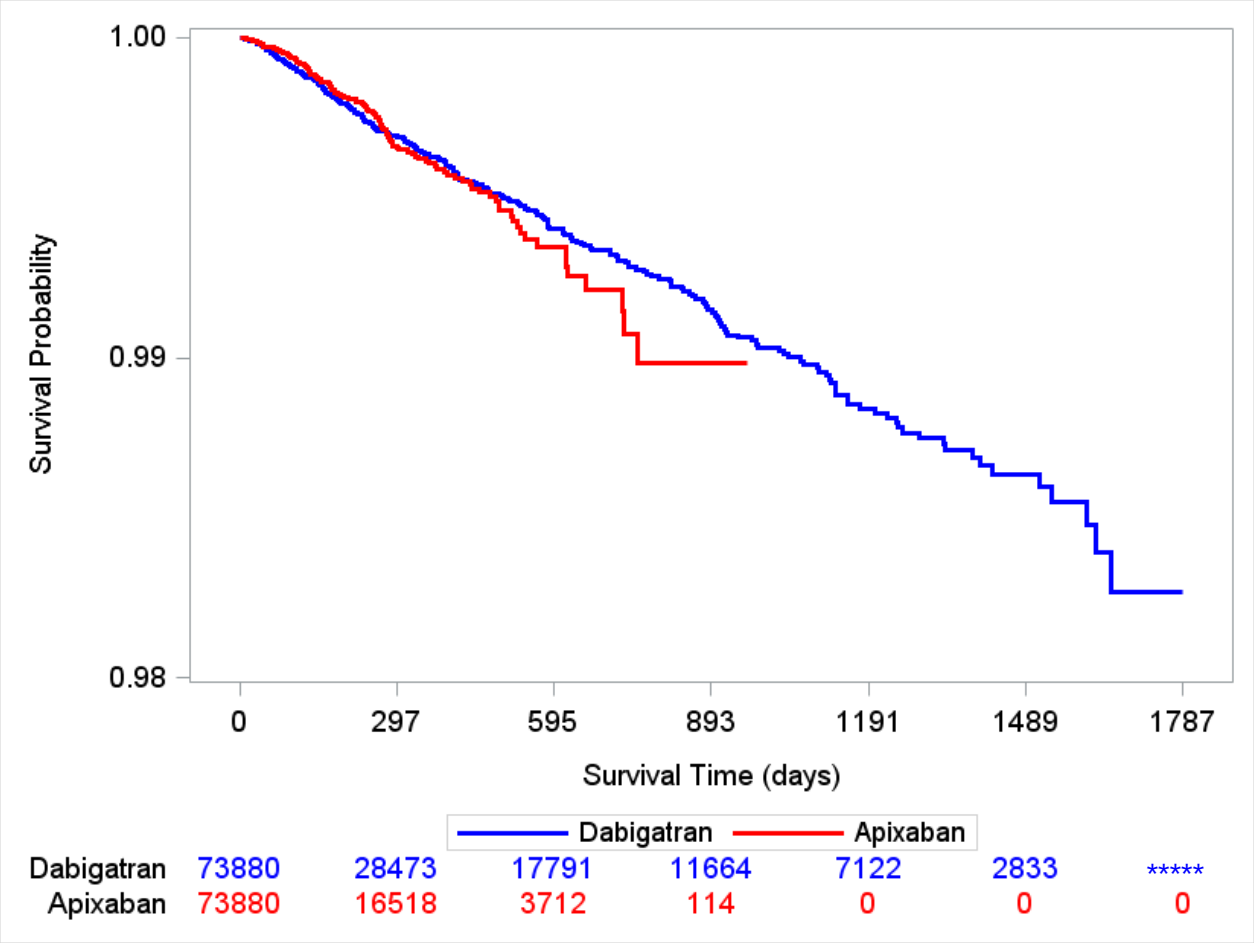
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2b. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Rivaroxaban and Apixaban, Unconditional Matched Cohort



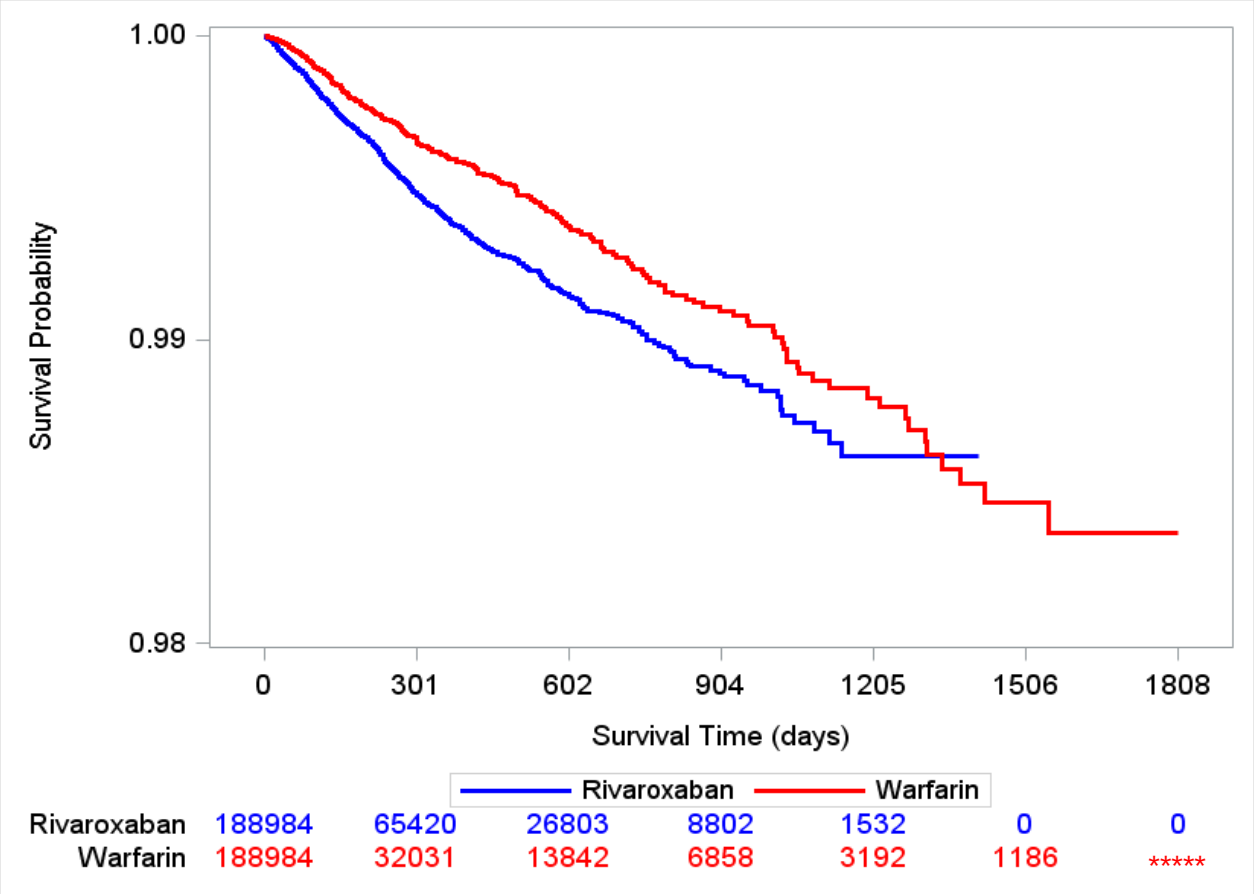
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2c. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Dabigatran and Apixaban, Unconditional Matched Cohort



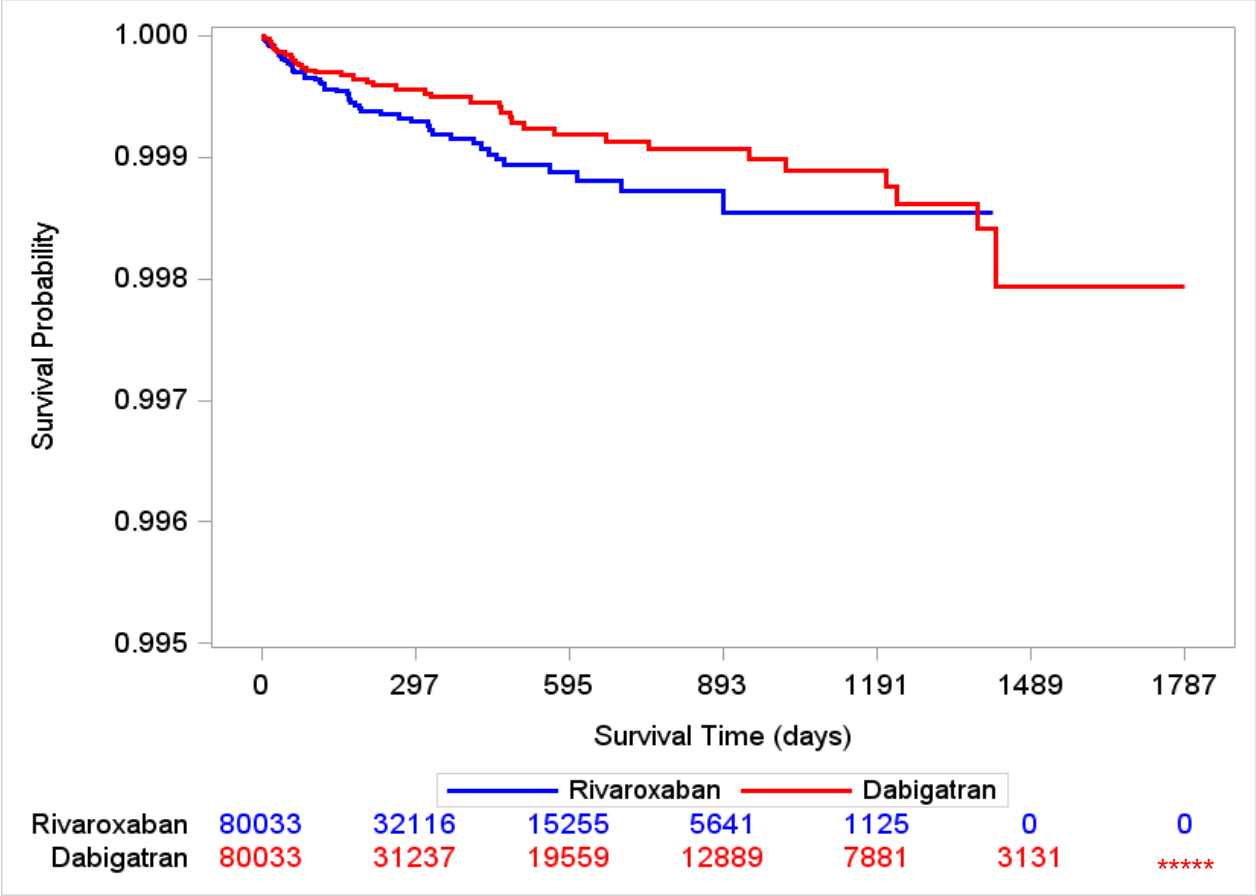
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2d. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Rivaroxaban and Warfarin, Unconditional Matched Cohort



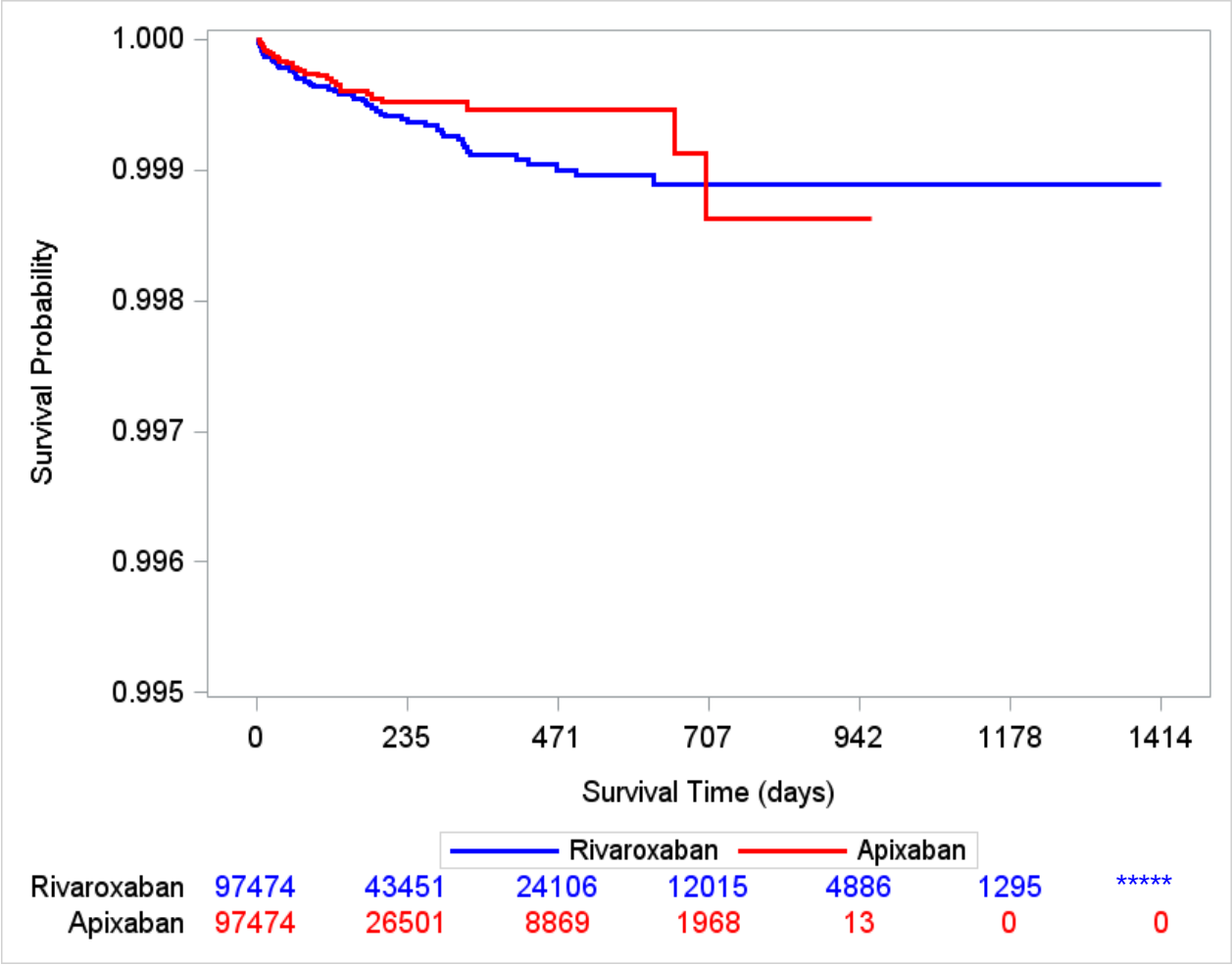
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2e. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Rivaroxaban and Dabigatran, Unconditional Matched Cohort



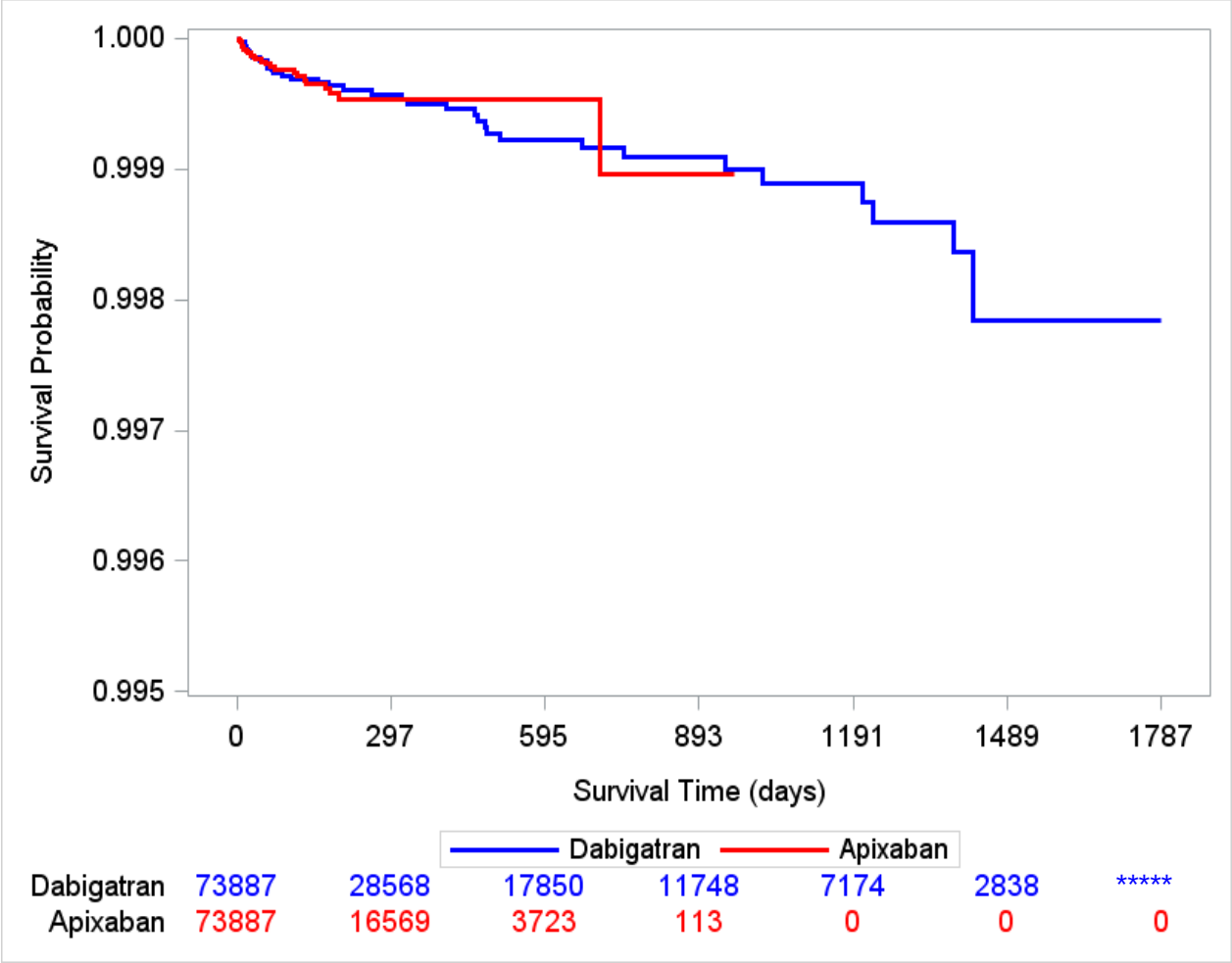
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2f. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Rivaroxaban and Apixaban, Unconditional Matched Cohort



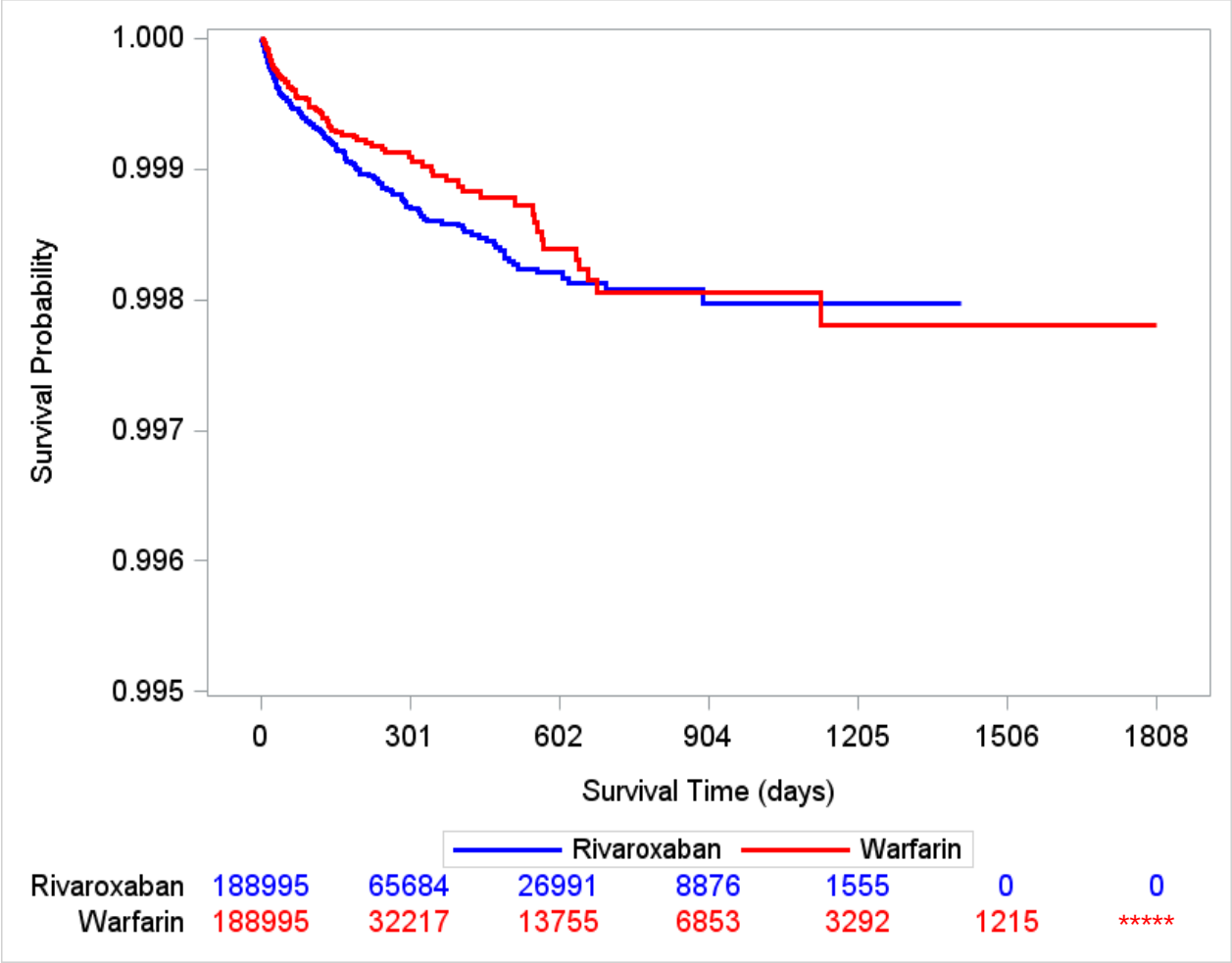
*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2g. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Dabigatran and Apixaban, Unconditional Matched Cohort



*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Figure 2h. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Rivaroxaban and Warfarin, Unconditional Matched Cohort



*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Appendix A. Dates of Available Data for Each Data Partner as of Request Distribution Date (December 30, 2019)"

Data Partner (Masked)	DP Start Date[1]	DP End Date[1]
DP01	01/01/2000	09/30/2015
DP02	01/01/2000	09/30/2015
DP03	01/01/2006	09/30/2015
DP04	01/01/2000	09/30/2015
DP05	01/01/2008	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 Oral Anticoagulants in this Request

Generic Name	Brand Name
Novel Oral Anticoagulants (NOACs) and Warfarin	
apixaban	Eliquis
dabigatran etexilate mesylate	Pradaxa
rivaroxaban	Xarelto
warfarin sodium	Coumadin
warfarin sodium	Warfarin
warfarin sodium	Jantoven
Incidence and Exclusion Criteria Only	
edoxaban tosylate	Savaysa

