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_wp007_nsdp_v01

Request ID: cder_mpl2p_wp007_nsdp_v01

Request Description: In this request, we performed a risk assessment of severe uterine bleed (SUB) among users of oral anticoagulants (rivaroxaban, dabigatran, apixaban, and warfarin) in the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 5.4.4, with Propensity Score Matching (PSM)

Data Source: We included data from October 19, 2010 through September 30, 2015 from five Data Partners contributing to the SDD in this report. We distributed the request on February 21, 2019. Please see Appendix A for a list of the latest dates of available data for each Data Partner.

Study Design: We used a retrospective new-user cohort design. Sixteen cohorts, or eight comparisons, were created to investigate the effect estimates for both overall populations and for subgroups defined by age groups (<50 vs. 50+ years of age), presence of any gynecological disorder (uterine myoma, endometrial hyperplasia, endometriosis, ovarian cyst, uterine or cervical polyp, adenomyosis, or uterine cancer/ovarian cancer/cervical cancer), and dose of index-defining novel oral anticoagulants (NOACs). Dose was approximated by product strength and defined as the following categories:

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

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

Additionally, effect estimates were obtained for subgroups defined as the cross-stratification between dose and age groups (<50 years of age, low dose; <50 years of age, high dose; 50+ years of age, low dose; 50+ years of age, high dose). This cross-stratified subgroup analysis was obtained using custom code.

Exposures of Interest: We used four exposures of interest in this report that are listed below in the eight paired comparisons of interest. Each were defined using National Drug Codes (NDCs). Please see Appendix B for generic and brand medical product names.

Comparison 1: Rivaroxaban vs. dabigatran, SUB with surgical management
Comparison 2: Rivaroxaban vs. apixaban, SUB with surgical management
Comparison 3: Dabigatran vs. apixaban, SUB with surgical management
Comparison 4: Rivaroxaban vs. warfarin, SUB with surgical management
Comparison 5: Rivaroxaban vs. dabigatran, SUB with transfusion management
Comparison 6: Rivaroxaban vs. apixaban, SUB with transfusion management
Comparison 7: Dabigatran vs. apixaban, SUB with transfusion management
Comparison 8: Rivaroxaban vs. warfarin, SUB with transfusion management

Cohort Eligibility Criteria: We required members included in each cohort to be continuously enrolled in plans with medical and drug coverage for at least 183 days prior to index dispensing date, during which gaps in coverage of up to 45 days were allowed. Members were excluded if they had any of the query exposures of interest or edoxaban in the 183 days prior to the index date. Incidence criteria were defined using NDCs. Please see Appendix B for generic and brand medical product names for incidence criteria. The following age groups were included in the cohort: <50 vs. 50+ years of age. Only female patients were considered. Only the first valid incident dispensing per patient was included.

Inclusion and Exclusion Criteria : Inclusion and exclusion criteria for the all cohorts were evaluated 183 days prior to index dispensing date. Patients were required to have a baseline condition of either atrial fibrillation or flutter, deep vein thrombosis or pulmonary embolism, or knee/hip joint replacement surgery. Members with baseline condition(s) of hysterectomy, vaginal bleed, medical managements of SUB, and either surgical managements (if SUB was defined using surgical managements) or same-day transfusion managements and conjugated equine estrogen dispensing (if SUB was defined using transfusion management) were excluded. Each management was defined as follows:

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

Additionally, each cohort in a comparison had a day 0 exclusion on non-comparison oral anti-coagulants (including warfarin). For example, for Comparison 1 (rivaroxaban vs. dabigatran), both cohorts had a index day exclusion criteria of apixaban, edoxaban, or warfarin.

We used NDCs, International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes, Healthcare Common Procedure Coding System (HCPCS) codes, Current Procedural Terminology, Fourth Edition (CPT-4), and Revenue Center (RE) codes to define the inclusion and exclusion criteria. Please see Appendix C for a list of diagnosis and procedure codes, and Appendix D for generic and brand medical product names of dispensings.

Follow-Up Time: We determined follow-up time by the length of the exposure episodes. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days' supply were less than three days. Follow-up began on the day on which the first exposure of interest was dispensed 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) the outcome of interest; or 6) dispensing of any oral anti-coagulant that did not define the exposure of each respective cohort.

Outcomes of Interest: We defined SUB as a combination of vaginal bleed and either transfusion or surgical management in non-institutional (non-IS) care settings. The date of SUB diagnosis was determined to be the date of the management. The SUB definitions used for each cohort were defined as below.

1) Vaginal bleed and transfusion management occurring on the same day (See Figure 1, Appendix M)
2) Vaginal bleed and surgical management occurring within 60 days after the vaginal bleed diagnosis (See Figure 2, Appendix M)

Please see Appendix E for the list of vaginal bleed defined using ICD-9-CM diagnosis codes. Please see Appendix F for a list of diagnosis and procedure code for managements defined using ICD-9-CM diagnosis and procedure codes, HCPCS codes, CPT-4 codes, and RE codes.

Baseline Covariates: We assessed the following covariates during the baseline period: continuous age, age group, calendar year, race, comorbidity score (Combined Comorbidity Index)[a], health service and drug utilizations, diabetes, hypertension, renal impairment, obesity, smoking, cardiovascular disease, 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, severe anemia (as defined by RBC-only transfusion codes), gynecological disorders, and Von Willebrand's disease. All above diagnoses and procedure codes were captured from all care settings. Occurrence of these covariates was evaluated in the 183 days prior to the index dispensing, including day of exposure. Please see Appendix I for a list of diagnosis and procedure codes, and Appendix J for generic and brand medical product names. Please see Appendix L for further information on what diagnoses, procedures, or drug classes comprised each baseline characteristics, which characteristics appeared in Table 1, and which were used in the final PSM.

Additional reporting : Within each cohort, vaginal bleed was assessed in the period of time starting the day after index date until the end of enrollment. Medical managements, as defined above, were assessed if a patient was diagnosed with vaginal bleed. This was done within the entire cohort, among patients with SUB events, and among patients without SUB events. Medical managements were assessed in the period starting from the first post-index vaginal bleed diagnosis date until whichever occurs first: the event-defining SUB diagnosis date or the censoring date. Medical managements were not assessed if no vaginal bleed diagnosis was present. Please see Appendix G for a list of diagnosis and procedure codes, and Appendix H for generic and brand medical product names.

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Additionally, the distributions of surgical management procedures that were used to identify SUB as the outcome events in comparisons 1-4 were reported.

Analysis: We assessed the following covariates during the baseline period and used to estimate propensity score (PS) in a logistic regression model: continuous age, comorbidity score (Combined Comorbidity Index)[a], health service and drug utilizations, diabetes, hypertension, renal impairment, obesity, smoking, cardiovascular disease, 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, severe anemia (as defined by RBC-only transfusion codes), gynecological disorders, and Von Willebrand's disease. Matching was performed using 1:1 nearest neighbor matching without replacement on the probability scale PS using a caliper of 0.05. Each patient per exposure group was matched one time, at most, within each comparison. A Cox regression model stratified on Data Partner site (and matched sample in the conditional analysis) was used to estimate the adjusted hazard ratio and 95% confidence interval. Subgroup analyses were also performed by age group, prior gynecological disorder, index-defining NOAC dose, and the cross-stratification of age group and NOAC dose. In subgroup analyses, patients were re-matched within the matched population.

Limitations: 1) As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. 2) Exposures, outcome, exclusions, episode truncation criteria, and covariates may be misclassified due to varying validities of the identification algorithms.

Please see Appendix K for the specifications of parameters used in the analyses for this request, Appendix L for the list of characteristics considered in this request, and Appendix M for pictorial summaries of the outcome definitions.

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-tooldocumentation/browse).

[a]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

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

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

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

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

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

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

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.

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

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

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

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 Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	289,011	100.0%	80,844	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73	10.6	76.8	9.1	-3.704	-0.375
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*11,150*	*3.9%*	*913*	*1.1%*	*2.729*	*0.176*
50+	*277,861*	*96.1%*	*79,931*	*98.9%*	*-2.729*	*-0.176*
Sex						
Female	289,011	100.0%	80,844	100.0%	0	-
Race						
American Indian or Alaska Native	*1,010*	*0.3%*	*229*	*0.3%*	*0.066*	*0.012*
Asian	*2,721*	*0.9%*	*1,258*	*1.6%*	*-0.615*	*-0.055*
Black or African American	*20,026*	*6.9%*	*4,115*	*5.1%*	*1.839*	*0.077*
Native Hawaiian or Other Pacific Islander	*150*	*0.1%*	*34*	*0.0%*	*0.01*	*0.005*
Unknown	*45,651*	*15.8%*	*10,382*	*12.8%*	*2.954*	*0.084*
White	*219,453*	*75.9%*	*64,826*	*80.2%*	*-4.254*	*-0.103*
Year						
2010	-	*0.0%*	*1,268*	*1.6%*	*-1.568*	-
2011	*3,053*	*1.1%*	*30,374*	*37.6%*	*-36.515*	*-1.043*
2012	*37,473*	*13.0%*	*23,003*	*28.5%*	*-15.488*	*-0.389*
2013	*79,856*	*27.6%*	*13,141*	*16.3%*	*11.376*	*0.278*
2014	*101,221*	*35.0%*	*8,642*	*10.7%*	*24.334*	*0.605*
2015	*67,408*	*23.3%*	*4,416*	*5.5%*	*17.861*	*0.526*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,648*	*3.3%*	*3,579*	*4.4%*	*-1.089*	*-0.056*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.4	2.8	3	2.6	-0.506	-0.189
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*186,449*	*64.5%*	*63,780*	*78.9%*	*-14.38*	*-0.323*
Severe anemia	21,198	7.3%	2,518	3.1%	4.22	0.191
Cardiovascular disease	103,298	35.7%	40,747	50.4%	-14.66	-0.299
Diabetes	86,977	30.1%	27,174	33.6%	-3.518	-0.076
Hypertension	238,832	82.6%	71,479	88.4%	-5.778	-0.165
Obesity	68,507	23.7%	12,885	15.9%	7.766	0.196
Renal Impairment	49,005	17.0%	14,273	17.7%	-0.699	-0.018
Smoking	62,065	21.5%	12,477	15.4%	6.042	0.156
Von Willebrands disease	81	0.0%	16	0.0%	0.008	0.005

Table 1a. Baseline Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Gynecological disorders of interest	7,232	2.5%	1,436	1.8%	0.726	0.05
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.011*	*0.014*
Endometrial hyperplasia	*145*	*0.1%*	*43*	*0.1%*	*-0.003*	*-0.001*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.008*	*0.009*
Ovarian cyst	*1,835*	*0.6%*	*368*	*0.5%*	*0.18*	*0.024*
Uterine myoma leiomyoma	*1,611*	*0.6%*	*357*	*0.4%*	*0.116*	*0.016*
Uterine or cervical polyp	*149*	*0.1%*	*45*	*0.1%*	*-0.004*	*-0.002*
Uterine ovarian or cervical cancer	*3,947*	*1.4%*	*726*	*0.9%*	*0.468*	*0.044*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	255,549	88.4%	78,869	97.6%	-9.135	-0.364
Medications that increase bleeding risk without interaction	172,119	59.6%	41,679	51.6%	8	0.162
Medications that inhibit metabolism of NOACs and increase bleeding risk	188,370	65.2%	57,286	70.9%	-5.682	-0.122
Medications that induce metabolism of NOACs and reduce bleeding risk	82,939	28.7%	22,280	27.6%	1.138	0.025
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.4	9.2	12.3	8.6	1.062	0.119
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1	0.055	0.051
Mean number of inpatient hospital encounters (IP)	1	0.9	0.7	0.9	0.222	0.239
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.2	0.6	0.086	0.14
Mean number of other ambulatory encounters (OA)	6.5	9.5	5.8	8.7	0.698	0.076
Mean number of unique drug classes	10	4.8	10.1	4.7	-0.122	-0.026
Mean number of generics	10.9	5.5	10.9	5.3	0.001	0
Mean number of filled prescriptions	25.2	19.5	26.2	19.1	-0.959	-0.05

[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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	80,844	28.0%	80,844	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	76.8	9.4	76.8	9.1	0.079	0.009
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*984*	*1.2%*	*913*	*1.1%*	*0.088*	*0.008*
50+	*79,860*	*98.8%*	*79,931*	*98.9%*	*-0.088*	*-0.008*
Sex						
Female	80,844	100.0%	80,844	100.0%	0	-
Race						
American Indian or Alaska Native	*263*	*0.3%*	*229*	*0.3%*	*0.042*	*0.008*
Asian	*1,020*	*1.3%*	*1,258*	*1.6%*	*-0.294*	*-0.025*
Black or African American	*5,457*	*6.8%*	*4,115*	*5.1%*	*1.66*	*0.07*
Native Hawaiian or Other Pacific Islander	*36*	*0.0%*	*34*	*0.0%*	*0.002*	*0.001*
Unknown	*10,086*	*12.5%*	*10,382*	*12.8%*	*-0.366*	*-0.011*
White	*63,982*	*79.1%*	*64,826*	*80.2%*	*-1.044*	*-0.026*
Year						
2010	-	*0.0%*	*1,268*	*1.6%*	*-1.568*	-
2011	*464*	*0.6%*	*30,374*	*37.6%*	*-36.997*	*-1.067*
2012	*9,759*	*12.1%*	*23,003*	*28.5%*	*-16.382*	*-0.416*
2013	*22,749*	*28.1%*	*13,141*	*16.3%*	*11.885*	*0.289*
2014	*28,779*	*35.6%*	*8,642*	*10.7%*	*24.908*	*0.618*
2015	*19,093*	*23.6%*	*4,416*	*5.5%*	*18.155*	*0.533*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*2,348*	*2.9%*	*3,579*	*4.4%*	*-1.523*	*-0.081*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.9	2.8	3	2.6	-0.015	-0.006
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*63,824*	*78.9%*	*63,780*	*78.9%*	*0.054*	*0.001*
Severe anemia	2,370	2.9%	2,518	3.1%	-0.183	-0.011
Cardiovascular disease	40,206	49.7%	40,747	50.4%	-0.669	-0.013
Diabetes	27,028	33.4%	27,174	33.6%	-0.181	-0.004
Hypertension	71,631	88.6%	71,479	88.4%	0.188	0.006
Obesity	12,545	15.5%	12,885	15.9%	-0.421	-0.012
Renal Impairment	14,463	17.9%	14,273	17.7%	0.235	0.006
Smoking	12,584	15.6%	12,477	15.4%	0.132	0.004
Von Willebrands disease	17	0.0%	16	0.0%	0.001	0.001
Gynecological disorders of interest	1,470	1.8%	1,436	1.8%	0.042	0.003
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0*	*0*

Table 1b. Baseline Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometrial hyperplasia	*26*	*0.0%*	*43*	*0.1%*	*-0.021*	*-0.01*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.005*	*0.006*
Ovarian cyst	*295*	*0.4%*	*368*	*0.5%*	*-0.09*	*-0.014*
Uterine myoma leiomyoma	*288*	*0.4%*	*357*	*0.4%*	*-0.085*	*-0.014*
Uterine or cervical polyp	*29*	*0.0%*	*45*	*0.1%*	*-0.02*	*-0.009*
Uterine ovarian or cervical cancer	*903*	*1.1%*	*726*	*0.9%*	*0.219*	*0.022*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	79,144	97.9%	78,869	97.6%	0.34	0.023
Medications that increase bleeding risk without interaction	41,345	51.1%	41,679	51.6%	-0.413	-0.008
Medications that inhibit metabolism of NOACs and increase bleeding risk	57,476	71.1%	57,286	70.9%	0.235	0.005
Medications that induce metabolism of NOACs and reduce bleeding risk	22,232	27.5%	22,280	27.6%	-0.059	-0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	12.3	8.4	12.3	8.6	-0.023	-0.003
Mean number of emergency room encounters (ED)	0.5	0.9	0.5	1	0.01	0.011
Mean number of inpatient hospital encounters (IP)	0.7	0.8	0.7	0.9	0.002	0.002
Mean number of non-acute institutional encounters (IS)	0.2	0.5	0.2	0.6	0.005	0.009
Mean number of other ambulatory encounters (OA)	5.9	8.2	5.8	8.7	0.097	0.011
Mean number of unique drug classes	10.1	4.6	10.1	4.7	-0.003	-0.001
Mean number of generics	10.8	5.2	10.9	5.3	-0.012	-0.002
Mean number of filled prescriptions	25.9	19.7	26.2	19.1	-0.246	-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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	290,780	100.0%	101,663	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73.1	10.6	77.7	9.5	-4.603	-0.458
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*11,171*	*3.8%*	*1,161*	*1.1%*	*2.7*	*0.174*
50+	*279,609*	*96.2%*	*100,502*	*98.9%*	*-2.7*	*-0.174*
Sex						
Female	290,780	100.0%	101,663	100.0%	0	-
Race						
American Indian or Alaska Native	*1,018*	*0.4%*	*244*	*0.2%*	*0.11*	*0.02*
Asian	*2,764*	*1.0%*	*1,188*	*1.2%*	*-0.218*	*-0.021*
Black or African American	*20,113*	*6.9%*	*6,117*	*6.0%*	*0.9*	*0.037*
Native Hawaiian or Other Pacific Islander	*152*	*0.1%*	*64*	*0.1%*	*-0.011*	*-0.004*
Unknown	*45,866*	*15.8%*	*10,739*	*10.6%*	*5.21*	*0.155*
White	*220,867*	*76.0%*	*83,311*	*81.9%*	*-5.991*	*-0.147*
Year						
2011	*3,054*	*1.1%*	-	*0.0%*	*1.05*	-
2012	*37,694*	*13.0%*	-	*0.0%*	*12.963*	-
2013	*80,481*	*27.7%*	*9,261*	*9.1%*	*18.568*	*0.494*
2014	*101,854*	*35.0%*	*37,245*	*36.6%*	*-1.608*	*-0.034*
2015	*67,697*	*23.3%*	*55,157*	*54.3%*	*-30.974*	*-0.67*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,703*	*3.3%*	*1,554*	*1.5%*	*1.808*	*0.118*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.5	2.8	3.3	2.8	-0.837	-0.299
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*188,046*	*64.70%*	*66,776*	*65.7%*	*-1.014*	*-0.021*
Severe anemia	21,246	7.3%	3,903	3.8%	3.467	0.152
Cardiovascular disease	104,146	35.8%	53,310	52.4%	-16.622	-0.34
Diabetes	87,508	30.1%	33,743	33.2%	-3.097	-0.067
Hypertension	240,406	82.7%	90,520	89.0%	-6.363	-0.183
Obesity	68,801	23.7%	20,343	20.0%	3.651	0.088
Renal Impairment	49,334	17.0%	25,817	25.4%	-8.429	-0.207
Smoking	62,329	21.4%	20,839	20.5%	0.937	0.023
Von Willebrands disease	81	0.0%	23	0.0%	0.005	0.003
Gynecological disorders of interest	7,267	2.5%	1,928	1.9%	0.603	0.041
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.006*	*0.007*

Table 1c. Baseline Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometrial hyperplasia	*146*	*0.1%*	*49*	*0.0%*	*0.002*	*0.001*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.008*	*0.01*
Ovarian cyst	*1,846*	*0.6%*	*496*	*0.5%*	*0.147*	*0.02*
Uterine myoma leiomyoma	*1,621*	*0.6%*	*440*	*0.4%*	*0.125*	*0.018*
Uterine or cervical polyp	*151*	*0.1%*	*41*	*0.0%*	*0.012*	*0.005*
Uterine ovarian or cervical cancer	*3,960*	*1.4%*	*1,007*	*1.0%*	*0.371*	*0.034*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	257,273	88.5%	98,427	96.8%	-8.34	-0.324
Medications that increase bleeding risk without interaction	172,986	59.5%	54,579	53.7%	5.804	0.117
Medications that inhibit metabolism of NOACs and increase bleeding risk	189,584	65.2%	73,251	72.1%	-6.854	-0.148
Medications that induce metabolism of NOACs and reduce bleeding risk	83,444	28.7%	28,764	28.3%	0.403	0.009
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.4	9.2	13.1	8.9	0.328	0.036
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1	-0.026	-0.023
Mean number of inpatient hospital encounters (IP)	1	0.9	0.8	1	0.133	0.139
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.2	0.7	0.023	0.034
Mean number of other ambulatory encounters (OA)	6.5	9.5	6.9	10.3	-0.459	-0.046
Mean number of unique drug classes	10	4.8	10.5	4.8	-0.44	-0.092
Mean number of generics	10.9	5.5	11.2	5.4	-0.33	-0.061
Mean number of filled prescriptions	25.2	19.5	25.8	19.2	-0.573	-0.03

[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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	101,661	35.0%	101,661	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	77.6	9.2	77.7	9.5	-0.028	-0.003
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*1,015*	*1.0%*	*1,161*	*1.1%*	*-0.144*	*-0.014*
50+	*100,646*	*99.0%*	*100,500*	*98.9%*	*0.144*	*0.014*
Sex						
Female	101,661	100.0%	101,661	100.0%	0	-
Race						
American Indian or Alaska Native	*316*	*0.3%*	*244*	*0.2%*	*0.071*	*0.014*
Asian	*1,221*	*1.2%*	*1,187*	*1.2%*	*0.033*	*0.003*
Black or African American	*7,081*	*7.0%*	*6,117*	*6.0%*	*0.948*	*0.038*
Native Hawaiian or Other Pacific Islander	*61*	*0.1%*	*64*	*0.1%*	*-0.003*	*-0.001*
Unknown	*10,812*	*10.6%*	*10,739*	*10.6%*	*0.072*	*0.002*
White	*82,170*	*80.8%*	*83,310*	*81.9%*	*-1.121*	*-0.029*
Year						
2011	*501*	*0.5%*	*-*	*0.0%*	*0.493*	*-*
2012	*11,487*	*11.3%*	*-*	*0.0%*	*11.299*	*-*
2013	*28,349*	*27.9%*	*9,261*	*9.1%*	*18.776*	*0.498*
2014	*36,879*	*36.3%*	*37,244*	*36.6%*	*-0.359*	*-0.007*
2015	*24,445*	*24.0%*	*55,156*	*54.3%*	*-30.209*	*-0.651*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*2,852*	*2.8%*	*1,554*	*1.5%*	*1.277*	*0.088*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3.3	2.9	3.3	2.8	-0.023	-0.008
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*80,473*	*79.2%*	*66,775*	*65.7%*	*13.474*	*0.305*
Severe anemia	3,701	3.6%	3,903	3.8%	-0.199	-0.01
Cardiovascular disease	52,753	51.9%	53,308	52.4%	-0.546	-0.011
Diabetes	33,730	33.2%	33,742	33.2%	-0.012	0
Hypertension	90,682	89.2%	90,518	89.0%	0.161	0.005
Obesity	20,103	19.8%	20,343	20.0%	-0.236	-0.006
Renal Impairment	24,746	24.3%	25,816	25.4%	-1.053	-0.024
Smoking	20,633	20.3%	20,839	20.5%	-0.203	-0.005
Von Willebrands disease	22	0.0%	23	0.0%	-0.001	-0.001
Gynecological disorders of interest	2,034	2.0%	1,928	1.9%	0.104	0.008
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.005*	*-0.008*