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) Diagnosis and Procedure Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type	Code Category
	Atrial Fibrillation / Atrial Flutter		
427.3	Atrial Fibrillation and flutter	ICD-9-CM	Diagnosis
427.31	Atrial Fibrillation	ICD-9-CM	Diagnosis
427.32	Atrial flutter	ICD-9-CM	Diagnosis
	Deep Vein Thrombosis / Pulmonary Embolism		
415.1	Pulmonary embolism and infarction	ICD-9-CM	Diagnosis
415.11	Iatrogenic pulmonary embolism and infarction	ICD-9-CM	Diagnosis
415.12	Septic pulmonary embolism	ICD-9-CM	Diagnosis
415.19	Other pulmonary embolism and infarction	ICD-9-CM	Diagnosis
416.2	Chronic pulmonary embolism	ICD-9-CM	Diagnosis
434.0	Cerebral thrombosis	ICD-9-CM	Diagnosis
434.00	Cerebral thrombosis without mention of cerebral infarction	ICD-9-CM	Diagnosis
434.01	Cerebral thrombosis with cerebral infarction	ICD-9-CM	Diagnosis
437.6	Nonpyogenic thrombosis of intracranial venous sinus	ICD-9-CM	Diagnosis
444	Arterial embolism and thrombosis	ICD-9-CM	Diagnosis
444.0	Arterial embolism and thrombosis of abdominal aorta	ICD-9-CM	Diagnosis
444.09	Other arterial embolism and thrombosis of abdominal aorta	ICD-9-CM	Diagnosis
444.1	Embolism and thrombosis of thoracic aorta	ICD-9-CM	Diagnosis
444.2	Embolism and thrombosis of arteries of the extremities	ICD-9-CM	Diagnosis
444.21	Embolism and thrombosis of arteries of upper extremity	ICD-9-CM	Diagnosis
444.22	Embolism and thrombosis of arteries of lower extremity	ICD-9-CM	Diagnosis
444.8	Embolism and thrombosis of other specified artery	ICD-9-CM	Diagnosis
444.81	Embolism and thrombosis of iliac artery	ICD-9-CM	Diagnosis
444.89	Embolism and thrombosis of other specified artery	ICD-9-CM	Diagnosis
444.9	Embolism and thrombosis of unspecified artery	ICD-9-CM	Diagnosis
451.11	Phlebitis and thrombophlebitis of femoral vein (deep) (superficial)	ICD-9-CM	Diagnosis
451.19	Phlebitis and thrombophlebitis of other deep vessels of lower extremities	ICD-9-CM	Diagnosis
451.2	Phlebitis and thrombophlebitis of lower extremities, unspecified	ICD-9-CM	Diagnosis
451.81	Phlebitis and thrombophlebitis of iliac vein	ICD-9-CM	Diagnosis
451.83	Phlebitis and thrombophlebitis of deep veins of upper extremities	ICD-9-CM	Diagnosis
452	Portal vein thrombosis	ICD-9-CM	Diagnosis
453	Other venous embolism and thrombosis	ICD-9-CM	Diagnosis
453.2	Other venous embolism and thrombosis, of inferior vena cava	ICD-9-CM	Diagnosis
453.3	Embolism and thrombosis of renal vein	ICD-9-CM	Diagnosis
453.4	Acute venous embolism and thrombosis of deep vessels of lower extremity	ICD-9-CM	Diagnosis
453.40	Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity	ICD-9-CM	Diagnosis
453.41	Acute venous embolism and thrombosis of deep vessels of proximal lower extremity	ICD-9-CM	Diagnosis
453.42	Acute venous embolism and thrombosis of deep vessels of distal lower extremity	ICD-9-CM	Diagnosis
453.5	Chronic venous embolism and thrombosis of deep vessels of lower extremity	ICD-9-CM	Diagnosis
453.50	Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity	ICD-9-CM	Diagnosis
453.51	Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity	ICD-9-CM	Diagnosis
453.52	Chronic venous embolism and thrombosis of deep vessels of distal lower extremity	ICD-9-CM	Diagnosis
453.6	Venous embolism and thrombosis of superficial vessels of lower extremity	ICD-9-CM	Diagnosis
453.7	Chronic venous embolism and thrombosis of other specified vessels	ICD-9-CM	Diagnosis

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) Diagnosis and Procedure Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type	Code Category
453.71	Chronic venous embolism and thrombosis of superficial veins of upper extremity	ICD-9-CM	Diagnosis
453.72	Chronic venous embolism and thrombosis of deep veins of upper extremity	ICD-9-CM	Diagnosis
453.73	Chronic venous embolism and thrombosis of upper extremity, unspecified	ICD-9-CM	Diagnosis
453.74	Chronic venous embolism and thrombosis of axillary veins	ICD-9-CM	Diagnosis
453.75	Chronic venous embolism and thrombosis of subclavian veins	ICD-9-CM	Diagnosis
453.76	Chronic venous embolism and thrombosis of internal jugular veins	ICD-9-CM	Diagnosis
453.77	Chronic venous embolism and thrombosis of other thoracic veins	ICD-9-CM	Diagnosis
453.79	Chronic venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.8	Acute venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.81	Acute venous embolism and thrombosis of superficial veins of upper extremity	ICD-9-CM	Diagnosis
453.82	Acute venous embolism and thrombosis of deep veins of upper extremity	ICD-9-CM	Diagnosis
453.83	Acute venous embolism and thrombosis of upper extremity, unspecified	ICD-9-CM	Diagnosis
453.84	Acute venous embolism and thrombosis of axillary veins	ICD-9-CM	Diagnosis
453.85	Acute venous embolism and thrombosis of subclavian veins	ICD-9-CM	Diagnosis
453.86	Acute venous embolism and thrombosis of internal jugular veins	ICD-9-CM	Diagnosis
453.87	Acute venous embolism and thrombosis of other thoracic veins	ICD-9-CM	Diagnosis
453.89	Acute venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.9	Embolism and thrombosis of unspecified site	ICD-9-CM	Diagnosis
671.3	Deep phlebothrombosis, antepartum	ICD-9-CM	Diagnosis
671.30	Deep phlebothrombosis, antepartum, unspecified as to episode of care	ICD-9-CM	Diagnosis
671.31	Deep phlebothrombosis, antepartum, with delivery	ICD-9-CM	Diagnosis
671.33	Deep phlebothrombosis, antepartum	ICD-9-CM	Diagnosis
671.4	Deep phlebothrombosis, postpartum	ICD-9-CM	Diagnosis
671.40	Deep phlebothrombosis, postpartum, unspecified as to episode of care	ICD-9-CM	Diagnosis
671.42	Deep phlebothrombosis, postpartum, with delivery	ICD-9-CM	Diagnosis
671.44	Deep phlebothrombosis, postpartum condition or complication	ICD-9-CM	Diagnosis
671.5	Other phlebitis and thrombosis in pregnancy and the puerperium	ICD-9-CM	Diagnosis
671.50	Other phlebitis and thrombosis complicating pregnancy and the puerperium, unspecified as to episode of care	ICD-9-CM	Diagnosis
671.51	Other phlebitis and thrombosis with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.52	Other phlebitis and thrombosis with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.53	Other antepartum phlebitis and thrombosis	ICD-9-CM	Diagnosis
671.54	Other phlebitis and thrombosis, postpartum condition or complication	ICD-9-CM	Diagnosis
673	Obstetrical pulmonary embolism	ICD-9-CM	Diagnosis
673.8	Other obstetrical pulmonary embolism	ICD-9-CM	Diagnosis
673.80	Other obstetrical pulmonary embolism, unspecified as to episode of care	ICD-9-CM	Diagnosis
673.81	Other obstetrical pulmonary embolism, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
673.82	Other obstetrical pulmonary embolism, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
673.83	Other obstetrical pulmonary embolism, antepartum	ICD-9-CM	Diagnosis
673.84	Other obstetrical pulmonary embolism, postpartum condition or complication	ICD-9-CM	Diagnosis
V12.51	Personal history of venous thrombosis and embolism	ICD-9-CM	Diagnosis
	Knee or Hip Joint Replacement Surgery		
01214	Anesthesia for open procedures involving hip joint; total hip arthroplasty	CPT-4	Procedure
01215	Anesthesia for open procedures involving hip joint; revision of total hip arthroplasty	CPT-4	Procedure

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) Diagnosis and Procedure Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type	Code Category
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	CPT-4	Procedure
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	CPT-4	Procedure
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	CPT-4	Procedure
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	CPT-4	Procedure
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	CPT-4	Procedure
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	CPT-4	Procedure
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	CPT-4	Procedure
27265	Closed treatment of post hip arthroplasty dislocation; without anesthesia	CPT-4	Procedure
27266	Closed treatment of post hip arthroplasty dislocation; requiring regional or general anesthesia	CPT-4	Procedure
27437	Arthroplasty, patella; without prosthesis	CPT-4	Procedure
27438	Arthroplasty, patella; with prosthesis	CPT-4	Procedure
27440	Arthroplasty, knee, tibial plateau;	CPT-4	Procedure
27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy	CPT-4	Procedure
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;	CPT-4	Procedure
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy	CPT-4	Procedure
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)	CPT-4	Procedure
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment	CPT-4	Procedure
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	CPT-4	Procedure
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	CPT-4	Procedure
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	CPT-4	Procedure
29862	Arthroscopy, hip, surgical; with debridement/shaving of articular cartilage (chondroplasty), abrasion arthroplasty, and/or resection of labrum	CPT-4	Procedure
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture	CPT-4	Procedure
81.5	Joint replacement of lower extremity	ICD-9-CM	Procedure
	Hysterectomy		
00846	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy	CPT-4	Procedure
00855	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy	CPT-4	Procedure
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	CPT-4	Procedure
01962	Anesthesia for urgent hysterectomy following delivery	CPT-4	Procedure
01963	Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care	CPT-4	Procedure
01969	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure performed)	CPT-4	Procedure
51925	closure of vesicouterine fistula; w/hysterectomy	CPT-4	Procedure
58150	tah w/wo removal of tube w/wo removal of ovary;	CPT-4	Procedure

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) Diagnosis and Procedure Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type	Code Category
58152	tah; w/wo remv tube-ovry w/colpo-urethrocystopex	CPT-4	Procedure
58180	supracerv abd hysterectomy w/wo remov tube-ovary	CPT-4	Procedure
58200	tah incl part vaginect w/pelv lymph node sampl	CPT-4	Procedure
58205	Total Hysterectomy, Extended, Corpus Cancer, Including Partial	CPT-4	Procedure
58210	rad abd hyst w/bilat tot pelvic lymphadenect bx	CPT-4	Procedure
58260	vag hyst 250 gm/<	CPT-4	Procedure
58262	vag hyst 250 gm/< w/rmvl tube&/ovary	CPT-4	Procedure
58263	vag hyst 250 gm/< w/rmvl tube ovary w/rpr ntrcl	CPT-4	Procedure
58265	Vaginal Hysterectomy With Plastic Repair Of Vagina, Anterior	CPT-4	Procedure
58267	vag hyst 250 gm/< w/colpo-urtcstopexy	CPT-4	Procedure
58270	vag hyst 250 gm/< w/rpr ntrcl	CPT-4	Procedure
58275	vag hyst with total or partial vaginectomy;	CPT-4	Procedure
58280	vag hyst w/tot/part vaginectomy; w/repr enterocl	CPT-4	Procedure
58285	vaginal hysterectomy radical	CPT-4	Procedure
58290	vag hyst for uterus greater than 250 grams;	CPT-4	Procedure
58291	vag hyst utrus >250 gms; w/remv tube &/ ovary	CPT-4	Procedure
58292	vag hyst utrus>250 gms; remv t&/o rep enterocl	CPT-4	Procedure
58293	vag hyst utrus > 250 gms; w/colpo-urethrocystProcedurey	CPT-4	Procedure
58294	vag hyst uterus > 250 grams; w/repair enterocele	CPT-4	Procedure
58541	laps supracrv hyst 250 g/<	CPT-4	Procedure
58542	laps supracrv hyst 250 g/< rmvl tube/ovary	CPT-4	Procedure
58543	laps supracrv hyst >250 g	CPT-4	Procedure
58544	laps supracrv hyst >250 g rmvl tube/ovary	CPT-4	Procedure
58548	laps w/rad hyst w/bilat lmphadec rmvl tube/ovary	CPT-4	Procedure
58550	laparscpy surg w/vag hyst uterus 250 gms/less;	CPT-4	Procedure
58552	lap vag hyst utrus 250 gms/<; w/remv tube&/ovry	CPT-4	Procedure
58553	laparscpy surgical w/vag hyst uterus > 250 gms;	CPT-4	Procedure
58554	lap w/vag hyst utrus >250 gms; w/remv tube&/ovry	CPT-4	Procedure
58570	laparoscopy w total hysterectomy uterus 250 g/<	CPT-4	Procedure
58571	laps total hysterectomy 250 g/<w tube/ovary	CPT-4	Procedure
58572	laparoscopy total hysterectomy uterus>250 g	CPT-4	Procedure
58573	laparoscopy tot hysterectomy >250 g w tube/ovary	CPT-4	Procedure
58951	rescj prim prtl mal w/bso&omntc tah&lmphadec	CPT-4	Procedure
58953	bilat s-o w/omentect tah&radl dissect debulking;	CPT-4	Procedure
58954	bil s-o w/omentect tah&radl dbulk; pelv lymphect	CPT-4	Procedure
58956	bil salpingooophorect w/tot omentect tah malig	CPT-4	Procedure
59100	hysterotomy abdominal	CPT-4	Procedure
59135	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy	CPT-4	Procedure
59525	subtotal/total hysterectomy after c-sect deliv	CPT-4	Procedure
59560	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59561	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59580	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
59581	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
S2078	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)	HCPCS	Procedure
68.3	Subtotal abdominal hysterectomy	ICD-9-CM	Procedure
68.31	Laparoscopic supracervical hysterectomy [LSH]	ICD-9-CM	Procedure
68.39	Other and unspecified subtotal abdominal hysterectomy	ICD-9-CM	Procedure
68.4	Total abdominal hysterectomy	ICD-9-CM	Procedure
68.41	Laparoscopic total abdominal hysterectomy	ICD-9-CM	Procedure

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) Diagnosis and Procedure Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type	Code Category
68.49	Other and unspecified total abdominal hysterectomy	ICD-9-CM	Procedure
68.5	Vaginal hysterectomy	ICD-9-CM	Procedure
68.51	Laparoscopically assisted vaginal hysterectomy (LAVH)	ICD-9-CM	Procedure
68.59	Other and unspecified vaginal hysterectomy	ICD-9-CM	Procedure
68.6	Radical abdominal hysterectomy	ICD-9-CM	Procedure
68.61	Laparoscopic radical abdominal hysterectomy	ICD-9-CM	Procedure
68.69	Other and unspecified radical abdominal hysterectomy	ICD-9-CM	Procedure
68.7	Radical vaginal hysterectomy	ICD-9-CM	Procedure
68.71	Laparoscopic radical vaginal hysterectomy [LRVH]	ICD-9-CM	Procedure
68.79	Other and unspecified radical vaginal hysterectomy	ICD-9-CM	Procedure
68.9	Other and unspecified hysterectomy	ICD-9-CM	Procedure
618.5	Prolapse of vaginal vault after hysterectomy	ICD-9-CM	Diagnosis
68.8	pelvic evisceration	ICD-9-CM	Procedure
Vaginal Bleed			
See Appendix E for diagnosis codes for vaginal bleed.			
Transfusion Management			
See Appendix F for procedure codes for transfusion management.			
Surgical Management			
See Appendix F for diagnosis and procedure codes for surgical management.			
Medical Management			
See Appendix G for diagnosis and procedure codes for medical management.			

Appendix D. List of Generic and Brand Names of Medical Products Used to Define Inclusion and Exclusion Criteria in this Request

Generic Name	Brand Name
Transfusion Managements	
Conjugated Estrogen	
estrogens, conjugated, synthetic A	Cenestin
estrogens, conjugated, synthetic B	Enjuvia
estrogens, conjugated	Premarin
estrogens, conjugated/medroxyprogesterone acetate	Prempro
estrogens, conjugated/bazedoxifene acetate	Duavee
estrogens, conjugated/medroxyprogesterone acetate	Premphase
Medical Management	
See Appendix H for generic and brand names of medical products used to define medical management.	
Novel Oral Anticoagulants (NOACs)	
See Appendix B for generic and brand names of medical products used to define NOACs.	

Appendix E. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Vaginal Bleed in this Request

Code	Description	Code Type	Code Category
623.8	Other specified noninflammatory disorder of vagina	ICD-9-CM	Diagnosis
623.9	Unspecified noninflammatory disorder of vagina	ICD-9-CM	Diagnosis
626.2	Excessive or frequent menstruation	ICD-9-CM	Diagnosis
626.3	Puberty bleeding	ICD-9-CM	Diagnosis
626.6	Metrorrhagia	ICD-9-CM	Diagnosis
626.8	Other disorder of menstruation and other abnormal bleeding from female genital tract	ICD-9-CM	Diagnosis
626.9	Unspecified disorder of menstruation and other abnormal bleeding from female genital tract	ICD-9-CM	Diagnosis
627.0	Menopausal and postmenopausal disorders	ICD-9-CM	Diagnosis
627.1	Postmenopausal bleeding	ICD-9-CM	Diagnosis
627.4	Symptomatic states associated with artificial menopause	ICD-9-CM	Diagnosis

Appendix F. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Revenue Center Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
	Transfusion Managements		
	Red Blood Cell-Only Transfusion		
C1010	Whole blood or red blood cells, leukoreduced, cmv negative, each unit	HCPCS	Procedure
C1016	Whole blood or red blood cells, leukoreduced, frozen, deglycerol, washed, each unit	HCPCS	Procedure
C1020	Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated.	HCPCS	Procedure
C1021	Red blood cells, leukocyte-reduced, cmv negative, irradiated, each unit	HCPCS	Procedure
P9016	Red blood cells, leukocytes reduced, each unit	HCPCS	Procedure
P9021	Red blood cells, each unit	HCPCS	Procedure
P9022	Red blood cells, washed, each unit	HCPCS	Procedure
P9038	Red blood cells, irradiated, each unit	HCPCS	Procedure
P9039	Red blood cells, deglycerolized, each unit	HCPCS	Procedure
P9040	Red blood cells, leukocytes reduced, irradiated, each unit	HCPCS	Procedure
P9051	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit	HCPCS	Procedure
P9054	Each unit whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed,	HCPCS	Procedure
P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	HCPCS	Procedure
P9058	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit	HCPCS	Procedure
9904	transfusion of packed cells	ICD-9-CM	Procedure
0381	Blood and blood products-packed red cells	Revenue Center	Procedure
	Surgical Managements		
	Hysteroscopic Polypectomy		
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C	CPT-4	Procedure
	Hysteroscopic/Laparoscopic/Abdominal Myomectomy		
218.0	Submucous leiomyoma of uterus	ICD-9-CM[A]	Diagnosis
218	Uterine leiomyoma	ICD-9-CM[A]	Diagnosis
218.1	Intramural leiomyoma of uterus	ICD-9-CM[A]	Diagnosis
218.2	Subserous leiomyoma of uterus	ICD-9-CM[A]	Diagnosis
218.9	Leiomyoma of uterus, unspecified	ICD-9-CM[A]	Diagnosis
56309	LAP SURG; W/REMOV LEIOMYOMATA (SINGL/MX)	CPT-4	Procedure
56354	HYSTEROSCOPY SURG; W/REMOV LEIOMYOMATA	CPT-4	Procedure
58140	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; abdominal approach	CPT-4	Procedure
58145	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; vaginal approach	CPT-4	Procedure
58146	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g, abdominal approach	CPT-4	Procedure
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas	CPT-4	Procedure
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g	CPT-4	Procedure
58561	Hysteroscopy, surgical; with removal of leiomyomata	CPT-4	Procedure
58994	Hysteroscopy; With Removal Of Submucous Leiomyomata (any Method)	CPT-4	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Revenue Center Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
68.19	Other diagnostic procedures on uterus and supporting structures	ICD-9-CM[B]	Procedure
68.29	Other excision or destruction of lesion of uterus	ICD-9-CM[B]	Procedure
69.19	Other excision or destruction of uterus and supporting structures	ICD-9-CM[B]	Procedure
[A]Myomectomy diagnosis codes and [B]myomectomy procedure codes are used in combination to detect myomectomy.			
	Dilation and Curettage (with or without Hysteroscopy)		
57558	Dilation and curettage of cervical stump	CPT-4	Procedure
57820	Dilation and curettage of cervical stump	CPT-4	Procedure
58120	Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical)	CPT-4	Procedure
69.0	Dilation and curettage of uterus	ICD-9-CM	Procedure
69.09	Other dilation and curettage of uterus	ICD-9-CM	Procedure
69.5	Aspiration curettage of uterus	ICD-9-CM	Procedure
69.59	Other aspiration curettage of uterus	ICD-9-CM	Procedure
	Hysteroscopy (Not Listed in Other Surgical Managements)		
00952	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); hysteroscopy and/or hysterosalpingography	CPT-4	Procedure
56352	HYSTEROSCOPY SURG; W/LYSIS INTRAUTERINE ADHESION	CPT-4	Procedure
56353	HYSTEROSCOPY SURG; W/DIVIS/RESECT SEPTUM	CPT-4	Procedure
56355	HYSTEROSCOPY SURG; W/REMOV IMPACTED F B	CPT-4	Procedure
56399	UNLISTED PROC-LAP/HYSTEROSCOPY	CPT-4	Procedure
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)	CPT-4	Procedure
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)	CPT-4	Procedure
58562	Hysteroscopy, surgical; with removal of impacted foreign body	CPT-4	Procedure
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants	CPT-4	Procedure
58992	Hysteroscopy; With Lysis Of Intrauterine Adhesions Or Resection Of Intrauterine Septum (any Method)	CPT-4	Procedure
58995	Hysteroscopy	CPT-4	Procedure
G9823	Endometrial sampling or hysteroscopy with biopsy and results documented	HCPCS	Procedure
G9824	Endometrial sampling or hysteroscopy with biopsy and results not documented	HCPCS	Procedure
S2255	Hysteroscopy, surgical; with occlusion of oviducts bilaterally by micro-inserts for permanent sterilization	HCPCS	Procedure
68.12	Hysteroscopy	ICD-9-CM	Procedure
68.14	Open biopsy of uterine ligaments	ICD-9-CM	Procedure
68.16	Closed biopsy of uterine ligaments	ICD-9-CM	Procedure
	Hysterectomy		
68.3	Subtotal abdominal hysterectomy	ICD-9-CM	Diagnosis
68.31	Laparoscopic supracervical hysterectomy [LSH]	ICD-9-CM	Diagnosis
68.39	Other and unspecified subtotal abdominal hysterectomy	ICD-9-CM	Diagnosis
68.4	Total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.41	Laparoscopic total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.49	Other and unspecified total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.5	Vaginal hysterectomy	ICD-9-CM	Diagnosis
68.51	Laparoscopically assisted vaginal hysterectomy (LAVH)	ICD-9-CM	Diagnosis
68.59	Other and unspecified vaginal hysterectomy	ICD-9-CM	Diagnosis
68.6	Radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.61	Laparoscopic radical abdominal hysterectomy	ICD-9-CM	Diagnosis

Appendix F. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Revenue Center Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
68.69	Other and unspecified radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.7	Radical vaginal hysterectomy	ICD-9-CM	Diagnosis
68.71	Laparoscopic radical vaginal hysterectomy [LRVH]	ICD-9-CM	Diagnosis
68.79	Other and unspecified radical vaginal hysterectomy	ICD-9-CM	Diagnosis
68.9	Other and unspecified hysterectomy	ICD-9-CM	Diagnosis
618.5	Prolapse of vaginal vault after hysterectomy	ICD-9-CM	Diagnosis
00846	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy	CPT-4	Procedure
00855	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy	CPT-4	Procedure
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	CPT-4	Procedure
01962	Anesthesia for urgent hysterectomy following delivery	CPT-4	Procedure
01963	Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care	CPT-4	Procedure
01969	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure performed)	CPT-4	Procedure
51925	closure of vesicouterine fistula; w/hysterectomy	CPT-4	Procedure
58150	tah w/wo removal of tube w/wo removal of ovary;	CPT-4	Procedure
58152	tah; w/wo remv tube-ovry w/colpo-urethrocystopex	CPT-4	Procedure
58180	supracerv abd hysterectomy w/wo remov tube-ovary	CPT-4	Procedure
58200	tah incl part vaginect w/pelv lymph node sampl	CPT-4	Procedure
58205	Total Hysterectomy, Extended, Corpus Cancer, Including Partial	CPT-4	Procedure
58210	rad abd hyst w/bilat tot pelvic lymphadenect bx	CPT-4	Procedure
58260	vag hyst 250 gm/<	CPT-4	Procedure
58262	vag hyst 250 gm/< w/rmvl tube&/ovary	CPT-4	Procedure
58263	vag hyst 250 gm/< w/rmvl tube ovary w/rpr ntrcl	CPT-4	Procedure
58265	Vaginal Hysterectomy With Plastic Repair Of Vagina, Anterior	CPT-4	Procedure
58267	vag hyst 250 gm/< w/colpo-urtcstopexy	CPT-4	Procedure
58270	vag hyst 250 gm/< w/rpr ntrcl	CPT-4	Procedure
58275	vag hyst with total or partial vaginectomy;	CPT-4	Procedure
58280	vag hyst w/tot/part vaginectomy; w/repr enterocl	CPT-4	Procedure
58285	vaginal hysterectomy radical	CPT-4	Procedure
58290	vag hyst for uterus greater than 250 grams;	CPT-4	Procedure
58291	vag hyst utrus >250 gms; w/remv tube &/ ovary	CPT-4	Procedure
58292	vag hyst utrus>250 gms; remv t&/o rep enterocl	CPT-4	Procedure
58293	vag hyst utrus > 250 gms; w/colpo-urethrocystProcedurey	CPT-4	Procedure
58294	vag hyst uterus > 250 grams; w/repair enterocele	CPT-4	Procedure
58541	laps supracrv hyst 250 g/<	CPT-4	Procedure
58542	laps supracrv hyst 250 g/< rmvl tube/ovary	CPT-4	Procedure
58543	laps supracrv hyst >250 g	CPT-4	Procedure
58544	laps supracrv hyst >250 g rmvl tube/ovary	CPT-4	Procedure
58548	laps w/rad hyst w/bilat lmphadec rmvl tube/ovary	CPT-4	Procedure
58550	laparscpy surg w/vag hyst uterus 250 gms/less;	CPT-4	Procedure
58552	lap vag hyst utrus 250 gms/<; w/remv tube&/ovry	CPT-4	Procedure
58553	laparscpy surgical w/vag hyst uterus > 250 gms;	CPT-4	Procedure
58554	lap w/vag hyst utrus >250 gms; w/remv tube&/ovry	CPT-4	Procedure
58570	laparoscopy w total hysterectomy uterus 250 g/<	CPT-4	Procedure
58571	laps total hysterectomy 250 g/<w tube/ovary	CPT-4	Procedure
58572	laparoscopy total hysterectomy uterus>250 g	CPT-4	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Revenue Center Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
58573	laparoscopy tot hysterectomy >250 g w tube/ovary	CPT-4	Procedure
58951	rescj prim prtl mal w/bso&omntc tah&lmphadec	CPT-4	Procedure
58953	bilat s-o w/omentect tah&radl dissect debulking;	CPT-4	Procedure
58954	bil s-o w/omentect tah&radl dbulk; pelv lymphect	CPT-4	Procedure
58956	bil salpingooophorect w/tot omentect tah malig	CPT-4	Procedure
59100	hysterotomy abdominal	CPT-4	Procedure
59135	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy	CPT-4	Procedure
59525	subtotal/total hysterectomy after c-sect deliv	CPT-4	Procedure
59560	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59561	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59580	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
59581	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
S2078	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)	HCPCS	Procedure
683	subtotal abdominal hysterectomy	ICD-9-CM	Procedure
684	total abdominal hysterectomy	ICD-9-CM	Procedure
685	vaginal hysterectomy	ICD-9-CM	Procedure
686	radical abdominal hysterectomy	ICD-9-CM	Procedure
687	radical vaginal hysterectomy	ICD-9-CM	Procedure
688	pelvic evisceration	ICD-9-CM	Procedure
689	hysterectomy nos	ICD-9-CM	Procedure
6831	laparoscopic supracervical hysterectomy	ICD-9-CM	Procedure
6839	other and unspecified subtotal abdominal hysterect	ICD-9-CM	Procedure
6841	laparoscopic total abdominal hysterectomy	ICD-9-CM	Procedure
6849	other and unspecified total abdoinal hysterectomy	ICD-9-CM	Procedure
6851	laparoscopically assisted vaginal hysterectomy	ICD-9-CM	Procedure
6859	other and unspecified vaginal hysterectomy	ICD-9-CM	Procedure
6861	laparoscopic radical abdominal hysterectomy	ICD-9-CM	Procedure
6869	other and unspecified radical abdominal hysterecto	ICD-9-CM	Procedure
6871	laparoscopic radical vaginal hysterectomy	ICD-9-CM	Procedure
6879	other and unspecified radical vaginal hysterectomy	ICD-9-CM	Procedure
	Endometrial Ablation (Thermal, Cryo, Section)		
0009T	Endometrial cryoablation with ultrasonic guidance	CPT Category III	Procedure
56351	HYSTEROSCOPY SURG; W/SAMPL ENDOMETRIUM W/WO D&C	CPT-4	Procedure
56356	HYSTEROSCOPY SURG; W/ENDOMETRIAL ABLATION	CPT-4	Procedure
58353	Endometrial ablation, thermal, without hysteroscopic guidance	CPT-4	Procedure
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed	CPT-4	Procedure
58558	HYSTEROSCOPY BX ENDOMETRIUM&/POLYPC W/WO D&C	CPT-4	Procedure
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)	CPT-4	Procedure
58996	Hysteroscopy; With Endometrial Ablation (any Method)	CPT-4	Procedure
68.23	Endometrial ablation	ICD-9-CM	Procedure
	Uterine Artery Embolization		
37210	Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure	CPT-4	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Revenue Center Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
S2250	Uterine artery embolization for uterine fibroids	HCPCS	Procedure
68.24	Uterine artery embolization [UAE] with coils	ICD-9-CM	Procedure
68.25	Uterine artery embolization [UAE] without coils	ICD-9-CM	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Medical Managements in this Request

Code	Description	Code Type	Code Category
	Medical Managements		
	Insertion of Intrauterine System Device (IUD)		
V25.11	Encounter for insertion of intrauterine contraceptive device	ICD-9-CM	Diagnosis
V25.13	Encounter for removal and reinsertion of intrauterine contraceptive device	ICD-9-CM	Diagnosis
V45.51	Presence of intrauterine contraceptive device	ICD-9-CM	Diagnosis
J7297	Levonorgestrel-releasing intrauterine contraceptive system (Liletta), 52 mg	HCPCS	Procedure
J7298	Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52 mg	HCPCS	Procedure
J7301	Levonorgestrel-releasing intrauterine contraceptive system, 13.5 mg	HCPCS	Procedure
J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg	HCPCS	Procedure
Q0090	Levonorgestrel-releasing intrauterine contraceptive system, (Skyla), 13.5 mg	HCPCS	Procedure
S4980	Levonorgestrel - releasing intrauterine system, each	HCPCS	Procedure
S4981	Insertion of levonorgestrel-releasing intrauterine system	HCPCS	Procedure
S4989	Contraceptive intrauterine device (e.g., Progestacert IUD), including implants and supplies	HCPCS	Procedure
69.7	INSERTION OF INTRAUTERINE CONTRACEPTIVE DEVICE	ICD-9-CM	Procedure
58300	Insertion of intrauterine device (IUD)	CPT-4	Procedure
	Vaginal Packing		
57180	Introduction of any hemostatic agent or pack for spontaneous or traumatic nonobstetrical vaginal hemorrhage (separate procedure)	CPT-4	Procedure
96.14	Vaginal packing	ICD-9-CM	Procedure

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

Generic Name	Brand Name
Medical Managements	
Levonorgestrel Intrauterine System Device (IUD)	
levonorgestrel	Kyleena
levonorgestrel	Liletta
levonorgestrel	Mirena
levonorgestrel	Skyla
Antifibrinolytic	
desmopressin acetate	DDAVP
desmopressin acetate	Desmopressin
desmopressin acetate	Stimate
aminocaproic acid	Amicar
aminocaproic acid	Aminocaproic Acid
tranexamic acid	Cyklokapron
tranexamic acid	Lysteda
tranexamic acid	Tranexamic Acid
Contraception (Combined Oral Contraceptives and Progestin-only Contraceptives)	
desogestrel-ethinyl estradiol	Cyclessa (28)
desogestrel-ethinyl estradiol	Velivet Triphasic Regimen (28)
desogestrel-ethinyl estradiol	Caziant (28)
desogestrel-ethinyl estradiol	Cesia (28)
desogestrel-ethinyl estradiol	Desogen
desogestrel-ethinyl estradiol	Ortho-Cept (28)
desogestrel-ethinyl estradiol	Reclipsen (28)
desogestrel-ethinyl estradiol	Desogestrel-Ethinyl Estradiol
desogestrel-ethinyl estradiol	Apri
desogestrel-ethinyl estradiol	Emoquette
desogestrel-ethinyl estradiol	Isibloom
desogestrel-ethinyl estradiol	Juleber
desogestrel-ethinyl estradiol	Cyred
desogestrel-ethinyl estradiol	Solia
desogestrel-ethinyl estradiol	Enskyce
desogestrel-ethinyl estradiol/ethinyl estradiol	Desog-E.estradiol/E.estradiol
desogestrel-ethinyl estradiol/ethinyl estradiol	Kariva (28)
desogestrel-ethinyl estradiol/ethinyl estradiol	Kimidess (28)
desogestrel-ethinyl estradiol/ethinyl estradiol	Pimtrea (28)
desogestrel-ethinyl estradiol/ethinyl estradiol	Mircette (28)
desogestrel-ethinyl estradiol/ethinyl estradiol	Azurette (28)
desogestrel-ethinyl estradiol/ethinyl estradiol	Viorele (28)
desogestrel-ethinyl estradiol/ethinyl estradiol	Bekyree (28)
drospirenone/ethinyl estradiol/levomefolate calcium	Drospirenone-E.estradiol-Lm.FA
drospirenone/ethinyl estradiol/levomefolate calcium	Beyaz
drospirenone/ethinyl estradiol/levomefolate calcium	Rajani
drospirenone/ethinyl estradiol/levomefolate calcium	Safyral
drospirenone/ethinyl estradiol/levomefolate calcium	Tydemy
estradiol valerate/dienogest	Natazia
ethinyl estradiol/drospirenone	Gianvi (28)
ethinyl estradiol/drospirenone	Drospirenone-Ethinyl Estradiol
ethinyl estradiol/drospirenone	Loryna (28)
ethinyl estradiol/drospirenone	YAZ (28)
ethinyl estradiol/drospirenone	Vestura (28)
ethinyl estradiol/drospirenone	Nikki (28)
ethinyl estradiol/drospirenone	Ocella
ethinyl estradiol/drospirenone	Syeda

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

Generic Name	Brand Name
ethinyl estradiol/drospirenone	Yasmin (28)
ethinyl estradiol/drospirenone	Zarah
ethynodiol diacetate-ethinyl estradiol	Ethynodiol Diac-Eth Estradiol
ethynodiol diacetate-ethinyl estradiol	Kelnor 1/35 (28)
ethynodiol diacetate-ethinyl estradiol	Zovia 1/35E (28)
ethynodiol diacetate-ethinyl estradiol	Kelnor 1-50
ethynodiol diacetate-ethinyl estradiol	Zovia 1/50E (28)
ethynodiol diacetate-ethinyl estradiol	Demulen 1/50 (28)
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Camrese Lo
levonorgestrel/ethinyl estradiol and ethinyl estradiol	L Norgest/E.estradiol-E.estrad
levonorgestrel/ethinyl estradiol and ethinyl estradiol	LoSeasonique
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Amethia Lo
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Rivelsa
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Quartette
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Fayosim
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Camrese
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Seasonique
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Amethia
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Ashlyna
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Daysee
levonorgestrel/ethinyl estradiol/ferrous bisglycinate	Balcoltra
levonorgestrel-ethinyl estradiol	Levonorgestrel-Ethinyl Estrad
levonorgestrel-ethinyl estradiol	Lessina
levonorgestrel-ethinyl estradiol	Aviane
levonorgestrel-ethinyl estradiol	Orsythia
levonorgestrel-ethinyl estradiol	Vienva
levonorgestrel-ethinyl estradiol	Falmina (28)
levonorgestrel-ethinyl estradiol	Lutera (28)
levonorgestrel-ethinyl estradiol	Aubra
levonorgestrel-ethinyl estradiol	Delyla (28)
levonorgestrel-ethinyl estradiol	Sronyx
levonorgestrel-ethinyl estradiol	Larissia
levonorgestrel-ethinyl estradiol	Portia
levonorgestrel-ethinyl estradiol	Altavera (28)
levonorgestrel-ethinyl estradiol	Levora-28
levonorgestrel-ethinyl estradiol	Chateal
levonorgestrel-ethinyl estradiol	Nordette (28)
levonorgestrel-ethinyl estradiol	Levora 0.15/30 (28)
levonorgestrel-ethinyl estradiol	Marlissa
levonorgestrel-ethinyl estradiol	Nordette
levonorgestrel-ethinyl estradiol	Kurvelo
levonorgestrel-ethinyl estradiol	Lillow
levonorgestrel-ethinyl estradiol	Enpresse
levonorgestrel-ethinyl estradiol	Myzilra
levonorgestrel-ethinyl estradiol	Levonest (28)
levonorgestrel-ethinyl estradiol	Trivora (28)
levonorgestrel-ethinyl estradiol	Levonorg-Eth Estrad Triphasic
levonorgestrel-ethinyl estradiol	Lybrel
levonorgestrel-ethinyl estradiol	Amethyst
levonorgestrel-ethinyl estradiol	Jolessa
levonorgestrel-ethinyl estradiol	Introvale
levonorgestrel-ethinyl estradiol	Setlakin
levonorgestrel-ethinyl estradiol	Seasonale Contraceptive

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

Generic Name	Brand Name
levonorgestrel-ethinyl estradiol	Quasense
norethindrone	Ortho Micronor
norethindrone	Norethindrone (contraceptive)
norethindrone	Errin
norethindrone	Camila
norethindrone	Deblitane
norethindrone	Sharobel
norethindrone	Lyza
norethindrone	Norlyroc
norethindrone	Nor-QD
norethindrone	Nora-BE
norethindrone	Jolivette
norethindrone	Micronor (28)
norethindrone	Jencycla
norethindrone	Heather
norethindrone	Norlyda
norethindrone acetate-ethinyl estradiol	Norethindrone Ac-Eth Estradiol
norethindrone acetate-ethinyl estradiol	Junel 1/20 (21)
norethindrone acetate-ethinyl estradiol	Gildess 1/20 (21)
norethindrone acetate-ethinyl estradiol	Larin 1/20 (21)
norethindrone acetate-ethinyl estradiol	Loestrin 1/20 (21)
norethindrone acetate-ethinyl estradiol	Microgestin 1/20 (21)
norethindrone acetate-ethinyl estradiol	Junel 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Gildess 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Larin 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Loestrin 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Microgestin 1.5/30 (21)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Taytulla
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Lo Minastrin Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Lo Loestrin Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Junel Fe 24
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Norethindrone-E.estradiol-Iron
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Loestrin 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Junel FE 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Gildess FE 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Gildess 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Larin Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Larin 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Microgestin FE 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Loestrin Fe 1/20 (28-Day)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Tarina Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Microgestin 24 FE
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Lomedia 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Blisovi 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Blisovi Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Junel FE 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Gildess FE 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Larin Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Loestrin Fe 1.5/30 (28-Day)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Microgestin Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Blisovi Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Estrostep Fe-28
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Tri-Legest Fe

Generic Name	Brand Name
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Tilia Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Minastrin 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Mibelas 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Melodetta 24 Fe
norethindrone-ethinyl estradiol	Ortho-Novum 1/35 (28)
norethindrone-ethinyl estradiol	Nortrel 1/35 (21)
norethindrone-ethinyl estradiol	Nortrel 1/35 (28)
norethindrone-ethinyl estradiol	Cyclafem 1/35 (28)
norethindrone-ethinyl estradiol	Dasetta 1/35 (28)
norethindrone-ethinyl estradiol	Necon 1/35 (28)
norethindrone-ethinyl estradiol	Norinyl 1/35 (28)
norethindrone-ethinyl estradiol	Pirmella
norethindrone-ethinyl estradiol	Alyacen 1/35 (28)
norethindrone-ethinyl estradiol	Ovcon-50 (28)
norethindrone-ethinyl estradiol	Zenchent (28)
norethindrone-ethinyl estradiol	Ovcon-35 (28)
norethindrone-ethinyl estradiol	Balziva (28)
norethindrone-ethinyl estradiol	Gildagia
norethindrone-ethinyl estradiol	Philith
norethindrone-ethinyl estradiol	Vyfemla (28)
norethindrone-ethinyl estradiol	Briellyn
norethindrone-ethinyl estradiol	Ortho-Novum 7/7/7 (28)
norethindrone-ethinyl estradiol	Nortrel 7/7/7 (28)
norethindrone-ethinyl estradiol	Cyclafem 7/7/7 (28)
norethindrone-ethinyl estradiol	Dasetta 7/7/7 (28)
norethindrone-ethinyl estradiol	Necon 7/7/7 (28)
norethindrone-ethinyl estradiol	Ortho-Novum 7/7/7 (21)
norethindrone-ethinyl estradiol	Alyacen 7/7/7 (28)
norethindrone-ethinyl estradiol	Aranelle (28)
norethindrone-ethinyl estradiol	Tri-Norinyl (28)
norethindrone-ethinyl estradiol	Leena 28
norethindrone-ethinyl estradiol	Modicon (28)
norethindrone-ethinyl estradiol	Nortrel 0.5/35 (28)
norethindrone-ethinyl estradiol	Wera (28)
norethindrone-ethinyl estradiol	Necon 0.5/35 (28)
norethindrone-ethinyl estradiol	Brevicon (28)
norethindrone-ethinyl estradiol	Necon 10/11 (28)
norethindrone-ethinyl estradiol/ferrous fumarate	Zeosa
norethindrone-ethinyl estradiol/ferrous fumarate	Noreth-Ethinyl Estradiol-Iron
norethindrone-ethinyl estradiol/ferrous fumarate	Femcon Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Zenchent Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Wymzya Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Layolis Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Generess Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Kaitlib Fe
norethindrone-mestranol	Necon 1/50 (28)
norethindrone-mestranol	Norinyl 1+50 (28)
norgestimate-ethinyl estradiol	Ortho Tri-Cyclen LO (28)
norgestimate-ethinyl estradiol	Ortho Tri-Cyclen (28)
norgestimate-ethinyl estradiol	Tri-Lo-Sprintec
norgestimate-ethinyl estradiol	Norgestimate-Ethinyl Estradiol
norgestimate-ethinyl estradiol	Tri-Sprintec (28)
norgestimate-ethinyl estradiol	Tri-Previfem (28)

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

Generic Name	Brand Name
norgestimate-ethinyl estradiol	Tri-Estarylla
norgestimate-ethinyl estradiol	Tri-Lo-Estarylla
norgestimate-ethinyl estradiol	Tri-Linyah
norgestimate-ethinyl estradiol	TriNessa (28)
norgestimate-ethinyl estradiol	Tri-VyLibra
norgestimate-ethinyl estradiol	TriNessa Lo
norgestimate-ethinyl estradiol	Tri-Lo-Marzia
norgestimate-ethinyl estradiol	Tri Femynor
norgestimate-ethinyl estradiol	Ortho-Cyclen (28)
norgestimate-ethinyl estradiol	Sprintec (28)
norgestimate-ethinyl estradiol	Previfem
norgestimate-ethinyl estradiol	Estarylla
norgestimate-ethinyl estradiol	Mono-Linyah
norgestimate-ethinyl estradiol	VyLibra
norgestimate-ethinyl estradiol	Mononessa (28)
norgestimate-ethinyl estradiol	Femynor
norgestrel-ethinyl estradiol	Lo-Ovral (28)
norgestrel-ethinyl estradiol	Cryselle (28)
norgestrel-ethinyl estradiol	Elinest
norgestrel-ethinyl estradiol	Norgestrel-Ethinyl Estradiol
norgestrel-ethinyl estradiol	Low-Ogestrel (28)
norgestrel-ethinyl estradiol	Lo-Ovral (8)
norgestrel-ethinyl estradiol	Ogestrel (28)
norgestrel-ethinyl estradiol	Ovral (21)
norgestrel-ethinyl estradiol	Ovral (28)

Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System (HCPCS), and Revenue Center Diagnosis and Procedure Codes Used to Define Covariates and Subgroups in this Request

Code	Description	Code Type	Code Category
	Diabetes		
250	Diabetes mellitus	ICD-9-CM	Diagnosis
250.0	Diabetes mellitus without mention of complication	ICD-9-CM	Diagnosis
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.1	Diabetes with ketoacidosis	ICD-9-CM	Diagnosis
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.2	Diabetes with hyperosmolarity	ICD-9-CM	Diagnosis
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.3	Diabetes with other coma	ICD-9-CM	Diagnosis
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.33	Diabetes with other coma, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.4	Diabetes with renal manifestations	ICD-9-CM	Diagnosis
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.5	Diabetes with ophthalmic manifestations	ICD-9-CM	Diagnosis
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.6	Diabetes with neurological manifestations	ICD-9-CM	Diagnosis
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis

Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System (HCPCS), and Revenue Center Diagnosis and Procedure Codes Used to Define Covariates and Subgroups in this Request

Code	Description	Code Type	Code Category
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.7	Diabetes with peripheral circulatory disorders	ICD-9-CM	Diagnosis
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.8	Diabetes with other specified manifestations	ICD-9-CM	Diagnosis
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.9	Diabetes with unspecified complication	ICD-9-CM	Diagnosis
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multidensity insert(s), per shoe	HCPCS	Procedure
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe	HCPCS	Procedure
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with roller or rigid rocker bottom, per shoe	HCPCS	Procedure
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe	HCPCS	Procedure
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe	HCPCS	Procedure
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe	HCPCS	Procedure
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe	HCPCS	Procedure
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe	HCPCS	Procedure
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe	HCPCS	Procedure

Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System (HCPCS), and Revenue Center Diagnosis and Procedure Codes Used to Define Covariates and Subgroups in this Request

Code	Description	Code Type	Code Category
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each	HCPCS	Procedure
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer or higher), includes arch filler and other shaping material, custom fabricated, each	HCPCS	Procedure
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	HCPCS	Procedure
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes	HCPCS	Procedure
G0245	Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) the diagnosis of LOPS, (2) a patient history, (3) a physical examination that consists of at least the following elements: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and	HCPCS	Procedure
G0246	Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) a patient history, (2) a physical examination that includes: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (3) patient	HCPCS	Procedure
G0247	Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include the local care of superficial wounds (i.e., superficial to muscle and fascia) and at least the following, if present: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails	HCPCS	Procedure
G8015	Diabetic patient with most recent hemoglobin A1c level (within the last 6 months) documented as greater than 9%	HCPCS	Procedure
G8016	Diabetic patient with most recent hemoglobin A1c level (within the last 6 months) documented as less than or equal to 9%	HCPCS	Procedure
G8017	Clinician documented that diabetic patient was not eligible candidate for hemoglobin A1c measure	HCPCS	Procedure
G8018	Clinician has not provided care for the diabetic patient for the required time for hemoglobin A1c measure (6 months)	HCPCS	Procedure
G8019	Diabetic patient with most recent low-density lipoprotein (within the last 12 months) documented as greater than or equal to 100 mg/dl	HCPCS	Procedure
G8020	Diabetic patient with most recent low-density lipoprotein (within the last 12 months) documented as less than 100 mg/dl	HCPCS	Procedure
G8021	Clinician documented that diabetic patient was not eligible candidate for low-density lipoprotein measure	HCPCS	Procedure
G8022	Clinician has not provided care for the diabetic patient for the required time for low-density lipoprotein measure (12 months)	HCPCS	Procedure