Table 1d. Baseline Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometrial hyperplasia	*39*	*0.0%*	*49*	*0.0%*	*-0.01*	*-0.005*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.003*	*0.004*
Ovarian cyst	*440*	*0.4%*	*496*	*0.5%*	*-0.055*	*-0.008*
Uterine myoma leiomyoma	*383*	*0.4%*	*440*	*0.4%*	*-0.056*	*-0.009*
Uterine or cervical polyp	*40*	*0.0%*	*41*	*0.0%*	*-0.001*	*0*
Uterine ovarian or cervical cancer	*1,261*	*1.2%*	*1,007*	*1.0%*	*0.25*	*0.024*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	98,775	97.2%	98,425	96.8%	0.344	0.02
Medications that increase bleeding risk without interaction	53,990	53.1%	54,578	53.7%	-0.578	-0.012
Medications that inhibit metabolism of NOACs and increase bleeding risk	73,283	72.1%	73,250	72.1%	0.032	0.001
Medications that induce metabolism of NOACs and reduce bleeding risk	28,836	28.4%	28,763	28.3%	0.072	0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13	8.9	13.1	8.9	-0.047	-0.005
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1	0.003	0.003
Mean number of inpatient hospital encounters (IP)	0.8	0.8	0.8	1	-0.005	-0.005
Mean number of non-acute institutional encounters (IS)	0.2	0.6	0.2	0.7	0.002	0.003
Mean number of other ambulatory	7	9.7	6.9	10.3	0.035	0.003
Mean number of unique drug classes	10.5	4.7	10.5	4.8	-0.002	0
Mean number of generics	11.2	5.3	11.2	5.4	-0.007	-0.001
Mean number of filled prescriptions	25.8	18.7	25.8	19.2	-0.017	-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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	81,021	100.0%	102,039	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	76.8	9.1	77.7	9.5	-0.898	-0.097
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*915*	*1.1%*	*1,170*	*1.1%*	*-0.017*	*-0.002*
50+	*80,106*	*98.9%*	*100,869*	*98.9%*	*0.017*	*0.002*
Sex						
Female	81,021	100.0%	102,039	100.0%	0	-
Race						
American Indian or Alaska Native	*230*	*0.3%*	*250*	*0.2%*	*0.039*	*0.008*
Asian	*1,257*	*1.6%*	*1,194*	*1.2%*	*0.381*	*0.033*
Black or African American	*4,121*	*5.1%*	*6,163*	*6.0%*	*-0.954*	*-0.042*
Native Hawaiian or Other Pacific Islander	*33*	*0.0%*	*62*	*0.1%*	*-0.02*	*-0.009*
Unknown	*10,400*	*12.8%*	*10,777*	*10.6%*	*2.275*	*0.071*
White	*64,980*	*80.2%*	*83,593*	*81.9%*	*-1.721*	*-0.044*
Year						
2010	*1,268*	*1.6%*	-	*0.0%*	*1.565*	-
2011	*30,374*	*37.5%*	-	*0.0%*	*37.489*	-
2012	*23,008*	*28.4%*	-	*0.0%*	*28.398*	-
2013	*13,181*	*16.3%*	*9,157*	*9.0%*	*7.295*	*0.221*
2014	*8,700*	*10.7%*	*37,209*	*36.5%*	*-25.728*	*-0.636*
2015	*4,490*	*5.5%*	*55,673*	*54.6%*	*-49.019*	*-1.265*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*3,581*	*4.4%*	*1,553*	*1.5%*	*2.898*	*0.171*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3	2.6	3.3	2.8	-0.33	-0.122
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*63,906*	*78.9%*	*67,016*	*65.7%*	*13.199*	*0.298*
Severe anemia	2,520	3.1%	3,918	3.8%	-0.729	-0.04
Cardiovascular disease	40,825	50.4%	53,447	52.4%	-1.991	-0.04
Diabetes	27,221	33.6%	33,860	33.2%	0.414	0.009
Hypertension	71,638	88.4%	90,867	89.1%	-0.632	-0.02
Obesity	12,923	16.0%	20,516	20.1%	-4.156	-0.108
Renal Impairment	14,313	17.7%	25,865	25.3%	-7.682	-0.188
Smoking	12,509	15.4%	20,935	20.5%	-5.077	-0.133
Von Willebrands disease	17	0.0%	23	0.0%	-0.002	-0.001
Gynecological disorders of interest	1,438	1.8%	1,923	1.9%	-0.11	-0.008

Table 1e. Baseline Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.005*	*-0.008*
Endometrial hyperplasia	*43*	*0.1%*	*46*	*0.0%*	*0.008*	*0.004*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.001*	*0.001*
Ovarian cyst	*368*	*0.5%*	*502*	*0.5%*	*-0.038*	*-0.006*
Uterine myoma leiomyoma	*357*	*0.4%*	*437*	*0.4%*	*0.012*	*0.002*
Uterine or cervical polyp	*45*	*0.1%*	*40*	*0.0%*	*0.016*	*0.008*
Uterine ovarian or cervical cancer	*728*	*0.9%*	*1,004*	*1.0%*	*-0.085*	*-0.009*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	79,041	97.6%	98,756	96.8%	0.774	0.047
Medications that increase bleeding risk without interaction	41,779	51.6%	54,893	53.8%	-2.23	-0.045
Medications that inhibit metabolism of NOACs and increase bleeding risk	57,403	70.8%	73,505	72.0%	-1.187	-0.026
Medications that induce metabolism of NOACs and reduce bleeding risk	22,334	27.6%	28,916	28.3%	-0.772	-0.017
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	12.3	8.6	13.1	8.9	-0.744	-0.085
Mean number of emergency room encounters (ED)	0.5	1	0.5	1	-0.081	-0.082
Mean number of inpatient hospital encounters (IP)	0.7	0.9	0.8	1	-0.088	-0.091
Mean number of non-acute institutional encounters (IS)	0.2	0.6	0.2	0.7	-0.063	-0.1
Mean number of other ambulatory encounters (OA)	5.8	8.7	6.9	10.3	-1.152	-0.121
Mean number of unique drug classes	10.1	4.7	10.5	4.8	-0.324	-0.068
Mean number of generics	10.9	5.4	11.2	5.4	-0.338	-0.063
Mean number of filled prescriptions	26.2	19.1	25.8	19.2	0.369	0.019

[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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	77,176	95.3%	77,176	75.6%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	77.1	8.9	77	9.5	0.053	0.006
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*782*	*1.0%*	*972*	*1.3%*	*-0.246*	*-0.023*
50+	*76,394*	*99.0%*	*76,204*	*98.7%*	*0.246*	*0.023*
Sex						
Female	77,176	100.0%	77,176	100.0%	0	-
Race						
American Indian or Alaska Native	*222*	*0.3%*	*200*	*0.3%*	*0.029*	*0.005*
Asian	*1,190*	*1.5%*	*970*	*1.3%*	*0.285*	*0.024*
Black or African American	*3,930*	*5.1%*	*4,423*	*5.7%*	*-0.639*	*-0.028*
Native Hawaiian or Other Pacific Islander	*32*	*0.0%*	*44*	*0.1%*	*-0.016*	*-0.007*
Unknown	*8,942*	*11.6%*	*8,723*	*11.3%*	*0.284*	*0.009*
White	*62,860*	*81.5%*	*62,816*	*81.4%*	*0.057*	*0.001*
Year						
2010	*1,185*	*1.5%*	-	*0.0%*	*1.535*	-
2011	*28,800*	*37.3%*	-	*0.0%*	*37.317*	-
2012	*21,903*	*28.4%*	-	*0.0%*	*28.381*	-
2013	*12,611*	*16.3%*	*7,265*	*9.4%*	*6.927*	*0.208*
2014	*8,354*	*10.8%*	*28,475*	*36.9%*	*-26.072*	*-0.642*
2015	*4,323*	*5.6%*	*41,436*	*53.7%*	*-48.089*	*-1.239*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*3,395*	*4.4%*	*1,165*	*1.5%*	*2.889*	*0.171*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3	2.6	3	2.7	-0.002	-0.001
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*60,463*	*78.3%*	*52,433*	*67.9%*	*10.405*	*0.236*
Severe anemia	2,450	3.2%	2,468	3.2%	-0.023	-0.001
Cardiovascular disease	39,005	50.5%	39,009	50.5%	-0.005	0
Diabetes	25,516	33.1%	25,510	33.1%	0.008	0
Hypertension	68,364	88.6%	68,338	88.5%	0.034	0.001
Obesity	12,743	16.5%	12,706	16.5%	0.048	0.001
Renal Impairment	14,246	18.5%	14,200	18.4%	0.06	0.002
Smoking	12,365	16.0%	12,356	16.0%	0.012	0
Von Willebrands disease	16	0.0%	16	0.0%	0	0
Gynecological disorders of interest	1,368	1.8%	1,374	1.8%	-0.008	-0.001

Table 1f. Baseline Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.004*	*-0.007*
Endometrial hyperplasia	*40*	*0.1%*	*34*	*0.0%*	*0.008*	*0.004*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.003*	*0.005*
Ovarian cyst	*351*	*0.5%*	*359*	*0.5%*	*-0.01*	*-0.002*
Uterine myoma leiomyoma	*335*	*0.4%*	*312*	*0.4%*	*0.03*	*0.005*
Uterine or cervical polyp	*40*	*0.1%*	*30*	*0.0%*	*0.013*	*0.006*
Uterine ovarian or cervical cancer	*702*	*0.9%*	*725*	*0.9%*	*-0.03*	*-0.003*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	75,210	97.5%	75,194	97.4%	0.021	0.001
Medications that increase bleeding risk without interaction	40,098	52.0%	40,140	52.0%	-0.054	-0.001
Medications that inhibit metabolism of NOACs and increase bleeding risk	54,824	71.0%	54,871	71.1%	-0.061	-0.001
Medications that induce metabolism of NOACs and reduce bleeding risk	21,399	27.7%	21,444	27.8%	-0.058	-0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	12.4	8.6	12.5	8.4	-0.012	-0.001
Mean number of emergency room encounters (ED)	0.5	1	0.5	0.9	-0.007	-0.007
Mean number of inpatient hospital encounters (IP)	0.7	0.9	0.8	0.9	-0.003	-0.003
Mean number of non-acute institutional encounters (IS)	0.2	0.6	0.2	0.6	-0.004	-0.008
Mean number of other ambulatory encounters (OA)	5.9	8.9	6	8.7	-0.051	-0.006
Mean number of unique drug classes	10.2	4.7	10.2	4.7	-0.014	-0.003
Mean number of generics	10.9	5.3	10.9	5.3	-0.014	-0.003
Mean number of filled prescriptions	26	18.8	25.9	19.8	0.076	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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	280,078	100.0%	895,730	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73	10.6	74.4	11.6	-1.385	-0.125
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*10,763*	*3.8%*	*38,928*	*4.3%*	*-0.503*	*-0.025*
50+	*269,315*	*96.2%*	*856,802*	*95.7%*	*0.503*	*0.025*
Sex						
Female	280,078	100.0%	895,730	100.0%	0	-
Race						
American Indian or Alaska Native	*973*	*0.3%*	*3,315*	*0.4%*	*-0.023*	*-0.004*
Asian	*2,660*	*0.9%*	*7,893*	*0.9%*	*0.069*	*0.007*
Black or African American	*19,213*	*6.9%*	*82,859*	*9.3%*	*-2.391*	*-0.088*
Native Hawaiian or Other Pacific Islander	*144*	*0.1%*	*292*	*0.0%*	*0.019*	*0.009*
Unknown	*44,575*	*15.9%*	*120,528*	*13.5%*	*2.459*	*0.07*
White	*212,513*	*75.9%*	*680,843*	*76.0%*	*-0.133*	*-0.003*
Year						
2010	-	*0.0%*	*48,477*	*5.4%*	*-5.412*	-
2011	*3,026*	*1.1%*	*220,582*	*24.6%*	*-23.546*	*-0.752*
2012	*36,915*	*13.2%*	*205,112*	*22.9%*	*-9.719*	*-0.255*
2013	*77,563*	*27.7%*	*179,472*	*20.0%*	*7.657*	*0.18*
2014	*97,723*	*34.9%*	*147,680*	*16.5%*	*18.404*	*0.431*
2015	*64,851*	*23.2%*	*94,407*	*10.5%*	*12.615*	*0.342*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,359*	*3.3%*	*40,084*	*4.5%*	*-1.133*	*-0.059*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.4	2.8	3.4	3.2	-0.961	-0.322
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Severe anemia	20,558	7.3%	96,238	10.7%	-3.404	-0.119
Cardiovascular disease	99,517	35.5%	419,294	46.8%	-11.278	-0.231
Diabetes	83,980	30.0%	314,439	35.1%	-5.12	-0.109
Hypertension	231,411	82.6%	757,243	84.5%	-1.915	-0.052
Obesity	66,165	23.6%	193,201	21.6%	2.055	0.049
Renal Impairment	47,038	16.8%	234,687	26.2%	-9.406	-0.23
Smoking	60,070	21.4%	184,594	20.6%	0.839	0.021
Von Willebrands disease	78	0.0%	395	0.0%	-0.016	-0.009
Gynecological disorders of interest	7,015	2.5%	24,328	2.7%	-0.211	-0.013
Adenomyosis	*36*	*0.0%*	*120*	*0.0%*	*-0.001*	*0*
Endometrial hyperplasia	*145*	*0.1%*	*482*	*0.1%*	*-0.002*	*-0.001*

Table 1g. Baseline Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometriosis	*34*	*0.0%*	*129*	*0.0%*	*-0.002*	*-0.002*
Ovarian cyst	*1,788*	*0.6%*	*6,254*	*0.7%*	*-0.06*	*-0.007*
Uterine myoma leiomyoma	*1,568*	*0.6%*	*5,528*	*0.6%*	*-0.057*	*-0.007*
Uterine or cervical polyp	*146*	*0.1%*	*430*	*0.0%*	*0.004*	*0.002*
Uterine ovarian or cervical cancer	*3,811*	*1.4%*	*13,225*	*1.5%*	*-0.116*	*-0.01*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	247,538	88.4%	804,348	89.8%	-1.416	-0.045
Medications that increase bleeding risk without interaction	166,532	59.5%	562,541	62.8%	-3.343	-0.069
Medications that inhibit metabolism of NOACs and increase bleeding risk	182,392	65.1%	596,466	66.6%	-1.468	-0.031
Medications that induce metabolism of NOACs and reduce bleeding risk	79,978	28.6%	273,032	30.5%	-1.926	-0.042
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.3	9.2	13.8	9.8	-0.504	-0.053
Mean number of emergency room encounters (ED)	0.5	1.2	0.6	1.3	-0.071	-0.058
Mean number of inpatient hospital encounters (IP)	1	0.9	1.2	1.1	-0.2	-0.196
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.4	0.8	-0.133	-0.176
Mean number of other ambulatory encounters (OA)	6.4	9.4	10	13.4	-3.536	-0.306
Mean number of unique drug classes	10	4.8	10.5	4.9	-0.461	-0.096
Mean number of generics	10.8	5.4	11.3	5.6	-0.489	-0.089
Mean number of filled prescriptions	25.1	19.4	26.5	19.7	-1.447	-0.074

[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 1h. Baseline Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	280,077	100.0%	280,077	31.3%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73	10.6	73	11.5	0.055	0.005
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*10,762*	*3.8%*	*14,393*	*5.1%*	*-1.296*	*-0.063*
50+	*269,315*	*96.2%*	*265,684*	*94.9%*	*1.296*	*0.063*
Sex						
Female	280,077	100.0%	280,077	100.0%	0	-
Race						
American Indian or Alaska Native	*973*	*0.3%*	*1,053*	*0.4%*	*-0.029*	*-0.005*
Asian	*2,660*	*0.9%*	*2,154*	*0.8%*	*0.181*	*0.02*
Black or African American	*19,213*	*6.9%*	*22,490*	*8.0%*	*-1.17*	*-0.045*
Native Hawaiian or Other Pacific Islander	*144*	*0.1%*	*121*	*0.0%*	*0.008*	*0.004*
Unknown	*44,574*	*15.9%*	*44,567*	*15.9%*	*0.002*	*0*
White	*212,513*	*75.9%*	*209,692*	*74.9%*	*1.007*	*0.023*
Year						
2010	-	*0.0%*	*15,276*	*5.5%*	*-5.454*	-
2011	*3,026*	*1.1%*	*68,943*	*24.6%*	*-23.535*	*-0.751*
2012	*36,915*	*13.2%*	*63,942*	*22.8%*	*-9.65*	*-0.253*
2013	*77,563*	*27.7%*	*56,232*	*20.1%*	*7.616*	*0.179*
2014	*97,722*	*34.9%*	*46,014*	*16.4%*	*18.462*	*0.432*
2015	*64,851*	*23.2%*	*29,670*	*10.6%*	*12.561*	*0.34*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,359*	*3.3%*	*12,927*	*4.6%*	*-1.274*	*-0.065*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.4	2.8	2.4	2.7	0.018	0.007
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Severe anemia	20,558	7.3%	20,671	7.4%	-0.04	-0.002
Cardiovascular disease	99,517	35.5%	98,032	35.0%	0.53	0.011
Diabetes	83,979	30.0%	83,663	29.9%	0.113	0.002
Hypertension	231,410	82.6%	231,732	82.7%	-0.115	-0.003
Obesity	66,164	23.6%	66,943	23.9%	-0.278	-0.007
Renal Impairment	47,038	16.8%	46,595	16.6%	0.158	0.004
Smoking	60,069	21.4%	60,593	21.6%	-0.187	-0.005
Von Willebrands disease	78	0.0%	68	0.0%	0.004	0.002
Gynecological disorders of interest	7,015	2.5%	7,043	2.5%	-0.01	-0.001
Adenomyosis	*36*	*0.0%*	*43*	*0.0%*	*-0.002*	*-0.002*
Endometrial hyperplasia	*145*	*0.1%*	*135*	*0.0%*	*0.004*	*0.002*

Table 1h. Baseline Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometriosis	*34*	*0.0%*	*47*	*0.0%*	*-0.005*	*-0.004*
Ovarian cyst	*1,788*	*0.6%*	*1,961*	*0.7%*	*-0.062*	*-0.008*
Uterine myoma leiomyoma	*1,568*	*0.6%*	*1,564*	*0.6%*	*0.001*	*0*
Uterine or cervical polyp	*146*	*0.1%*	*139*	*0.0%*	*0.002*	*0.001*
Uterine ovarian or cervical cancer	*3,811*	*1.4%*	*3,687*	*1.3%*	*0.044*	*0.004*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	247,537	88.4%	247,506	88.4%	0.011	0
Medications that increase bleeding risk without interaction	166,531	59.5%	166,466	59.4%	0.023	0
Medications that inhibit metabolism of NOACs and increase bleeding risk	182,391	65.1%	182,792	65.3%	-0.143	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	79,977	28.6%	80,080	28.6%	-0.037	-0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.3	9.2	13.3	9.3	0.012	0.001
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1.1	-0.003	-0.003
Mean number of inpatient hospital encounters (IP)	1	0.9	1	0.9	-0.006	-0.006
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.3	0.7	-0.008	-0.013
Mean number of other ambulatory encounters (OA)	6.4	9.4	6.6	9.2	-0.178	-0.019
Mean number of unique drug classes	10	4.8	10	4.7	-0.024	-0.005
Mean number of generics	10.8	5.4	10.9	5.4	-0.029	-0.005
Mean number of filled prescriptions	25.1	19.4	25.1	18.7	-0.029	-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 1i. Baseline Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	288,893	100.0%	80,832	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73	10.6	76.8	9.1	-3.702	-0.375
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*11,155*	*3.9%*	*914*	*1.1%*	*2.731*	*0.176*
50+	*277,738*	*96.1%*	*79,918*	*98.9%*	*-2.731*	*-0.176*
Sex						
Female	288,893	100.0%	80,832	100.0%	0	-
Race						
American Indian or Alaska Native	*1,010*	*0.3%*	*229*	*0.3%*	*0.066*	*0.012*
Asian	*2,721*	*0.9%*	*1,258*	*1.6%*	*-0.614*	*-0.055*
Black or African American	*20,020*	*6.9%*	*4,116*	*5.1%*	*1.838*	*0.077*
Native Hawaiian or Other Pacific Islander	*150*	*0.1%*	*34*	*0.0%*	*0.01*	*0.005*
Unknown	*45,654*	*15.8%*	*10,385*	*12.8%*	*2.955*	*0.084*
White	*219,338*	*75.9%*	*64,810*	*80.2%*	*-4.255*	*-0.103*
Year						
2010	-	*0.0%*	*1,267*	*1.6%*	*-1.567*	-
2011	*3,043*	*1.1%*	*30,365*	*37.6%*	*-36.512*	*-1.043*
2012	*37,421*	*13.0%*	*23,004*	*28.5%*	*-15.506*	*-0.39*
2013	*79,806*	*27.6%*	*13,140*	*16.3%*	*11.369*	*0.277*
2014	*101,202*	*35.0%*	*8,640*	*10.7%*	*24.342*	*0.606*
2015	*67,421*	*23.3%*	*4,416*	*5.5%*	*17.875*	*0.526*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,662*	*3.3%*	*3,583*	*4.4%*	*-1.088*	*-0.056*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.4	2.8	3	2.6	-0.506	-0.188
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*186,456*	*64.5%*	*63,773*	*78.9%*	*-14.354*	*-0.323*
Severe anemia	20,985	7.3%	2,492	3.1%	4.181	0.19
Cardiovascular disease	103,256	35.7%	40,739	50.4%	-14.658	-0.299
Diabetes	86,947	30.1%	27,169	33.6%	-3.515	-0.075
Hypertension	238,711	82.6%	71,464	88.4%	-5.781	-0.165
Obesity	68,489	23.7%	12,885	15.9%	7.767	0.196
Renal Impairment	48,970	17.0%	14,262	17.6%	-0.693	-0.018
Smoking	62,019	21.5%	12,473	15.4%	6.037	0.156
Von Willebrands disease	82	0.0%	16	0.0%	0.009	0.006
Gynecological disorders of interest	7,329	2.5%	1,452	1.8%	0.741	0.051
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*0.011*	*0.012*

Table 1i. Baseline Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometrial hyperplasia	*176*	*0.1%*	*49*	*0.1%*	*0*	*0*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0.009*	*0.01*
Ovarian cyst	*1,861*	*0.6%*	*370*	*0.5%*	*0.186*	*0.025*
Uterine myoma leiomyoma	*1,649*	*0.6%*	*364*	*0.5%*	*0.12*	*0.017*
Uterine or cervical polyp	*198*	*0.1%*	*56*	*0.1%*	*-0.001*	*0*
Uterine ovarian or cervical cancer	*3,961*	*1.4%*	*730*	*0.9%*	*0.468*	*0.044*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	255,433	88.4%	78,856	97.6%	-9.138	-0.364
Medications that increase bleeding risk without interaction	171,985	59.5%	41,673	51.6%	7.977	0.161
Medications that inhibit metabolism of NOACs and increase bleeding risk	188,291	65.2%	57,273	70.9%	-5.678	-0.122
Medications that induce metabolism of NOACs and reduce bleeding risk	82,862	28.7%	22,271	27.6%	1.13	0.025
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.4	9.2	12.3	8.6	1.06	0.119
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1	0.054	0.051
Mean number of inpatient hospital encounters (IP)	1	0.9	0.7	0.9	0.222	0.239
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.2	0.6	0.086	0.141
Mean number of other ambulatory encounters (OA)	6.5	9.5	5.8	8.7	0.697	0.076
Mean number of unique drug classes	10	4.8	10.1	4.7	-0.125	-0.026
Mean number of generics	10.9	5.5	10.9	5.3	-0.002	0
Mean number of filled prescriptions	25.2	19.4	26.2	19.1	-0.969	-0.05