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Code	Description	Code Type	Code Category
G8023	Diabetic patient with most recent blood pressure (within the last 6 months) documented as equal to or greater than 140 systolic or equal to or greater than 80 mm Hg diastolic	HCPCS	Procedure
G8024	Diabetic patient with most recent blood pressure (within the last 6 months) documented as less than 140 systolic and less than 80 diastolic	HCPCS	Procedure
G8025	Clinician documented that the diabetic patient was not eligible candidate for blood pressure measure	HCPCS	Procedure
G8026	Clinician has not provided care for the diabetic patient for the required time for blood pressure measure (within the last 6 months)	HCPCS	Procedure
G8332	Clinician has not provided care for the diabetic retinopathy patient for the required time for macular edema and retinopathy measurement	HCPCS	Procedure
G8333	Patient documented to have had findings of macular or fundus exam communicated to the physician managing the diabetes care	HCPCS	Procedure
G8334	Documentation of findings of macular or fundus exam not communicated to the physician managing the patient's ongoing diabetes care	HCPCS	Procedure
G8335	Clinician documentation that patient was not an eligible candidate for the findings of their macular or fundus exam being communicated to the physician managing their diabetes care during the reporting year	HCPCS	Procedure
G8336	Clinician has not provided care for the diabetic retinopathy patient for the required time for physician communication measurement	HCPCS	Procedure
G8385	Diabetic patients with no documentation of hemoglobin A1c level (within the last 12 months)	HCPCS	Procedure
G8386	Diabetic patients with no documentation of low-density lipoprotein (within the last 12 months)	HCPCS	Procedure
G8390	Diabetic patients with no documentation of blood pressure measurement (within the last 12 months)	HCPCS	Procedure
	Hypertension		
401	Essential hypertension	ICD-9-CM	Diagnosis
401.0	Essential hypertension, malignant	ICD-9-CM	Diagnosis
401.1	Essential hypertension, benign	ICD-9-CM	Diagnosis
401.9	Unspecified essential hypertension	ICD-9-CM	Diagnosis
402	Hypertensive heart disease	ICD-9-CM	Diagnosis
402.0	Malignant hypertensive heart disease	ICD-9-CM	Diagnosis
402.00	Malignant hypertensive heart disease without heart failure	ICD-9-CM	Diagnosis
402.01	Malignant hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.1	Benign hypertensive heart disease	ICD-9-CM	Diagnosis
402.10	Benign hypertensive heart disease without heart failure	ICD-9-CM	Diagnosis
402.11	Benign hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.9	Unspecified hypertensive heart disease	ICD-9-CM	Diagnosis
402.90	Unspecified hypertensive heart disease without heart failure	ICD-9-CM	Diagnosis
402.91	Hypertensive heart disease, unspecified, with heart failure	ICD-9-CM	Diagnosis
403	Hypertensive chronic kidney disease	ICD-9-CM	Diagnosis
403.0	Hypertensive chronic kidney disease, malignant	ICD-9-CM	Diagnosis
403.00	Hypertensive chronic kidney disease, malignant, with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
403.01	Hypertensive chronic kidney disease, malignant, with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
403.1	Hypertensive chronic kidney disease, benign	ICD-9-CM	Diagnosis
403.10	Hypertensive chronic kidney disease, benign, with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
403.11	Hypertensive chronic kidney disease, benign, with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
403.9	Hypertensive chronic kidney disease, unspecified	ICD-9-CM	Diagnosis
403.90	Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
403.91	Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404	Hypertensive heart and chronic kidney disease	ICD-9-CM	Diagnosis
404.0	Hypertensive heart and chronic kidney disease, malignant	ICD-9-CM	Diagnosis
404.00	Hypertensive heart and chronic kidney disease, malignant, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.02	Hypertensive heart and chronic kidney disease, malignant, without heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.1	Hypertensive heart and chronic kidney disease, benign	ICD-9-CM	Diagnosis
404.10	Hypertensive heart and chronic kidney disease, benign, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.12	Hypertensive heart and chronic kidney disease, benign, without heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.9	Hypertensive heart and chronic kidney disease, unspecified	ICD-9-CM	Diagnosis
404.90	Hypertensive heart and chronic kidney disease, unspecified, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.92	Hypertensive heart and chronic kidney disease, unspecified, without heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
405	Secondary hypertension	ICD-9-CM	Diagnosis
405.0	Secondary hypertension, malignant	ICD-9-CM	Diagnosis
405.01	Secondary renovascular hypertension, malignant	ICD-9-CM	Diagnosis
405.09	Other secondary hypertension, malignant	ICD-9-CM	Diagnosis
405.1	Secondary hypertension, benign	ICD-9-CM	Diagnosis
405.11	Secondary renovascular hypertension, benign	ICD-9-CM	Diagnosis
405.19	Other secondary hypertension, benign	ICD-9-CM	Diagnosis
405.9	Unspecified secondary hypertension, unspecified	ICD-9-CM	Diagnosis
405.91	Secondary renovascular hypertension, unspecified	ICD-9-CM	Diagnosis
405.99	Other secondary hypertension, unspecified	ICD-9-CM	Diagnosis
997.91	Hypertension	ICD-9-CM	Diagnosis
	Renal Impairment		
584	Acute kidney failure	ICD-9-CM	Diagnosis
584.5	Acute kidney failure with lesion of tubular necrosis	ICD-9-CM	Diagnosis
584.6	Acute kidney failure with lesion of renal cortical necrosis	ICD-9-CM	Diagnosis
584.7	Acute kidney failure with lesion of medullary [papillary] necrosis	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
584.8	Acute kidney failure with other specified pathological lesion in kidney	ICD-9-CM	Diagnosis
584.9	Acute kidney failure, unspecified	ICD-9-CM	Diagnosis
585	Chronic kidney disease (CKD)	ICD-9-CM	Diagnosis
585.1	Chronic kidney disease, Stage I	ICD-9-CM	Diagnosis
585.2	Chronic kidney disease, Stage II (mild)	ICD-9-CM	Diagnosis
585.3	Chronic kidney disease, Stage III (moderate)	ICD-9-CM	Diagnosis
585.4	Chronic kidney disease, Stage IV (severe)	ICD-9-CM	Diagnosis
585.5	Chronic kidney disease, Stage V	ICD-9-CM	Diagnosis
585.6	End stage renal disease	ICD-9-CM	Diagnosis
585.9	Chronic kidney disease, unspecified	ICD-9-CM	Diagnosis
586	Unspecified renal failure	ICD-9-CM	Diagnosis
587	Unspecified renal sclerosis	ICD-9-CM	Diagnosis
	Obesity		
278.0	Overweight and obesity	ICD-9-CM	Diagnosis
278.00	Obesity, unspecified	ICD-9-CM	Diagnosis
278.01	Morbid obesity	ICD-9-CM	Diagnosis
278.02	Overweight	ICD-9-CM	Diagnosis
278.1	Localized adiposity	ICD-9-CM	Diagnosis
V45.86	Bariatric surgery status	ICD-9-CM	Diagnosis
V85.3	Body Mass Index between 30-39, adult	ICD-9-CM	Diagnosis
V85.30	Body Mass Index 30.0-30.9, adult	ICD-9-CM	Diagnosis
V85.31	Body Mass Index 31.0-31.9, adult	ICD-9-CM	Diagnosis
V85.32	Body Mass Index 32.0-32.9, adult	ICD-9-CM	Diagnosis
V85.33	Body Mass Index 33.0-33.9, adult	ICD-9-CM	Diagnosis
V85.34	Body Mass Index 34.0-34.9, adult	ICD-9-CM	Diagnosis
V85.35	Body Mass Index 35.0-35.9, adult	ICD-9-CM	Diagnosis
V85.36	Body Mass Index 36.0-36.9, adult	ICD-9-CM	Diagnosis
V85.37	Body Mass Index 37.0-37.9, adult	ICD-9-CM	Diagnosis
V85.38	Body Mass Index 38.0-38.9, adult	ICD-9-CM	Diagnosis
V85.39	Body Mass Index 39.0-39.9, adult	ICD-9-CM	Diagnosis
V85.4	Body Mass Index 40 and over, adult	ICD-9-CM	Diagnosis
44.31	High gastric bypass	ICD-9-CM	Procedure
44.68	Laparoscopic gastroplasty	ICD-9-CM	Procedure
44.95	Laparoscopic gastric restrictive procedure	ICD-9-CM	Procedure
	Smoking		
305.1	Nondependent tobacco use disorder	ICD-9-CM	Diagnosis
989.84	Toxic effect of tobacco	ICD-9-CM	Diagnosis
V15.82	Personal history of tobacco use, presenting hazards to health	ICD-9-CM	Diagnosis
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	CPT-4	Procedure
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	CPT-4	Procedure
C9801	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	HCPCS	Procedure
C9802	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes	HCPCS	Procedure
G0375	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	HCPCS	Procedure
G0376	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	HCPCS	Procedure

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Code	Description	Code Type	Code Category
G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	HCPCS	Procedure
G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes	HCPCS	Procedure
G8093	Newly diagnosed chronic obstructive pulmonary disease (copd) patient documented to have received smoking cessation intervention, within 3 months of diagnosis	HCPCS	Procedure
G8094	Newly diagnosed chronic obstructive pulmonary disease (copd) patient not documented to have received smoking cessation intervention, within 3 months of diagnosis	HCPCS	Procedure
G8402	Tobacco (smoke) use cessation intervention, counseling	HCPCS	Procedure
G8403	Tobacco (smoke) use cessation intervention not counseled	HCPCS	Procedure
G8453	Tobacco use cessation intervention, counseling	HCPCS	Procedure
G8454	Tobacco use cessation intervention not counseled, reason not specified	HCPCS	Procedure
G8455	Current tobacco smoker	HCPCS	Procedure
G8456	Current smokeless tobacco user	HCPCS	Procedure
G8688	Currently a smokeless tobacco user (eg, chew, snuff) and no exposure to secondhand smoke	HCPCS	Procedure
G9016	Smoking cessation counseling, individual, in the absence of or in addition to any other evaluation and management service, per session (6-10 minutes) [demo project code only]	HCPCS	Procedure
S4990	Nicotine patches, legend	HCPCS	Procedure
S4991	Nicotine patches, non-legend	HCPCS	Procedure
S4995	Smoking cessation gum	HCPCS	Procedure
S9075	Smoking cessation treatment	HCPCS	Procedure
S9453	Smoking cessation classes, non-physician provider, per session	HCPCS	Procedure
	Cardiovascular Disease		
	Acute Myocardial Infarction		
410	Acute myocardial infarction	ICD-9-CM	Diagnosis
410.0	Acute myocardial infarction of anterolateral wall	ICD-9-CM	Diagnosis
410.00	Acute myocardial infarction of anterolateral wall, episode of care unspecified	ICD-9-CM	Diagnosis
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care	ICD-9-CM	Diagnosis
410.02	Acute myocardial infarction of anterolateral wall, subsequent episode of care	ICD-9-CM	Diagnosis
410.1	Acute myocardial infarction of other anterior wall	ICD-9-CM	Diagnosis
410.10	Acute myocardial infarction of other anterior wall, episode of care unspecified	ICD-9-CM	Diagnosis
410.11	Acute myocardial infarction of other anterior wall, initial episode of care	ICD-9-CM	Diagnosis
410.12	Acute myocardial infarction of other anterior wall, subsequent episode of care	ICD-9-CM	Diagnosis
410.2	Acute myocardial infarction of inferolateral wall	ICD-9-CM	Diagnosis
410.20	Acute myocardial infarction of inferolateral wall, episode of care unspecified	ICD-9-CM	Diagnosis
410.21	Acute myocardial infarction of inferolateral wall, initial episode of care	ICD-9-CM	Diagnosis
410.22	Acute myocardial infarction of inferolateral wall, subsequent episode of care	ICD-9-CM	Diagnosis
410.3	Acute myocardial infarction of inferoposterior wall	ICD-9-CM	Diagnosis
410.30	Acute myocardial infarction of inferoposterior wall, episode of care unspecified	ICD-9-CM	Diagnosis
410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care	ICD-9-CM	Diagnosis
410.32	Acute myocardial infarction of inferoposterior wall, subsequent episode of care	ICD-9-CM	Diagnosis
410.4	Acute myocardial infarction of other inferior wall	ICD-9-CM	Diagnosis
410.40	Acute myocardial infarction of other inferior wall, episode of care unspecified	ICD-9-CM	Diagnosis
410.41	Acute myocardial infarction of other inferior wall, initial episode of care	ICD-9-CM	Diagnosis
410.42	Acute myocardial infarction of other inferior wall, subsequent episode of care	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
410.5	Acute myocardial infarction of other lateral wall	ICD-9-CM	Diagnosis
410.50	Acute myocardial infarction of other lateral wall, episode of care unspecified	ICD-9-CM	Diagnosis
410.51	Acute myocardial infarction of other lateral wall, initial episode of care	ICD-9-CM	Diagnosis
410.52	Acute myocardial infarction of other lateral wall, subsequent episode of care	ICD-9-CM	Diagnosis
410.6	Acute myocardial infarction, true posterior wall infarction	ICD-9-CM	Diagnosis
410.60	Acute myocardial infarction, true posterior wall infarction, episode of care unspecified	ICD-9-CM	Diagnosis
410.61	Acute myocardial infarction, true posterior wall infarction, initial episode of care	ICD-9-CM	Diagnosis
410.62	Acute myocardial infarction, true posterior wall infarction, subsequent episode of care	ICD-9-CM	Diagnosis
410.7	Acute myocardial infarction, subendocardial infarction	ICD-9-CM	Diagnosis
410.70	Acute myocardial infarction, subendocardial infarction, episode of care unspecified	ICD-9-CM	Diagnosis
410.71	Acute myocardial infarction, subendocardial infarction, initial episode of care	ICD-9-CM	Diagnosis
410.72	Acute myocardial infarction, subendocardial infarction, subsequent episode of care	ICD-9-CM	Diagnosis
410.8	Acute myocardial infarction of other specified sites	ICD-9-CM	Diagnosis
410.80	Acute myocardial infarction of other specified sites, episode of care unspecified	ICD-9-CM	Diagnosis
410.81	Acute myocardial infarction of other specified sites, initial episode of care	ICD-9-CM	Diagnosis
410.82	Acute myocardial infarction of other specified sites, subsequent episode of care	ICD-9-CM	Diagnosis
410.9	Acute myocardial infarction, unspecified site	ICD-9-CM	Diagnosis
410.90	Acute myocardial infarction, unspecified site, episode of care unspecified	ICD-9-CM	Diagnosis
410.91	Acute myocardial infarction, unspecified site, initial episode of care	ICD-9-CM	Diagnosis
410.92	Acute myocardial infarction, unspecified site, subsequent episode of care	ICD-9-CM	Diagnosis
	Coronary Revascularization		
36.1	Bypass Anastomosis For Heart Revascularization	ICD-9-CM	Diagnosis
V45.81	Postprocedural aortocoronary bypass status	ICD-9-CM	Diagnosis
00566	Anesthesia for direct coronary artery bypass grafting; without pump oxygenator	CPT-4	Procedure
00567	Anesthesia for direct coronary artery bypass grafting; with pump oxygenator	CPT-4	Procedure
33508	Endoscopy, surgical, including video-assisted harvest of vein(s) for coronary artery bypass procedure (List separately in addition to code for primary procedure)	CPT-4	Procedure
33510	Coronary artery bypass, vein only; single coronary venous graft	CPT-4	Procedure
33511	Coronary artery bypass, vein only; 2 coronary venous grafts	CPT-4	Procedure
33512	Coronary artery bypass, vein only; 3 coronary venous grafts	CPT-4	Procedure
33513	Coronary artery bypass, vein only; 4 coronary venous grafts	CPT-4	Procedure
33514	Coronary artery bypass, vein only; 5 coronary venous grafts	CPT-4	Procedure
33516	Coronary artery bypass, vein only; 6 or more coronary venous grafts	CPT-4	Procedure
33517	Coronary artery bypass, using venous graft(s) and arterial graft(s); single vein graft (List separately in addition to code for primary procedure)	CPT-4	Procedure
33518	Coronary artery bypass, using venous graft(s) and arterial graft(s); 2 venous grafts (List separately in addition to code for primary procedure)	CPT-4	Procedure
33519	Coronary artery bypass, using venous graft(s) and arterial graft(s); 3 venous grafts (List separately in addition to code for primary procedure)	CPT-4	Procedure
33520	Coronary Artery Bypass, Nonautogenous Graft (eg, Synthetic Or Cadaver); Single Graft	CPT-4	Procedure

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Code	Description	Code Type	Code Category
33521	Coronary artery bypass, using venous graft(s) and arterial graft(s); 4 venous grafts (List separately in addition to code for primary procedure)	CPT-4	Procedure
33522	Coronary artery bypass, using venous graft(s) and arterial graft(s); 5 venous grafts (List separately in addition to code for primary procedure)	CPT-4	Procedure
33523	Coronary artery bypass, using venous graft(s) and arterial graft(s); 6 or more venous grafts (List separately in addition to code for primary procedure)	CPT-4	Procedure
33525	Coronary Artery Bypass, Nonautogenous Graft (eg, Synthetic Or Cadaver); Two Coronary Grafts	CPT-4	Procedure
33528	Coronary Artery Bypass, Nonautogenous Graft (eg, Synthetic Or Cadaver); Three Or More Coronary Grafts	CPT-4	Procedure
33530	Reoperation, coronary artery bypass procedure or valve procedure, more than 1 month after original operation (List separately in addition to code for primary procedure)	CPT-4	Procedure
33533	Coronary artery bypass, using arterial graft(s); single arterial graft	CPT-4	Procedure
33534	Coronary artery bypass, using arterial graft(s); 2 coronary arterial grafts	CPT-4	Procedure
33535	Coronary artery bypass, using arterial graft(s); 3 coronary arterial grafts	CPT-4	Procedure
33536	Coronary artery bypass, using arterial graft(s); 4 or more coronary arterial grafts	CPT-4	Procedure
33560	Myocardial Operation Combined With Coronary Bypass Procedure	CPT-4	Procedure
33570	CORONARY ANGIOPLASTY W/BYPASS	CPT-4	Procedure
33572	Coronary endarterectomy, open, any method, of left anterior descending, circumflex, or right coronary artery performed in conjunction with coronary artery bypass graft procedure, each vessel (List separately in addition to primary procedure)	CPT-4	Procedure
36.10	Aortocoronary bypass for heart revascularization, not otherwise specified	ICD-9-CM	Procedure
36.11	(Aorto)coronary bypass of one coronary artery	ICD-9-CM	Procedure
36.12	(Aorto)coronary bypass of two coronary arteries	ICD-9-CM	Procedure
36.13	(Aorto)coronary bypass of three coronary arteries	ICD-9-CM	Procedure
36.14	(Aorto)coronary bypass of four or more coronary arteries	ICD-9-CM	Procedure
36.15	Single internal mammary-coronary artery bypass	ICD-9-CM	Procedure
36.16	Double internal mammary-coronary artery bypass	ICD-9-CM	Procedure
36.17	Abdominal-coronary artery bypass	ICD-9-CM	Procedure
36.19	Other bypass anastomosis for heart revascularization	ICD-9-CM	Procedure
36.2	Heart revascularization by arterial implant	ICD-9-CM	Procedure
V45.82	Postprocedural percutaneous transluminal coronary angioplasty status	ICD-9-CM	Diagnosis
33575	CORON ANGIOPLSTY W/BYPASS; COMBO W/VASCULARIZAT	CPT-4	Procedure
35600	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure (List separately in addition to code for primary procedure)	CPT-4	Procedure
92920	Percutaneous transluminal coronary angioplasty; single major coronary artery or branch	CPT-4	Procedure
92921	Percutaneous transluminal coronary angioplasty; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	CPT-4	Procedure
92924	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; single major coronary artery or branch	CPT-4	Procedure
92925	Percutaneous transluminal coronary atherectomy, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	CPT-4	Procedure
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	CPT-4	Procedure

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Code	Description	Code Type	Code Category
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	CPT-4	Procedure
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	CPT-4	Procedure
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	CPT-4	Procedure
G0290	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel	HCPCS	Procedure
G0291	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel	HCPCS	Procedure
00.66	Percutaneous transluminal coronary angioplasty [PTCA]	ICD-9-CM	Procedure
17.55	Transluminal coronary atherectomy	ICD-9-CM	Procedure
36.0	Removal Of Coronary Artery Obstruction And Insertion Of Stent(s)	ICD-9-CM	Procedure
36.01	Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy without mention of thrombolytic agent	ICD-9-CM	Procedure
36.02	Single vessel percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy with thrombolytic agent	ICD-9-CM	Procedure
36.03	Open chest coronary artery angioplasty	ICD-9-CM	Procedure
36.04	Intracoronary artery thrombolytic infusion	ICD-9-CM	Procedure
36.05	Multiple vessel (percutaneous) transluminal coronary angioplasty [PTCA] or coronary atherectomy performed during the same operation, with or without mention of thrombolytic agent	ICD-9-CM	Procedure
36.06	Insertion of non-drug-eluting coronary artery stent(s)	ICD-9-CM	Procedure
36.07	Insertion of drug-eluting coronary artery stent(s)	ICD-9-CM	Procedure
36.09	Other removal of coronary artery obstruction	ICD-9-CM	Procedure
V45.88	Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to a	ICD-9-CM	Diagnosis
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	CPT-4	Procedure
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure)	CPT-4	Procedure
92941	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	CPT-4	Procedure
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single	CPT-4	Procedure

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Code	Description	Code Type	Code Category
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)	CPT-4	Procedure
92973	Percutaneous transluminal coronary thrombectomy mechanical (List separately in addition to code for primary procedure)	CPT-4	Procedure
92974	Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy (List separately in addition to code for primary procedure)	CPT-4	Procedure
92975	Thrombolysis, coronary; by intracoronary infusion, including selective coronary angiography	CPT-4	Procedure
92977	Thrombolysis, coronary; by intravenous infusion	CPT-4	Procedure
92980	Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel	CPT-4	Procedure
92981	Transcatheter placement of an intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel (List separately in addition to code for primary procedure)	CPT-4	Procedure
92982	Percutaneous transluminal coronary balloon angioplasty; single vessel	CPT-4	Procedure
92984	Percutaneous transluminal coronary balloon angioplasty; each additional vessel (List separately in addition to code for primary procedure)	CPT-4	Procedure
92987	Percutaneous balloon valvuloplasty; mitral valve	CPT-4	Procedure
92995	Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; single vessel	CPT-4	Procedure
92996	Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; each additional vessel (List separately in addition to code for primary procedure)	CPT-4	Procedure
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography	CPT-4	Procedure
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization	CPT-4	Procedure
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	CPT-4	Procedure
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	CPT-4	Procedure

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Code	Description	Code Type	Code Category
93508	Catheter placement in coronary artery(s), arterial coronary conduit(s), and/or venous coronary bypass graft(s) for coronary angiography without concomitant left heart catheterization	CPT-4	Procedure
93540	Injection procedure during cardiac catheterization; for selective opacification of aortocoronary venous bypass grafts, 1 or more coronary arteries	CPT-4	Procedure
93556	Imaging supervision, interpretation and report for injection procedure(s) during cardiac catheterization; pulmonary angiography, aortography, and/or selective coronary angiography including venous bypass grafts and arterial conduits (whether native or used in bypass)	CPT-4	Procedure
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during congenital heart catheterization, when performed (List separately in addition to code for	CPT-4	Procedure
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	HCPCS	Procedure
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	HCPCS	Procedure
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	HCPCS	Procedure
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	HCPCS	Procedure
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	HCPCS	Procedure
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	HCPCS	Procedure
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	HCPCS	Procedure
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	HCPCS	Procedure

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Code	Description	Code Type	Code Category
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	HCPCS	Procedure
G8158	Patient documented to have received coronary artery bypass graft with use of internal mammary artery	HCPCS	Procedure
G8159	Patient documented to have received coronary artery bypass graft without use of internal mammary artery	HCPCS	Procedure
G8161	Patient with isolated coronary artery bypass graft documented to have received pre-operative beta-blockade	HCPCS	Procedure
G8162	Patient with isolated coronary artery bypass graft not documented to have received preoperative beta-blockade	HCPCS	Procedure
G8163	Clinician documented that patient with isolated coronary artery bypass graft was not an eligible candidate for pre-operative beta-blockade measure	HCPCS	Procedure
G8164	Patient with isolated coronary artery bypass graft documented to have prolonged intubation	HCPCS	Procedure
G8165	Patient with isolated coronary artery bypass graft not documented to have prolonged intubation	HCPCS	Procedure
G8166	Patient with isolated coronary artery bypass graft documented to have required surgical re-exploration	HCPCS	Procedure
G8167	Patient with isolated coronary artery bypass graft did not require surgical re-exploration	HCPCS	Procedure
G8170	Patient with isolated coronary artery bypass graft documented to have been discharged on aspirin or clopidogrel	HCPCS	Procedure
G8171	Patient with isolated coronary artery bypass graft not documented to have been discharged on aspirin or clopidogrel	HCPCS	Procedure
G8172	Clinician documented that patient with isolated coronary artery bypass graft was not an eligible candidate for antiplatelet therapy at discharge measure	HCPCS	Procedure
36.3	Other heart revascularization	ICD-9-CM	Procedure
36.31	Open chest transmyocardial revascularization	ICD-9-CM	Procedure
36.32	Other transmyocardial revascularization	ICD-9-CM	Procedure
36.33	Endoscopic transmyocardial revascularization	ICD-9-CM	Procedure
36.34	Percutaneous transmyocardial revascularization	ICD-9-CM	Procedure
36.39	Other heart revascularization	ICD-9-CM	Procedure
	Heart Failure		
402.01	Malignant hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.11	Benign hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.91	Unspecified hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
428	Heart failure	ICD-9-CM	Diagnosis
428.0	Congestive heart failure, unspecified	ICD-9-CM	Diagnosis
428.1	Left heart failure	ICD-9-CM	Diagnosis
428.2	Systolic heart failure	ICD-9-CM	Diagnosis
428.20	Systolic heart failure, unspecified	ICD-9-CM	Diagnosis
428.21	Acute systolic heart failure	ICD-9-CM	Diagnosis
428.22	Chronic systolic heart failure	ICD-9-CM	Diagnosis
428.23	Acute on chronic systolic heart failure	ICD-9-CM	Diagnosis
428.3	Diastolic heart failure	ICD-9-CM	Diagnosis
428.30	Diastolic heart failure, unspecified	ICD-9-CM	Diagnosis
428.31	Acute diastolic heart failure	ICD-9-CM	Diagnosis
428.32	Chronic diastolic heart failure	ICD-9-CM	Diagnosis
428.33	Acute on chronic diastolic heart failure	ICD-9-CM	Diagnosis
428.4	Combined systolic and diastolic heart failure	ICD-9-CM	Diagnosis
428.40	Combined systolic and diastolic heart failure, unspecified	ICD-9-CM	Diagnosis
428.41	Acute combined systolic and diastolic heart failure	ICD-9-CM	Diagnosis
428.42	Chronic combined systolic and diastolic heart failure	ICD-9-CM	Diagnosis
428.43	Acute on chronic combined systolic and diastolic heart failure	ICD-9-CM	Diagnosis
428.9	Heart failure, unspecified	ICD-9-CM	Diagnosis
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle	CPT-4	Procedure
92970	Cardioassist-method of circulatory assist; internal	CPT-4	Procedure
92971	Cardioassist-method of circulatory assist; external	CPT-4	Procedure
G8027	Heart failure patient with left ventricular systolic dysfunction (LVSD) documented to be on either angiotensin-converting enzyme-inhibitor or angiotensin-receptor blocker (ACE-1 or ARB) therapy	HCPCS	Procedure
G8028	Heart failure patient with left ventricular systolic dysfunction (LVSD) not documented to be on either angiotensin-converting enzyme-inhibitor or angiotensin-receptor blocker (ACE-1 or ARB) therapy	HCPCS	Procedure
G8029	Clinician documented that heart failure patient was not an eligible candidate for either angiotensin-converting enzyme-inhibitor or angiotensin-receptor blocker (ACE-1 or ARB) therapy measure	HCPCS	Procedure
G8030	Heart failure patient with left ventricular systolic dysfunction (LVSD) documented to be on beta-blocker therapy	HCPCS	Procedure
G8031	Heart failure patient with left ventricular systolic dysfunction (LVSD) not documented to be on beta-blocker therapy	HCPCS	Procedure
G8032	Clinician documented that heart failure patient was not eligible candidate for beta-blocker therapy measure	HCPCS	Procedure
G8183	Patient with heart failure and atrial fibrillation documented to be on warfarin therapy	HCPCS	Procedure
G8184	Clinician documented that patient with heart failure and atrial fibrillation was not an eligible candidate for warfarin therapy measure	HCPCS	Procedure
G8681	Patient hospitalized with principal diagnosis of heart failure during the measurement period	HCPCS	Procedure
37.66	Insertion of implantable heart assist system	ICD-9-CM	Procedure
	Stroke		
430	Subarachnoid hemorrhage	ICD-9-CM	Diagnosis
431	Intracerebral hemorrhage	ICD-9-CM	Diagnosis
433.01	Occlusion and stenosis of basilar artery with cerebral infarction	ICD-9-CM	Diagnosis
433.11	Occlusion and stenosis of carotid artery with cerebral infarction	ICD-9-CM	Diagnosis
433.21	Occlusion and stenosis of vertebral artery with cerebral infarction	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
433.31	Occlusion and stenosis of multiple and bilateral precerebral arteries with cerebral infarction	ICD-9-CM	Diagnosis
433.81	Occlusion and stenosis of other specified precerebral artery with cerebral infarction	ICD-9-CM	Diagnosis
433.91	Occlusion and stenosis of unspecified precerebral artery with cerebral infarction	ICD-9-CM	Diagnosis
434.01	Cerebral thrombosis with cerebral infarction	ICD-9-CM	Diagnosis
434.11	Cerebral embolism with cerebral infarction	ICD-9-CM	Diagnosis
434.91	Unspecified cerebral artery occlusion with cerebral infarction	ICD-9-CM	Diagnosis
436	Acute, but ill-defined, cerebrovascular disease	ICD-9-CM	Diagnosis
	Other Cerebrovascular Disease		
437.0	Cerebral atherosclerosis	ICD-9-CM	Diagnosis
437.1	Other generalized ischemic cerebrovascular disease	ICD-9-CM	Diagnosis
437.2	Hypertensive encephalopathy	ICD-9-CM	Diagnosis
437.3	Cerebral aneurysm, nonruptured	ICD-9-CM	Diagnosis
437.4	Cerebral arteritis	ICD-9-CM	Diagnosis
437.5	Moyamoya disease	ICD-9-CM	Diagnosis
437.6	Nonpyogenic thrombosis of intracranial venous sinus	ICD-9-CM	Diagnosis
437.7	Transient global amnesia	ICD-9-CM	Diagnosis
437.8	Other ill-defined cerebrovascular disease	ICD-9-CM	Diagnosis
437.9	Unspecified cerebrovascular disease	ICD-9-CM	Diagnosis
438	Late effects of cerebrovascular disease	ICD-9-CM	Diagnosis
438.0	Cognitive deficits due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.1	Speech and language deficits due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.10	Unspecified speech and language deficit due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.11	Aphasia due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.12	Dysphasia due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.13	Late effects of cerebrovascular disease, speech and language deficits, dysarthria	ICD-9-CM	Diagnosis
438.14	Late effects of cerebrovascular disease, speech and language deficits, fluency disorder	ICD-9-CM	Diagnosis
438.19	Other speech and language deficits due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.2	Hemiplegia/hemiparesis due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.20	Hemiplegia affecting unspecified side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.21	Hemiplegia affecting dominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.22	Hemiplegia affecting nondominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.3	Monoplegia of upper limb due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.30	Monoplegia of upper limb affecting unspecified side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.31	Monoplegia of upper limb affecting dominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.32	Monoplegia of upper limb affecting nondominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.4	Monoplegia of lower limb due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.40	Monoplegia of lower limb affecting unspecified side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.41	Monoplegia of lower limb affecting dominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.42	Monoplegia of lower limb affecting nondominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.5	Other paralytic syndrome due to cerebrovascular disease	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
438.50	Other paralytic syndrome affecting unspecified side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.51	Other paralytic syndrome affecting dominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.52	Other paralytic syndrome affecting nondominant side due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.53	Other paralytic syndrome, bilateral	ICD-9-CM	Diagnosis
438.6	Alteration of sensations as late effect of cerebrovascular disease	ICD-9-CM	Diagnosis
438.7	Disturbance of vision as late effect of cerebrovascular disease	ICD-9-CM	Diagnosis
438.8	Other late effects of cerebrovascular disease due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.81	Apraxia due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.82	Dysphagia due to cerebrovascular disease	ICD-9-CM	Diagnosis
438.83	Facial weakness as late effect of cerebrovascular disease	ICD-9-CM	Diagnosis
438.84	Ataxia as late effect of cerebrovascular disease	ICD-9-CM	Diagnosis
438.85	Vertigo as late effect of cerebrovascular disease	ICD-9-CM	Diagnosis
438.89	Other late effects of cerebrovascular disease	ICD-9-CM	Diagnosis
438.9	Unspecified late effects of cerebrovascular disease due to cerebrovascular disease	ICD-9-CM	Diagnosis
V12.54	Personal history of transient ischemic attack [TIA], and cerebral infarction without residual deficits	ICD-9-CM	Diagnosis
35301	Removal of blood clot and portion of artery of neck	HCPCS	Procedure
35390	Reoperation of cartiod artery removal of blood clot and portion of affected artery more than one month after original procedure	HCPCS	Procedure
35501	Bypass of diseased or blocked artery (neck to brain artery)	HCPCS	Procedure
35506	Bypass of diseased or blocked artery (neck to chest artery)	HCPCS	Procedure
35507	Bypass graft, with vein; subclavian-carotid	HCPCS	Procedure
35508	Bypass of diseased or blocked artery (neck to brain artery)	HCPCS	Procedure
35509	Bypass of diseased or blocked artery (neck to opposite neck artery)	HCPCS	Procedure
35510	Bypass of diseased or blocked artery (neck to arm artery)	HCPCS	Procedure
35515	Bypass of diseased or blocked artery (chest to brain artery)	HCPCS	Procedure
35526	Bypass of diseased or blocked artery (chest to neck artery)	HCPCS	Procedure
35601	Bypass of diseased or blocked artery (neck to brain artery)	HCPCS	Procedure
35606	Bypass of diseased or blocked artery (neck to chest artery)	HCPCS	Procedure
35642	Bypass of diseased or blocked artery (neck to brain artery)	HCPCS	Procedure
35645	Bypass of diseased or blocked artery (chest to brain artery)	HCPCS	Procedure
35701	Exploration of neck artery	HCPCS	Procedure
61711	Anastomosis, arterial, extracranial-intracranial (eg, middle cerebral/cortical) arteries	HCPCS	Procedure
00.61	Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessel(s)	ICD-9-CM	Procedure
00.62	Percutaneous angioplasty or atherectomy of intracranial vessel(s)	ICD-9-CM	Procedure
00.63	Percutaneous insertion of carotid artery stent(s)	ICD-9-CM	Procedure
00.64	Percutaneous insertion of other precerebral (extracranial) artery stent(s)	ICD-9-CM	Procedure
00.65	Percutaneous insertion of intracranial vascular stent(s)	ICD-9-CM	Procedure
38.01	Incision of intracranial vessels	ICD-9-CM	Procedure
38.02	Incision of other vessels of head and neck	ICD-9-CM	Procedure
38.11	Endarterectomy, Intracranial Vessels	ICD-9-CM	Procedure
38.12	Endarterectomy, other vessels of head and neck	ICD-9-CM	Procedure
39.22	Aorta-subclavian-carotid-bypass	ICD-9-CM	Procedure
39.74	Endovascular removal of obstruction from head and neck vessel(s)	ICD-9-CM	Procedure
	Transient Ischemic Attack		

Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System (HCPCS), and Revenue Center Diagnosis and Procedure Codes Used to Define Covariates and Subgroups in this Request

Code	Description	Code Type	Code Category
435	Transient cerebral ischemia	ICD-9-CM	Diagnosis
435.0	Basilar artery syndrome	ICD-9-CM	Diagnosis
435.1	Vertebral artery syndrome	ICD-9-CM	Diagnosis
435.2	Subclavian steal syndrome	ICD-9-CM	Diagnosis
435.3	Vertebrobasilar artery syndrome	ICD-9-CM	Diagnosis
435.8	Other specified transient cerebral ischemias	ICD-9-CM	Diagnosis
435.9	Unspecified transient cerebral ischemia	ICD-9-CM	Diagnosis
	Severe Anemia (Red Blood Cell-Only Transfusion Codes)		
C1010	Whole blood or red blood cells, leukoreduced, cmv negative, each unit	HCPCS	Procedure
C1016	Whole blood or red blood cells, leukoreduced, frozen, deglycerol, washed, each unit	HCPCS	Procedure
C1020	Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated,	HCPCS	Procedure
C1021	Red blood cells, leukocyte-reduced, cmv negative, irradiated, each unit	HCPCS	Procedure
P9016	Red blood cells, leukocytes reduced, each unit	HCPCS	Procedure
P9021	Red blood cells, each unit	HCPCS	Procedure
P9022	Red blood cells, washed, each unit	HCPCS	Procedure
P9038	Red blood cells, irradiated, each unit	HCPCS	Procedure
P9039	Red blood cells, deglycerolized, each unit	HCPCS	Procedure
P9040	Red blood cells, leukocytes reduced, irradiated, each unit	HCPCS	Procedure
P9051	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit	HCPCS	Procedure
P9054	Each unit whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed,	HCPCS	Procedure
P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	HCPCS	Procedure
P9058	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit	HCPCS	Procedure
9904	transfusion of packed cells	ICD-9-CM	Procedure
0381	Blood and blood products-packed red cells	Revenue Center	Procedure
	Gynecological Disorders		
	Adenomyosis		
617.0	Endometriosis of uterus	ICD-9-CM	Diagnosis
	Endometrial Hyperplasia		
621.30	Endometrial hyperplasia, unspecified	ICD-9-CM	Diagnosis
621.3	Endometrial hyperplasia	ICD-9-CM	Diagnosis
621.31	Simple endometrial hyperplasia without atypia	ICD-9-CM	Diagnosis
621.32	Complex endometrial hyperplasia without atypia	ICD-9-CM	Diagnosis
621.33	Endometrial hyperplasia with atypia	ICD-9-CM	Diagnosis
621.34	Benign endometrial hyperplasia	ICD-9-CM	Diagnosis
	Endometriosis		
617.0	Endometriosis of uterus	ICD-9-CM	Diagnosis
617.1	Endometriosis of ovary	ICD-9-CM	Diagnosis
617.2	Endometriosis of fallopian tube	ICD-9-CM	Diagnosis
617.3	Endometriosis of pelvic peritoneum	ICD-9-CM	Diagnosis
617.4	Endometriosis of rectovaginal septum and vagina	ICD-9-CM	Diagnosis
	Uterine, Ovarian or Cervical Cancer		
179	Malignant neoplasm of uterus, part unspecified	ICD-9-CM	Diagnosis
180	Malignant neoplasm of cervix uteri	ICD-9-CM	Diagnosis
180.0	Malignant neoplasm of endocervix	ICD-9-CM	Diagnosis
180.1	Malignant neoplasm of exocervix	ICD-9-CM	Diagnosis
180.8	Malignant neoplasm of other specified sites of cervix	ICD-9-CM	Diagnosis

Appendix I. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Current Procedural Terminology, Fourth Edition (CPT-4), Healthcare Common Procedure Coding System (HCPCS), and Revenue Center Diagnosis and Procedure Codes Used to Define Covariates and Subgroups in this Request

Code	Description	Code Type	Code Category
180.9	Malignant neoplasm of cervix uteri, unspecified site	ICD-9-CM	Diagnosis
181	Malignant neoplasm of placenta	ICD-9-CM	Diagnosis
182	Malignant neoplasm of body of uterus	ICD-9-CM	Diagnosis
182.0	Malignant neoplasm of corpus uteri, except isthmus	ICD-9-CM	Diagnosis
182.1	Malignant neoplasm of isthmus	ICD-9-CM	Diagnosis
182.8	Malignant neoplasm of other specified sites of body of uterus	ICD-9-CM	Diagnosis
183	Malignant neoplasm of ovary and other uterine adnexa	ICD-9-CM	Diagnosis
183.0	Malignant neoplasm of ovary	ICD-9-CM	Diagnosis
183.2	Malignant neoplasm of fallopian tube	ICD-9-CM	Diagnosis
183.3	Malignant neoplasm of broad ligament of uterus	ICD-9-CM	Diagnosis
183.4	Malignant neoplasm of parametrium of uterus	ICD-9-CM	Diagnosis
183.5	Malignant neoplasm of round ligament of uterus	ICD-9-CM	Diagnosis
183.8	Malignant neoplasm of other specified sites of uterine adnexa	ICD-9-CM	Diagnosis
183.9	Malignant neoplasm of uterine adnexa, unspecified site	ICD-9-CM	Diagnosis
184	Malignant neoplasm of other and unspecified female genital organs	ICD-9-CM	Diagnosis
184.0	Malignant neoplasm of vagina	ICD-9-CM	Diagnosis
184.1	Malignant neoplasm of labia majora	ICD-9-CM	Diagnosis
184.3	Malignant neoplasm of clitoris	ICD-9-CM	Diagnosis
184.4	Malignant neoplasm of vulva, unspecified site	ICD-9-CM	Diagnosis
184.8	Malignant neoplasm of other specified sites of female genital organs	ICD-9-CM	Diagnosis
184.9	Malignant neoplasm of female genital organ, site unspecified	ICD-9-CM	Diagnosis
198.6	Secondary malignant neoplasm of ovary	ICD-9-CM	Diagnosis
198.82	Secondary malignant neoplasm of genital organs	ICD-9-CM	Diagnosis
236.0	Neoplasm of uncertain behavior of uterus	ICD-9-CM	Diagnosis
236.2	Neoplasm of uncertain behavior of ovary	ICD-9-CM	Diagnosis
236.3	Neoplasm of uncertain behavior of other and unspecified female genital organs	ICD-9-CM	Diagnosis
	Ovarian Cyst		
620.0	Follicular cyst of ovary	ICD-9-CM	Diagnosis
620.1	Corpus luteum cyst or hematoma	ICD-9-CM	Diagnosis
620.2	Other and unspecified ovarian cyst	ICD-9-CM	Diagnosis
	Uterine Myoma		
218	UTERINE LEIOMYOMA	ICD-9-CM	Diagnosis
218.0	SUBMUCOUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218	UTERINE LEIOMYOMA	ICD-9-CM	Diagnosis
218.0	SUBMUCOUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.1	INTRAMURAL LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.1	INTRAMURAL LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.2	SUBSEROUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.2	SUBSEROUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.9	LEIOMYOMA OF UTERUS UNSPECIFIED	ICD-9-CM	Diagnosis
218.9	LEIOMYOMA OF UTERUS UNSPECIFIED	ICD-9-CM	Diagnosis
	Uterine or Cervical Polyp		
621.0	Polyp of corpus uteri	ICD-9-CM	Diagnosis
622.7	Mucous polyp of cervix	ICD-9-CM	Diagnosis
	Von Willebrand's Disease		
286.4	Von Willebrand's disease	ICD-9-CM	Diagnosis

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
Cardiovascular and Antidiabetic Agents	
Angiotensin-Converting-Enzyme (ACE) Inhibitors	
amlodipine besylate/benazepril HCl	Lotrel
amlodipine besylate/benazepril HCl	Amlodipine-Benazepril
benazepril HCl	Lotensin
benazepril HCl	Benazepril
benazepril HCl/hydrochlorothiazide	Lotensin HCT
benazepril HCl/hydrochlorothiazide	Benazepril-Hydrochlorothiazide
captopril	Captopril
captopril/hydrochlorothiazide	Captopril-Hydrochlorothiazide
enalapril maleate	Epaned
enalapril maleate	Enalapril Maleate
enalapril maleate	Vasotec
enalapril maleate/hydrochlorothiazide	Enalapril-Hydrochlorothiazide
enalapril maleate/hydrochlorothiazide	Vaseretic
enalaprilat dihydrate	Enalaprilat
fosinopril sodium	Fosinopril
fosinopril sodium	Monopril
fosinopril sodium/hydrochlorothiazide	Fosinopril-Hydrochlorothiazide
lisinopril	Qbrelis
lisinopril	Lisinopril
lisinopril	Zestril
lisinopril	Prinivil
lisinopril/dietary supplement,comb.10	Lytensopril
lisinopril/dietary supplement,comb.10	Lytensopril-90
lisinopril/hydrochlorothiazide	Prinzide
lisinopril/hydrochlorothiazide	Lisinopril-Hydrochlorothiazide
lisinopril/hydrochlorothiazide	Zestoretic
moexipril HCl	Univasc
moexipril HCl	Moexipril
moexipril HCl/hydrochlorothiazide	Uniretic
moexipril HCl/hydrochlorothiazide	Moexipril-Hydrochlorothiazide
perindopril arginine/amlodipine besylate	Prestalia
perindopril erbumine	Aceon
perindopril erbumine	Perindopril Erbumine
quinapril HCl	Accupril
quinapril HCl	Quinapril
quinapril HCl/hydrochlorothiazide	Accuretic
quinapril HCl/hydrochlorothiazide	Quinapril-Hydrochlorothiazide
ramipril	Ramipril
ramipril	Altace
trandolapril	Mavik
trandolapril	Trandolapril
trandolapril/verapamil HCl	Tarka
trandolapril/verapamil HCl	Trandolapril-Verapamil
Aldosterone Receptor Antagonists (ARAs)	
eplerenone	Inspra
eplerenone	Eplerenone
spironolactone	CaroSpir
spironolactone	Aldactone
spironolactone	Spironolactone
spironolactone/hydrochlorothiazide	Aldactazide

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
spironolactone/hydrochlorothiazide	Spironolacton-Hydrochlorothiaz
Angiotensin II Receptor Blockers (ARBs)	
amlodipine besylate/olmesartan medoxomil	Amlodipine-Olmesartan
amlodipine besylate/olmesartan medoxomil	Azor
amlodipine besylate/valsartan	Exforge
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge HCT
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
azilsartan medoxomil	Edarbi
azilsartan medoxomil/chlorthalidone	Edarbyclor
candesartan cilexetil	Atacand
candesartan cilexetil	Candesartan
candesartan cilexetil/hydrochlorothiazide	Atacand HCT
candesartan cilexetil/hydrochlorothiazide	Candesartan-Hydrochlorothiazid
eprosartan mesylate	Teveten
eprosartan mesylate	Eprosartan
eprosartan mesylate/hydrochlorothiazide	Teveten HCT
irbesartan	Avapro
irbesartan	Irbesartan
irbesartan/hydrochlorothiazide	Avalide
irbesartan/hydrochlorothiazide	Irbesartan-Hydrochlorothiazide
losartan potassium	Cozaar
losartan potassium	Losartan
losartan potassium/hydrochlorothiazide	Hyzaar
losartan potassium/hydrochlorothiazide	Losartan-Hydrochlorothiazide
nebivolol HCl/valsartan	Byvalson
olmesartan medoxomil	Olmesartan
olmesartan medoxomil	Benicar
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Tribenzor
olmesartan medoxomil/hydrochlorothiazide	Olmesartan-Hydrochlorothiazide
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
sacubitril/valsartan	Entresto
telmisartan	Telmisartan
telmisartan	Micardis
telmisartan/amlodipine besylate	Telmisartan-Amlodipine
telmisartan/amlodipine besylate	Twynsta
telmisartan/hydrochlorothiazide	Telmisartan-Hydrochlorothiazid
telmisartan/hydrochlorothiazide	Micardis HCT
valsartan	Diovan
valsartan	Valsartan
valsartan/hydrochlorothiazide	Diovan HCT
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Antianginal Vasodilators	
amyl nitrite	Amyl Nitrite
isosorbide dinitrate	Dilatrate-SR
isosorbide dinitrate	Isosorbide Dinitrate
isosorbide dinitrate	Isordil Titradose
isosorbide dinitrate	Isordil
isosorbide dinitrate	Isochron

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
isosorbide dinitrate	IsoDitrate
isosorbide dinitrate/hydralazine HCl	BiDil
isosorbide mononitrate	Monoket
isosorbide mononitrate	Isosorbide Mononitrate
isosorbide mononitrate	Ismo
isosorbide mononitrate	Imdur
nitroglycerin	Nitronal
nitroglycerin	Nitroglycerin
nitroglycerin	Nitro-Time
nitroglycerin	GoNitro
nitroglycerin	Nitrostat
nitroglycerin	NitroQuick
nitroglycerin	Nitro-Bid
nitroglycerin	Nitro-Dur
nitroglycerin	Minitran
nitroglycerin	Nitromist
nitroglycerin	Nitrolingual
nitroglycerin in 5 % dextrose in water	Nitroglycerin in 5 % Dextrose
Anti-Arrhythmic Agents	
adenosine	Adenosine
adenosine	Adenocard
adenosine in 0.9 % sodium chloride	Adenosine in 0.9 % Sod Chlor
amiodarone HCl	Amiodarone
amiodarone HCl	Pacerone
amiodarone HCl	Cordarone
amiodarone HCl/dextrose 5 % in water	Amiodarone in Dextrose 5 %
amiodarone in dextrose, iso-osmotic	Nexterone
diltiazem HCl	Diltiazem HCl
disopyramide phosphate	Norpace
disopyramide phosphate	Disopyramide Phosphate
disopyramide phosphate	Norpace CR
dofetilide	Tikosyn
dofetilide	Dofetilide
dronedarone HCl	Multaq
esmolol HCl	Esmolol
esmolol HCl	Brevibloc
esmolol HCl in sodium chloride, iso-osmotic	Brevibloc in NaCl (iso-osm)
esmolol HCl in sterile water	Esmolol in Sterile Water
flecainide acetate	Flecainide
flecainide acetate	Tambocor
ibutilide fumarate	Corvert
ibutilide fumarate	Ibutilide Fumarate
lidocaine HCl in dextrose 5% in water/pf	Lidocaine in 5 % Dextrose (PF)
lidocaine HCl in sodium chloride, iso-osmotic/pf	Lidocaine in NaCl, Iso-osmo (PF)
lidocaine HCl/pf	Xylocaine (Cardiac) (PF)
lidocaine HCl/pf	Lidocaine (PF)
mexiletine HCl	Mexiletine
phenytoin sodium	Phenytoin Sodium
procainamide HCl	Procainamide
propafenone HCl	Rythmol SR
propafenone HCl	Propafenone
propafenone HCl	Rythmol

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
quinidine gluconate	Quinidine Gluconate
quinidine sulfate	Quinidine Sulfate
quinidine sulfate	Quinidex Extentabs
sotalol HCl	Sotalol
sotalol HCl	Sotylize
sotalol HCl	Sorine
sotalol HCl	Sotalol AF
sotalol HCl	Betapace
sotalol HCl	Betapace AF
verapamil HCl	Verapamil
verapamil HCl	Calan
Beta Blockers	
acebutolol HCl	Acebutolol
acebutolol HCl	Sectral
atenolol	Atenolol
atenolol	Tenormin
atenolol/chlorthalidone	Tenoretic 100
atenolol/chlorthalidone	Atenolol-Chlorthalidone
atenolol/chlorthalidone	Tenoretic 50
betaxolol HCl	Kerlone
betaxolol HCl	Betaxolol
bisoprolol fumarate	Bisoprolol Fumarate
bisoprolol fumarate	Zebeta
bisoprolol fumarate/hydrochlorothiazide	Bisoprolol-Hydrochlorothiazide
bisoprolol fumarate/hydrochlorothiazide	Ziac
carvedilol	Coreg
carvedilol	Carvedilol
carvedilol phosphate	Coreg CR
carvedilol phosphate	Carvedilol Phosphate
esmolol HCl	Esmolol
esmolol HCl	Brevibloc
esmolol HCl in sodium chloride, iso-osmotic	Brevibloc in NaCl (iso-osm)
esmolol HCl in sterile water	Esmolol in Sterile Water
labetalol HCl	Labetalol
labetalol HCl	Trandate
labetalol in dextrose 5 % in water	Labetalol in Dextrose 5 %
metoprolol succinate	Kapspargo Sprinkle
metoprolol succinate	Metoprolol Succinate
metoprolol succinate	Toprol XL
metoprolol succinate/hydrochlorothiazide	Dutoprol
metoprolol succinate/hydrochlorothiazide	Metoprolol Su-Hydrochlorothiaz
metoprolol tartrate	Lopressor
metoprolol tartrate	Metoprolol Tartrate
metoprolol tartrate/dietary supplement,comb.10	Hypertensolol
metoprolol tartrate/hydrochlorothiazide	Lopressor HCT
metoprolol tartrate/hydrochlorothiazide	Metoprolol Ta-Hydrochlorothiaz
nadolol	Nadolol
nadolol	Corgard
nadolol/bendroflumethiazide	Nadolol-Bendroflumethiazide
nadolol/bendroflumethiazide	Corzide
nebivolol HCl	Bystolic
penbutolol sulfate	Levatol