[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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	80,832	28.0%	80,832	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	76.8	9.4	76.8	9.1	0.043	0.005
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*956*	*1.2%*	*914*	*1.1%*	*0.052*	*0.005*
50+	*79,876*	*98.8%*	*79,918*	*98.9%*	*-0.052*	*-0.005*
Sex						
Female	80,832	100.0%	80,832	100.0%	0	-
Race						
American Indian or Alaska Native	*245*	*0.3%*	*229*	*0.3%*	*0.02*	*0.004*
Asian	*1,049*	*1.3%*	*1,258*	*1.6%*	*-0.259*	*-0.022*
Black or African American	*5,501*	*6.8%*	*4,116*	*5.1%*	*1.713*	*0.072*
Native Hawaiian or Other Pacific Islander	*38*	*0.0%*	*34*	*0.0%*	*0.005*	*0.002*
Unknown	*10,053*	*12.4%*	*10,385*	*12.8%*	*-0.411*	*-0.012*
White	*63,946*	*79.1%*	*64,810*	*80.2%*	*-1.069*	*-0.027*
Year						
2010	-	*0.0%*	*1,267*	*1.6%*	*-1.567*	-
2011	*437*	*0.5%*	*30,365*	*37.6%*	*-37.025*	*-1.069*
2012	*9,667*	*12.0%*	*23,004*	*28.5%*	*-16.5*	*-0.42*
2013	*22,802*	*28.2%*	*13,140*	*16.3%*	*11.953*	*0.29*
2014	*29,104*	*36.0%*	*8,640*	*10.7%*	*25.317*	*0.627*
2015	*18,822*	*23.3%*	*4,416*	*5.5%*	*17.822*	*0.525*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*2,341*	*2.9%*	*3,583*	*4.4%*	*-1.537*	*-0.082*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3	2.8	3	2.6	0.001	0
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*63,808*	*78.9%*	*63,773*	*78.9%*	*0.043*	*0.001*
Severe anemia	2,376	2.9%	2,492	3.1%	-0.144	-0.008
Cardiovascular disease	40,204	49.7%	40,739	50.4%	-0.662	-0.013
Diabetes	27,068	33.5%	27,169	33.6%	-0.125	-0.003
Hypertension	71,616	88.6%	71,464	88.4%	0.188	0.006
Obesity	12,705	15.7%	12,885	15.9%	-0.223	-0.006
Renal Impairment	14,512	18.0%	14,262	17.6%	0.309	0.008
Smoking	12,524	15.5%	12,473	15.4%	0.063	0.002
Von Willebrands disease	15	0.0%	16	0.0%	-0.001	-0.001
Gynecological disorders of interest	1,441	1.8%	1,452	1.8%	-0.014	-0.001

Table 1j. Baseline Covariates of New Initiators of Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0.001*	*0.002*
Endometrial hyperplasia	*49*	*0.1%*	*49*	*0.1%*	*0*	*0*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0*	*0*
Ovarian cyst	*335*	*0.4%*	*370*	*0.5%*	*-0.043*	*-0.007*
Uterine myoma leiomyoma	*264*	*0.3%*	*364*	*0.5%*	*-0.124*	*-0.02*
Uterine or cervical polyp	*34*	*0.0%*	*56*	*0.1%*	*-0.027*	*-0.012*
Uterine ovarian or cervical cancer	*857*	*1.1%*	*730*	*0.9%*	*0.157*	*0.016*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	79,085	97.8%	78,856	97.6%	0.283	0.019
Medications that increase bleeding risk without interaction	41,236	51.0%	41,673	51.6%	-0.541	-0.011
Medications that inhibit metabolism of NOACs and increase bleeding risk	57,404	71.0%	57,273	70.9%	0.162	0.004
Medications that induce metabolism of NOACs and reduce bleeding risk	22,317	27.6%	22,271	27.6%	0.057	0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	12.3	8.3	12.3	8.6	-0.039	-0.005
Mean number of emergency room encounters (ED)	0.5	0.9	0.5	1	0.01	0.011
Mean number of inpatient hospital encounters (IP)	0.7	0.8	0.7	0.9	0.004	0.004
Mean number of non-acute institutional encounters (IS)	0.2	0.5	0.2	0.6	0.003	0.006
Mean number of other ambulatory encounters (OA)	5.9	8.1	5.8	8.7	0.08	0.009
Mean number of unique drug classes	10.1	4.6	10.1	4.7	0	0
Mean number of generics	10.8	5.2	10.9	5.3	-0.01	-0.002
Mean number of filled prescriptions	25.9	19.7	26.2	19.1	-0.235	-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.

[4]Novel Oral Anticoagulants

*****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 1k. Baseline Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	290,663	100.0%	101,667	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73.1	10.6	77.7	9.5	-4.601	-0.458
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*11,176*	*3.8%*	*1,162*	*1.1%*	*2.702*	*0.174*
50+	*279,487*	*96.2%*	*100,505*	*98.9%*	*-2.702*	*-0.174*
Sex						
Female	290,663	100.0%	101,667	100.0%	0	-
Race						
American Indian or Alaska Native	*1,018*	*0.4%*	*244*	*0.2%*	*0.11*	*0.02*
Asian	*2,764*	*1.0%*	*1,188*	*1.2%*	*-0.218*	*-0.021*
Black or African American	*20,107*	*6.9%*	*6,118*	*6.0%*	*0.9*	*0.037*
Native Hawaiian or Other Pacific Islander	*152*	*0.1%*	*64*	*0.1%*	*-0.011*	*-0.004*
Unknown	*45,869*	*15.8%*	*10,739*	*10.6%*	*5.218*	*0.155*
White	*220,753*	*75.9%*	*83,314*	*81.9%*	*-6*	*-0.148*
Year						
2011	*3,044*	*1.0%*	-	*0.0%*	*1.047*	-
2012	*37,642*	*13.0%*	-	*0.0%*	*12.95*	-
2013	*80,432*	*27.7%*	*9,258*	*9.1%*	*18.566*	*0.494*
2014	*101,835*	*35.0%*	*37,247*	*36.6%*	*-1.601*	*-0.033*
2015	*67,710*	*23.3%*	*55,162*	*54.3%*	*-30.963*	*-0.67*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,717*	*3.3%*	*1,555*	*1.5%*	*1.814*	*0.118*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.5	2.8	3.3	2.8	-0.837	-0.299
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*188,054*	*64.7%*	*66,784*	*65.7%*	*-0.991*	*-0.021*
Severe anemia	21,033	7.2%	3,882	3.8%	3.418	0.15
Cardiovascular disease	104,105	35.8%	53,305	52.4%	-16.615	-0.339
Diabetes	87,478	30.1%	33,742	33.2%	-3.093	-0.067
Hypertension	240,286	82.7%	90,518	89.0%	-6.366	-0.183
Obesity	68,783	23.7%	20,346	20.0%	3.652	0.088
Renal Impairment	49,300	17.0%	25,806	25.4%	-8.422	-0.207
Smoking	62,283	21.4%	20,836	20.5%	0.934	0.023
Von Willebrands disease	82	0.0%	23	0.0%	0.006	0.004
Gynecological disorders of interest	7,365	2.5%	1,951	1.9%	0.615	0.042
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*0.006*	*0.005*
Endometrial hyperplasia	*178*	*0.1%*	*58*	*0.1%*	*0.004*	*0.002*

Table 1k. Baseline Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0.008*	*0.009*
Ovarian cyst	*1,872*	*0.6%*	*502*	*0.5%*	*0.15*	*0.02*
Uterine myoma leiomyoma	*1,659*	*0.6%*	*445*	*0.4%*	*0.133*	*0.019*
Uterine or cervical polyp	*201*	*0.1%*	*52*	*0.1%*	*0.018*	*0.007*
Uterine ovarian or cervical cancer	*3,975*	*1.4%*	*1,011*	*1.0%*	*0.373*	*0.035*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	257,158	88.5%	98,428	96.8%	-8.341	-0.324
Medications that increase bleeding risk without interaction	172,852	59.5%	54,575	53.7%	5.788	0.117
Medications that inhibit metabolism of NOACs and increase bleeding risk	189,505	65.2%	73,254	72.1%	-6.855	-0.148
Medications that induce metabolism of NOACs and reduce bleeding risk	83,368	28.7%	28,765	28.3%	0.389	0.009
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.4	9.2	13.1	8.9	0.326	0.036
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1	-0.025	-0.023
Mean number of inpatient hospital encounters (IP)	1	0.9	0.8	1	0.133	0.139
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.2	0.7	0.023	0.034
Mean number of other ambulatory encounters (OA)	6.5	9.5	6.9	10.3	-0.461	-0.047
Mean number of unique drug classes	10	4.8	10.5	4.8	-0.442	-0.092
Mean number of generics	10.9	5.5	11.2	5.4	-0.332	-0.061
Mean number of filled prescriptions	25.2	19.4	25.8	19.2	-0.582	-0.03

[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.

[4]Novel Oral Anticoagulants

*****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 1l. Baseline Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	101,665	35.0%	101,665	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	77.7	9.2	77.7	9.5	-0.014	-0.002
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*982*	*1.0%*	*1,162*	*1.1%*	*-0.177*	*-0.017*
50+	*100,683*	*99.0%*	*100,503*	*98.9%*	*0.177*	*0.017*
Sex						
Female	101,665	100.0%	101,665	100.0%	0	-
Race						
American Indian or Alaska Native	*322*	*0.3%*	*244*	*0.2%*	*0.077*	*0.015*
Asian	*1,204*	*1.2%*	*1,187*	*1.2%*	*0.017*	*0.002*
Black or African American	*7,088*	*7.0%*	*6,118*	*6.0%*	*0.954*	*0.039*
Native Hawaiian or Other Pacific Islander	*62*	*0.1%*	*64*	*0.1%*	*-0.002*	*-0.001*
Unknown	*10,856*	*10.7%*	*10,739*	*10.6%*	*0.115*	*0.004*
White	*82,133*	*80.8%*	*83,313*	*81.9%*	*-1.161*	*-0.03*
Year						
2011	*516*	*0.5%*	*-*	*0.0%*	*0.508*	*-*
2012	*11,499*	*11.3%*	*-*	*0.0%*	*11.311*	*-*
2013	*28,382*	*27.9%*	*9,258*	*9.1%*	*18.811*	*0.499*
2014	*36,796*	*36.2%*	*37,246*	*36.6%*	*-0.443*	*-0.009*
2015	*24,472*	*24.1%*	*55,161*	*54.3%*	*-30.186*	*-0.65*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*2,782*	*2.7%*	*1,555*	*1.5%*	*1.207*	*0.084*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3.3	2.9	3.3	2.8	-0.018	-0.006
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*80,485*	*79.2%*	*66,783*	*65.7%*	*13.478*	*0.305*
Severe anemia	3,789	3.7%	3,882	3.8%	-0.091	-0.005
Cardiovascular disease	52,794	51.9%	53,303	52.4%	-0.501	-0.01
Diabetes	33,911	33.4%	33,741	33.2%	0.167	0.004
Hypertension	90,570	89.1%	90,516	89.0%	0.053	0.002
Obesity	20,073	19.7%	20,346	20.0%	-0.269	-0.007
Renal Impairment	24,931	24.5%	25,805	25.4%	-0.86	-0.02
Smoking	20,605	20.3%	20,836	20.5%	-0.227	-0.006
Von Willebrands disease	19	0.0%	23	0.0%	-0.004	-0.003
Gynecological disorders of interest	1,988	2.0%	1,951	1.9%	0.036	0.003
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.005*	*-0.007*

Table 1l. Baseline Covariates of New Initiators of Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometrial hyperplasia	*44*	*0.0%*	*58*	*0.1%*	*-0.014*	*-0.006*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*-0.001*	*-0.002*
Ovarian cyst	*423*	*0.4%*	*502*	*0.5%*	*-0.078*	*-0.012*
Uterine myoma leiomyoma	*387*	*0.4%*	*445*	*0.4%*	*-0.057*	*-0.009*
Uterine or cervical polyp	*46*	*0.0%*	*52*	*0.1%*	*-0.006*	*-0.003*
Uterine ovarian or cervical cancer	*1,198*	*1.2%*	*1,011*	*1.0%*	*0.184*	*0.018*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	98,867	97.2%	98,426	96.8%	0.434	0.026
Medications that increase bleeding risk without interaction	54,309	53.4%	54,574	53.7%	-0.261	-0.005
Medications that inhibit metabolism of NOACs and increase bleeding risk	73,165	72.0%	73,253	72.1%	-0.087	-0.002
Medications that induce metabolism of NOACs and reduce bleeding risk	28,830	28.4%	28,764	28.3%	0.065	0.001
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13	8.9	13.1	8.9	-0.042	-0.005
Mean number of emergency room encounters (ED)	0.5	1.1	0.5	1	0.003	0.003
Mean number of inpatient hospital encounters (IP)	0.8	0.8	0.8	1	-0.003	-0.003
Mean number of non-acute institutional encounters (IS)	0.2	0.6	0.2	0.7	0.003	0.004
Mean number of other ambulatory encounters (OA)	7	9.9	6.9	10.3	0.073	0.007
Mean number of unique drug classes	10.5	4.7	10.5	4.8	-0.003	-0.001
Mean number of generics	11.2	5.3	11.2	5.4	-0.005	-0.001
Mean number of filled prescriptions	25.8	18.7	25.8	19.2	-0.009	0

[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.

[4]Novel Oral Anticoagulants

*****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 1m. Baseline Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	81,010	100.0%	102,043	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	76.8	9.1	77.6	9.5	-0.898	-0.097
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*916*	*1.1%*	*1,171*	*1.1%*	*-0.017*	*-0.002*
50+	*80,094*	*98.9%*	*100,872*	*98.9%*	*0.017*	*0.002*
Sex						
Female	81,010	100.0%	102,043	100.0%	0	-
Race						
American Indian or Alaska Native	*230*	*0.3%*	*250*	*0.2%*	*0.039*	*0.008*
Asian	*1,257*	*1.6%*	*1,194*	*1.2%*	*0.382*	*0.033*
Black or African American	*4,122*	*5.1%*	*6,164*	*6.0%*	*-0.952*	*-0.042*
Native Hawaiian or Other Pacific Islander	*33*	*0.0%*	*62*	*0.1%*	*-0.02*	*-0.009*
Unknown	*10,403*	*12.8%*	*10,775*	*10.6%*	*2.282*	*0.071*
White	*64,965*	*80.2%*	*83,598*	*81.9%*	*-1.73*	*-0.044*
Year						
2010	*1,267*	*1.6%*	-	*0.0%*	*1.564*	-
2011	*30,365*	*37.5%*	-	*0.0%*	*37.483*	-
2012	*23,009*	*28.4%*	-	*0.0%*	*28.403*	-
2013	*13,180*	*16.3%*	*9,154*	*9.0%*	*7.299*	*0.221*
2014	*8,699*	*10.7%*	*37,213*	*36.5%*	*-25.73*	*-0.636*
2015	*4,490*	*5.5%*	*55,676*	*54.6%*	*-49.019*	*-1.265*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*3,585*	*4.4%*	*1,554*	*1.5%*	*2.902*	*0.171*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3	2.6	3.3	2.8	-0.331	-0.122
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*63,899*	*78.9%*	*67,023*	*65.7%*	*13.197*	*0.298*
Severe anemia	2,494	3.1%	3,897	3.8%	-0.74	-0.041
Cardiovascular disease	40,817	50.4%	53,442	52.4%	-1.987	-0.04
Diabetes	27,216	33.6%	33,860	33.2%	0.414	0.009
Hypertension	71,623	88.4%	90,866	89.0%	-0.634	-0.02
Obesity	12,923	16.0%	20,519	20.1%	-4.156	-0.108
Renal Impairment	14,302	17.7%	25,854	25.3%	-7.682	-0.188
Smoking	12,505	15.4%	20,934	20.5%	-5.079	-0.133
Von Willebrands disease	17	0.0%	23	0.0%	-0.002	-0.001
Gynecological disorders of interest	1,455	1.8%	1,946	1.9%	-0.111	-0.008

Table 1m. Baseline Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Adenomyosis	*****	*0.0%*	*****	*0.0%*	*-0.005*	*-0.007*
Endometrial hyperplasia	*49*	*0.1%*	*55*	*0.1%*	*0.007*	*0.003*
Endometriosis	*****	*0.0%*	*****	*0.0%*	*0*	*0*
Ovarian cyst	*370*	*0.5%*	*508*	*0.5%*	*-0.041*	*-0.006*
Uterine myoma leiomyoma	*365*	*0.5%*	*442*	*0.4%*	*0.017*	*0.003*
Uterine or cervical polyp	*57*	*0.1%*	*51*	*0.0%*	*0.02*	*0.008*
Uterine ovarian or cervical cancer	*732*	*0.9%*	*1,008*	*1.0%*	*-0.084*	*-0.009*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	79,029	97.6%	98,757	96.8%	0.775	0.047
Medications that increase bleeding risk without interaction	41,774	51.6%	54,892	53.8%	-2.227	-0.045
Medications that inhibit metabolism of NOACs and increase bleeding risk	57,391	70.8%	73,509	72.0%	-1.193	-0.026
Medications that induce metabolism of NOACs and reduce bleeding risk	22,325	27.6%	28,918	28.3%	-0.781	-0.017
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	12.3	8.6	13.1	8.9	-0.744	-0.085
Mean number of emergency room encounters (ED)	0.5	1	0.5	1	-0.081	-0.082
Mean number of inpatient hospital encounters (IP)	0.7	0.9	0.8	1	-0.088	-0.091
Mean number of non-acute institutional encounters (IS)	0.2	0.6	0.2	0.7	-0.063	-0.1
Mean number of other ambulatory encounters (OA)	5.8	8.7	6.9	10.3	-1.153	-0.121
Mean number of unique drug classes	10.1	4.7	10.5	4.8	-0.324	-0.068
Mean number of generics	10.9	5.4	11.2	5.4	-0.338	-0.063
Mean number of filled prescriptions	26.2	19.1	25.8	19.2	0.37	0.019

[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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	77,156	95.2%	77,156	75.6%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	77.1	8.9	77.1	9.5	0.042	0.005
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*743*	*1.0%*	*951*	*1.2%*	*-0.27*	*-0.026*
50+	*76,413*	*99.0%*	*76,205*	*98.8%*	*0.27*	*0.026*
Sex						
Female	77,156	100.0%	77,156	100.0%	0	-
Race						
American Indian or Alaska Native	*220*	*0.3%*	*182*	*0.2%*	*0.049*	*0.01*
Asian	*1,185*	*1.5%*	*965*	*1.3%*	*0.285*	*0.024*
Black or African American	*3,905*	*5.1%*	*4,436*	*5.7%*	*-0.688*	*-0.03*
Native Hawaiian or Other Pacific Islander	*32*	*0.0%*	*47*	*0.1%*	*-0.019*	*-0.009*
Unknown	*8,953*	*11.6%*	*8,706*	*11.3%*	*0.32*	*0.01*
White	*62,861*	*81.5%*	*62,820*	*81.4%*	*0.053*	*0.001*
Year						
2010	*1,176*	*1.5%*	-	*0.0%*	*1.524*	-
2011	*28,765*	*37.3%*	-	*0.0%*	*37.282*	-
2012	*21,898*	*28.4%*	-	*0.0%*	*28.381*	-
2013	*12,643*	*16.4%*	*7,340*	*9.5%*	*6.873*	*0.206*
2014	*8,333*	*10.8%*	*28,508*	*36.9%*	*-26.148*	*-0.644*
2015	*4,341*	*5.6%*	*41,308*	*53.5%*	*-47.912*	*-1.233*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*3,394*	*4.4%*	*1,192*	*1.5%*	*2.854*	*0.169*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	3	2.6	3	2.7	-0.004	-0.002
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
NOAC[4] high dose subgroup rivaroxaban, dabigatran	*60,474*	*78.4%*	*52,463*	*68.0%*	*10.383*	*0.236*
Severe anemia	2,429	3.1%	2,464	3.2%	-0.045	-0.003
Cardiovascular disease	38,987	50.5%	38,983	50.5%	0.005	0
Diabetes	25,455	33.0%	25,432	33.0%	0.03	0.001
Hypertension	68,287	88.5%	68,331	88.6%	-0.057	-0.002
Obesity	12,750	16.5%	12,705	16.5%	0.058	0.002
Renal Impairment	14,226	18.4%	14,217	18.4%	0.012	0
Smoking	12,369	16.0%	12,405	16.1%	-0.047	-0.001
Von Willebrands disease	15	0.0%	16	0.0%	-0.001	-0.001
Gynecological disorders of interest	1,392	1.8%	1,390	1.8%	0.003	0

Table 1n. Baseline Covariates of New Initiators of Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Adenomyosis	*******	*0.0%*	*******	*0.0%*	*-0.003*	*-0.004*
Endometrial hyperplasia	*45*	*0.1%*	*41*	*0.1%*	*0.005*	*0.002*
Endometriosis	*******	*0.0%*	*******	*0.0%*	*0*	*0*
Ovarian cyst	*354*	*0.5%*	*365*	*0.5%*	*-0.014*	*-0.002*
Uterine myoma leiomyoma	*349*	*0.5%*	*307*	*0.4%*	*0.054*	*0.008*
Uterine or cervical polyp	*54*	*0.1%*	*40*	*0.1%*	*0.018*	*0.007*
Uterine ovarian or cervical cancer	*707*	*0.9%*	*725*	*0.9%*	*-0.023*	*-0.002*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	75,185	97.4%	75,191	97.5%	-0.008	0
Medications that increase bleeding risk without interaction	40,063	51.9%	40,157	52.0%	-0.122	-0.002
Medications that inhibit metabolism of NOACs and increase bleeding risk	54,771	71.0%	54,734	70.9%	0.048	0.001
Medications that induce metabolism of NOACs and reduce bleeding risk	21,371	27.7%	21,448	27.8%	-0.1	-0.002
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	12.4	8.6	12.5	8.4	-0.016	-0.002
Mean number of emergency room encounters (ED)	0.5	1	0.5	0.9	-0.007	-0.007
Mean number of inpatient hospital encounters (IP)	0.7	0.9	0.7	0.9	-0.003	-0.003
Mean number of non-acute institutional encounters (IS)	0.2	0.6	0.2	0.6	-0.004	-0.006
Mean number of other ambulatory encounters (OA)	5.9	8.9	6	8.7	-0.037	-0.004
Mean number of unique drug classes	10.2	4.7	10.2	4.7	-0.002	0
Mean number of generics	10.9	5.4	10.9	5.3	-0.001	0
Mean number of filled prescriptions	26	18.9	25.9	19.8	0.083	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.

[4]Novel Oral Anticoagulants

*****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 Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	279,971	100.0%	895,208	100.0%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73	10.6	74.4	11.6	-1.385	-0.125
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*10,770*	*3.8%*	*38,973*	*4.4%*	*-0.507*	*-0.026*
50+	*269,201*	*96.2%*	*856,235*	*95.6%*	*0.507*	*0.026*
Sex						
Female	279,971	100.0%	895,208	100.0%	0	-
Race						
American Indian or Alaska Native	*973*	*0.3%*	*3,311*	*0.4%*	*-0.022*	*-0.004*
Asian	*2,660*	*1.0%*	*7,890*	*0.9%*	*0.069*	*0.007*
Black or African American	*19,211*	*6.9%*	*82,847*	*9.3%*	*-2.393*	*-0.088*
Native Hawaiian or Other Pacific Islander	*144*	*0.1%*	*292*	*0.0%*	*0.019*	*0.009*
Unknown	*44,579*	*15.9%*	*120,529*	*13.50%*	*2.459*	*0.069*
White	*212,404*	*75.9%*	*680,339*	*76.0%*	*-0.131*	*-0.003*
Year						
2010	-	*0.0%*	*48,417*	*5.4%*	*-5.408*	-
2011	*3,016*	*1.1%*	*220,338*	*24.6%*	*-23.536*	*-0.751*
2012	*36,862*	*13.2%*	*204,971*	*22.9%*	*-9.73*	*-0.255*
2013	*77,522*	*27.7%*	*179,407*	*20.0%*	*7.648*	*0.18*
2014	*97,709*	*34.9%*	*147,654*	*16.5%*	*18.406*	*0.431*
2015	*64,862*	*23.2%*	*94,421*	*10.5%*	*12.62*	*0.342*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,371*	*3.3%*	*40,109*	*4.5%*	*-1.133*	*-0.058*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.4	2.8	3.4	3.2	-0.961	-0.322
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Severe anemia	20,346	7.3%	95,414	10.7%	-3.391	-0.119
Cardiovascular disease	99,477	35.5%	419,010	46.8%	-11.275	-0.231
Diabetes	83,955	30.0%	314,307	35.1%	-5.123	-0.109
Hypertension	231,297	82.6%	756,722	84.5%	-1.916	-0.052
Obesity	66,146	23.6%	193,134	21.6%	2.052	0.049
Renal Impairment	47,003	16.8%	234,496	26.2%	-9.406	-0.231
Smoking	60,027	21.4%	184,422	20.6%	0.839	0.021
Von Willebrands disease	79	0.0%	393	0.0%	-0.016	-0.008
Gynecological disorders of interest	7,110	2.5%	24,621	2.8%	-0.211	-0.013
Adenomyosis	*39*	*0.0%*	*123*	*0.0%*	*0*	*0*
Endometrial hyperplasia	*177*	*0.1%*	*565*	*0.1%*	*0*	*0*

Table 1o. Baseline Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Endometriosis	*37*	*0.0%*	*133*	*0.0%*	*-0.002*	*-0.001*
Ovarian cyst	*1,812*	*0.6%*	*6,321*	*0.7%*	*-0.059*	*-0.007*
Uterine myoma leiomyoma	*1,604*	*0.6%*	*5,631*	*0.6%*	*-0.056*	*-0.007*
Uterine or cervical polyp	*193*	*0.1%*	*596*	*0.1%*	*0.002*	*0.001*
Uterine ovarian or cervical cancer	*3,826*	*1.4%*	*13,285*	*1.5%*	*-0.117*	*-0.01*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	247,433	88.4%	803,800	89.8%	-1.411	-0.045
Medications that increase bleeding risk without interaction	166,403	59.4%	562,108	62.8%	-3.355	-0.069
Medications that inhibit metabolism of NOACs and increase bleeding risk	182,317	65.1%	596,040	66.6%	-1.461	-0.031
Medications that induce metabolism of NOACs and reduce bleeding risk	79,912	28.5%	272,721	30.5%	-1.922	-0.042
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.3	9.2	13.8	9.8	-0.503	-0.053
Mean number of emergency room encounters (ED)	0.5	1.2	0.6	1.3	-0.071	-0.057
Mean number of inpatient hospital encounters (IP)	1	0.9	1.2	1.1	-0.2	-0.196
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.4	0.8	-0.132	-0.176
Mean number of other ambulatory encounters (OA)	6.4	9.4	10	13.4	-3.535	-0.306
Mean number of unique drug classes	10	4.8	10.5	4.8	-0.459	-0.095
Mean number of generics	10.8	5.4	11.3	5.5	-0.487	-0.089
Mean number of filled prescriptions	25.1	19.3	26.5	19.7	-1.445	-0.074

[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 1p. Baseline Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Characteristic[1, 2]	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Patients	279,970	100.0%	279,970	31.3%	-	-
Demographics[3]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean age (years)	73	10.6	72.9	11.5	0.081	0.007
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Age (years)						
00-49	*10,769*	*3.8%*	*14,456*	*5.2%*	*-1.317*	*-0.064*
50+	*269,201*	*96.2%*	*265,514*	*94.8%*	*1.317*	*0.064*
Sex						
Female	279,970	100.0%	279,970	100.0%	0	-
Race						
American Indian or Alaska Native	*973*	*0.3%*	*981*	*0.4%*	*-0.003*	*0*
Asian	*2,660*	*1.0%*	*2,197*	*0.8%*	*0.165*	*0.018*
Black or African American	*19,211*	*6.9%*	*22,284*	*8.0%*	*-1.098*	*-0.042*
Native Hawaiian or Other Pacific Islander	*144*	*0.1%*	*115*	*0.0%*	*0.01*	*0.005*
Unknown	*44,578*	*15.9%*	*44,689*	*16.0%*	*-0.04*	*-0.001*
White	*212,404*	*75.9%*	*209,704*	*74.9%*	*0.964*	*0.022*
Year						
2010	-	*0.0%*	*14,991*	*5.4%*	*-5.355*	-
2011	*3,016*	*1.1%*	*69,376*	*24.8%*	*-23.703*	*-0.755*
2012	*36,862*	*13.2%*	*63,959*	*22.8%*	*-9.679*	*-0.254*
2013	*77,522*	*27.7%*	*56,365*	*20.1%*	*7.557*	*0.178*
2014	*97,708*	*34.9%*	*45,887*	*16.4%*	*18.509*	*0.434*
2015	*64,862*	*23.2%*	*29,392*	*10.5%*	*12.669*	*0.344*
Presence of condition in post-index enrollment:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Vaginal bleeding	*9,371*	*3.3%*	*12,999*	*4.6%*	*-1.296*	*-0.066*
Recorded history of:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Prior combined comorbidity raw score	2.4	2.8	2.4	2.7	0.016	0.006
	Number	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Severe anemia	20,346	7.3%	20,484	7.3%	-0.049	-0.002
Cardiovascular disease	99,477	35.5%	97,734	34.9%	0.623	0.013
Diabetes	83,954	30.0%	83,343	29.8%	0.218	0.005
Hypertension	231,296	82.6%	231,099	82.5%	0.07	0.002
Obesity	66,145	23.6%	66,842	23.9%	-0.249	-0.006
Renal Impairment	47,003	16.8%	46,180	16.5%	0.294	0.008
Smoking	60,026	21.4%	60,199	21.5%	-0.062	-0.002
Von Willebrands disease	79	0.0%	94	0.0%	-0.005	-0.003
Gynecological disorders of interest	7,110	2.5%	7,132	2.5%	-0.008	0
Adenomyosis	*39*	*0.0%*	*41*	*0.0%*	*-0.001*	*-0.001*
Endometrial hyperplasia	*177*	*0.1%*	*186*	*0.1%*	*-0.003*	*-0.001*
Endometriosis	*37*	*0.0%*	*53*	*0.0%*	*-0.006*	*-0.005*

Table 1p. Baseline Covariates of New Initiators of Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Medical Product					
	Rivaroxaban		Dabigatran		Covariate Balance	
Ovarian cyst	*1,812*	*0.6%*	*1,944*	*0.7%*	*-0.047*	*-0.006*
Uterine myoma leiomyoma	*1,604*	*0.6%*	*1,679*	*0.6%*	*-0.027*	*-0.004*
Uterine or cervical polyp	*193*	*0.1%*	*222*	*0.1%*	*-0.01*	*-0.004*
Uterine ovarian or cervical cancer	*3,826*	*1.4%*	*3,623*	*1.3%*	*0.073*	*0.006*
History of use:	**Number**	**Percent**	**Number**	**Percent**	**Absolute Difference**	**Standardized Difference**
Cardiovascular and antidiabetic agents	247,432	88.4%	247,341	88.3%	0.033	0.001
Medications that increase bleeding risk without interaction	166,402	59.4%	165,777	59.2%	0.223	0.005
Medications that inhibit metabolism of NOACs and increase bleeding risk	182,316	65.1%	182,765	65.3%	-0.16	-0.003
Medications that induce metabolism of NOACs and reduce bleeding risk	79,911	28.5%	79,898	28.5%	0.005	0
Health Service Utilization Intensity:	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Absolute Difference**	**Standardized Difference**
Mean number of ambulatory encounters (AV)	13.3	9.2	13.3	9.3	0.029	0.003
Mean number of emergency room encounters (ED)	0.5	1.2	0.5	1.1	0.001	0.001
Mean number of inpatient hospital encounters (IP)	1	0.9	1	0.9	-0.004	-0.005
Mean number of non-acute institutional encounters (IS)	0.2	0.7	0.3	0.7	-0.008	-0.012
Mean number of other ambulatory encounters (OA)	6.4	9.4	6.6	9.2	-0.185	-0.02
Mean number of unique drug classes	10	4.8	10	4.7	-0.003	-0.001
Mean number of generics	10.8	5.4	10.8	5.4	-0.006	-0.001
Mean number of filled prescriptions	25.1	19.3	25	18.7	0.015	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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	289,011	155,142.97	196.07	0.54	801	5.16	2.77	1.54	-1.05	1.35 (1.17, 1.54)	<0.001
Dabigatran	80,844	85,311.95	385.44	1.06	309	3.62	3.82				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	80,844	27,967.12	126.35	0.35	120	4.29	1.48	0.57	0.20	1.15 (0.89, 1.50)	0.285
Dabigatran	80,844	27,967.12	126.35	0.35	104	3.72	1.29				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	80,844	55,251.85	249.63	0.68	224	4.05	2.77	0.43	-1.05	1.09 (0.91, 1.30)	0.344
Dabigatran	80,844	85,311.95	385.44	1.06	309	3.62	3.82				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	289,011									1.21 (1.05, 1.39)	0.008
Dabigatran	80,844										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2b. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	290,780	156,551.15	196.64	0.54	805	5.14	2.77	1.61	1.11	1.47 (1.24, 1.73)	<0.001
Apixaban	101,663	47,900.96	172.10	0.47	169	3.53	1.66				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	101,661	25,105.80	90.20	0.25	93	3.70	0.91	0.48	0.12	1.15 (0.85, 1.55)	0.363
Apixaban	101,661	25,105.80	90.20	0.25	81	3.23	0.80				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	101,661	67,938.18	244.09	0.67	259	3.81	2.55	0.28	0.89	1.11 (0.91, 1.35)	0.315
Apixaban	101,661	47,900.54	172.10	0.47	169	3.53	1.66				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	290,780									1.26 (1.06, 1.49)	0.008
Dabigatran	101,663										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2c. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Dabigatran	81,021	85,394.28	384.97	1.05	309	3.62	3.81	0.07	2.15	1.00 (0.82, 1.22)	0.991
Apixaban	102,039	47,876.22	171.37	0.47	170	3.55	1.67				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	77,176	22,425.98	106.14	0.29	74	3.30	0.96	0.09	0.03	1.03 (0.74, 1.42)	0.869
Apixaban	77,176	22,425.98	106.14	0.29	72	3.21	0.93				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	77,176	81,206.58	384.33	1.05	299	3.68	3.87	0.06	2.11	1.02 (0.82, 1.27)	0.836
Apixaban	77,176	37,532.15	177.63	0.49	136	3.62	1.76				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	81,021									0.99 (0.80, 1.21)	0.889
Dabigatran	102,039										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2d. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	280,078	150,414.25	196.16	0.54	777	5.17	2.77	1.59	1.24	1.37 (1.25, 1.50)	<0.001
Warfarin	895,730	385,624.29	157.25	0.43	1,377	3.57	1.54				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	280,077	47,505.54	61.95	0.17	231	4.86	0.82	1.41	0.24	1.41 (1.15, 1.72)	<0.001
Warfarin	280,077	47,505.54	61.95	0.17	164	3.45	0.59				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	280,077	150,413.33	196.15	0.54	777	5.17	2.77	1.19	1.16	1.27 (1.13, 1.43)	<0.001
Warfarin	280,077	114,081.63	148.77	0.41	453	3.97	1.62				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	280,078									1.27 (1.16, 1.39)	<0.001
Dabigatran	895,730										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2e. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	288,893	155,613.94	196.74	0.54	200	1.29	0.69	0.78	0.16	2.10 (1.49, 2.96)	<0.001
Dabigatran	80,832	85,645.92	387.00	1.06	43	0.50	0.53				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	80,832	27,900.31	126.07	0.35	29	1.04	0.36	0.36	0.12	1.53 (0.86, 2.72)	0.152
Dabigatran	80,832	27,900.31	126.07	0.35	19	0.68	0.24				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	80,832	55,428.03	250.46	0.69	49	0.88	0.61	0.38	0.07	1.57 (1.03, 2.40)	0.038
Dabigatran	80,832	85,645.92	387.00	1.06	43	0.50	0.53				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	288,893									1.67 (1.17, 2.38)	0.005
Dabigatran	80,832										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2f. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	290,663	157,029.10	197.32	0.54	200	1.27	0.69	0.59	0.36	2.06 (1.42, 2.98)	<0.001
Apixaban	101,667	47,978.33	172.37	0.47	33	0.69	0.32				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	101,665	25,217.77	90.60	0.25	28	1.11	0.28	0.12	0.03	1.12 (0.65, 1.92)	0.68
Apixaban	101,665	25,217.77	90.60	0.25	25	0.99	0.25				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	101,665	67,919.73	244.01	0.67	47	0.69	0.46	0.00	0.14	1.24 (0.79, 1.95)	0.345
Apixaban	101,665	47,977.91	172.37	0.47	33	0.69	0.32				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	290,663									1.57 (1.07, 2.29)	0.02
Dabigatran	101,667										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2g. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Dabigatran	81,010	85,728.50	386.52	1.06	43	0.50	0.53	-0.19	0.21	0.95 (0.58, 1.55)	0.836
Apixaban	102,043	47,953.28	171.64	0.47	33	0.69	0.32				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	77,156	22,360.30	105.85	0.29	16	0.72	0.21	-0.13	-0.04	0.84 (0.43, 1.64)	0.613
Apixaban	77,156	22,360.30	105.85	0.29	19	0.85	0.25				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	77,156	81,430.33	385.48	1.06	42	0.52	0.54	-0.07	0.26	1.12 (0.65, 1.94)	0.68
Apixaban	77,156	37,610.37	178.04	0.49	22	0.58	0.29				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	81,010									1.00 (0.61, 1.65)	1
Dabigatran	102,043										

Data are not presented in shaded cells due to their inability to be calculated.

Table 2h. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type, 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
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	279,971	150,876.34	196.83	0.54	196	1.30	0.70	-0.29	0.01	0.87 (0.74, 1.02)	0.093
Warfarin	895,208	386,231.70	157.58	0.43	615	1.59	0.69				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	279,970	47,711.17	62.24	0.17	98	2.05	0.35	0.13	0.02	1.07 (0.80, 1.42)	0.663
Warfarin	279,970	47,711.17	62.24	0.17	92	1.93	0.33				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	279,970	150,875.42	196.83	0.54	196	1.30	0.70	-0.14	0.11	0.98 (0.80, 1.21)	0.878
Warfarin	279,970	115,027.53	150.07	0.41	166	1.44	0.59				
Predefined Percentile Analysis; Percentile = 10											
Rivaroxaban	279,971									1.04 (0.88, 1.23)	0.628
Dabigatran	895,208										

Data are not presented in shaded cells due to their inability to be calculated.

Table 3a. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	11,150	4,140.09	135.62	0.37	147	35.51	13.18	13.42	-1.05	1.49 (0.82, 2.70)	0.188
Dabigatran	913	588.62	235.48	0.64	13	22.09	14.24				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	851	198.81	85.33	0.23	*****	*****	*****	-5.03	-1.18	0.83 (0.25, 2.73)	0.763
Dabigatran	851	198.81	85.33	0.23	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	851	393.40	168.85	0.46	*****	*****	*****	3.40	-2.35	1.17 (0.49, 2.78)	0.727
Dabigatran	851	544.91	233.88	0.64	*****	*****	*****				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	277,861	151,002.88	198.49	0.54	654	4.33	2.35	0.84	-1.35	1.20 (1.04, 1.39)	0.011
Dabigatran	79,931	84,723.33	387.15	1.06	296	3.49	3.70				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,800	27,736.93	126.95	0.35	*****	*****	*****	0.54	0.19	1.15 (0.88, 1.51)	0.302
Dabigatran	79,800	27,736.93	126.95	0.35	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,800	54,766.21	250.67	0.69	*****	*****	*****	0.37	-1.05	1.08 (0.90, 1.29)	0.412
Dabigatran	79,800	84,624.49	387.33	1.06	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	11,171	4,149.87	135.69	0.37	147	35.42	13.16	14.66	*****	1.73 (0.85, 3.52)	0.134
Apixaban	1,161	*****	*****	*****	*****	20.77	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	958	160.11	61.04	0.17	*****	*****	*****	31.23	5.22	3.50 (0.73, 16.85)	0.118
Apixaban	958	160.11	61.04	0.17	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	958	417.68	159.25	0.44	17	40.70	17.75	*****	*****	1.68 (0.72, 3.96)	0.233
Apixaban	958	317.70	121.13	0.33	*****	*****	*****				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	279,609	152,401.28	199.08	0.55	658	4.32	2.35	0.93	*****	1.30 (1.09, 1.54)	0.004
Apixaban	100,502	*****	*****	*****	*****	3.39	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	100,443	24,921.42	90.62	0.25	*****	*****	*****	0.44	0.11	1.14 (0.84, 1.55)	0.395
Apixaban	100,443	24,921.42	90.62	0.25	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	100,443	67,430.20	245.20	0.67	242	3.59	2.41	*****	*****	1.07 (0.88, 1.31)	0.497
Apixaban	100,443	47,491.80	172.70	0.47	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	915	589.29	235.23	0.64	13	22.06	14.21	1.32	*****	1.06 (0.42, 2.71)	0.897
Apixaban	1,170	*****	*****	*****	*****	20.74	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	746	147.61	72.27	0.20	*****	*****	*****	13.55	2.68	2.00 (0.37, 10.92)	0.423
Apixaban	746	147.61	72.27	0.20	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	746	455.98	223.25	0.61	11	24.12	14.75	*****	*****	1.03 (0.36, 2.94)	0.958
Apixaban	746	257.00	125.83	0.34	*****	*****	*****				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	80,106	84,804.99	386.68	1.06	296	3.49	3.70	0.08	*****	1.00 (0.81, 1.23)	0.995
Apixaban	100,869	*****	*****	*****	*****	3.41	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	76,175	22,260.10	106.73	0.29	*****	*****	*****	-0.13	-0.04	0.96 (0.68, 1.34)	0.796
Apixaban	76,175	22,260.10	106.73	0.29	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	76,175	80,517.23	386.07	1.06	286	3.55	3.75	*****	*****	1.02 (0.82, 1.27)	0.861
Apixaban	76,175	37,190.02	178.32	0.49	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	10,763	3,972.14	134.80	0.37	146	36.76	13.56	15.16	5.78	1.56 (1.27, 1.90)	<0.001
Warfarin	38,928	14,031.79	131.66	0.36	303	21.59	7.78				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,737	1,499.51	51.01	0.14	51	34.01	4.75	13.34	1.86	1.65 (1.05, 2.57)	0.029
Warfarin	10,737	1,499.51	51.01	0.14	31	20.67	2.89				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,737	3,966.46	134.93	0.37	146	36.81	13.60	12.82	5.31	1.51 (1.16, 1.98)	0.003
Warfarin	10,737	3,709.71	126.20	0.35	89	23.99	8.29				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	269,315	146,442.11	198.61	0.54	631	4.31	2.34	1.42	1.09	1.44 (1.30, 1.59)	<0.001
Warfarin	856,802	371,592.50	158.41	0.43	1,074	2.89	1.25				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	265,658	45,388.67	62.40	0.17	178	3.92	0.67	1.15	0.20	1.41 (1.12, 1.77)	0.003
Warfarin	265,658	45,388.67	62.40	0.17	126	2.78	0.47				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	265,658	144,646.95	198.87	0.54	621	4.29	2.34	1.25	1.09	1.38 (1.21, 1.58)	<0.001
Warfarin	265,658	108,987.80	149.85	0.41	332	3.05	1.25				

Table 3e. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	11,155	4,186.34	137.07	0.38	76	18.15	6.81	14.80	*****	4.06 (1.00, 16.52)	0.051
Dabigatran	914	*****	*****	*****	*****	3.35	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	843	190.64	82.60	0.23	*****	*****	*****	*****	*****	-	-
Dabigatran	843	190.64	82.60	0.23	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	843	367.78	159.35	0.44	*****	*****	*****	26.34	10.68	6.62 (1.47, 29.92)	0.014
Dabigatran	843	559.84	242.57	0.66	*****	*****	*****				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	277,738	151,427.60	199.14	0.55	124	0.82	0.45	0.34	*****	1.50 (1.03, 2.17)	0.033
Dabigatran	79,918	*****	*****	*****	*****	0.48	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,805	27,677.44	126.67	0.35	*****	*****	*****	*****	*****	1.11 (0.59, 2.10)	0.746
Dabigatran	79,805	27,677.44	126.67	0.35	18	0.65	0.23				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,805	54,971.50	251.59	0.69	*****	*****	*****	0.17	-0.06	1.24 (0.78, 1.97)	0.366
Dabigatran	79,805	84,953.91	388.82	1.06	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	11,176	4,196.12	137.14	0.38	76	18.11	6.80	0.05	*****	1.11 (0.51, 2.42)	0.784
Apixaban	1,162	*****	*****	*****	*****	18.06	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	921	149.60	59.33	0.16	*****	*****	*****	-13.37	-2.17	0.60 (0.14, 2.51)	0.484
Apixaban	921	149.60	59.33	0.16	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	921	365.58	144.98	0.40	*****	*****	*****	-8.81	-2.17	0.62 (0.19, 1.96)	0.414
Apixaban	921	311.31	123.46	0.34	*****	*****	*****				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	279,487	152,832.97	199.73	0.55	124	0.81	0.44	0.27	*****	1.71 (1.12, 2.62)	0.013
Apixaban	100,505	*****	*****	*****	*****	0.55	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	100,443	25,017.05	90.97	0.25	*****	*****	*****	0.20	0.05	1.26 (0.69, 2.31)	0.447
Apixaban	100,443	25,017.05	90.97	0.25	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	100,443	67,464.48	245.33	0.67	*****	*****	*****	0.08	0.16	1.41 (0.86, 2.31)	0.171
Apixaban	100,443	47,560.86	172.95	0.47	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	916	*****	*****	*****	*****	3.35	*****	-14.68	-3.79	0.25 (0.05, 1.28)	0.096
Apixaban	1,171	*****	*****	*****	*****	18.03	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	718	141.45	71.95	0.20	0	0.00	0.00	*****	*****	-	-
Apixaban	718	141.45	71.95	0.20	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	718	461.35	234.69	0.64	*****	*****	*****	-12.18	-2.79	0.33 (0.06, 1.94)	0.222
Apixaban	718	242.16	123.19	0.34	*****	*****	*****				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	80,094	*****	*****	*****	*****	0.48	*****	-0.07	0.25	1.16 (0.69, 1.96)	0.579
Apixaban	100,872	*****	*****	*****	*****	0.55	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	76,187	22,173.93	106.30	0.29	15	0.68	0.20	*****	*****	1.00 (0.49, 2.05)	1
Apixaban	76,187	22,173.93	106.30	0.29	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	76,187	80,697.17	386.87	1.06	*****	*****	*****	0.04	0.30	1.38 (0.76, 2.51)	0.29
Apixaban	76,187	37,280.74	178.73	0.49	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group, 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: 00-49 years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	10,770	4,021.83	136.39	0.37	74	18.40	6.87	8.89	3.41	2.11 (1.59, 2.82)	<0.001
Warfarin	38,973	14,198.49	133.07	0.36	135	9.51	3.46				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,751	1,510.21	51.31	0.14	46	30.46	4.28	19.20	2.70	2.71 (1.55, 4.72)	<0.001
Warfarin	10,751	1,510.21	51.31	0.14	17	11.26	1.58				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,751	4,016.61	136.46	0.37	74	18.42	6.88	10.46	4.09	2.41 (1.57, 3.69)	<0.001
Warfarin	10,751	3,766.71	127.97	0.35	30	7.96	2.79				
Age Group: 50+ years											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	269,201	146,854.51	199.25	0.55	122	0.83	0.45	-0.46	-0.11	0.69 (0.57, 0.85)	<0.001
Warfarin	856,235	372,033.22	158.70	0.43	480	1.29	0.56				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	265,496	45,603.74	62.74	0.17	53	1.16	0.20	-0.35	-0.06	0.77 (0.54, 1.10)	0.149
Warfarin	265,496	45,603.74	62.74	0.17	69	1.51	0.26				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	265,496	145,006.79	199.49	0.55	120	0.83	0.45	-0.29	-0.01	0.79 (0.61, 1.02)	0.072
Warfarin	265,496	109,870.15	151.15	0.41	123	1.12	0.46				