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
pindolol	Pindolol
propranolol HCl	Propranolol
propranolol HCl	Inderal LA
propranolol HCl	InnoPran XL
propranolol HCl	Inderal XL
propranolol HCl	Hemangeol
propranolol HCl/hydrochlorothiazide	Propranolol-Hydrochlorothiazid
sotalol HCl	Sotalol
sotalol HCl	Sotylize
sotalol HCl	Sorine
sotalol HCl	Sotalol AF
sotalol HCl	Betapace
sotalol HCl	Betapace AF
timolol maleate	Timolol Maleate
Calcium Channel Blockers	
aliskiren hemifumarate/amlodipine besylate	Tekamlo
aliskiren hemifumarate/amlodipine/hydrochlorothiazide	Amturnide
amlodipine besylate	Amlodipine
amlodipine besylate	Norvasc
amlodipine besylate/atorvastatin calcium	Caduet
amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
amlodipine besylate/benazepril HCl	Lotrel
amlodipine besylate/benazepril HCl	Amlodipine-Benazepril
amlodipine besylate/olmesartan medoxomil	Amlodipine-Olmesartan
amlodipine besylate/olmesartan medoxomil	Azor
amlodipine besylate/valsartan	Exforge
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge HCT
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
clevidipine butyrate	Cleviprex
diltiazem HCl	Diltiazem HCl
diltiazem HCl	Diltia XT
diltiazem HCl	Dilacor XR
diltiazem HCl	DILT-XR
diltiazem HCl	Tiazac
diltiazem HCl	Diltzac ER
diltiazem HCl	Taztia XT
diltiazem HCl	Cardizem CD
diltiazem HCl	DILT-CD
diltiazem HCl	Cartia XT
diltiazem HCl	Cardizem
diltiazem HCl	Cardizem LA
diltiazem HCl	Matzim LA
diltiazem HCl in 0.9 % sodium chloride	Diltiazem HCl in 0.9% NaCl
diltiazem HCl/dextrose 5 % in water	Diltiazem in Dextrose 5 %
felodipine	Felodipine
isradipine	Isradipine
isradipine	DynaCirc CR
nicardipine HCl	Nicardipine
nicardipine HCl	Cardene IV
nicardipine HCl	Cardene SR
nicardipine HCl in 0.9 % sodium chloride	Nicardipine in 0.9 % NaCl

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
nicardipine in 5 % dextrose in water	Nicardipine in 5 % Dextrose
nicardipine in dextrose, iso-osmotic	Cardene IV in Dextrose
nicardipine in sodium chloride, iso-osmotic	Cardene IV in Sodium Chloride
nifedipine	Procardia
nifedipine	Nifedipine
nifedipine	Adalat CC
nifedipine	Nifediac CC
nifedipine	Afeditab CR
nifedipine	Procardia XL
nifedipine	Nifedical XL
nimodipine	Nimodipine
nimodipine	Nymalize
nisoldipine	Nisoldipine
nisoldipine	Sular
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Tribenzor
perindopril arginine/amlodipine besylate	Prestalia
telmisartan/amlodipine besylate	Telmisartan-Amlodipine
telmisartan/amlodipine besylate	Twynsta
trandolapril/verapamil HCl	Tarka
trandolapril/verapamil HCl	Trandolapril-Verapamil
verapamil HCl	Verapamil
verapamil HCl	Verelan PM
verapamil HCl	Verelan
verapamil HCl	Calan
verapamil HCl	Calan SR
verapamil HCl	Isoptin SR
verapamil HCl	Covera-HS
Diuretics	
acetazolamide	Acetazolamide
acetazolamide	Diamox Sequels
acetazolamide sodium	Acetazolamide Sodium
aliskiren hemifumarate/hydrochlorothiazide	Tekturna HCT
amiloride HCl	Midamor
amiloride HCl	Amiloride
amiloride HCl/hydrochlorothiazide	Amiloride-Hydrochlorothiazide
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge HCT
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
ammonium chloride	Ammonium Chloride
atenolol/chlorthalidone	Tenoretic 100
atenolol/chlorthalidone	Atenolol-Chlorthalidone
atenolol/chlorthalidone	Tenoretic 50
azilsartan medoxomil/chlorthalidone	Edarbyclor
benazepril HCl/hydrochlorothiazide	Lotensin HCT
benazepril HCl/hydrochlorothiazide	Benazepril-Hydrochlorothiazide
bisoprolol fumarate/hydrochlorothiazide	Bisoprolol-Hydrochlorothiazide
bisoprolol fumarate/hydrochlorothiazide	Ziac
bumetanide	Bumetanide
candesartan cilexetil/hydrochlorothiazide	Atacand HCT
candesartan cilexetil/hydrochlorothiazide	Candesartan-Hydrochlorothiazid

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
captopril/hydrochlorothiazide	Captopril-Hydrochlorothiazide
chlorothiazide	Diuril
chlorothiazide	Chlorothiazide
chlorothiazide sodium	Chlorothiazide Sodium
chlorothiazide sodium	Diuril IV
chlorthalidone	Thalitone
chlorthalidone	Chlorthalidone
clonidine HCl/chlorthalidone	Clorpres
conivaptan HCl/dextrose 5 % in water	Vaprisol in 5 % Dextrose
enalapril maleate/hydrochlorothiazide	Enalapril-Hydrochlorothiazide
enalapril maleate/hydrochlorothiazide	Vaseretic
eplerenone	Inspra
eplerenone	Eplerenone
eprosartan mesylate/hydrochlorothiazide	Teveten HCT
ethacrynate sodium	Sodium Edecrin
ethacrynate sodium	Ethacrynate Sodium
ethacrynic acid	Edecrin
ethacrynic acid	Ethacrynic Acid
fosinopril sodium/hydrochlorothiazide	Fosinopril-Hydrochlorothiazide
furosemide	Furosemide
furosemide	Lasix
furosemide in 0.9 % sodium chloride	Furosemide in 0.9 % NaCl
furosemide/dextrose 5 % in water	Furosemide in Dextrose 5 %
glycerin	Introl
hydrochlorothiazide	Hydrochlorothiazide
hydrochlorothiazide	Microzide
indapamide	Indapamide
irbesartan/hydrochlorothiazide	Avalide
irbesartan/hydrochlorothiazide	Irbesartan-Hydrochlorothiazide
lisinopril/hydrochlorothiazide	Prinzide
lisinopril/hydrochlorothiazide	Lisinopril-Hydrochlorothiazide
lisinopril/hydrochlorothiazide	Zestoretic
losartan potassium/hydrochlorothiazide	Hyzaar
losartan potassium/hydrochlorothiazide	Losartan-Hydrochlorothiazide
mannitol	Osmitrol 5 %
mannitol	Mannitol 5 %
mannitol	Osmitrol 10 %
mannitol	Mannitol 10 %
mannitol	Osmitrol 15 %
mannitol	Mannitol 15 %
mannitol	Mannitol 20 %
mannitol	Osmitrol 20 %
mannitol	Mannitol 25 %
methazolamide	Methazolamide
methazolamide	Neptazane
methyclothiazide	Methyclothiazide
methyclothiazide	Enduron
methyldopa/hydrochlorothiazide	Methyldopa-Hydrochlorothiazide
metolazone	Metolazone
metolazone	Zaroxolyn
metoprolol succinate/hydrochlorothiazide	Dutoprol
metoprolol succinate/hydrochlorothiazide	Metoprolol Su-Hydrochlorothiaz

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
metoprolol tartrate/hydrochlorothiazide	Lopressor HCT
metoprolol tartrate/hydrochlorothiazide	Metoprolol Ta-Hydrochlorothiaz
moexipril HCl/hydrochlorothiazide	Uniretic
moexipril HCl/hydrochlorothiazide	Moexipril-Hydrochlorothiazide
nadolol/bendroflumethiazide	Nadolol-Bendroflumethiazide
nadolol/bendroflumethiazide	Corzide
olmesartan medoxomil/amlodipine besvlate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besvlate/hydrochlorothiazide	Tribenzor
olmesartan medoxomil/hydrochlorothiazide	Olmesartan-Hydrochlorothiazide
olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
propranolol HCl/hydrochlorothiazide	Propranolol-Hydrochlorothiazid
quinapril HCl/hydrochlorothiazide	Accuretic
quinapril HCl/hydrochlorothiazide	Quinapril-Hydrochlorothiazide
spironolactone	CaroSpir
spironolactone	Aldactone
spironolactone	Spironolactone
spironolactone/hydrochlorothiazide	Aldactazide
spironolactone/hydrochlorothiazide	Spironolacton-Hydrochlorothiaz
telmisartan/hydrochlorothiazide	Telmisartan-Hydrochlorothiazid
telmisartan/hydrochlorothiazide	Micardis HCT
tolvaptan	Samsca
torsemide	Torsemide
torsemide	Demadex
triamterene	Dyrenium
triamterene/hydrochlorothiazide	Dyazide
triamterene/hydrochlorothiazide	Triamterene-Hydrochlorothiazid
triamterene/hydrochlorothiazide	Maxzide-25mg
triamterene/hydrochlorothiazide	Maxzide
valsartan/hydrochlorothiazide	Diovan HCT
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Insulins	
insulin aspart	Novolog PenFill U-100 Insulin
insulin aspart	Novolog Flexpen U-100 Insulin
insulin aspart	Novolog U-100 Insulin aspart
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30FlexPen U-100
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 U-100 Insuln
insulin degludec	Tresiba FlexTouch U-100
insulin degludec	Tresiba FlexTouch U-200
insulin detemir	Levemir FlexTouch U-100 Insuln
insulin detemir	Levemir Flexpen
insulin detemir	Levemir U-100 Insulin
insulin glargine,human recombinant analog	Lantus U-100 Insulin
insulin glargine,human recombinant analog	Basaglar KwikPen U-100 Insulin
insulin glargine,human recombinant analog	Lantus Solostar U-100 Insulin
insulin glargine,human recombinant analog	Toujeo SoloStar U-300 Insulin
insulin glargine,human recombinant analog	Toujeo Max SoloStar
insulin glulisine	Apidra U-100 Insulin
insulin glulisine	Apidra SoloStar U-100 Insulin

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
insulin lispro	Humalog U-100 Insulin
insulin lispro	Humalog Pen
insulin lispro	Humalog KwikPen Insulin
insulin lispro	Admelog SoloStar U-100 Insulin
insulin lispro	Humalog Junior KwikPen U-100
insulin lispro	Admelog U-100 Insulin lispro
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Insuln U-100
insulin lispro protamine and insulin lispro	Humalog Mix 75-25(U-100)Insuln
insulin lispro protamine and insulin lispro	Humalog Mix 75-25 KwikPen
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 KwikPen
insulin regular, human	Afrezza
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Humulin R U-500 (Conc) Insulin
Non-Statin Lipid Lowering Drugs	
alirocumab	Praluent Pen
alirocumab	Praluent Syringe
cholestyramine (with sugar)	Cholestyramine (with sugar)
cholestyramine (with sugar)	Questran
cholestyramine/aspartame	Cholestyramine Light
cholestyramine/aspartame	Prevalite
cholestyramine/aspartame	Questran Light
colesevelam HCl	WelChol
colesevelam HCl	Colesevelam
colestipol HCl	Colestid
colestipol HCl	Colestid Flavored
colestipol HCl	Colestipol
evolocumab	Repatha SureClick
evolocumab	Repatha Syringe
evolocumab	Repatha Pushtronex
ezetimibe	Ezetimibe
ezetimibe	Zetia
fenofibrate	Fenofibrate
fenofibrate	Lipofen
fenofibrate	Fenoglide
fenofibrate	Lofibra
fenofibrate nanocrystallized	Tricor
fenofibrate nanocrystallized	Fenofibrate Nanocrystallized
fenofibrate nanocrystallized	Triglide
fenofibrate,micronized	Antara
fenofibrate,micronized	Fenofibrate Micronized
fenofibrate,micronized	Lofibra
fenofibric acid	Fibricor
fenofibric acid	Fenofibric Acid
fenofibric acid (choline)	Trilipix
fenofibric acid (choline)	Fenofibric Acid (Choline)
gemfibrozil	Lopid
gemfibrozil	Gemfibrozil
icosapent ethyl	Vascepa
lomitapide mesylate	Juxtapid
mipomersen sodium	Kynamro
niacin	Niacor
niacin	Niaspan Extended-Release

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Generic Name	Brand Name
niacin	Niacin
Oral Antidiabetic Agents	
acarbose	Precose
acarbose	Acarbose
alogliptin benzoate	Alogliptin
alogliptin benzoate	Nesina
alogliptin benzoate/metformin HCl	Alogliptin-Metformin
alogliptin benzoate/metformin HCl	Kazano
alogliptin benzoate/pioglitazone HCl	Alogliptin-Pioglitazone
alogliptin benzoate/pioglitazone HCl	Oseni
bromocriptine mesylate	Cycloset
canagliflozin	Invokana
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
chlorpropamide	Chlorpropamide
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/metformin HCl	Xigduo XR
dapagliflozin propanediol/saxagliptin HCl	Qtern
empagliflozin	Jardiance
empagliflozin/linagliptin	Glyxambi
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
ertugliflozin pidolate	Steglatro
ertugliflozin pidolate/metformin HCl	Segluromet
ertugliflozin pidolate/sitagliptin phosphate	Steglujan
glimepiride	Amaryl
glimepiride	Glimepiride
glipizide	Glucotrol
glipizide	Glipizide
glipizide	Glucotrol XL
glipizide/metformin HCl	Glipizide-Metformin
glipizide/metformin HCl	Metaglip
glyburide	Diabeta
glyburide	Glyburide
glyburide,micronized	Glynase
glyburide,micronized	Glyburide Micronized
glyburide/metformin HCl	Glyburide-Metformin
glyburide/metformin HCl	Glucovance
linagliptin	Tradjenta
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
metformin HCl	Riomet
metformin HCl	Glucophage
metformin HCl	Metformin
metformin HCl	Glucophage XR
metformin HCl	Fortamet
metformin HCl	Glumetza
metformin HCl/blood sugar diagnostic	DM2
metformin/amino acids no.7/herbal cmb.125/choline bitartrate	Appformin-D
metformin/caffeine/amino acids 7/herbal comb 125/choline bit	Appformin

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Generic Name	Brand Name
mifepristone	Korlym
miglitol	Glyset
miglitol	Miglitol
nateglinide	Starlix
nateglinide	Nateglinide
pioglitazone HCl	Pioglitazone
pioglitazone HCl	Actos
pioglitazone HCl/glimepiride	Pioglitazone-Glimepiride
pioglitazone HCl/glimepiride	Duetact
pioglitazone HCl/metformin HCl	Pioglitazone-Metformin
pioglitazone HCl/metformin HCl	Actoplus MET
pioglitazone HCl/metformin HCl	Actoplus Met XR
repaglinide	Prandin
repaglinide	Repaglinide
repaglinide/metformin HCl	Prandimet
repaglinide/metformin HCl	Repaglinide-Metformin
rosiglitazone maleate	Avandia
rosiglitazone maleate/glimepiride	Avandaryl
rosiglitazone maleate/metformin HCl	Avandamet
saxagliptin HCl	Onglyza
saxagliptin HCl/metformin HCl	Kombiglyze XR
sitagliptin phosphate	Januvia
sitagliptin phosphate/metformin HCl	Janumet
sitagliptin phosphate/metformin HCl	Janumet XR
sitagliptin phosphate/simvastatin	Juvisync
tolazamide	Tolazamide
tolbutamide	Tolbutamide
Other Antihypertensive Medications	
aliskiren hemifumarate	Tekturna
aliskiren/valsartan	Valturna
clonidine	Clonidine
clonidine	Catapres-TTS-1
clonidine	Catapres-TTS-2
clonidine	Catapres-TTS-3
clonidine HCl	Nexiclon XR
clonidine HCl	Clonidine HCl
clonidine HCl	Catapres
doxazosin mesylate	Cardura
doxazosin mesylate	Doxazosin
doxazosin mesylate	Cardura XL
eplerenone	Inspra
eplerenone	Eplerenone
fenoldopam mesylate	Corlopam
fenoldopam mesylate	Fenoldopam
guanabenz acetate	Guanabenz
guanfacine HCl	Guanfacine
guanfacine HCl	Tenex
hydralazine HCl	Hydralazine
isosorbide dinitrate/hydralazine HCl	BiDil
isoxsuprine HCl	Isoxsuprine
mecamylamine HCl	Vecamyl
methyldopa	Methyldopa

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
methyldopate HCl	Methyldopate
metyrosine	Demser
minoxidil	Minoxidil
nitroprusside sodium	Nitropress
nitroprusside sodium	Sodium Nitroprusside
nitroprusside sodium in 0.9 % sodium chloride	Nipride RTU
papaverine HCl	Papaverine
phenoxybenzamine HCl	Phenoxybenzamine
phenoxybenzamine HCl	Dibenzyline
phentolamine mesylate	Phentolamine
prazosin HCl	Minipress
prazosin HCl	Prazosin
reserpine	Reserpine
spironolactone	Aldactone
spironolactone	Spironolactone
terazosin HCl	Terazosin
terazosin HCl	Hytrin
Statins	
amlodipine besylate/atorvastatin calcium	Caduet
amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
atorvastatin calcium	Lipitor
atorvastatin calcium	Atorvastatin
ezetimibe/atorvastatin calcium	Liptruzet
ezetimibe/simvastatin	Ezetimibe-Simvastatin
ezetimibe/simvastatin	Vytorin 10-40
ezetimibe/simvastatin	Vytorin 10-80
ezetimibe/simvastatin	Vytorin 10-10
ezetimibe/simvastatin	Vytorin 10-20
fluvastatin sodium	Lescol
fluvastatin sodium	Fluvastatin
fluvastatin sodium	Lescol XL
lovastatin	Lovastatin
lovastatin	Mevacor
lovastatin	Altoprev
niacin/lovastatin	Advicor
niacin/simvastatin	Simcor
pitavastatin calcium	Livalo
pitavastatin magnesium	Zypitamag
pravastatin sodium	Pravachol
pravastatin sodium	Pravastatin
rosuvastatin calcium	Rosuvastatin
rosuvastatin calcium	Crestor
simvastatin	FloLipid
simvastatin	Zocor
simvastatin	Simvastatin
sitagliptin phosphate/simvastatin	Juvisync
Medications that Increase Bleeding Risk Without Interaction with Warfarin or Novel Oral Anticoagulants (NOACs)	
Antiplatelet Agents	
abciximab	Reopro
anagrelide HCl	Anagrelide
anagrelide HCl	Agrylin
aspirin	Durlaza

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
aspirin/dipyridamole	Aspirin-Dipyridamole
aspirin/dipyridamole	Aggrenox
aspirin/omeprazole	Yosprala
cangrelor tetrasodium	Kengreal
cilostazol	Cilostazol
cilostazol	Pletal
clopidogrel bisulfate	Clopidogrel
clopidogrel bisulfate	Plavix
dipyridamole	Dipyridamole
dipyridamole	Persantine
eptifibatide	Integrilin
eptifibatide	Eptifibatide
prasugrel HCl	Effient
prasugrel HCl	Prasugrel
ticagrelor	Brilinta
ticlopidine HCl	Ticlopidine
tirofiban HCl monohydrate	Aggrastat Concentrate
tirofiban HCl monohydrate in 0.9 % sodium chloride	Aggrastat in sodium chloride
vorapaxar sulfate	Zontivity
Aspirins	
aspirin	Durlaza
aspirin	Zorprin
aspirin	Aspirin
aspirin	Easprin
aspirin/caffeine/dihydrocodeine bitartrate	Synalgos-DC
aspirin/caffeine/dihydrocodeine bitartrate	Aspirin-Caffeine-Dihydrocodein
aspirin/dipyridamole	Aspirin-Dipyridamole
aspirin/dipyridamole	Aggrenox
aspirin/omeprazole	Yosprala
aspirin/salicylamide/acetaminophen/caffeine	Levacet
butalbital/aspirin/caffeine	Butalbital-Aspirin-Caffeine
butalbital/aspirin/caffeine	Butalbital Compound
butalbital/aspirin/caffeine	Fiorinal
carisoprodol/aspirin	Carisoprodol-Aspirin
carisoprodol/aspirin	Carisoprodol Compound
carisoprodol/aspirin/codeine phosphate	Carisoprodol-ASA-Codeine
carisoprodol/aspirin/codeine phosphate	Carisoprodol Compound-Codeine
choline salicylate/magnesium salicylate	Choline, Magnesium Salicylate
choline salicylate/magnesium salicylate	Choline-Mag Trisalicylate
codeine phosphate/butalbital/aspirin/caffeine	Butalbital Compound W/Codeine
codeine phosphate/butalbital/aspirin/caffeine	Butalbital Compound-Codeine
codeine phosphate/butalbital/aspirin/caffeine	Ascomp with Codeine
codeine phosphate/butalbital/aspirin/caffeine	Fiorinal-Codeine #3
codeine phosphate/butalbital/aspirin/caffeine	Codeine-Butalbital-ASA-Caff
diflunisal	Diflunisal
magnesium salicylate	MST 600
orphenadrine citrate/aspirin/caffeine	Orphenadrine Compound
orphenadrine citrate/aspirin/caffeine	orphenadrine-ASA-caffeine
orphenadrine citrate/aspirin/caffeine	Orphenadrine Compound-DS
orphenadrine citrate/aspirin/caffeine	Orphenadrine Compound Forte
orphenadrine citrate/aspirin/caffeine	Norgesic Forte
oxycodone HCl/aspirin	Oxycodone-Aspirin

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Generic Name	Brand Name
oxycodone HCl/aspirin	Endodan
oxycodone HCl/aspirin	Percodan
oxycodone HCl/oxycodone terephthalate/aspirin	Oxycodone HCl-Oxycodone-ASA
salicylamide/acetaminophen	Frenadol
salicylamide/acetaminophen/phenyltoloxamine	Ed-Flex
salicylamide/acetaminophen/phenyltoloxamine	Duraxin
salicylamide/acetaminophen/phenyltoloxamine	Be-Flex Plus
salicylamide/acetaminophen/phenyltoloxamine	Anabar
salicylamide/acetaminophen/phenyltoloxamine/caffeine	Durabac
salicylamide/acetaminophen/phenyltoloxamine/caffeine	Cafgesic
salsalate	Salsalate
salsalate	Disalcid
sodium thiosalicylate	Thiocyl
Cephalosporin Antibiotics	
cefaclor	Cefaclor
cefaclor	Ceclor
cefadroxil	Cefadroxil
cefadroxil	Duricef
cefazolin sodium	Cefazolin
cefazolin sodium in 0.9 % sodium chloride	Cefazolin in 0.9% Sod Chloride
cefazolin sodium/dextrose 5 % in water	Cefazolin in Dextrose 5 %
cefazolin sodium/dextrose, iso-osmotic	Cefazolin in Dextrose (iso-os)
cefazolin sodium/water for injection,sterile	Cefazolin in Sterile Water
cefdinir	Omnicef
cefdinir	Cefdinir
cefditoren pivoxil	Spectracef
cefditoren pivoxil	Cefditoren Pivoxil
cefepime HCl	Maxipime
cefepime HCl	Cefepime
cefepime HCl in dextrose 5 % in water	Cefepime in Dextrose 5 %
cefepime HCl in iso-osmotic dextrose	Cefepime in Dextrose, Iso-Osm
cefixime	Suprax
cefixime	Cefixime
cefotaxime sodium	Claforan
cefotaxime sodium	Cefotaxime
cefotaxime sodium/dextrose, iso-osmotic	Claforan in dextrose (iso-osm)
cefotetan disodium	Cefotetan
cefotetan disodium	Cefotan
cefotetan disodium in iso-osmotic dextrose	Cefotetan in Dextrose, Iso-Osm
cefoxitin sodium	Cefoxitin
cefoxitin sodium/dextrose 5 % in water	Mefoxin in Dextrose (iso-osm)
cefoxitin sodium/dextrose, iso-osmotic	Cefoxitin in Dextrose, Iso-Osm
cefpodoxime proxetil	Cefpodoxime
cefprozil	Cefprozil
ceftaroline fosamil acetate	Teflaro
ceftazidime	Ceftazidime
ceftazidime	Fortaz
ceftazidime	Tazicef
ceftazidime in dextrose 5% and water	Ceftazidime in D5W
ceftazidime sodium in iso-osmotic dextrose	Fortaz in Dextrose 5 %
ceftazidime/avibactam sodium	Avycaz
ceftibuten	Ceftibuten

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Generic Name	Brand Name
ceftibuten	Cedax
ceftolozane sulfate/tazobactam sodium	Zerbaxa
ceftriaxone sodium	Rocephin
ceftriaxone sodium	Ceftriaxone
ceftriaxone sodium in iso-osmotic dextrose	Ceftriaxone in Dextrose, Iso-Os
cefuroxime axetil	Ceftin
cefuroxime axetil	Cefuroxime Axetil
cefuroxime sodium	Zinacef
cefuroxime sodium	Cefuroxime Sodium
cefuroxime sodium/dextrose, iso-osmotic	Cefuroxime-Dextrose (iso-osm)
cefuroxime sodium/dextrose, iso-osmotic	Zinacef in Dextrose (iso-osm)
cefuroxime sodium/water for injection,sterile	Zinacef in Sterile Water
cephalexin	Cephalexin
cephalexin	Keflex
cephalexin	Daxbia
Cyclooxygenase-2 (COX-2) Inhibitors	
celecoxib	Celebrex
celecoxib	Celecoxib
celecoxib/capsaicin/menthol	CapXib
celecoxib/lidocaine/menthol	LidoXib
Fondaparinux	
fondaparinux sodium	Arixtra
fondaparinux sodium	Fondaparinux
Heparin and Low Molecular Weight Heparin	
dalteparin sodium,porcine	Fragmin
enoxaparin sodium	Lovenox
enoxaparin sodium	Enoxaparin
heparin sodium,porcine	Heparin (porcine)
heparin sodium,porcine in 0.45 % sodium chloride/pf	Heparin (porc)-0.45% NaCl (PF)
heparin sodium,porcine in 0.9 % sodium chloride	Heparin (porcine) in 0.9% NaCl
heparin sodium,porcine/dextrose 5 % in water/pf	Heparin (porcine) in D5W (PF)
heparin sodium,porcine/pf	Heparin, Porcine (PF)
heparin sodium,porcine/pf	Monoject Prefill Advanced (PF)
heparin sodium,porcine/pf	Monoject Prefill (PF)
Prescription Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	
celecoxib	Celebrex
celecoxib	Celecoxib
celecoxib/capsaicin/menthol	CapXib
celecoxib/lidocaine/menthol	LidoXib
diclofenac epolamine	Flector
diclofenac potassium	Zipsor
diclofenac potassium	Cambia
diclofenac potassium	Cataflam
diclofenac potassium	Diclofenac Potassium
diclofenac sodium	Dyloject
diclofenac sodium	Voltaren-XR
diclofenac sodium	Diclofenac Sodium
diclofenac sodium	Voltaren
diclofenac sodium/capsaicin	Flexipak
diclofenac sodium/capsaicin	NuDiclo TabPAK
diclofenac sodium/capsicum oleoresin	Inflammacin
diclofenac sodium/capsicum oleoresin	DermaSilkRx DicloPak

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Generic Name	Brand Name
diclofenac sodium/capsicum oleoresin	Xenaflamm
diclofenac sodium/capsicum oleoresin	PrevidolRx Plus Analgesic Pak
diclofenac sodium/misoprostol	Arthrotec 50
diclofenac sodium/misoprostol	Diclofenac-Misoprostol
diclofenac sodium/misoprostol	Arthrotec 75
diclofenac submicronized	Zorvolex
etodolac	Etodolac
etodolac	Lodine
fenoprofen calcium	Nalfon
fenoprofen calcium	Fenortho
fenoprofen calcium	Fenoprofen
fenoprofen calcium	ProFeno
flurbiprofen	Flurbiprofen
flurbiprofen	Ansaid
hydrocodone/ibuprofen	Hydrocodone-Ibuprofen
hydrocodone/ibuprofen	Reprexain
hydrocodone/ibuprofen	Ibudone
hydrocodone/ibuprofen	Xylon 10
hydrocodone/ibuprofen	Vicoprofen
ibuprofen	Caldolor
ibuprofen	Ibuprofen
ibuprofen	Motrin
ibuprofen	IBU
ibuprofen lysine/pf	Ibuprofen Lysine (PF)
ibuprofen lysine/pf	NeoProfen (ibuprofen lysn) (PF)
ibuprofen/caffeine/vitamins b1, b2, b6, & b12	IC400
ibuprofen/caffeine/vitamins b1, b2, b6, & b12	IC800
ibuprofen/dietary supplement,misc. cb.11	Theraprofen-60
ibuprofen/dietary supplement,misc. cb.11	Theraprofen-90
ibuprofen/famotidine	Duexis
ibuprofen/irritants counter-irritants combination no.2	Comfort Pac-Ibuprofen
ibuprofen/oxycodone HCl	Ibuprofen-Oxycodone
ibuprofen/oxycodone HCl	Combunox
indomethacin	Indomethacin
indomethacin	Indocin
indomethacin sodium	Indomethacin Sodium
indomethacin sodium	Indocin
indomethacin, submicronized	Tivorbex
ketoprofen	Ketoprofen
ketorolac tromethamine	Ketorolac
ketorolac tromethamine	ReadySharp Ketorolac
ketorolac tromethamine	Sprix
ketorolac tromethamine	Toradol
ketorolac/norflurane and pentafluoropropane (hfc 245fa)	Toronova SUIK
ketorolac/norflurane and pentafluoropropane (hfc 245fa)	Toronova II SUIK
meclofenamate sodium	Meclofenamate
mefenamic acid	Mefenamic Acid
mefenamic acid	Ponstel
meloxicam	Meloxicam
meloxicam	Mobic
meloxicam, submicronized	Vivlodex
meloxicam/irritants counter-irritants combination no.2	Comfort Pac-Meloxicam

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Generic Name	Brand Name
nabumetone	Nabumetone
nabumetone	Relafen
naproxen	Naprosyn
naproxen	Naproxen
naproxen	EC-Naprosyn
naproxen sodium	Anaprox
naproxen sodium	Naproxen Sodium
naproxen sodium	Anaprox DS
naproxen sodium	Naprelan CR
naproxen sodium	Naprelan CR Dose Card
naproxen sodium/menthol	NaproPak Cool
naproxen/capsaicin/menthol	NaproxenPax
naproxen/capsaicin/menthol	NaproPax
naproxen/capsaicin/menthol/methyl salicylate	Pain Relief Collection
naproxen/dietary supplement,misc. cb.11	Theraproxen
naproxen/dietary supplement,misc. cb.11	Theraproxen-90
naproxen/esomeprazole magnesium	Vimovo
naproxen/irritant counter-irritant combination no.2	Comfort Pac-Naproxen
oxaprozin	Daypro
oxaprozin	Oxaprozin
phenylephrine HCl/ketorolac tromethamine	Omidria
piroxicam	Feldene
piroxicam	Piroxicam
piroxicam/dietary supplement,misc. cb.11	Therafeldamine
ropivacaine HCl/epinephrine/clonidine HCl/ketorolac trometh	Ropivacaine-Epi-Clonid-Ketorol
sulindac	Sulindac
sulindac	Clinoril
sumatriptan succinate/naproxen sodium	Treximet
sumatriptan succinate/naproxen sodium	Sumatriptan-Naproxen
tolmetin sodium	Tolmetin
Serotonin–Norepinephrine Reuptake Inhibitors (SNRIs)	
desvenlafaxine	Desvenlafaxine
desvenlafaxine	Khedezla
desvenlafaxine fumarate	Desvenlafaxine Fumarate
desvenlafaxine succinate	Pristiq
desvenlafaxine succinate	Desvenlafaxine Succinate
duloxetine HCl	Cymbalta
duloxetine HCl	Duloxetine
duloxetine HCl	Irenka
levomilnacipran HCl	Fetzima
milnacipran HCl	Savella
venlafaxine HCl	Effexor XR
venlafaxine HCl	Venlafaxine
venlafaxine HCl	Effexor
Selective Serotonin Reuptake Inhibitors (SSRIs)	
citalopram hydrobromide	Citalopram
citalopram hydrobromide	Celexa
escitalopram oxalate	Lexapro
escitalopram oxalate	Escitalopram Oxalate
fluoxetine HCl	Fluoxetine
fluoxetine HCl	Selfemra

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
fluoxetine HCl	Prozac
fluoxetine HCl	Prozac Weekly
fluoxetine HCl	Sarafem
fluoxetine HCl	Rapiflux
fluoxetine HCl/dietary supplement no.17	Gaboxetine
fluoxetine HCl/dietary supplement no.8	Sentroxatine
fluvoxamine maleate	Fluvoxamine
fluvoxamine maleate	Luvox CR
paroxetine HCl	Paxil
paroxetine HCl	Paroxetine HCl
paroxetine HCl	Paxil CR
paroxetine mesylate	Pexeva
sertraline HCl	Zoloft
sertraline HCl	Sertraline

Medications that Inhibit Metabolism of Warfarin or Novel Oral Anticoagulants (NOACs) and Increase Bleeding Risk	
Cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) Inhibitors and Substrates	
atazanavir sulfate	Reyataz
atazanavir sulfate	Atazanavir
atazanavir sulfate/cobicistat	Evotaz
chloramphenicol sod succinate	Chloramphenicol Sod Succinate
conivaptan HCl/dextrose 5 % in water	Vaprisol in 5 % Dextrose
darunavir ethanolate	Prezista
darunavir ethanolate/cobicistat	Prezcobix
fluconazole	Diflucan
fluconazole	Fluconazole
fluconazole in dextrose, iso-osmotic	Fluconazole in Dextrose (iso-o)
fluconazole in dextrose, iso-osmotic	Diflucan in Dextrose (iso-osm)
fluconazole in sodium chloride, iso-osmotic	Fluconazole in NaCl (iso-osm)
fluconazole in sodium chloride, iso-osmotic	Diflucan in NaCl (iso-osm)
fosamprenavir calcium	Lexiva
fosamprenavir calcium	Fosamprenavir
indinavir sulfate	Crixivan
itraconazole	Itraconazole
itraconazole	Sporanox
itraconazole	Sporanox Pulsepak
itraconazole	Onmel
ketoconazole	Ketoconazole
ketoconazole	Nizoral
lopinavir/ritonavir	Kaletra
lopinavir/ritonavir	Lopinavir-Ritonavir
midazolam HCl	Midazolam
midazolam HCl in 0.9 % sodium chloride	Midazolam in 0.9 % Sod Chlorid
midazolam HCl in 0.9 % sodium chloride/pf	Midazolam (PF) in 0.9 % NaCl
midazolam HCl in 5 % dextrose and water/pf	Midazolam in Dextrose 5 % (PF)
midazolam HCl in dextrose 5% in water	Midazolam in Dextrose 5 %
midazolam HCl/pf	Midazolam (PF)
nefazodone HCl	Nefazodone
nelfinavir mesylate	Viracept
saquinavir mesylate	Invirase
tipranavir	Aptivus

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
tipranavir/vitamin e tpgs	Aptivus
trandolapril/verapamil HCl	Tarka
trandolapril/verapamil HCl	Trandolapril-Verapamil
triazolam	Triazolam
triazolam	Halcion
verapamil HCl	Verapamil
verapamil HCl	Verelan PM
verapamil HCl	Verelan
verapamil HCl	Calan
verapamil HCl	Calan SR
verapamil HCl	Isoptin SR
verapamil HCl	Covera-HS
Fibrates	
fenofibrate	Fenofibrate
fenofibrate	Lipofen
fenofibrate	Fenoglide
fenofibrate	Lofibra
fenofibrate nanocrystallized	Tricor
fenofibrate nanocrystallized	Fenofibrate Nanocrystallized
fenofibrate nanocrystallized	Triglide
fenofibrate,micronized	Antara
fenofibrate,micronized	Fenofibrate Micronized
fenofibrate,micronized	Lofibra
fenofibric acid	Fibricor
fenofibric acid	Fenofibric Acid
fenofibric acid (choline)	Trilipix
fenofibric acid (choline)	Fenofibric Acid (choline)
gemfibrozil	Lopid
gemfibrozil	Gemfibrozil
Statins	
amlodipine besylate/atorvastatin calcium	Caduet
amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
atorvastatin calcium	Lipitor
atorvastatin calcium	Atorvastatin
ezetimibe/atorvastatin calcium	Liptruzet
ezetimibe/simvastatin	Ezetimibe-Simvastatin
ezetimibe/simvastatin	Vytorin 10-40
ezetimibe/simvastatin	Vytorin 10-80
ezetimibe/simvastatin	Vytorin 10-10
ezetimibe/simvastatin	Vytorin 10-20
fluvastatin sodium	Lescol
fluvastatin sodium	Fluvastatin
fluvastatin sodium	Lescol XL
lovastatin	Lovastatin
lovastatin	Mevacor
lovastatin	Altoprev
niacin/lovastatin	Advicor
niacin/simvastatin	Simcor
pitavastatin calcium	Livalo
pitavastatin magnesium	Zypitamag
pravastatin sodium	Pravachol
pravastatin sodium	Pravastatin

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
rosuvastatin calcium	Rosuvastatin
rosuvastatin calcium	Crestor
simvastatin	FloLipid
simvastatin	Zocor
simvastatin	Simvastatin
sitagliptin phosphate/simvastatin	Juvisync
Other Medications that Inhibit CYP3A4, P-gp, Cytochrome P450 2C9 (CYP2C9), or Cytochrome P450 1A2 (CYP1A2)	
amiodarone HCl	Amiodarone
amiodarone HCl	Pacerone
amiodarone HCl	Cordarone
amiodarone HCl/dextrose 5 % in water	Amiodarone in Dextrose 5 %
amiodarone in dextrose, iso-osmotic	Nexterone
cimetidine	Cimetidine
cimetidine	Tagamet
cimetidine HCl	Cimetidine HCl
ciprofloxacin	Otiprio
ciprofloxacin	Cipro
ciprofloxacin	Ciprofloxacin
ciprofloxacin HCl	Ciprofloxacin HCl
ciprofloxacin HCl	Cipro
ciprofloxacin HCl	ProQuin XR
ciprofloxacin lactate	Ciprofloxacin Lactate
ciprofloxacin lactate/dextrose 5 % in water	Ciprofloxacin in 5 % Dextrose
ciprofloxacin lactate/dextrose 5 % in water	Cipro in D5W
ciprofloxacin/ciprofloxacin HCl	Ciprofloxacin (mixture)
ciprofloxacin/ciprofloxacin HCl	Cipro XR
clarithromycin	Biaxin
clarithromycin	Clarithromycin
clarithromycin	Biaxin XL
clarithromycin	Biaxin XL Pak
clopidogrel bisulfate	Clopidogrel
clopidogrel bisulfate	Plavix
erythromycin base	Erythromycin
erythromycin base	PCE
erythromycin base	Ery-Tab
erythromycin base	E-Mycin
erythromycin ethylsuccinate	EryPed 200
erythromycin ethylsuccinate	E.E.S. Granules
erythromycin ethylsuccinate	E.E.S. 200
erythromycin ethylsuccinate	Erythromycin Ethylsuccinate
erythromycin ethylsuccinate	EryPed
erythromycin ethylsuccinate	EryPed 400
erythromycin ethylsuccinate	E.E.S. 400
erythromycin ethylsuccinate/sulfisoxazole acetyl	Erythromycin-Sulfisoxazole
erythromycin lactobionate	Erythrocin
erythromycin stearate	Erythrocin (as stearate)
erythromycin stearate	Erythromycin Stearate
lansoprazole/amoxicillin trihydrate/clarithromycin	Amoxicil-Clarithromy-Lansopraz
lansoprazole/amoxicillin trihydrate/clarithromycin	Prevpac
sulfamethoxazole/trimethoprim	Sulfamethoxazole-Trimethoprim
sulfamethoxazole/trimethoprim	Sulfatrim
sulfamethoxazole/trimethoprim	Septra

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
sulfamethoxazole/trimethoprim	Bactrim
sulfamethoxazole/trimethoprim	Bactrim DS
sulfamethoxazole/trimethoprim	SMZ-TMP DS
sulfamethoxazole/trimethoprim	Septra DS
trimethoprim	Primsol
trimethoprim	Trimpex
trimethoprim	Trimethoprim
Medications that Induce Metabolism of Warfarin or Novel Oral Anticoagulants (NOACs) and Decrease Bleeding Risk	
CYP3A4 and P-gp Inducers	
carbamazepine	Carbamazepine
carbamazepine	Equetro
carbamazepine	Carbatrol
carbamazepine	Tegretol
carbamazepine	Epitol
carbamazepine	Tegretol XR
fosphenytoin sodium	Cerebyx
fosphenytoin sodium	Fosphenytoin
omacetaxine mepesuccinate	Synribo
phenytoin	Phenytoin
phenytoin	Dilantin-125
phenytoin	Dilantin Infatabs
phenytoin sodium	Phenytoin Sodium
phenytoin sodium extended	Dilantin
phenytoin sodium extended	Dilantin Kapseal
phenytoin sodium extended	Dilantin Extended
phenytoin sodium extended	Phenytoin sodium extended
phenytoin sodium extended	Phenytek
rifampin	Rifadin
rifampin	Rifampin
rifampin	Rimactane
rifampin/isoniazid	Rifamate
rifampin/isoniazid	IsonaRif
rifampin/isoniazid/pyrazinamide	Rifater
CYP2C9 Inducers	
bosentan	Tracleer
phenobarbital	Phenobarbital
phenobarbital sodium	Phenobarbital Sodium
phenobarbital sodium	Luminal
phenobarbital sodium in 0.9 % sodium chloride	Phenobarbital in 0.9 % Sod Chl
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Donnatal
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	SE-Donna PB Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Phenobarb-Hyoscy-Atropine-Scop
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Belladonna-Phenobarbital
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Quadrapax
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	PB-HYOS

Appendix J. List of Generic and Brand Names of Medical Products Used to Define Covariates and Subgroups in this Request

Generic Name	Brand Name
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Antispasmodic
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Me-PB-Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	RE-PB Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	B-Donna
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Phenohytro
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Servira
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Donnatal Extentabs
CYP1A2 Inducers	
aspirin/omeprazole	Yosprala
esomeprazole magnesium	Esomeprazole Magnesium
esomeprazole magnesium	Nexium
esomeprazole magnesium	Nexium Packet
esomeprazole magnesium/glycerin	Esomep-EZS
esomeprazole sodium	Nexium IV
esomeprazole sodium	Esomeprazole Sodium
esomeprazole strontium	Esomeprazole Strontium
montelukast sodium	Singulair
montelukast sodium	Montelukast
naproxen/esomeprazole magnesium	Vimovo
omeprazole	Omeprazole
omeprazole	Prilosec
omeprazole	Omeprazole+SyrSpend SF Alka
omeprazole	FIRST-Omeprazole
omeprazole magnesium	Prilosec
omeprazole/clarithromycin/amoxicillin trihydrate	Omeclamox-Pak
omeprazole/sodium bicarbonate	Omeprazole-Sodium Bicarbonate
omeprazole/sodium bicarbonate	Zegerid
omeprazole/sodium bicarbonate	OmePPi
Novel Oral Anticoagulant (High Dose)	
See Appendix B for generic and brand names for NOACs.	

Appendix K. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool to perform a risk assessment of severe uterine bleed (SUB) among users of oral anticoagulants (rivaroxaban vs. dabigatran, rivaroxaban vs. apixaban, dabigatran vs. apixaban, rivaroxaban vs. warfarin). This was an expansion of the previous request (cder_mpl2p_wp007) that used custom code for propensity score (PS) stratification analysis.

Query Period: October 19, 2010 to September 30, 2015
Coverage Requirement: Medical and Drug
Pre-exposure Enrollment: 183 days
Post-index enrollment requirement: 0 days
Enrollment Gap: 45 days
Sex: Female
Stratifications: Age: 18-50; 51+ years
Index-defining Novel Oral Anticoagulant (NOAC) Dose: low; high
Any gynecological disorder: see "Appendix L"
Age*dose: 18-50, low; 18-50, high; 51+, low; 51+, high
DVT/PE
Age*DVT/PE
AF
Age*AF
Return: Aggregate-level, index code distribution, censoring table
Only one report were produced. The report will not reflect a non-CMS vs. CMS split.
Envelope Macro Use: On
Frozen Data: Yes
Notes: Default stockpiling specifications were used; stockpiling were done by generic name only

	Drug/Exposure								
Comparison	**Exposure**	**Exposure Episode Truncation Criteria**	**Incident with respect to:**	**Washout Period**	**Cohort Definition**	**Exposure Episode Gap (Days)**	**Exposure Extension Period (Days)**	**Minimum Episode Duration (Days)**	**Minimum Days Supplied (Days)**
1	Rivaroxaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, dabigatran, apixaban, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Dabigatran	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, rivaroxaban, apixaban, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1

Appendix K. Specifications Defining Parameters for this Request

	Drug/Exposure								
Comparison	Exposure	Exposure Episode Truncation Criteria	Incident with respect to:	Washout Period	Cohort Definition	Exposure Episode Gap (Days)	Exposure Extension Period (Days)	Minimum Episode Duration (Days)	Minimum Days Supplied (Days)
2	Rivaroxaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, apixaban, dabigatran, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Apixaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, rivaroxaban, dabigatran, edoxaban, warfarin							
3	Dabigatran	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, apixaban, rivaroxaban, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Apixaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, dabigatran, rivaroxaban, edoxaban, warfarin							
4	Rivaroxaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, warfarin, dabigatran, apixaban, edoxaban	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Warfarin	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, rivaroxaban, dabigatran, apixaban, edoxaban							

Appendix K. Specifications Defining Parameters for this Request

	Drug/Exposure								
Comparison	Exposure	Exposure Episode Truncation Criteria	Incident with respect to:	Washout Period	Cohort Definition	Exposure Episode Gap (Days)	Exposure Extension Period (Days)	Minimum Episode Duration (Days)	Minimum Days Supplied (Days)
5	Rivaroxaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, dabigatran, apixaban, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Dabigatran	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, rivaroxaban, apixaban, edoxaban, warfarin							
6	Rivaroxaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, apixaban, dabigatran, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Apixaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, rivaroxaban, dabigatran, edoxaban, warfarin							
7	Dabigatran	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, apixaban, rivaroxaban, edoxaban, warfarin	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Apixaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, dabigatran, rivaroxaban, edoxaban, warfarin							

Appendix K. Specifications Defining Parameters for this Request

	Drug/Exposure								
Comparison	**Exposure**	**Exposure Episode Truncation Criteria**	**Incident with respect to:**	**Washout Period**	**Cohort Definition**	**Exposure Episode Gap (Days)**	**Exposure Extension Period (Days)**	**Minimum Episode Duration (Days)**	**Minimum Days Supplied (Days)**
8	Rivaroxaban	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, warfarin, dabigatran, apixaban, edoxaban	Rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	183 days	Only the first valid treatment episode during the query period (01)	3	3	1	1
	Warfarin	Occurrence of first SUB, end of query period, disenrollment, death, end of exposure use, rivaroxaban, dabigatran, apixaban, edoxaban							

Appendix K. Specifications Defining Parameters for this Request

	Inclusion/Exclusion Criteria				Event/Outcome				
Comparison	Conditions	Inclusion/ Exclusion	Care Setting/ Primary Diagonsis	Lookback Period (Days)	Event/Outcome	Event Time	Care Setting/ Primary Diagnosis	Event Washout (Days)	Blackout Period (Days)
1	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see "Overview" and "Appendix M", Figure 1 for definition)	Transfusion Date	Inpatient Hospital Stay (IP), Emergency Department (ED), Ambulatory Visit (AV), or Other Ambulatory VIsit (OA)	0	0
	Hysterectomy; vaginal bleed (VB); transfusion management for Severe Uterine Bleed (SUB) with same-day conjugated equine estrogen; medical managements for SUB	Exclusion	Any	(-183, 0)					
	Apixaban, edoxaban, warfarin	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					
2	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see "Overview" and "Appendix M", Figure 1 for definition)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); transfusion management for Severe Uterine Bleed (SUB) with same-day conjugated equine estrogen; medical managements for SUB	Exclusion	Any	(-183, 0)					
	Dabigatran, edoxaban, warfarin	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					
3	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see "Overview" and "Appendix M", Figure 1 for definition)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); transfusion management for Severe Uterine Bleed (SUB) with same-day conjugated equine estrogen; medical managements for SUB	Exclusion	Any	(-183, 0)					
	Rivaroxaban, edoxaban, warfarin	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					

Appendix K. Specifications Defining Parameters for this Request

	Inclusion/Exclusion Criteria				Event/Outcome				
Comparison	Conditions	Inclusion/ Exclusion	Care Setting/ Primary Diagonsis	Lookback Period (Days)	Event/Outcome	Event Time	Care Setting/ Primary Diagnosis	Event Washout (Days)	Blackout Period (Days)
4	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see "Overview" and "Appendix M", Figure 1 for definition)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); transfusion management for Severe Uterine Bleed (SUB) with same-day conjugated equine estrogen; medical managements for SUB	Exclusion	Any	(-183, 0)					
	Dabigatran, apixaban, edoxaban	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					
5	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see "Overview" and "Appendix M", Figure 2 for definition)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Apixaban, edoxaban, warfarin	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					
6	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see "Overview" and "Appendix M", Figure 2 for definition)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Dabigatran, edoxaban, warfarin	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					