Table 4a. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Novel Oral Anticoagulants (NOAC) High Dose Group, 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 NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	102,562	8,675.72	30.90	0.08	16	1.84	0.16	-0.08	-0.61	1.44 (0.67, 3.12)	0.354
Dabigatran	17,064	6,761.95	144.74	0.40	13	1.92	0.76				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,311	815.73	28.90	0.08	*****	*****	*****	1.23	0.10	2.00 (0.18, 22.06)	0.571
Dabigatran	10,311	815.73	28.90	0.08	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,311	1,566.09	55.48	0.15	*****	*****	*****	0.58	-0.39	1.19 (0.34, 4.17)	0.791
Dabigatran	10,311	4,057.37	143.73	0.39	*****	*****	*****				
NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	186,449	146,467.26	286.93	0.79	785	5.36	4.21	1.59	-0.43	1.32 (1.15, 1.52)	<0.001
Dabigatran	63,780	78,550.00	449.83	1.23	296	3.77	4.64				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	57,071	26,525.90	169.76	0.46	114	4.30	2.00	0.30	0.14	1.08 (0.83, 1.40)	0.59
Dabigatran	57,071	26,525.90	169.76	0.46	106	4.00	1.86				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	57,071	47,536.21	304.23	0.83	197	4.14	3.45	0.66	-0.91	1.15 (0.94, 1.39)	0.168
Dabigatran	57,071	71,423.49	457.10	1.25	249	3.49	4.36				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Novel Oral Anticoagulants (NOAC) High Dose Group, 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 NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	102,734	8,719.09	31.00	0.08	16	1.84	0.16	-0.38	-0.47	1.23 (0.61, 2.48)	0.567
Apixaban	34,887	9,924.27	103.90	0.28	22	2.22	0.63				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,350	1,142.40	27.18	0.07	*****	*****	*****	0.00	0.00	1.00 (0.06, 15.99)	1
Apixaban	15,350	1,142.40	27.18	0.07	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,350	2,236.08	53.21	0.15	*****	*****	*****	-0.94	-0.39	0.52 (0.13, 2.07)	0.356
Apixaban	15,350	3,938.85	93.72	0.26	*****	*****	*****				
NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	188,046	147,832.06	287.14	0.79	789	5.34	4.20	1.47	1.99	1.41 (1.18, 1.68)	<0.001
Apixaban	66,776	37,976.69	207.72	0.57	147	3.87	2.20				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,938	20,655.04	123.80	0.34	*****	*****	*****	0.77	0.26	1.21 (0.89, 1.63)	0.223
Apixaban	60,938	20,655.04	123.80	0.34	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,938	49,773.70	298.33	0.82	216	4.34	3.54	0.66	1.43	1.22 (0.97, 1.52)	0.084
Apixaban	60,938	35,014.79	209.87	0.57	129	3.68	2.12				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Novel Oral Anticoagulants (NOAC) High Dose Group, 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 NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	17,115	6,774.09	144.57	0.40	13	1.92	0.76	-0.30	0.13	0.74 (0.36, 1.54)	0.421
Apixaban	35,023	9,916.70	103.42	0.28	22	2.22	0.63				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,706	2,270.74	49.65	0.14	*****	*****	*****	0.00	0.00	1.00 (0.25, 4.00)	1
Apixaban	16,706	2,270.74	49.65	0.14	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,706	6,589.75	144.07	0.39	12	1.82	0.72	-0.92	-0.06	0.67 (0.29, 1.50)	0.328
Apixaban	16,706	4,746.21	103.77	0.28	13	2.74	0.78				
NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	63,906	78,620.19	449.35	1.23	296	3.76	4.63	-0.13	2.42	0.99 (0.80, 1.22)	0.892
Apixaban	67,016	37,959.53	206.89	0.57	148	3.90	2.21				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	52,426	19,253.09	134.14	0.37	68	3.53	1.30	-0.16	-0.06	0.96 (0.69, 1.34)	0.799
Apixaban	52,426	19,253.09	134.14	0.37	71	3.69	1.35				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	52,426	64,306.72	448.02	1.23	252	3.92	4.81	0.04	2.56	1.07 (0.84, 1.34)	0.595
Apixaban	52,426	30,399.66	211.79	0.58	118	3.88	2.25				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Novel Oral Anticoagulants (NOAC) High Dose Group, 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 NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	102,437	8,676.54	30.94	0.08	13	1.50	0.13	0.61	*****	1.63 (0.56, 4.73)	0.365
Dabigatran	17,059	*****	*****	*****	*****	0.89	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,262	822.07	29.26	0.08	*****	*****	*****	*****	*****	-	-
Dabigatran	10,262	822.07	29.26	0.08	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,262	1,592.40	56.68	0.16	*****	*****	*****	1.52	0.00	2.29 (0.56, 9.43)	0.25
Dabigatran	10,262	4,048.54	144.10	0.39	*****	*****	*****				
NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	186,456	146,937.41	287.84	0.79	187	1.27	1.00	0.80	*****	2.28 (1.57, 3.30)	<0.001
Dabigatran	63,773	*****	*****	*****	*****	0.47	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	57,013	26,538.60	170.02	0.47	*****	*****	*****	*****	*****	2.07 (1.09, 3.92)	0.025
Dabigatran	57,013	26,538.60	170.02	0.47	14	0.53	0.25				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	57,013	47,602.37	304.96	0.83	*****	*****	*****	0.44	0.19	1.81 (1.10, 2.95)	0.019
Dabigatran	57,013	71,574.24	458.54	1.26	*****	*****	*****				

*****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 4e. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Novel Oral Anticoagulants (NOAC) High Dose Group, 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 NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	102,609	8,719.91	31.04	0.08	13	1.49	0.13	0.79	*****	2.14 (0.77, 5.94)	0.143
Apixaban	34,883	*****	*****	*****	*****	0.70	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,291	1,125.59	26.89	0.07	*****	*****	*****	0.00	0.00	1.00 (0.14, 7.10)	1
Apixaban	15,291	1,125.59	26.89	0.07	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,291	2,191.44	52.35	0.14	*****	*****	*****	0.59	0.00	1.87 (0.36, 9.67)	0.454
Apixaban	15,291	3,849.61	91.95	0.25	*****	*****	*****				
NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	188,054	148,309.19	288.06	0.79	187	1.26	0.99	0.58	*****	2.10 (1.39, 3.17)	<0.001
Apixaban	66,784	*****	*****	*****	*****	0.68	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,894	20,779.43	124.64	0.34	*****	*****	*****	0.29	0.10	1.40 (0.72, 2.72)	0.32
Apixaban	60,894	20,779.43	124.64	0.34	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,894	49,743.91	298.37	0.82	*****	*****	*****	-0.02	0.15	1.16 (0.68, 1.98)	0.576
Apixaban	60,894	35,058.90	210.29	0.58	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Novel Oral Anticoagulants (NOAC) High Dose Group, 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 NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	17,111	*****	*****	*****	*****	0.89	*****	0.18	0.15	1.39 (0.44, 4.38)	0.575
Apixaban	35,020	*****	*****	*****	*****	0.71	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,674	2,284.98	50.05	0.14	*****	*****	*****	-0.44	-0.06	0.75 (0.17, 3.35)	0.706
Apixaban	16,674	2,284.98	50.05	0.14	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,674	6,566.48	143.84	0.39	*****	*****	*****	-0.14	0.06	0.93 (0.27, 3.22)	0.911
Apixaban	16,674	4,742.66	103.89	0.28	*****	*****	*****				
NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	63,899	*****	*****	*****	*****	0.47	*****	-0.22	0.19	0.87 (0.51, 1.49)	0.61
Apixaban	67,023	*****	*****	*****	*****	0.68	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	52,456	19,317.63	134.51	0.37	*****	*****	*****	0.05	0.02	1.08 (0.51, 2.29)	0.847
Apixaban	52,456	19,317.63	134.51	0.37	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	52,456	64,952.97	452.27	1.24	*****	*****	*****	-0.02	0.32	1.25 (0.66, 2.34)	0.493
Apixaban	52,456	30,485.58	212.27	0.58	*****	*****	*****				

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Table 5a. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 00-49 years and no NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	3,823	*****	*****	*****	*****	16.01	*****	16.01	*****	-	-
Dabigatran	42	15.51	134.86	0.37	0	0.00	0.00				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	40	4.18	38.20	0.10	0	0.00	0.00	0.00	0.00	-	-
Dabigatran	40	4.18	38.20	0.10	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	40	4.89	44.63	0.12	0	0.00	0.00	0.00	0.00	-	-
Dabigatran	40	15.07	137.63	0.38	0	0.00	0.00				
Age Group: 00-49 years and NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,327	3,890.17	193.92	0.53	143	36.76	19.52	14.08	4.59	1.48 (0.82, 2.68)	0.196
Dabigatran	871	573.11	240.33	0.66	13	22.68	14.93				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	705	204.30	105.84	0.29	*****	*****	*****	4.89	1.42	1.25 (0.34, 4.65)	0.739
Dabigatran	705	204.30	105.84	0.29	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	705	416.63	215.85	0.59	12	28.80	17.02	*****	*****	1.62 (0.65, 4.04)	0.298
Dabigatran	705	472.34	244.71	0.67	*****	*****	*****				
Age Group: 50+ years and no NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	98,739	*****	*****	*****	*****	1.42	*****	-0.50	*****	1.15 (0.50, 2.62)	0.743
Dabigatran	17,022	6,746.44	144.76	0.40	13	1.93	0.76				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,264	810.86	28.86	0.08	*****	*****	*****	1.23	0.10	2.00 (0.18, 22.06)	0.571
Dabigatran	10,264	810.86	28.86	0.08	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,264	1,560.01	55.51	0.15	*****	*****	*****	0.58	-0.39	1.18 (0.34, 4.16)	0.792
Dabigatran	10,264	4,040.34	143.78	0.39	*****	*****	*****				

Table 5a. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 50+ years and NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	179,122	142,577.09	290.73	0.80	642	4.50	3.58	0.87	-0.91	1.18 (1.02, 1.36)	0.026
Dabigatran	62,909	77,976.89	452.73	1.24	283	3.63	4.50				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	56,317	26,311.79	170.65	0.47	*****	*****	*****	0.27	0.12	1.07 (0.82, 1.40)	0.628
Dabigatran	56,317	26,311.79	170.65	0.47	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	56,317	47,088.83	305.40	0.84	185	3.93	3.28	0.54	-0.98	1.12 (0.92, 1.37)	0.266
Dabigatran	56,317	70,854.65	459.54	1.26	240	3.39	4.26				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 00-49 years and no NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	3,824	*****	*****	*****	*****	16.00	*****	16.00	*****	-	-
Apixaban	199	22.88	41.99	0.11	0	0.00	0.00				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	176	8.56	17.76	0.05	0	0.00	0.00	0.00	0.00	-	-
Apixaban	176	8.56	17.76	0.05	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	176	12.57	26.08	0.07	0	0.00	0.00	0.00	0.00	-	-
Apixaban	176	19.68	40.84	0.11	0	0.00	0.00				
Age Group: 00-49 years and NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,347	*****	*****	*****	*****	36.67	*****	14.59	11.15	1.69 (0.83, 3.45)	0.149
Apixaban	962	*****	*****	*****	*****	22.08	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	684	157.85	84.29	0.23	*****	*****	*****	19.01	4.39	1.75 (0.51, 5.98)	0.372
Apixaban	684	157.85	84.29	0.23	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	684	394.98	210.92	0.58	17	43.04	24.85	*****	*****	1.49 (0.63, 3.50)	0.361
Apixaban	684	261.49	139.63	0.38	*****	*****	*****				
Age Group: 50+ years and no NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	98,910	*****	*****	*****	*****	1.42	*****	-0.80	*****	1.00 (0.47, 2.13)	0.991
Apixaban	34,688	9,901.39	104.26	0.29	22	2.22	0.63				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,151	1,130.23	27.25	0.07	*****	*****	*****	0.00	0.00	1.00 (0.06, 15.99)	1
Apixaban	15,151	1,130.23	27.25	0.07	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,151	2,224.51	53.63	0.15	*****	*****	*****	-0.95	-0.40	0.52 (0.13, 2.07)	0.355
Apixaban	15,151	3,915.14	94.38	0.26	*****	*****	*****				

Table 5b. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 50+ years and NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	180,699	*****	*****	*****	*****	4.49	*****	0.79	1.46	1.25 (1.04, 1.50)	0.018
Apixaban	65,814	*****	*****	*****	*****	3.70	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,239	20,490.66	124.24	0.34	*****	*****	*****	0.44	0.15	1.12 (0.82, 1.52)	0.481
Apixaban	60,239	20,490.66	124.24	0.34	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,239	49,362.04	299.30	0.82	199	4.03	3.30	0.49	1.26	1.17 (0.93, 1.46)	0.188
Apixaban	60,239	34,733.08	210.60	0.58	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 00-49 years and no NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	42	15.51	134.86	0.37	0	0.00	0.00	0.00	0.00	-	-
Apixaban	205	23.48	41.83	0.11	0	0.00	0.00				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	37	2.42	23.92	0.07	0	0.00	0.00	0.00	0.00	-	-
Apixaban	37	2.42	23.92	0.07	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	37	14.56	143.76	0.39	0	0.00	0.00	0.00	0.00	-	-
Apixaban	37	3.17	31.32	0.09	0	0.00	0.00				
Age Group: 00-49 years and NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	873	573.78	240.06	0.66	13	22.66	14.89	0.57	*****	1.04 (0.41, 2.64)	0.936
Apixaban	965	*****	*****	*****	*****	22.08	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	688	154.57	82.06	0.22	*****	*****	*****	0.00	0.00	1.00 (0.20, 4.95)	1
Apixaban	688	154.57	82.06	0.22	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	688	424.37	225.29	0.62	11	25.92	15.99	*****	*****	1.12 (0.39, 3.20)	0.83
Apixaban	688	268.95	142.78	0.39	*****	*****	*****				
Age Group: 50+ years and no NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	17,073	6,758.58	144.59	0.40	13	1.92	0.76	-0.30	0.13	0.74 (0.36, 1.54)	0.422
Apixaban	34,818	9,893.22	103.78	0.28	22	2.22	0.63				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,669	2,269.95	49.74	0.14	*****	*****	*****	0.00	0.00	1.00 (0.25, 4.00)	1
Apixaban	16,669	2,269.95	49.74	0.14	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,669	6,575.19	144.08	0.39	12	1.83	0.72	-0.91	-0.06	0.67 (0.30, 1.51)	0.333
Apixaban	16,669	4,756.07	104.21	0.29	13	2.73	0.78				

Table 5c. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 50+ years and NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	63,033	78,046.41	452.25	1.24	283	3.63	4.49	-0.10	*****	0.99 (0.80, 1.23)	0.934
Apixaban	66,051	*****	*****	*****	*****	3.72	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	51,611	19,092.75	135.12	0.37	*****	*****	*****	-0.16	-0.06	0.95 (0.68, 1.35)	0.792
Apixaban	51,611	19,092.75	135.12	0.37	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	51,611	63,714.03	450.90	1.23	241	3.78	4.67	*****	*****	1.07 (0.85, 1.36)	0.557
Apixaban	51,611	30,087.37	212.93	0.58	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 00-49 years and no NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	3,818	*****	*****	*****	*****	11.96	*****	11.96	*****	-	-
Dabigatran	42	15.51	134.86	0.37	0	0.00	0.00				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	40	2.07	18.88	0.05	0	0.00	0.00	0.00	0.00	-	-
Dabigatran	40	2.07	18.88	0.05	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	40	2.59	23.68	0.06	0	0.00	0.00	0.00	0.00	-	-
Dabigatran	40	15.07	137.63	0.38	0	0.00	0.00				
Age Group: 00-49 years and NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,337	*****	*****	*****	*****	18.55	*****	15.11	7.66	4.29 (1.05, 17.49)	0.042
Dabigatran	872	*****	*****	*****	*****	3.44	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	664	191.30	105.23	0.29	*****	*****	*****	41.82	12.05	9.00 (1.14, 71.04)	0.037
Dabigatran	664	191.30	105.23	0.29	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	664	380.76	209.45	0.57	*****	*****	*****	29.34	16.57	11.78 (1.53, 90.64)	0.018
Dabigatran	664	460.35	253.23	0.69	*****	*****	*****				
Age Group: 50+ years and no NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	98,619	*****	*****	*****	*****	1.19	*****	0.30	-0.25	1.45 (0.48, 4.37)	0.508
Dabigatran	17,017	*****	*****	*****	*****	0.89	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,214	817.18	29.22	0.08	*****	*****	*****	1.22	0.10	2.00 (0.18, 22.06)	0.571
Dabigatran	10,214	817.18	29.22	0.08	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	10,214	1,586.46	56.73	0.16	*****	*****	*****	0.90	-0.10	1.90 (0.42, 8.63)	0.407
Dabigatran	10,214	4,030.44	144.13	0.39	*****	*****	*****				

Table 5d. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 50+ years and NOAC high dose subgroup rivaroxaban, dabigatran											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	179,119	*****	*****	*****	*****	0.80	*****	0.35	*****	1.59 (1.06, 2.37)	0.024
Dabigatran	62,901	78,301.43	454.68	1.24	35	0.45	0.56				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	56,300	26,353.07	170.97	0.47	*****	*****	*****	0.19	0.09	1.36 (0.68, 2.71)	0.386
Dabigatran	56,300	26,353.07	170.97	0.47	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	56,300	47,180.27	306.09	0.84	*****	*****	*****	0.19	-0.02	1.30 (0.77, 2.22)	0.328
Dabigatran	56,300	71,064.19	461.03	1.26	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 00-49 years and no NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	3,819	*****	*****	*****	*****	11.96	*****	-31.96	-4.26	0.26 (0.03, 2.75)	0.265
Apixaban	198	*****	*****	*****	*****	43.92	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	168	8.61	18.71	0.05	0	0.00	0.00	*****	*****	-	-
Apixaban	168	8.61	18.71	0.05	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	168	13.31	28.93	0.08	0	0.00	0.00	*****	*****	-	-
Apixaban	168	18.14	39.43	0.11	*****	*****	*****				
Age Group: 00-49 years and NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,357	*****	*****	*****	*****	18.50	*****	2.06	3.70	1.32 (0.57, 3.04)	0.516
Apixaban	964	*****	*****	*****	*****	16.44	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	681	149.33	80.09	0.22	*****	*****	*****	-13.39	-2.94	0.50 (0.09, 2.73)	0.423
Apixaban	681	149.33	80.09	0.22	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	681	343.44	184.20	0.50	*****	*****	*****	-4.44	0.00	0.78 (0.22, 2.71)	0.691
Apixaban	681	263.18	141.15	0.39	*****	*****	*****				
Age Group: 50+ years and no NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	98,790	*****	*****	*****	*****	1.18	*****	0.58	-0.07	2.38 (0.79, 7.20)	0.124
Apixaban	34,685	*****	*****	*****	*****	0.61	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,100	1,115.38	26.98	0.07	*****	*****	*****	0.90	0.07	2.00 (0.18, 22.06)	0.571
Apixaban	15,100	1,115.38	26.98	0.07	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	15,100	2,178.08	52.68	0.14	*****	*****	*****	0.85	0.07	3.21 (0.52, 19.85)	0.209
Apixaban	15,100	3,827.71	92.59	0.25	*****	*****	*****				

Table 5e. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 50+ years and NOAC high dose subgroup rivaroxaban, apixaban											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	180,697	*****	*****	*****	*****	0.79	*****	0.26	*****	1.71 (1.06, 2.76)	0.027
Apixaban	65,820	37,683.07	209.11	0.57	20	0.53	0.30				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,198	20,599.43	124.99	0.34	*****	*****	*****	0.34	0.12	1.64 (0.77, 3.46)	0.198
Apixaban	60,198	20,599.43	124.99	0.34	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	60,198	49,385.57	299.65	0.82	*****	*****	*****	0.02	0.15	1.25 (0.70, 2.25)	0.448
Apixaban	60,198	34,781.22	211.03	0.58	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 00-49 years and no NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	42	15.51	134.86	0.37	0	0.00	0.00	-42.81	*****	-	-
Apixaban	204	*****	*****	*****	*****	42.81	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	35	3.40	35.51	0.10	0	0.00	0.00	*****	*****	-	-
Apixaban	35	3.40	35.51	0.10	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	35	14.06	146.71	0.40	0	0.00	0.00	*****	*****	-	-
Apixaban	35	4.70	49.03	0.13	*****	*****	*****				
Age Group: 00-49 years and NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	874	*****	*****	*****	*****	3.44	*****	-13.01	-3.92	0.26 (0.05, 1.38)	0.114
Apixaban	967	*****	*****	*****	*****	16.45	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	659	146.41	81.15	0.22	*****	*****	*****	-6.83	-1.52	0.50 (0.05, 5.51)	0.571
Apixaban	659	146.41	81.15	0.22	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	659	426.44	236.36	0.65	*****	*****	*****	-6.99	-1.52	0.49 (0.08, 3.06)	0.446
Apixaban	659	256.94	142.41	0.39	*****	*****	*****				
Age Group: 50+ years and no NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	17,069	*****	*****	*****	*****	0.89	*****	0.28	0.18	1.62 (0.49, 5.30)	0.428
Apixaban	34,816	*****	*****	*****	*****	0.61	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,636	2,280.28	50.06	0.14	*****	*****	*****	-0.44	-0.06	0.67 (0.11, 3.99)	0.657
Apixaban	16,636	2,280.28	50.06	0.14	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	16,636	6,551.40	143.84	0.39	*****	*****	*****	0.07	0.12	1.16 (0.31, 4.32)	0.825
Apixaban	16,636	4,748.84	104.26	0.29	*****	*****	*****				

Table 5f. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group and Novel Oral Anticoagulants (NOAC) Dose Group, 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: 50+ years and NOAC high dose subgroup dabigatran, apixaban											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	63,025	78,370.94	454.18	1.24	35	0.45	0.56	-0.08	0.25	1.08 (0.60, 1.94)	0.803
Apixaban	66,056	37,665.58	208.27	0.57	20	0.53	0.30				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	51,658	19,163.45	135.50	0.37	*****	*****	*****	0.21	0.08	1.40 (0.62, 3.15)	0.416
Apixaban	51,658	19,163.45	135.50	0.37	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	51,658	64,362.80	455.08	1.25	31	0.48	0.60	0.08	0.37	1.56 (0.77, 3.12)	0.214
Apixaban	51,658	30,178.88	213.38	0.58	12	0.40	0.23				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	281,779	151,312.15	196.14	0.54	746	4.93	2.65	1.44	-1.04	1.35 (1.17, 1.55)	<0.001
Dabigatran	79,408	83,848.24	385.67	1.06	293	3.49	3.69				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,226	27,431.21	126.46	0.35	*****	*****	*****	0.87	0.30	1.26 (0.96, 1.65)	0.1
Dabigatran	79,226	27,431.21	126.46	0.35	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,226	54,289.55	250.29	0.69	*****	*****	*****	*****	*****	1.13 (0.94, 1.35)	0.189
Dabigatran	79,226	83,629.49	385.55	1.06	292	3.49	3.69				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,232	3,830.82	193.47	0.53	55	14.36	7.61	3.43	-3.54	0.98 (0.55, 1.73)	0.943
Dabigatran	1,436	1,463.71	372.30	1.02	16	10.93	11.14				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,290	411.35	116.47	0.32	*****	*****	*****	-7.29	-2.33	0.50 (0.13, 2.00)	0.327
Dabigatran	1,290	411.35	116.47	0.32	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,290	792.55	224.40	0.61	*****	*****	*****	*****	*****	0.62 (0.23, 1.65)	0.336
Dabigatran	1,290	1,305.91	369.75	1.01	13	9.95	10.08				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	283,513	152,691.05	196.71	0.54	750	4.91	2.65	1.51	*****	1.45 (1.22, 1.72)	<0.001
Apixaban	99,735	*****	*****	*****	*****	3.40	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	99,481	24,632.56	90.44	0.25	*****	*****	*****	0.69	0.17	1.22 (0.90, 1.66)	0.192
Apixaban	99,481	24,632.56	90.44	0.25	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	99,481	66,674.10	244.80	0.67	*****	*****	*****	0.33	0.89	1.12 (0.91, 1.37)	0.283
Apixaban	99,481	46,959.96	172.42	0.47	*****	*****	*****				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,267	3,860.10	194.01	0.53	55	14.25	7.57	3.34	*****	1.35 (0.66, 2.74)	0.409
Apixaban	1,928	*****	*****	*****	*****	10.91	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,781	412.11	84.52	0.23	*****	*****	*****	2.43	0.56	1.50 (0.25, 8.98)	0.657
Apixaban	1,781	412.11	84.52	0.23	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,781	1,063.71	218.15	0.60	*****	*****	*****	-2.48	0.00	0.79 (0.27, 2.27)	0.658
Apixaban	1,781	772.46	158.42	0.43	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	79,583	83,929.91	385.20	1.05	293	3.49	3.68	0.07	*****	0.97 (0.79, 1.20)	0.803
Apixaban	100,116	*****	*****	*****	*****	3.42	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	75,753	22,016.15	106.15	0.29	*****	*****	*****	0.27	0.08	1.09 (0.78, 1.51)	0.615
Apixaban	75,753	22,016.15	106.15	0.29	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	75,753	79,747.32	384.51	1.05	284	3.56	3.75	*****	*****	1.00 (0.80, 1.25)	0.992
Apixaban	75,753	36,894.57	177.89	0.49	*****	*****	*****				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	1,438	1,464.37	371.95	1.02	16	10.93	11.13	-0.02	*****	1.49 (0.65, 3.42)	0.351
Apixaban	1,923	*****	*****	*****	*****	10.94	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	1,330	375.08	103.01	0.28	*****	*****	*****	2.67	0.75	1.20 (0.37, 3.93)	0.763
Apixaban	1,330	375.08	103.01	0.28	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	1,330	1,383.13	379.84	1.04	15	10.84	11.28	*****	*****	1.41 (0.56, 3.51)	0.463
Apixaban	1,330	594.02	163.13	0.45	*****	*****	*****				

*****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 Severe Uterine Bleed (SUB) Defined by Surgical Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	273,063	146,698.20	196.22	0.54	724	4.94	2.65	1.61	1.22	1.40 (1.28, 1.54)	<0.001
Warfarin	871,402	375,854.88	157.54	0.43	1,251	3.33	1.44				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	272,806	46,213.34	61.87	0.17	213	4.61	0.78	1.34	0.23	1.41 (1.15, 1.74)	0.001
Warfarin	272,806	46,213.34	61.87	0.17	151	3.27	0.55				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	272,806	146,604.57	196.28	0.54	724	4.94	2.65	1.22	1.14	1.30 (1.15, 1.47)	<0.001
Warfarin	272,806	111,195.97	148.88	0.41	413	3.71	1.51				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,015	3,716.05	193.48	0.53	53	14.26	7.56	1.37	2.38	1.05 (0.76, 1.45)	0.761
Warfarin	24,328	9,769.41	146.67	0.40	126	12.90	5.18				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	6,787	1,186.82	63.87	0.17	22	18.54	3.24	5.90	1.03	1.47 (0.76, 2.83)	0.253
Warfarin	6,787	1,186.82	63.87	0.17	15	12.64	2.21				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	6,787	3,599.02	193.69	0.53	52	14.45	7.66	-0.11	1.92	0.99 (0.65, 1.50)	0.945
Warfarin	6,787	2,679.21	144.18	0.39	39	14.56	5.75				

Table 6e. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	281,564	151,706.78	196.80	0.54	169	1.11	0.60	0.60	0.06	1.82 (1.28, 2.58)	<0.001
Dabigatran	79,380	84,157.70	387.23	1.06	43	0.51	0.54				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,202	27,372.89	126.23	0.35	*****	*****	*****	*****	*****	1.16 (0.63, 2.14)	0.64
Dabigatran	79,202	27,372.89	126.23	0.35	19	0.69	0.24				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	79,202	54,404.31	250.89	0.69	*****	*****	*****	*****	*****	1.32 (0.85, 2.06)	0.213
Dabigatran	79,202	83,954.22	387.17	1.06	43	0.51	0.54				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,329	3,907.16	194.72	0.53	31	7.93	4.23	7.93	4.23	-	-
Dabigatran	1,452	1,488.22	374.36	1.02	0	0.00	0.00				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,262	412.34	119.34	0.33	*****	*****	*****	*****	*****	-	-
Dabigatran	1,262	412.34	119.34	0.33	0	0.00	0.00				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,262	819.53	237.19	0.65	*****	*****	*****	*****	*****	-	-
Dabigatran	1,262	1,293.52	374.37	1.02	0	0.00	0.00				

*****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 Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	283,298	153,090.21	197.38	0.54	169	1.10	0.60	0.47	*****	1.92 (1.30, 2.84)	0.001
Apixaban	99,716	*****	*****	*****	*****	0.64	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	99,502	24,723.24	90.75	0.25	*****	*****	*****	0.08	0.02	1.09 (0.62, 1.91)	0.773
Apixaban	99,502	24,723.24	90.75	0.25	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	99,502	66,652.80	244.67	0.67	*****	*****	*****	0.01	0.13	1.23 (0.77, 1.98)	0.381
Apixaban	99,502	47,037.73	172.67	0.47	*****	*****	*****				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,365	3,938.88	195.34	0.53	31	7.87	4.21	4.30	*****	2.48 (0.75, 8.13)	0.135
Apixaban	1,951	*****	*****	*****	*****	3.57	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,775	389.28	80.10	0.22	*****	*****	*****	-2.57	-0.56	0.67 (0.11, 3.99)	0.657
Apixaban	1,775	389.28	80.10	0.22	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	1,775	1,077.60	221.74	0.61	*****	*****	*****	-0.19	0.56	1.24 (0.28, 5.55)	0.778
Apixaban	1,775	767.87	158.01	0.43	*****	*****	*****				

*****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 6g. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	79,555	84,239.37	386.76	1.06	43	0.51	0.54	-0.13	*****	1.03 (0.63, 1.71)	0.893
Apixaban	100,097	*****	*****	*****	*****	0.64	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	75,711	22,001.82	106.14	0.29	16	0.73	0.21	*****	*****	0.94 (0.48, 1.86)	0.862
Apixaban	75,711	22,001.82	106.14	0.29	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	75,711	79,935.99	385.63	1.06	42	0.53	0.55	*****	*****	1.23 (0.70, 2.15)	0.476
Apixaban	75,711	36,974.99	178.38	0.49	*****	*****	*****				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Dabigatran	1,455	1,489.13	373.82	1.02	0	0.00	0.00	-3.58	*****	-	-
Apixaban	1,946	*****	*****	*****	*****	3.58	*****				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Dabigatran	1,345	370.23	100.54	0.28	0	0.00	0.00	*****	*****	-	-
Apixaban	1,345	370.23	100.54	0.28	*****	*****	*****				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Dabigatran	1,345	1,392.58	378.17	1.04	0	0.00	0.00	*****	*****	-	-
Apixaban	1,345	588.56	159.83	0.44	*****	*****	*****				

*****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 6h. Effect Estimates for Severe Uterine Bleed (SUB) Defined by Transfusion Management in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Gynecological Disorders of Interest, 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 Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	272,861	147,082.54	196.88	0.54	165	1.12	0.60	-0.29	-0.01	0.84 (0.70, 1.00)	0.051
Warfarin	870,587	376,282.07	157.87	0.43	531	1.41	0.61				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	272,640	46,441.57	62.22	0.17	82	1.77	0.30	0.04	0.01	1.02 (0.75, 1.39)	0.875
Warfarin	272,640	46,441.57	62.22	0.17	80	1.72	0.29				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	272,640	147,007.21	196.94	0.54	165	1.12	0.61	-0.17	0.07	0.93 (0.74, 1.17)	0.54
Warfarin	272,640	112,153.46	150.25	0.41	145	1.29	0.53				
Gynecological disorders of interest											
Unmatched Analysis (Site-adjusted only)											
Rivaroxaban	7,110	3,793.81	194.89	0.53	31	8.17	4.36	-0.27	0.95	1.11 (0.73, 1.68)	0.622
Warfarin	24,621	9,949.63	147.60	0.40	84	8.44	3.41				
1:1 Matched Conditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	6,912	1,216.43	64.28	0.18	20	16.44	2.89	6.58	1.16	1.67 (0.81, 3.41)	0.162
Warfarin	6,912	1,216.43	64.28	0.18	12	9.86	1.74				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Rivaroxaban	6,912	3,704.46	195.75	0.54	30	8.10	4.34	0.38	1.30	1.28 (0.73, 2.25)	0.382
Warfarin	6,912	2,720.87	143.78	0.39	21	7.72	3.04				

Table 7a. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Dabigatran new user						
	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	289,011		801		288,210		80,844		309		80,535		
Vaginal Bleed	9,648	100.0%	801	100.0%	8,847	100.0%	3,579	100.0%	309	100.0%	3,270	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	97	1.0%	23	2.9%	74	0.8%	*****	*****	*****	*****	*****	*****	0.11
Antifibrinolytic	11	0.1%	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0.032
Contraceptive use	26	0.3%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.053
Intrauterine device	66	0.7%	16	2.0%	50	0.6%	*****	*****	0	0.0%	*****	*****	0.104
Vaginal packing	*****	0.0%	0	0.0%	*****	*****	*****	*****	*****	*****	0	0.0%	-0.005
Management Count[4]	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Standardized difference (total)[3]
Any medical management	2	2.2	1.7	1.1	2.1	2.4	1.7	1.6	1	0	2	0	0.171
Antifibrinolytic	1.3	0.3	1.5	0	1.1	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	0.8	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Dabigatran new user						
	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	80,844		224		80,620		80,844		309		80,535		
Vaginal Bleed	2,348	100.0%	224	100.0%	2,124	100.0%	3,579	100.0%	309	100.0%	3,270	100.0%	-
Patient Count	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Standardized difference (total)[3]**
Any medical management	*****	0.9%	*****	*****	13	0.6%	*****	*****	*****	*****	*****	*****	0.1
Antifibrinolytic	*****	0.0%	0	0.0%	*****	*****	*****	*****	*****	*****	0	0.0%	0.008
Contraceptive use	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.058
Intrauterine device	13	0.6%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.09
Vaginal packing	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	0	0.0%	0.024
Management Count[4]	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	**Standardized difference (total)[3]**
Any medical management	1.5	1.1	1.6	1.5	1.5	0.8	1.7	1.1	1	0	2	0	-0.127
Antifibrinolytic	2	0	0	-	2	0	1	0	1	0	0	-	-
Contraceptive use	1.9	0.4	2.3	0	1.5	0.6	2	0	0	-	2	0	-
Intrauterine device	1.2	0.3	1	0	1.3	0.6	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Apixaban new user						
	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	290,780		805		289,975		101,663		169		101,494		
Vaginal Bleed	9,703	100.0%	805	100.0%	8,898	100.0%	1,554	100.0%	169	100.0%	1,385	100.0%	-
Patient Count	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Standardized difference (total)[3]**
Any medical management	97	1.0%	23	2.9%	74	0.8%	*****	*****	*****	*****	*****	*****	0.084
Antifibrinolytic	11	0.1%	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	*****	*****	21	0.2%	*****	*****	0	0.0%	*****	*****	0.031
Intrauterine device	66	0.7%	16	2.0%	50	0.6%	*****	*****	*****	*****	*****	*****	0.062
Vaginal packing	*****	*****	0	0.0%	*****	*****	0	0.00%	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**	**Standardized difference (total)[3]**
Any medical management	2	2.2	1.7	1.1	2.1	2.4	1.8	0	1	0	2	0	-
Antifibrinolytic	1.3	0.3	1.5	0	1.1	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	0.8	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Apixaban new user						
	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	101,661		259		101,402		101,661		169		101,492		
Vaginal Bleed	2,852	100.0%	259	100.0%	2,593	100.0%	1,554	100.0%	169	100.0%	1,385	100.0%	-
Patient Count	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Standardized difference (total)[3]**
Any medical management	15	0.5%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	0.031
Antifibrinolytic	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	-0.019
Intrauterine device	11	0.4%	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	0.023
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**	**Standardized difference (total)[3]**
Any medical management	1.3	0.8	1.7	1.3	1.1	0.4	1.8	1.2	1	0	2	2.2	-0.444
Antifibrinolytic	1	0	1	0	0	-	0	-	0	-	0	-	-
Contraceptive use	1	0	1	0	1	0	2.5	0.7	0	-	2.5	0.7	-
Intrauterine device	1.4	0.9	1.6	1.5	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7e. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Dabigatran new user						Apixaban new user						
	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	81,021		309		80,712		102,039		170		101,869		
Vaginal Bleed	3,581	100.0%	309	100.0%	3,272	100.0%	1,553	100.0%	170	100.0%	1,383	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	-0.031
Antifibrinolytic	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.024
Intrauterine device	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****	-0.051
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	Standardized difference (total)[3]
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Dabigatran new user						Apixaban new user						
	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	77,176		299		76,877		77,176		136		77,040		
Vaginal Bleed	3,395	100.0%	299	100.0%	3,096	100.0%	1,165	100.0%	136	100.0%	1,029	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	-0.033
Antifibrinolytic	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.033
Intrauterine device	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****	-0.05
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	Standardized difference (total)[3]
Any medical management	1.7	0.8	1	0	2	0.7	2	1	1	0	2.3	1.4	-0.37
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Warfarin new user						
	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	280,078		777		279,301		895,730		1,377		894353		
Vaginal Bleed	9,359	100.0%	777	100.0%	8,582	100.0%	40,084	100.0%	1,377	100.0%	38,707	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	97	1.0%	23	3.0%	74	0.9%	150	0.4%	28	2.0%	122	0.3%	0.079
Antifibrinolytic	12	0.1%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.042
Contraceptive use	*****	0.3%	*****	*****	23	0.3%	*****	0.1%	*****	*****	53	0.1%	0.033
Intrauterine device	63	0.7%	16	2.1%	47	0.5%	87	0.2%	22	1.6%	65	0.2%	0.069
Vaginal packing	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****	0.009
Management Count[4]	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Standardized difference (total)[3]
Any medical management	2.1	2.3	1.7	1.1	2.2	2.6	2.3	3.8	1.4	1.1	2.6	4.1	-0.076
Antifibrinolytic	1.3	0.6	1.5	0	1.1	0.3	5.7	12.7	0	-	5.7	9	-0.491
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	0.8	1.2	0.4	1.2	0.6	1.1	0.3	1.2	0.7	0.13
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users with Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Warfarin new user						
	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	280,077		777		279,300		280,077		453		279,624		
Vaginal Bleed	9,359	100.0%	777	100.0%	8,582	100.0%	12,927	100.0%	453	100.0%	12,474	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	97	1.0%	23	3.0%	74	0.9%	*****	0.4%	*****	*****	50	0.4%	0.072
Antifibrinolytic	12	0.1%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.038
Contraceptive use	*****	0.3%	*****	*****	23	0.3%	18	0.1%	0	0.0%	18	0.1%	0.034
Intrauterine device	63	0.7%	16	2.1%	47	0.5%	*****	0.3%	*****	*****	31	0.2%	0.059
Vaginal packing	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****	0.004
Management Count[4]	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Standardized difference (total)[3]
Any medical management	2.1	2.3	1.7	1.1	2.2	2.6	2.4	4.6	1.2	0.8	2.6	4.8	-0.092
Antifibrinolytic	1.3	0.6	1.5	0	1.1	0.3	10.3	0	0	-	10.3	0	-
Contraceptive use	3.8	3.2	2	0	4.2	3.7	3.4	5.7	0	-	3.4	6.1	0.082
Intrauterine device	1.3	0.5	1.4	0.8	1.2	0.4	1.1	0.3	1.3	0.7	1.1	0.3	0.345
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7i. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Dabigatran new user						
	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	288,893		200		288,693		80,832		43		80,789		
Vaginal Bleed	9,662	100.0%	200	100.0%	9,462	100.0%	3,583	100.0%	43	100.0%	3,540	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	1.0%	*****	*****	96	1.0%	*****	*****	0	0.0%	*****	*****	0.108
Antifibrinolytic	*****	0.1%	*****	*****	12	0.1%	*****	*****	0	0.0%	*****	*****	0.037
Contraceptive use	*****	0.3%	*****	*****	28	0.3%	*****	*****	0	0.0%	*****	*****	0.058
Intrauterine device	*****	0.7%	*****	*****	61	0.6%	*****	*****	0	0.0%	*****	*****	0.095
Vaginal packing	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.005
Management Count[4]	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Standardized difference (total)[3]
Any medical management	2.3	2.7	1.2	0.4	2.3	2.7	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7j. Medical Management after Vaginal Bleed among Rivaroxaban and Dabigatran New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Dabigatran new user						
	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	80,832		49		80,783		80,832		43		80,789		
Vaginal Bleed	2,341	100.0%	49	100.0%	2,292	100.0%	3,583	100.0%	43	100.0%	3,540	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	0.9%	*****	*****	19	0.8%	*****	*****	0	0.0%	*****	*****	0.095
Antifibrinolytic	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	0.036
Contraceptive use	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.051
Intrauterine device	10	0.4%	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.068
Vaginal packing	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	0.024
Management Count[4]	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Standardized difference (total)[3]
Any medical management	1.3	0.5	1.5	0	1.3	0.4	1.6	1	0	-	1.6	0.8	-0.374
Antifibrinolytic	1	0	0	-	1	0	1	0	0	-	1	0	-
Contraceptive use	1.5	0.4	2	0	1.4	0.4	2	0	0	-	2	0	-
Intrauterine device	1.3	0.5	1	0	1.3	0.5	1.3	0.8	0	-	1.3	0.8	-0.05
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7k. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Apixaban new user						
	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	290,663		200		290,463		101,667		33		101,634		
Vaginal Bleed	9,717	100.0%	200	100.0%	9,517	100.0%	1,555	100.0%	33	100.0%	1,522	100.0%	-
Patient Count	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Standardized difference (total)[3]**
Any medical management	*****	1.0%	*****	*****	96	1.0%	*****	*****	0	0.0%	*****	*****	0.069
Antifibrinolytic	*****	0.1%	*****	*****	12	0.1%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	0.3%	*****	*****	28	0.3%	*****	*****	0	0.0%	*****	*****	0.037
Intrauterine device	*****	0.7%	*****	*****	61	0.6%	*****	*****	0	0.0%	*****	*****	0.038
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**	**Standardized difference (total)[3]**
Any medical management	2.3	2.7	1.2	0.4	2.3	2.7	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7l. Medical Management after Vaginal Bleed among Rivaroxaban and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Apixaban new user						
	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	101,665		47		101,618		101,665		33		101,632		
Vaginal Bleed	2,782	100.0%	47	100.0%	2,735	100.0%	1,555	100.0%	33	100.0%	1,522	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	0.7%	*****	*****	18	0.7%	*****	*****	0	0.0%	*****	*****	0.035
Antifibrinolytic	*****	*****	0	0.0%	*****	*****	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****	0.004
Intrauterine device	*****	0.4%	*****	*****	11	0.4%	*****	*****	0	0.0%	*****	*****	0.007
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	Standardized difference (total)[3]
Any medical management	1.8	3.1	1.5	0	1.8	3.4	1.7	1.1	0	-	1.7	1.2	0.036
Antifibrinolytic	5.3	6.5	0	-	5.3	6.5	0	-	0	-	0	-	-
Contraceptive use	1.3	0.4	2	0	1	0	2.5	0.7	0	-	2.5	0.5	-2.165
Intrauterine device	1.1	0.3	1	0	1.1	0.3	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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7m. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Dabigatran new user						Apixaban new user						
	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	81,010		43		80,967		102,043		33		102,010		
Vaginal Bleed	3,585	100.0%	43	100.0%	3,542	100.0%	1,554	100.0%	33	100.0%	1,521	100.0%	-
Patient Count	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Standardized difference (total)[3]**
Any medical management	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.045
Antifibrinolytic	*****	*****	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.024
Intrauterine device	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.063
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**	**Standardized difference (total)[3]**
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7n. Medical Management after Vaginal Bleed among Dabigatran and Apixaban New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Dabigatran new user						Apixaban new user						
	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	77,156		42		77,114		77,156		22		77,134		
Vaginal Bleed	3,394	100.0%	42	100.0%	3,352	100.0%	1,192	100.0%	22	100.0%	1,170	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.061
Antifibrinolytic	*****	*****	0	0.0%	*****	0.0%	0	0.0%	0	0.0%	0	0.0%	-
Contraceptive use	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.032
Intrauterine device	*****	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****	-0.076
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	Standardized difference (total)[3]
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 7o. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Warfarin new user						
	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	279,971		196		279,775		895,208		615		894,593		
Vaginal Bleed	9,371	100.0%	196	100.0%	9,175	100.0%	40,109	100.0%	615	100.0%	39,494	100.0%	-
Patient Count	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Standardized difference (total)[3]
Any medical management	*****	1.1%	*****	*****	94	1.0%	*****	0.4%	*****	*****	138	0.3%	0.083
Antifibrinolytic	*****	0.1%	*****	*****	11	0.1%	*****	*****	0	0.0%	*****	*****	0.042
Contraceptive use	*****	0.3%	*****	*****	30	0.3%	*****	0.1%	*****	*****	54	0.1%	0.038
Intrauterine device	*****	0.7%	*****	*****	58	0.6%	*****	0.2%	*****	*****	80	0.2%	0.068
Vaginal packing	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****	0.009
Management Count[4]	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Standardized difference (total)[3]
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	-0.019
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	0.08
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

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Table 7p. Medical Management after Vaginal Bleed among Rivaroxaban and Warfarin New Users with Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

	Rivaroxaban new user						Warfarin new user						
	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	279,970		196		279,774		279,970		166		279,804		
Vaginal Bleed	9,371	100.0%	196	100.0%	9,175	100.0%	12,999	100.0%	166	100.0%	12,833	100.0%	-
Patient Count	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Standardized difference (total)[3]**
Any medical management	*****	1.1%	*****	*****	94	1.0%	*****	0.4%	*****	*****	49	0.4%	0.078
Antifibrinolytic	*****	0.1%	*****	*****	11	0.1%	*****	*****	0	0.0%	*****	*****	0.046
Contraceptive use	*****	0.3%	*****	*****	30	0.3%	*****	0.2%	*****	*****	22	0.2%	0.031
Intrauterine device	*****	0.7%	*****	*****	58	0.6%	*****	0.2%	*****	*****	28	0.2%	0.065
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**	**Standardized difference (total)[3]**
Any medical management	2.4	2.8	1.2	0.4	2.5	2.9	2.6	4.4	1.5	0.7	2.7	4.5	-0.058
Antifibrinolytic	2.3	3.9	1	0	2.5	4	1	0	0	-	1	0	-
Contraceptive use	4.1	3.6	2	0	4.1	3.7	4	6.2	2	0	4.1	6.3	0.004
Intrauterine device	1.3	0.6	1	0	1.3	0.6	1.3	0.7	1	0	1.4	0.7	-0.027
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 during follow-up time.