Appendix K. Specifications Defining Parameters for this Request

	Inclusion/Exclusion Criteria				Event/Outcome				
Comparison	Conditions	Inclusion/ Exclusion	Care Setting/ Primary Diagonsis	Lookback Period (Days)	Event/Outcome	Event Time	Care Setting/ Primary Diagnosis	Event Washout (Days)	Blackout Period (Days)
7	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see "Overview" and "Appendix M", Figure 2 for definition)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Rivaroxaban, edoxaban, warfarin	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					
8	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation or atrial flutter (AF)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see "Overview" and "Appendix M", Figure 2 for definition)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleed (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Dabigatran, apixaban, edoxaban	Exclusion	N/A	(0, 0)					
	Joint replacement surgery (knee or hip)	Exclusion	N/A	(-183, 0)					

Appendix K. Specifications Defining Parameters for this Request

	Baseline Covariates			
Comparison	**Covariates**	**Care Setting/Principal Diagnosis Position**	**Covariate Evaluation Window (days)**	**Comorbidity Score Evaluation Window (days)**
1	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
2	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
3	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
4	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
5	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
6	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
7	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)
8	(See "Appendix L")	(See "Appendix L")	(-183, 0)	(-183, 0)

Appendix K. Specifications Defining Parameters for this Request

	Propensity Score Analysis					Utilization		
Comparison	Perform HDPS Analysis	Matching Ratio	Matching Caliper Settings	Subgroup	Matching Reperformed Within Subgroups	Medical Utilization Evaluation Window	Medical Utilization Care Setting	Drug Utilization Evaluation Window
1	No	1:1	0.05	Age (18-50; 51+) Index-Defining NOAC Dose (low; high) Age*Dose (18-50, low; 18-50, high; 51+, low; 51+, high) Gynecological disorders (Yes; No)	Matched Population	(-183, 0)	(-183, 0)	(-183, 0)
2	No	1:1	0.05	Age (18-50; 51+) Index-Defining NOAC Dose (low; high) Age*Dose (18-50, low; 18-50, high; 51+, low; 51+, high) Gynecological disorders (Yes; No)	Matched population	(-183, 0)	(-183, 0)	(-183, 0)
3	No	1:1	0.05	Age (18-50; 51+) Index-Defining NOAC Dose (low; high) Age*Dose (18-50, low; 18-50, high; 51+, low; 51+, high) Gynecological disorders (Yes; No)	Matched population	(-183, 0)	(-183, 0)	(-183, 0)

Appendix K. Specifications Defining Parameters for this Request

	Propensity Score Analysis					Utilization		
Comparison	Perform HDPS Analysis	Matching Ratio	Matching Caliper Settings	Subgroup	Matching Reperformed Within Subgroups	Medical Utilization Evaluation Window	Medical Utilization Care Setting	Drug Utilization Evaluation Window
4	No	1:1	0.05	Age (18-50; 51+) Gynecological disorders (Yes; No)	Matched population	(-183, 0)	(-183, 0)	(-183, 0)
5	No	1:1	0.05	Age (18-50; 51+) Index-Defining NOAC Dose (low; high) Age*Dose (18-50, low; 18-50, high; 51+, low; 51+, high) Gynecological disorders (Yes; No)	Test: Matched population Use for final analysis	(-183, 0)	(-183, 0)	(-183, 0)
6	No	1:1	0.05	Age (18-50; 51+) Index-Defining NOAC Dose (low; high) Age*Dose (18-50, low; 18-50, high; 51+, low; 51+, high) Gynecological disorders (Yes; No)	Matched population	(-183, 0)	(-183, 0)	(-183, 0)

Appendix K. Specifications Defining Parameters for this Request

	Propensity Score Analysis					Utilization		
Comparison	Perform HDPS Analysis	Matching Ratio	Matching Caliper Settings	Subgroup	Matching Reperformed Within Subgroups	Medical Utilization Evaluation Window	Medical Utilization Care Setting	Drug Utilization Evaluation Window
7	No	1:1	0.05	Age (18-50; 51+) Index-Defining NOAC Dose (low; high) Age*Dose (18-50, low; 18-50, high; 51+, low; 51+, high) Gynecological disorders (Yes; No)	Matched population	(-183, 0)	(-183, 0)	(-183, 0)
8	No	1:1	0.05	Age (18-50; 51+) Gynecological disorders (Yes; No)	Matched population	(-183, 0)	(-183, 0)	(-183, 0)

Appendix L. List and Definition of Covariates Included in Characteristic Tables (Table 1s), Propensity Score Model, or Subgroup Definitions in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PS Covariates	Subgroup
Medical history	Diabetes	Any	(-183, 0)	Y	Y	N
	Hypertension	Any	(-183, 0)	Y	Y	N
	Renal impairment	Any	(-183, 0)	Y	Y	N
	Obesity	Any	(-183, 0)	Y	Y	N
	Smoking	Any	(-183, 0)	Y	Y	N
Cardiovascular disease	Acute myocardial infarction	Any	(-183, 0)	N	N	N
	Coronary revascularization	Any	(-183, 0)	N	N	N
	Heart failure	Any	(-183, 0)	N	N	N
	Stroke	Any	(-183, 0)	N	N	N
	Other cerebrovascular disease	Any	(-183, 0)	N	N	N
	Transient ischemic attack	Any	(-183, 0)	N	N	N
	All cardiovascular disease diagnoses	Any	(-183, 0)	Y	Y	N
Cardiovascular and antidiabetic agents	Statins	N/A	(-183, 0)	N	N	N
	Non-statin lipid lowering agents	N/A	(-183, 0)	N	N	N
	ACE inhibitors	N/A	(-183, 0)	N	N	N
	Angiotensin receptor blockers	N/A	(-183, 0)	N	N	N
	Anti-arrhythmic agents	N/A	(-183, 0)	N	N	N
	Aldosterone receptor antagonists	N/A	(-183, 0)	N	N	N
	Beta blockers	N/A	(-183, 0)	N	N	N
	Calcium channel blockers	N/A	(-183, 0)	N	N	N
	Diuretics	N/A	(-183, 0)	N	N	N
	Other antihypertensives	N/A	(-183, 0)	N	N	N
	Antianginal vasodilators	N/A	(-183, 0)	N	N	N
	Oral antidiabetic agents	N/A	(-183, 0)	N	N	N
	Insulin	N/A	(-183, 0)	N	N	N
	All cardiovascular and antidiabetic agents	N/A	(-183, 0)	Y	Y	N

Appendix L. List and Definition of Covariates Included in Characteristic Tables (Table 1s), Propensity Score Model, or Subgroup Definitions in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PS Covariates	Subgroup
Medications that increase bleeding risk without interaction with warfarin or NOACs	Aspirin	N/A	(-183, 0)	N	N	N
	Antiplatelet agents	N/A	(-183, 0)	N	N	N
	Prescription NSAIDs	N/A	(-183, 0)	N	N	N
	COX-2 inhibitors	N/A	(-183, 0)	N	N	N
	SSRIs	N/A	(-183, 0)	N	N	N
	SNRIs	N/A	(-183, 0)	N	N	N
	Heparin, low molecular weight heparin, fondaparinux	N/A	(-183, 0)	N	N	N
	Cephalosporins	N/A	(-183, 0)	N	N	N
	All medications that increase bleeding risk	N/A	(-183, 0)	Y	Y	N
Medications that inhibit metabolism of warfarin or NOACs and increase bleeding risk	CYP3A4 and P-gp inhibitors (protease inhibitors (atazanavir, darunavir, fosamprenavir, nelfinavir, saquinavir, tipranavir, lopinavir/ritonavir, indinavir), azole antifungals (ketoconazole, itraconazole, fluconazole), nefazodone, chloramphenicol, conivaptan, verapamil, midazolam, triazolam)	N/A	(-183, 0)	N	N	N
	Fibrates	N/A	(-183, 0)	N	N	N
	Statins	N/A	(-183, 0)	N	N	N
	Other medications that inhibit CYP3A4, P-gp, CYP2C9, or CYP1A2 (amiodarone, cimetidine, ciprofloxacin, clopidogrel, co-trimoxazole (trimethoprim), erythromycin, clarithromycin)	N/A	(-183, 0)	N	N	N
	All medications listed on label as having clinically significant interactions with warfarin or NOACs (inhibitors and substrates)	N/A	(-183, 0)	Y	Y	N

Appendix L. List and Definition of Covariates Included in Characteristic Tables (Table 1s), Propensity Score Model, or Subgroup Definitions in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PS Covariates	Subgroup
Medications that induce metabolism of warfarin or NOACs and decrease bleeding risk	CYP3A4 and P-gp inducers (rifampin, phenytoin, carbamazepine, omacetaxine)	N/A	(-183, 0)	N	N	N
	CYP2C9 inducers (bosentan, phenobarbital)	N/A	(-183, 0)	N	N	N
	CYP1A2 inducers (montelukast, omeprazole)	N/A	(-183, 0)	N	N	N
	All medications listed on label as having clinically significant interactions with warfarin or NOACs (inducers)	N/A	(-183, 0)	Y	Y	N
Severe anemia	Red blood cell transfusion	Any	(-183, 0)	Y	Y	N
Gynecological disorders of interest	Uterine myoma	Any	(-183, 0)	Y	N	N
	Endometrial hyperplasia	Any	(-183, 0)	Y	N	N
	Endometriosis	Any	(-183, 0)	Y	N	N
	Ovarian cyst	Any	(-183, 0)	Y	N	N
	Uterine or cervical polyp	Any	(-183, 0)	Y	N	N
	Adenomyosis	Any	(-183, 0)	Y	N	N
	Uterine, ovarian or cervical cancer	Any	(-183, 0)	Y	N	N
	Any gynecological disorder of interest	Any	(-183, 0)	Y	Y	Y
Von Willebrand's disease	Von Willebrand's disease	Any	(-183, 0)	Y	Y	N
Inclusion criteria	Deep vein thrombosis (DVT) / pulmonary embolism (PE)	N/A	(-183, 0)	Y	Y	Y
	Atrial Fibrillation (AF) or atrial flutter	N/A	(-183, 0)	Y	Y	Y
Treatment dose[1]	High dosage (rivaroxaban, apixaban)	N/A	(0, 0)	Y	N	Y
	High dosage (rivaroxaban, dabigatran)	N/A	(0, 0)	Y	N	Y
	High dosage (dabigatran, apixaban)	N/A	(0, 0)	Y	N	Y
Demographics	Race/ethnicity	N/A	NA	Y	N	N
	Continuous age	N/A	NA	Y	Y	N
	Age groups 18-50 and 51+ years	N/A	NA	Y	N	Y
	Calendar year	N/A	NA	Y	N	N

Appendix L. List and Definition of Covariates Included in Characteristic Tables (Table 1s), Propensity Score Model, or Subgroup Definitions in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PS Covariates	Subgroup
Comorbidity	Comorbidity Score	N/A	(-183, 0)	Y	Y	N
Health care / medical utilization	Number of inpatient hospital stays	N/A	(-183, 0)	Y	Y	N
	Number of non-acute institutional stays	N/A	(-183, 0)	Y	Y	N
	Number of emergency department visits	N/A	(-183, 0)	Y	Y	N
	Number of ambulatory visits	N/A	(-183, 0)	Y	Y	N
	Number of other ambulatory visits (includes other non overnight ambulatory encounters such as home health visits, telemedicine, telephone and email consultations)	N/A	(-183, 0)	Y	Y	N
Drug utilization	Number of dispensings	N/A	(-183, 0)	Y	Y	N
	Number of unique generics dispensed	N/A	(-183, 0)	Y	Y	N
	Number of unique drug classes dispensed	N/A	(-183, 0)	Y	Y	N
Additional reporting (vaginal bleed for custom code)[2]	Vaginal bleed	Inpatient Hospital Stay (IP)*, Emergency Department (ED)*, Ambulatory visit (AV)*, or Other Ambulatory Visit	(1, end of enrollment)	Y	N	N
Additional reporting (medical managements for SUB)[3]	Insertion of intrauterine system device	IP*, ED*, AV*, or OA*	(VB date,	N	N	N
	Initiation of contraception (combined oral contraceptives and progestin-only contraceptives)	N/A	(VB date, SUB/censoring)[4]	N	N	N
	Vaginal packing	IP*, ED*, AV*, or OA*	(VB date,	N	N	N
	Initiation of an antifibrinolytic drug (tranexamic acid, aminocaproic acid, aprotinin,	N/A	(VB date, SUB/censoring)[4]	N	N	N
	Any medical management	IP*, ED*, AV*, or OA*	(VB date,	N	N	N

[1]Only the relevant High Dosage subgroup covariate was shown in the Table 1 for each comparison.

[2]Post-index vaginal bleed was reported independently in Table 1 and along with medical managements in Table 11.

[3]Medical management observed after the first post-index vaginal bleed was summarized in Table 11.

[4]If individuals did not have a VB diagnosis (see footnote 2), then they were not included in medical management metrics.

Note 1: The maximum allowable gap was 60 days.

Note 2: The exposure episode ended if one of the following occurred: end of treatment episode, SUB occurrence, disenrollment, death, end of available data, or end of query period

Note 3: Vaginal Bleed (VB) event date was the date a patient is diagnosed with vaginal bleed. Management date is taken as the date of Severe Uterine Bleed (SUB).

Note 4: SUB event date is taken as the date of HOI.

Figure 1

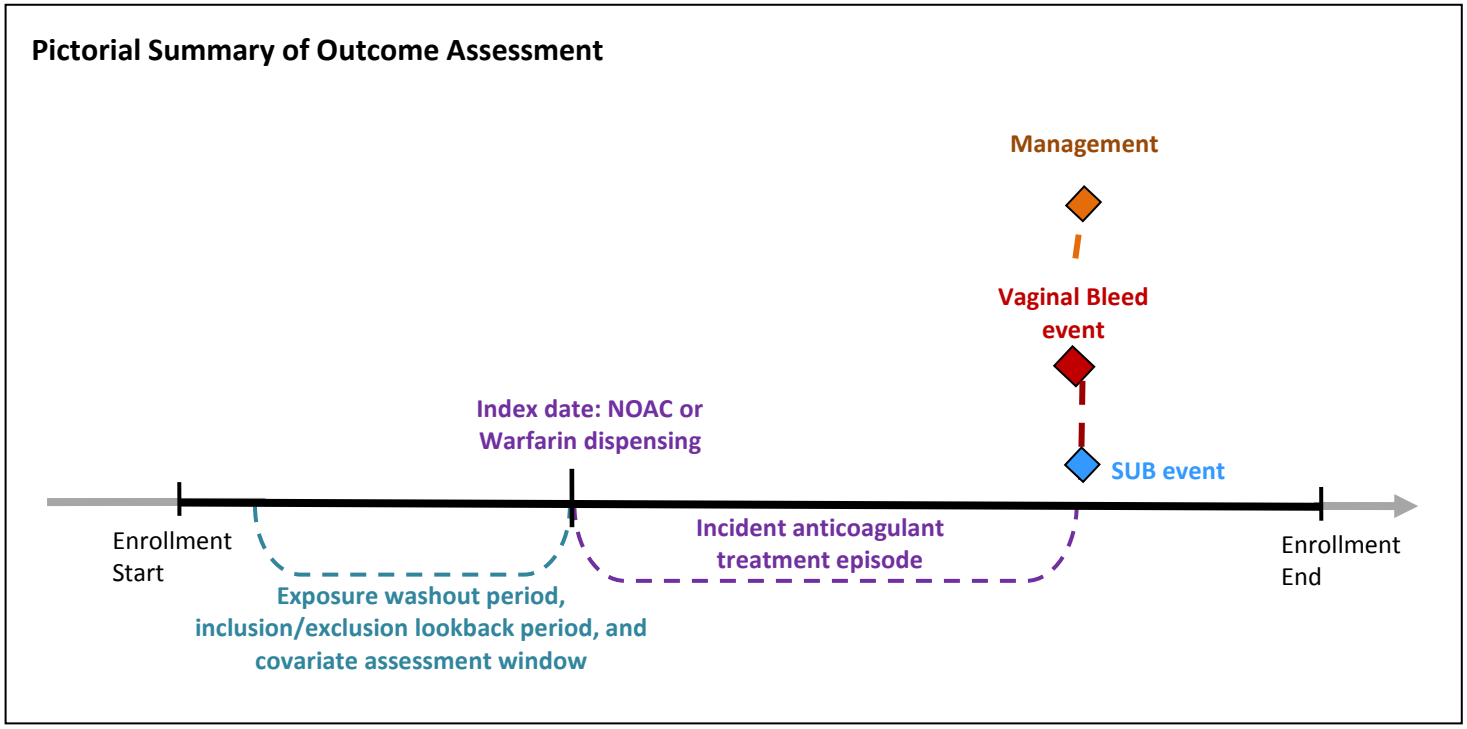

Figure 2

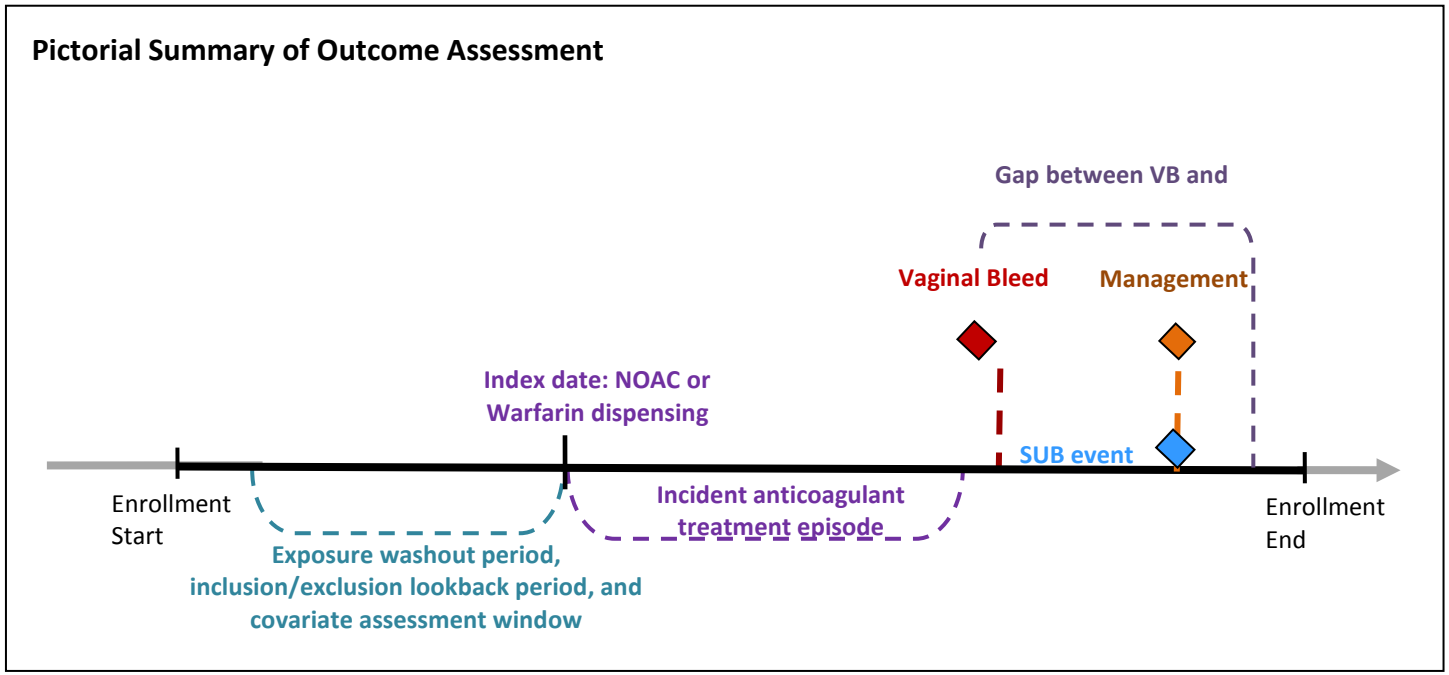
Pictorial Summary of Outcome Assessment
Gap between VB and
Vaginal Bleed
Management
Index date: NOAC or
Warfarin dispensing
SUB event
Enrollment
Start
Incident anticoagulant
treatment episode
Enrollment
End
Exposure washout period,
inclusion/exclusion lookback period, and
covariate assessment window

Figure 3

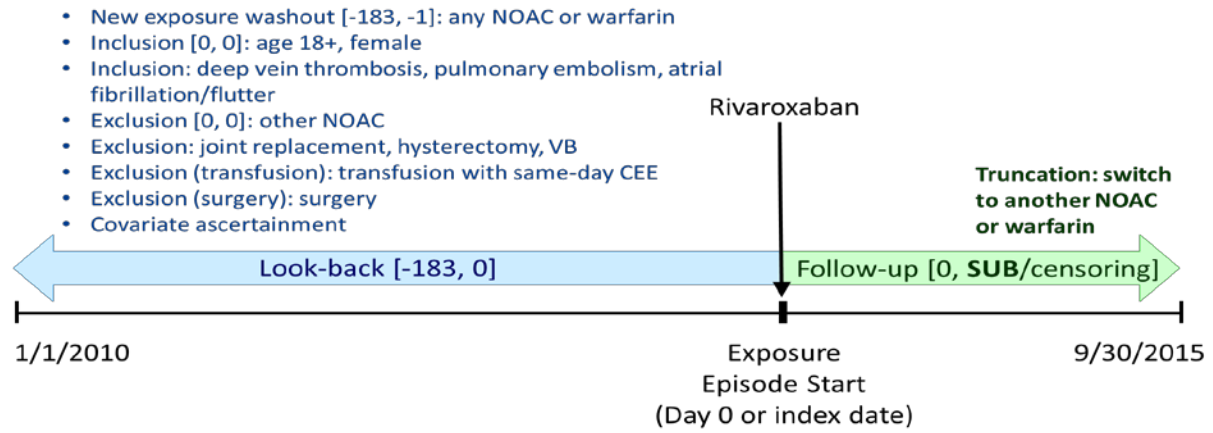

Figure 4

Post-Index Medical Management Window Definition with Surgical Management Severe Uterine Bleed Definition

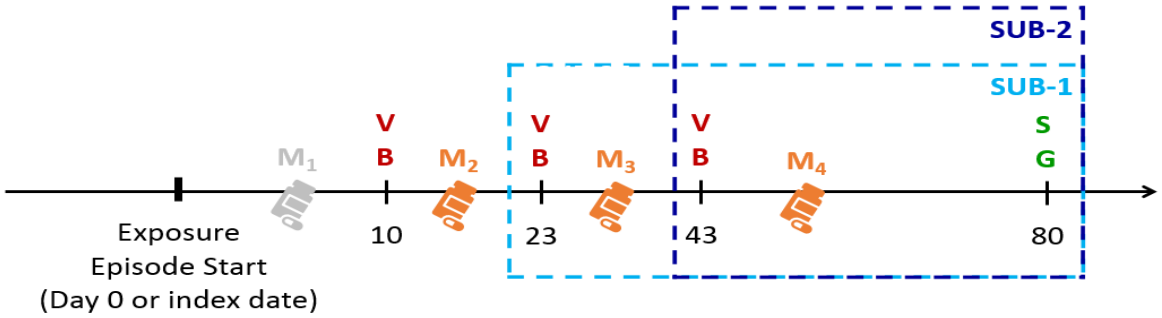

Figure 5
Post-Index Medical Management Window Definition with Transfusion Management Severe Uterine Bleed Definition

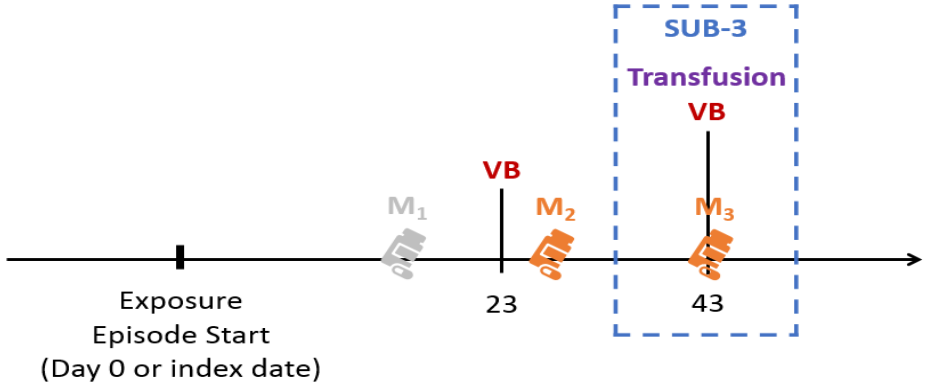

Figure 6
Post-Index Medical Management Window Definition without Severe Uterine Bleed