[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 had received at least one of that medical management following their first vaginal bleed. Mean was calculated as medical management count per patient.

*****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 8a. Distribution of Surgical Managements[1] Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Rivaroxaban vs. Dabigatran (Unmatched)

Exposure	Description	Management Count	Percent of Total Management Count
Rivaroxaban	Dilation and curettage with or without hysteroscopy	102	12.7%
Rivaroxaban	Thermal, cryo or section endometrial ablation	270	33.5%
Rivaroxaban	Hysterectomy	180	22.3%
Rivaroxaban	Hysteroscopy (not listed in other surgical managements)	128	15.9%
Rivaroxaban	Hysteroscopic, laparoscopic or abdominal myomectomy	*****	*****
Rivaroxaban	Hysteroscopic polypectomy	118	14.6%
Rivaroxaban	Uterine artery embolization	*****	*****
Dabigatran	Dilation and curettage with or without hysteroscopy	47	15.2%
Dabigatran	Thermal, cryo or section endometrial ablation	91	29.4%
Dabigatran	Hysterectomy	68	22.0%
Dabigatran	Hysteroscopy (not listed in other surgical managements)	50	16.2%
Dabigatran	Hysteroscopic, laparoscopic or abdominal myomectomy	*****	*****
Dabigatran	Hysteroscopic polypectomy	50	16.2%
Dabigatran	Uterine artery embolization	0	0.0%

[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 8b. Distribution of Surgical Managements[1] Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Rivaroxaban vs. Apixaban (Unmatched)

Exposure	Description	Management Count	Percent of Total Management Count
Rivaroxaban	Dilation and curettage with or without hysteroscopy	102	12.7%
Rivaroxaban	Thermal, cryo or section endometrial ablation	270	33.5%
Rivaroxaban	Hysterectomy	180	22.3%
Rivaroxaban	Hysteroscopy (not listed in other surgical managements)	128	15.9%
Rivaroxaban	Hysteroscopic, laparoscopic or abdominal myomectomy	*****	*****
Rivaroxaban	Hysteroscopic polypectomy	118	14.6%
Rivaroxaban	Uterine artery embolization	*****	*****
Apixaban	Dilation and curettage with or without hysteroscopy	26	15.3%
Apixaban	Thermal, cryo or section endometrial ablation	38	22.4%
Apixaban	Hysterectomy	44	25.9%
Apixaban	Hysteroscopy (not listed in other surgical managements)	31	18.2%
Apixaban	Hysteroscopic, laparoscopic or abdominal myomectomy	0	0.0%
Apixaban	Hysteroscopic polypectomy	31	18.2%
Apixaban	Uterine artery embolization	0	0.0%

[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.

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Table 8c. Distribution of Surgical Managements[1] Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Dabigatran vs. Apixaban (Unmatched)

Exposure	Description	Management Count	Percent of Total Management Count
Dabigatran	Dilation and curettage with or without hysteroscopy	47	15.2%
Dabigatran	Thermal, cryo or section endometrial ablation	91	29.4%
Dabigatran	Hysterectomy	68	22.0%
Dabigatran	Hysteroscopy (not listed in other surgical managements)	50	16.2%
Dabigatran	Hysteroscopic, laparoscopic or abdominal myomectomy	*****	*****
Dabigatran	Hysteroscopic polypectomy	50	16.2%
Dabigatran	Uterine artery embolization	0	0.0%
Apixaban	Dilation and curettage with or without hysteroscopy	26	15.3%
Apixaban	Thermal, cryo or section endometrial ablation	38	22.4%
Apixaban	Hysterectomy	44	25.9%
Apixaban	Hysteroscopy (not listed in other surgical managements)	31	18.2%
Apixaban	Hysteroscopic, laparoscopic or abdominal myomectomy	0	0.0%
Apixaban	Hysteroscopic polypectomy	31	18.2%
Apixaban	Uterine artery embolization	0	0.0%

[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.

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Table 8d. Distribution of Surgical Managements[1] Used to Identify Severe Uterine Bleed (SUB) as Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Rivaroxaban vs. Warfarin (Unmatched)

Exposure	Description	Management Count	Percent of Total Management Count
Rivaroxaban	Dilation and curettage with or without hysteroscopy	106	13.1%
Rivaroxaban	Thermal, cryo or section endometrial ablation	182	22.5%
Rivaroxaban	Hysterectomy	181	22.4%
Rivaroxaban	Hysteroscopy (not listed in other surgical managements)	154	19.1%
Rivaroxaban	Hysteroscopic, laparoscopic or abdominal myomectomy	*****	*****
Rivaroxaban	Hysteroscopic polypectomy	175	21.7%
Rivaroxaban	Uterine artery embolization	*****	*****
Warfarin	Dilation and curettage with or without hysteroscopy	233	16.9%
Warfarin	Thermal, cryo or section endometrial ablation	266	19.3%
Warfarin	Hysterectomy	354	25.7%
Warfarin	Hysteroscopy (not listed in other surgical managements)	252	18.3%
Warfarin	Hysteroscopic, laparoscopic or abdominal myomectomy	*****	*****
Warfarin	Hysteroscopic polypectomy	261	19.0%
Warfarin	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.

Figure 1a. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

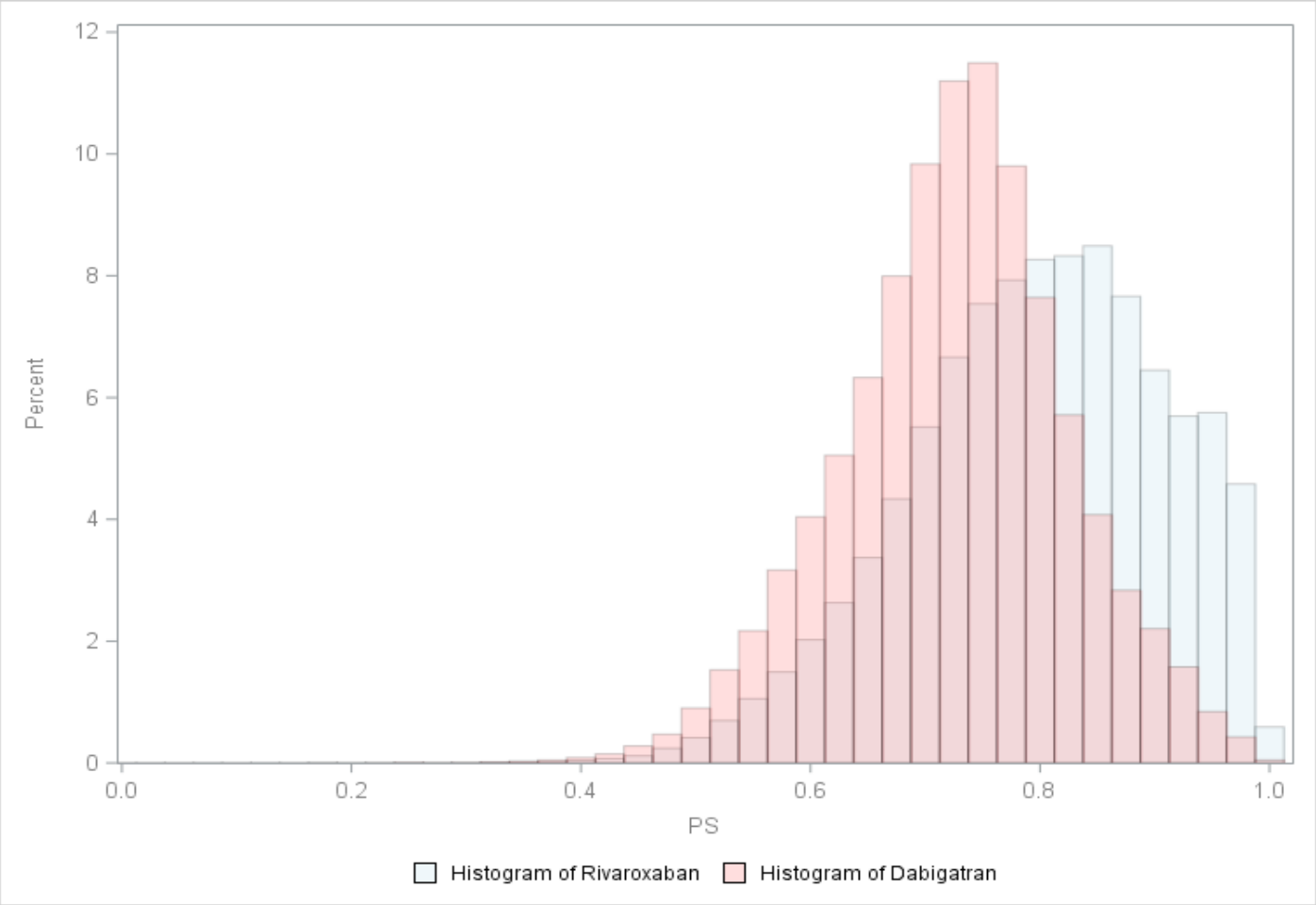


Figure 1b. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

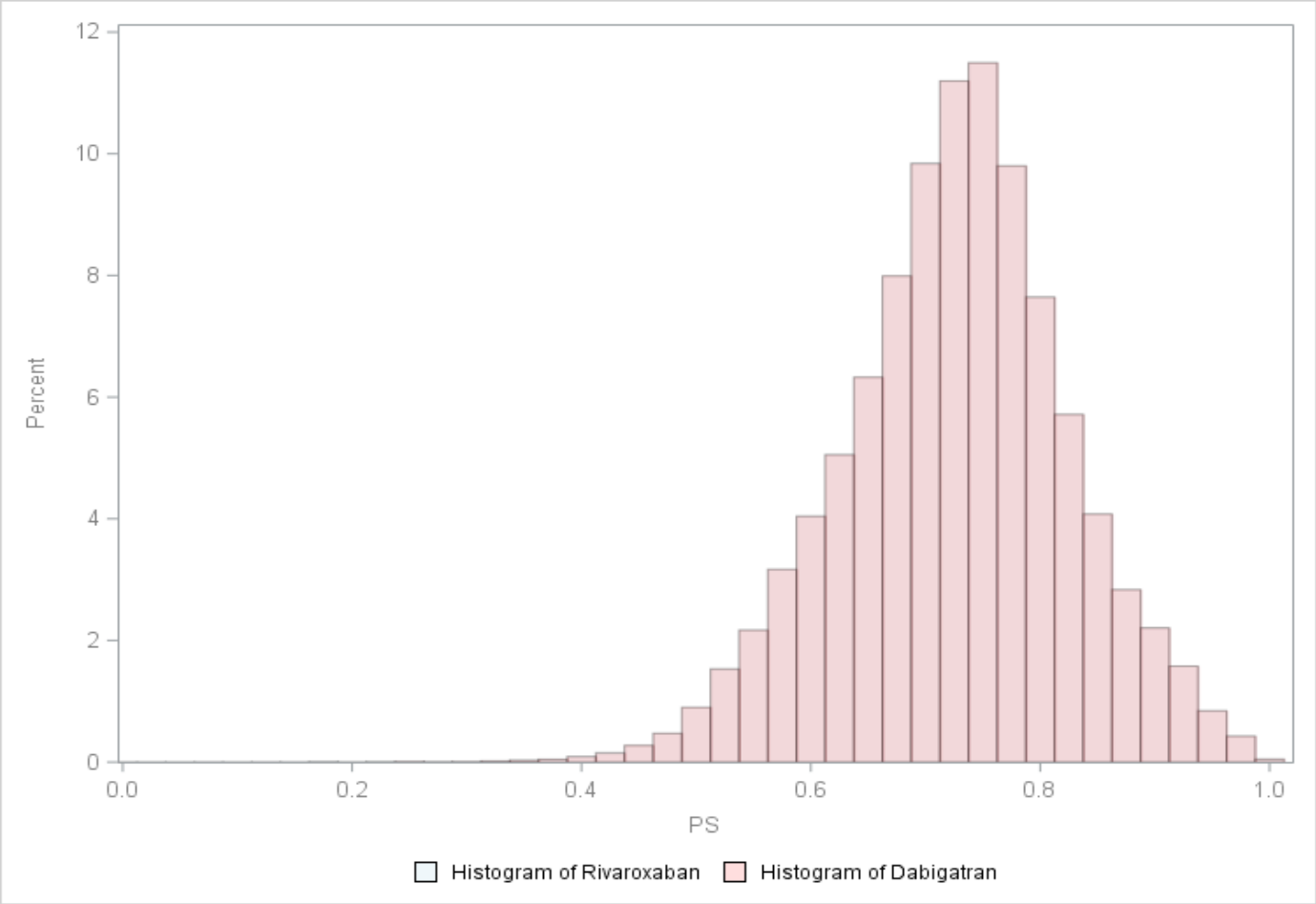


Figure 1c. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

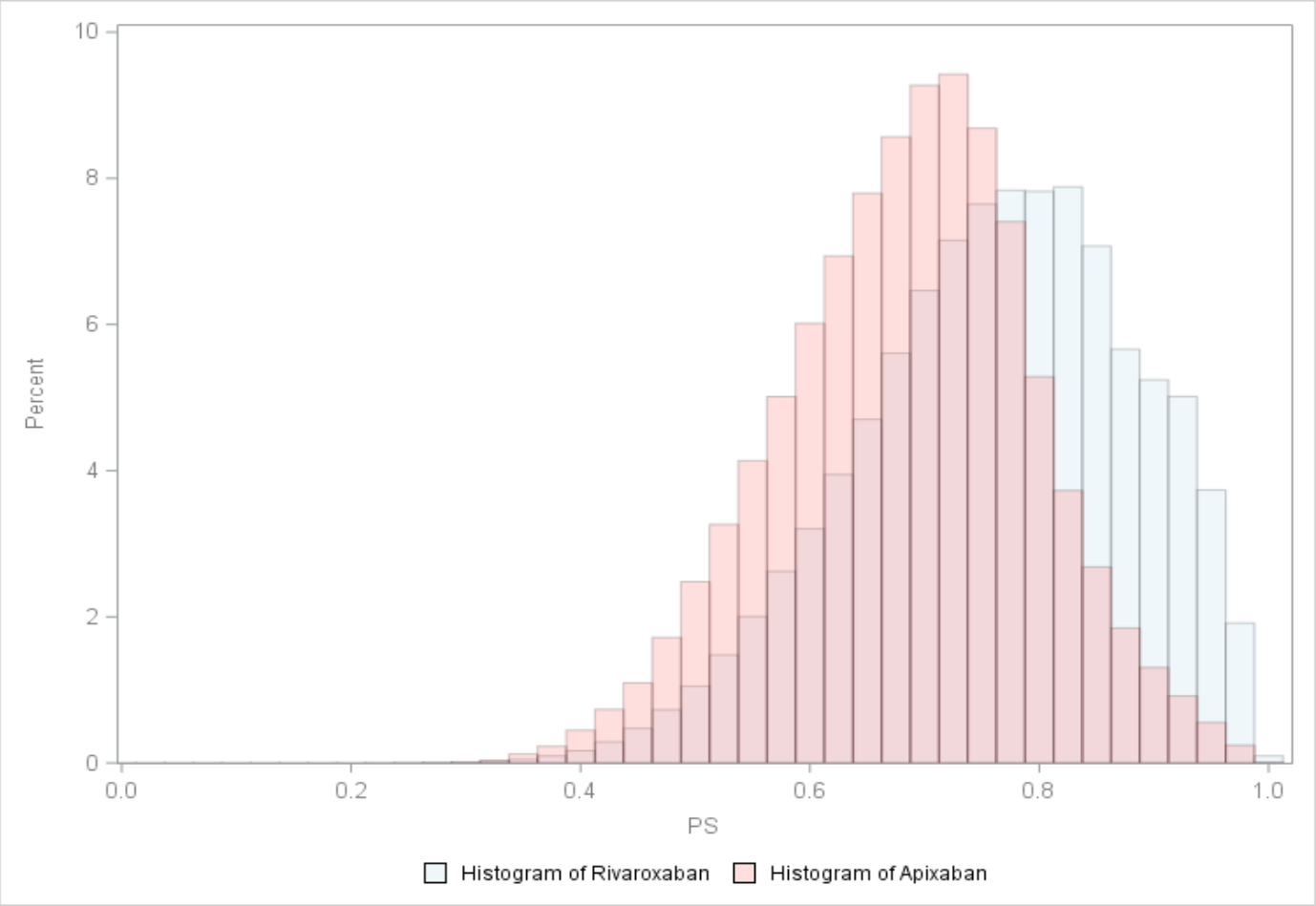


Figure 1d. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

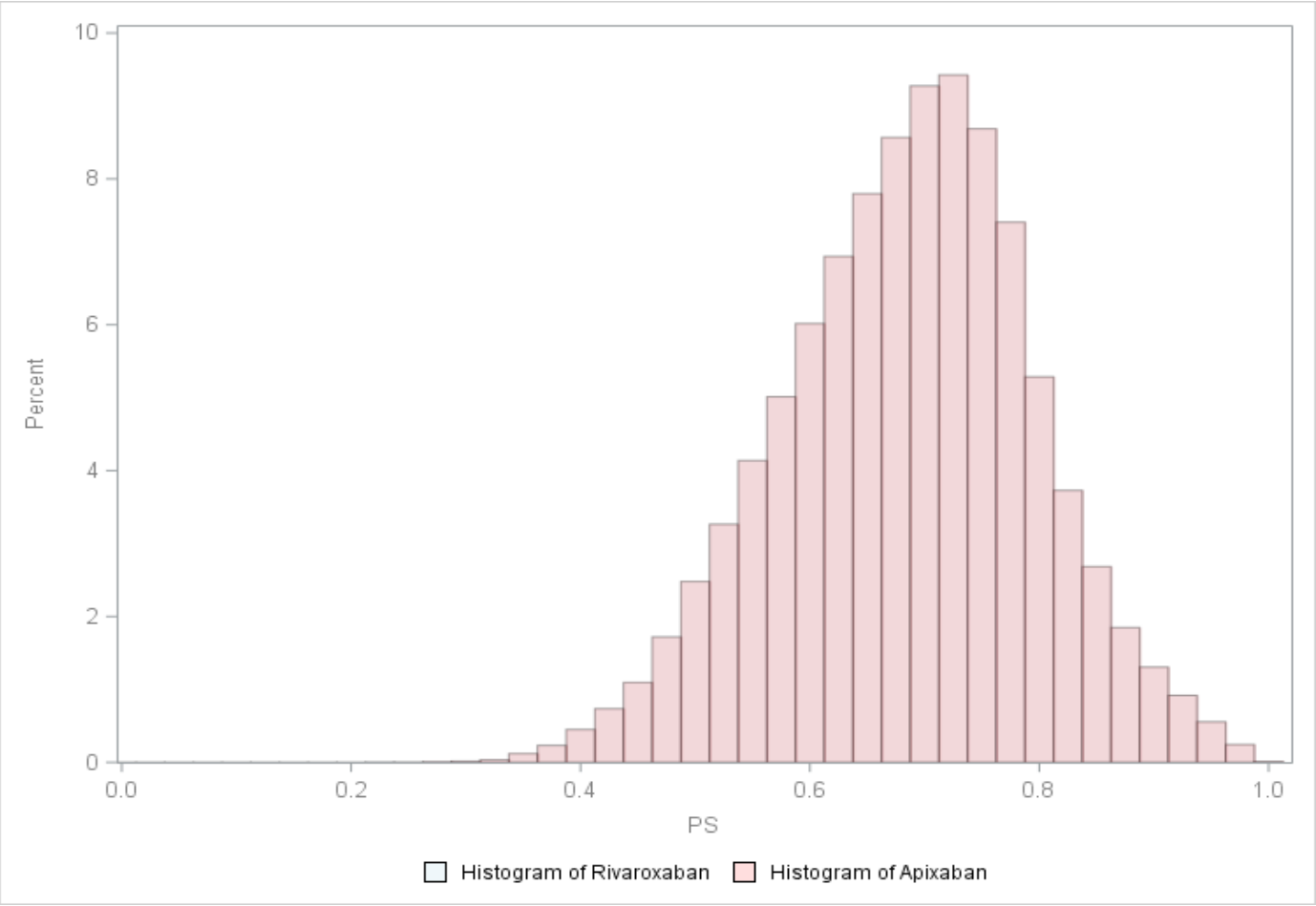


Figure 1e. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

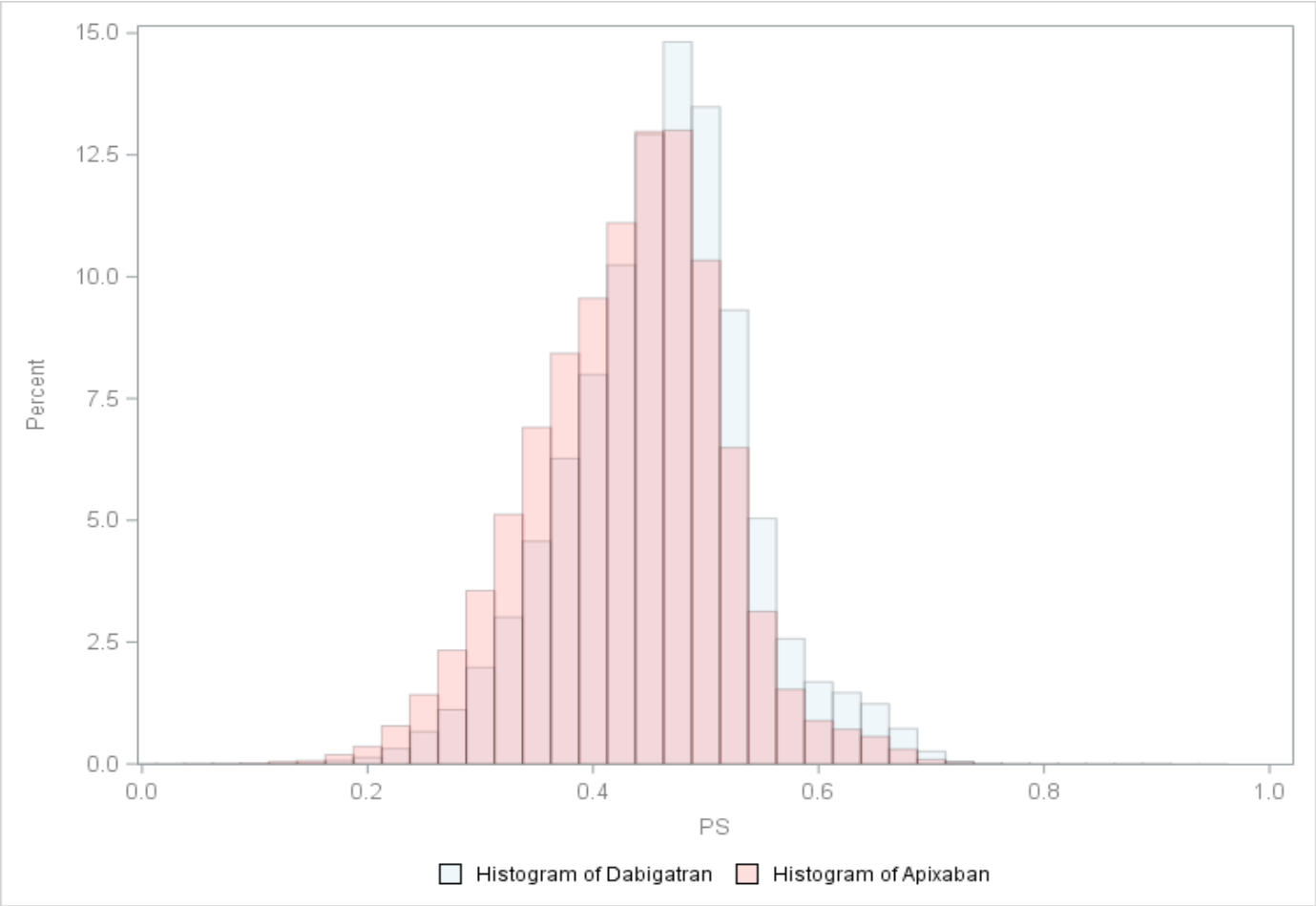


Figure 1f. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

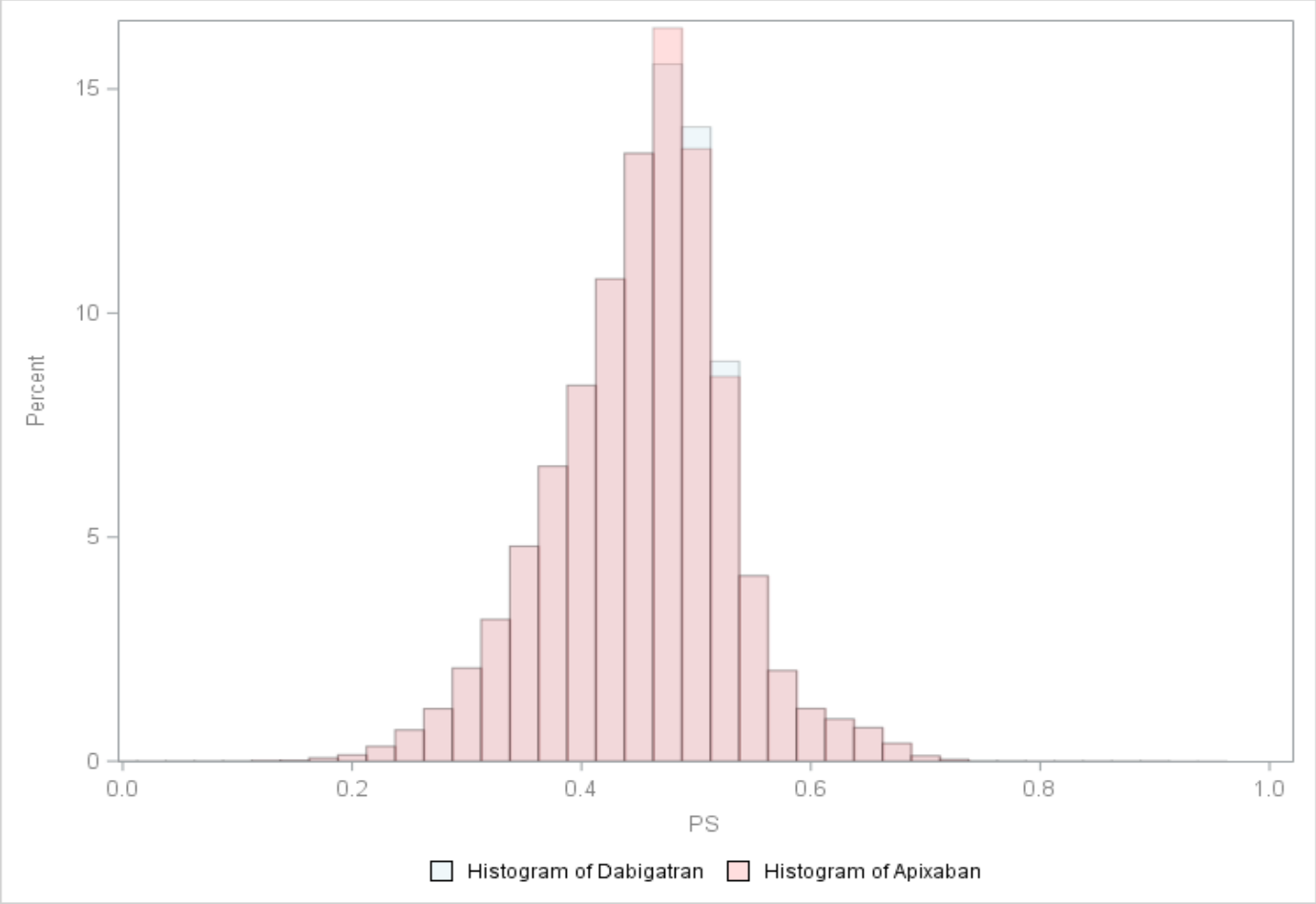


Figure 1g. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Surgical Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

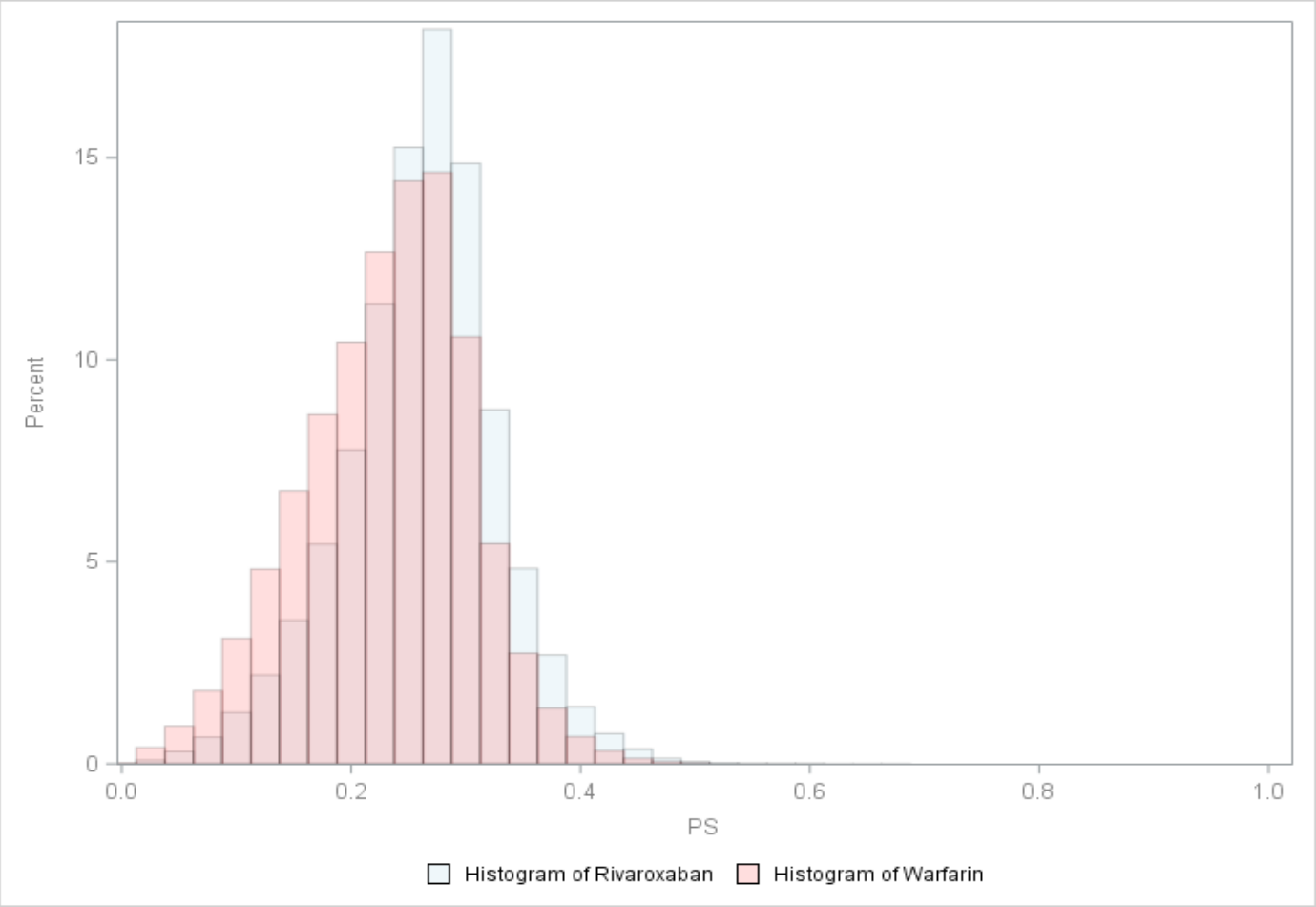


Figure 1h. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Surgical Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

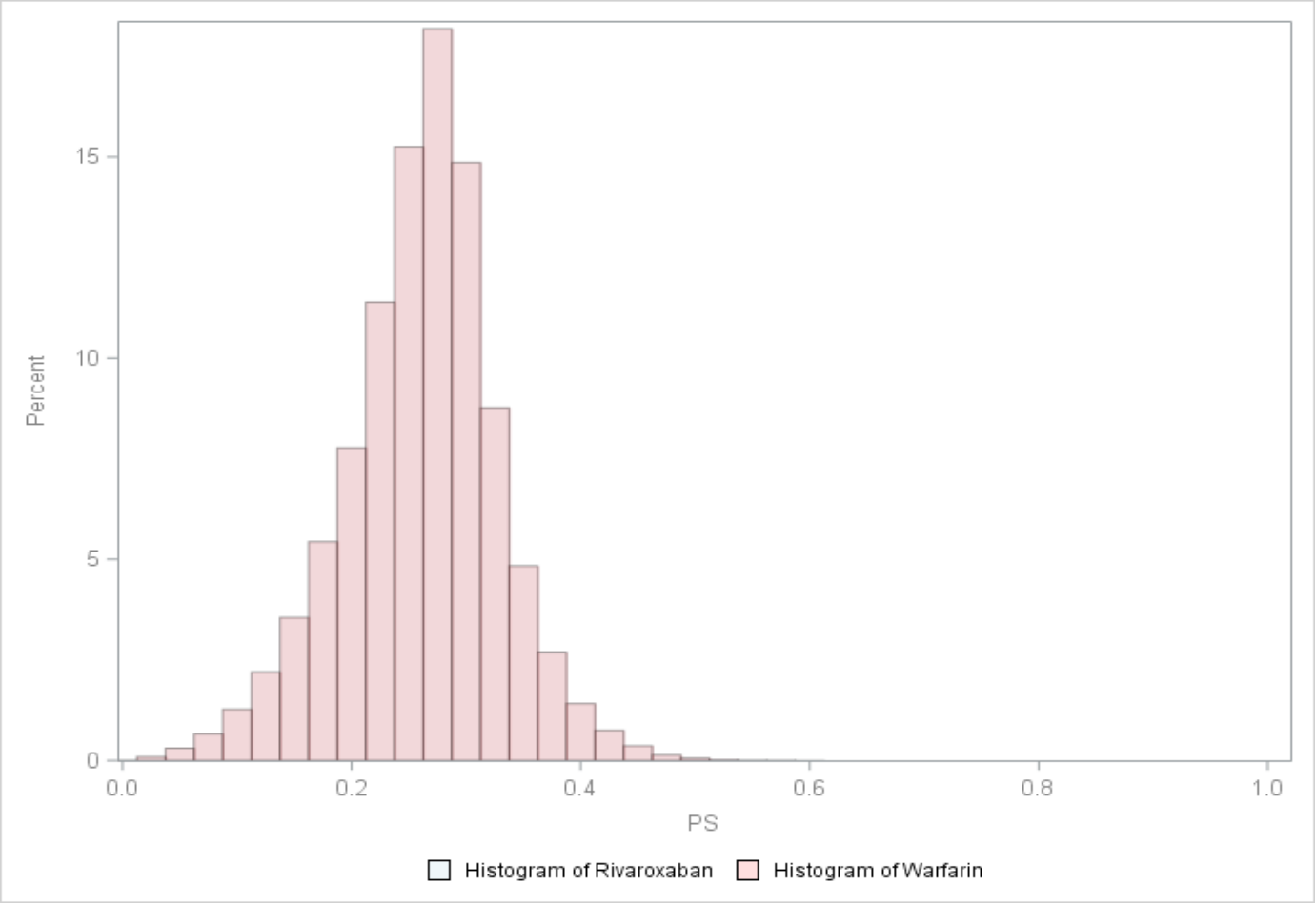


Figure 1i. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

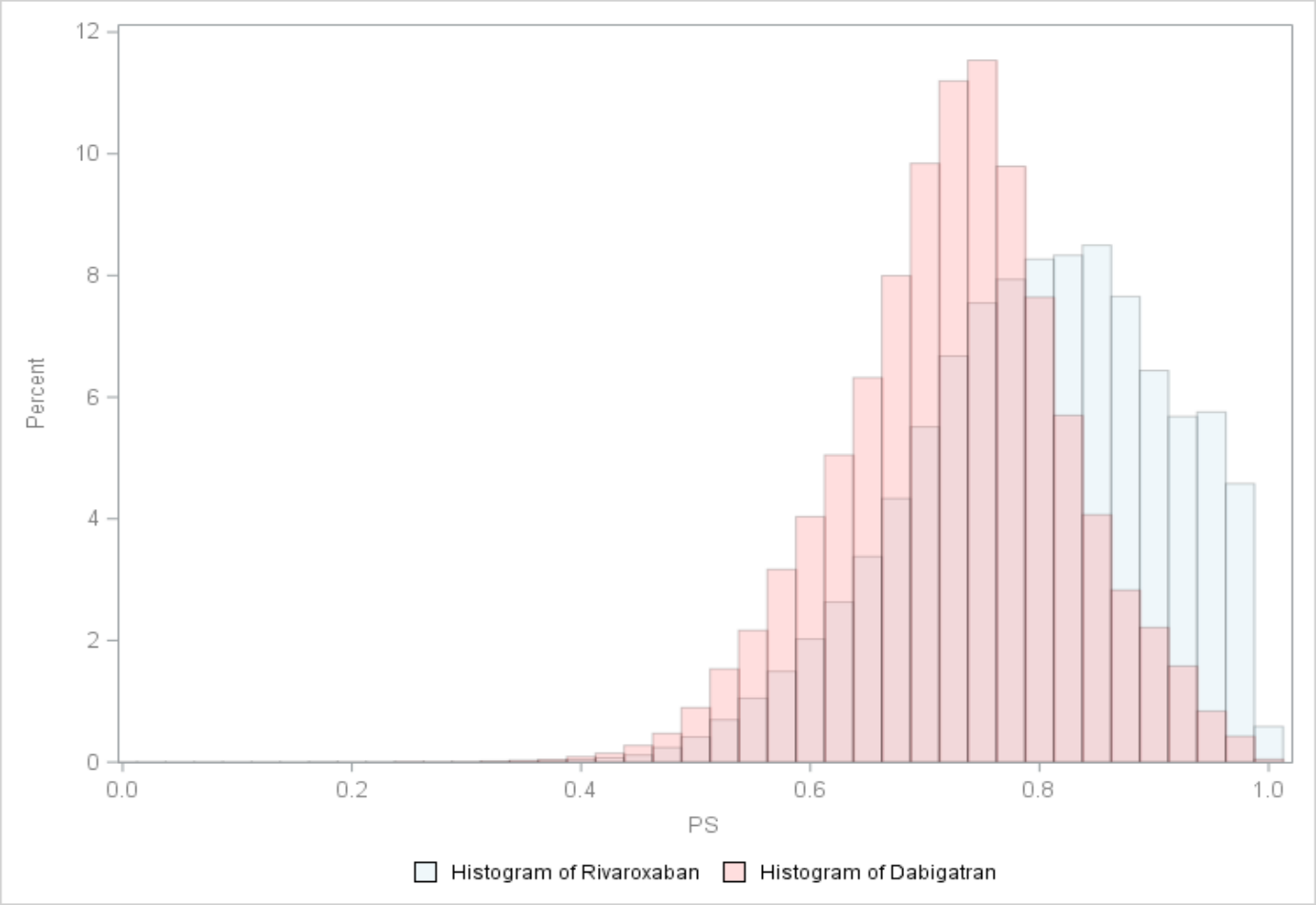


Figure 1j. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Dabigatran, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

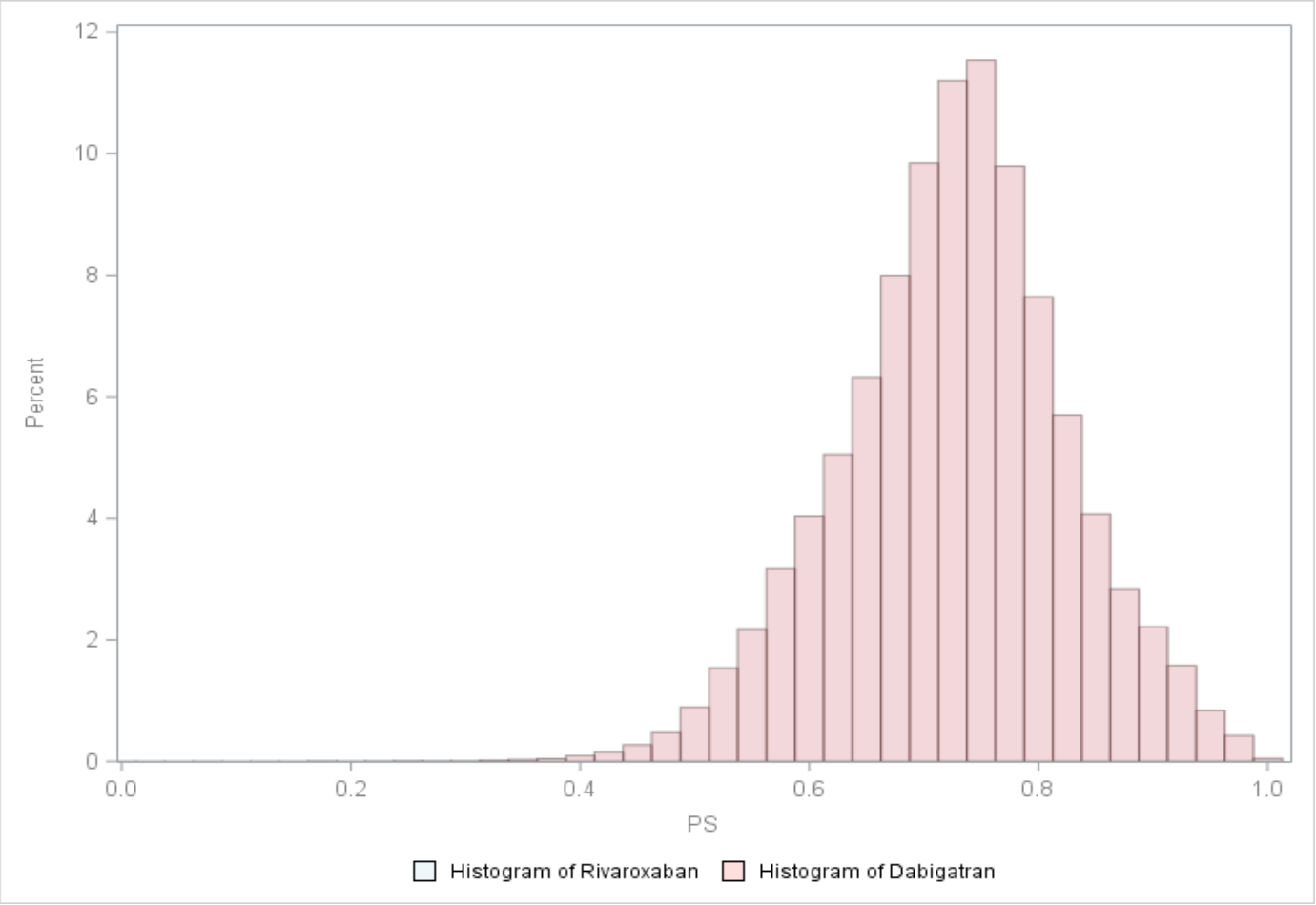


Figure 1k. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

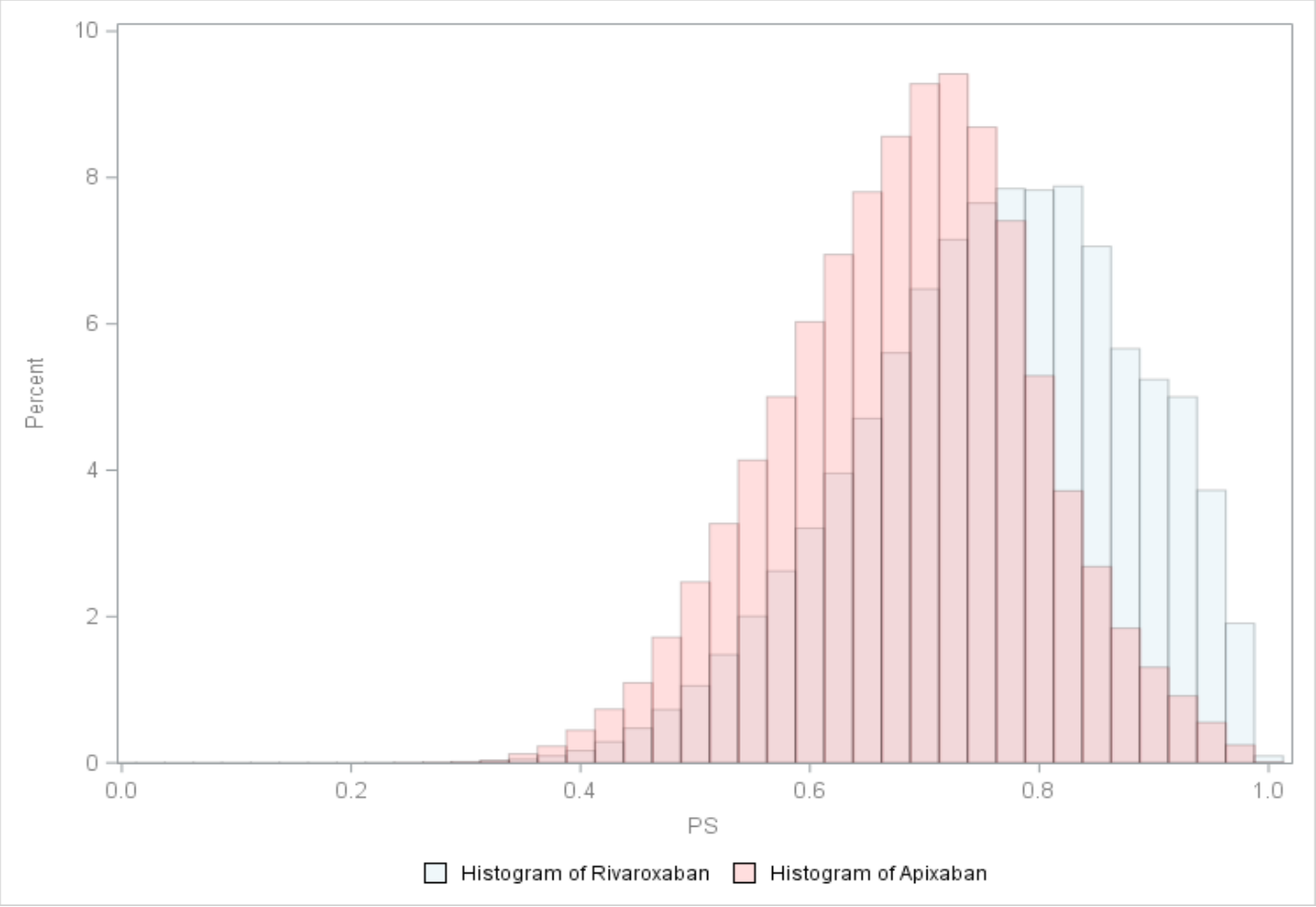


Figure 1l. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

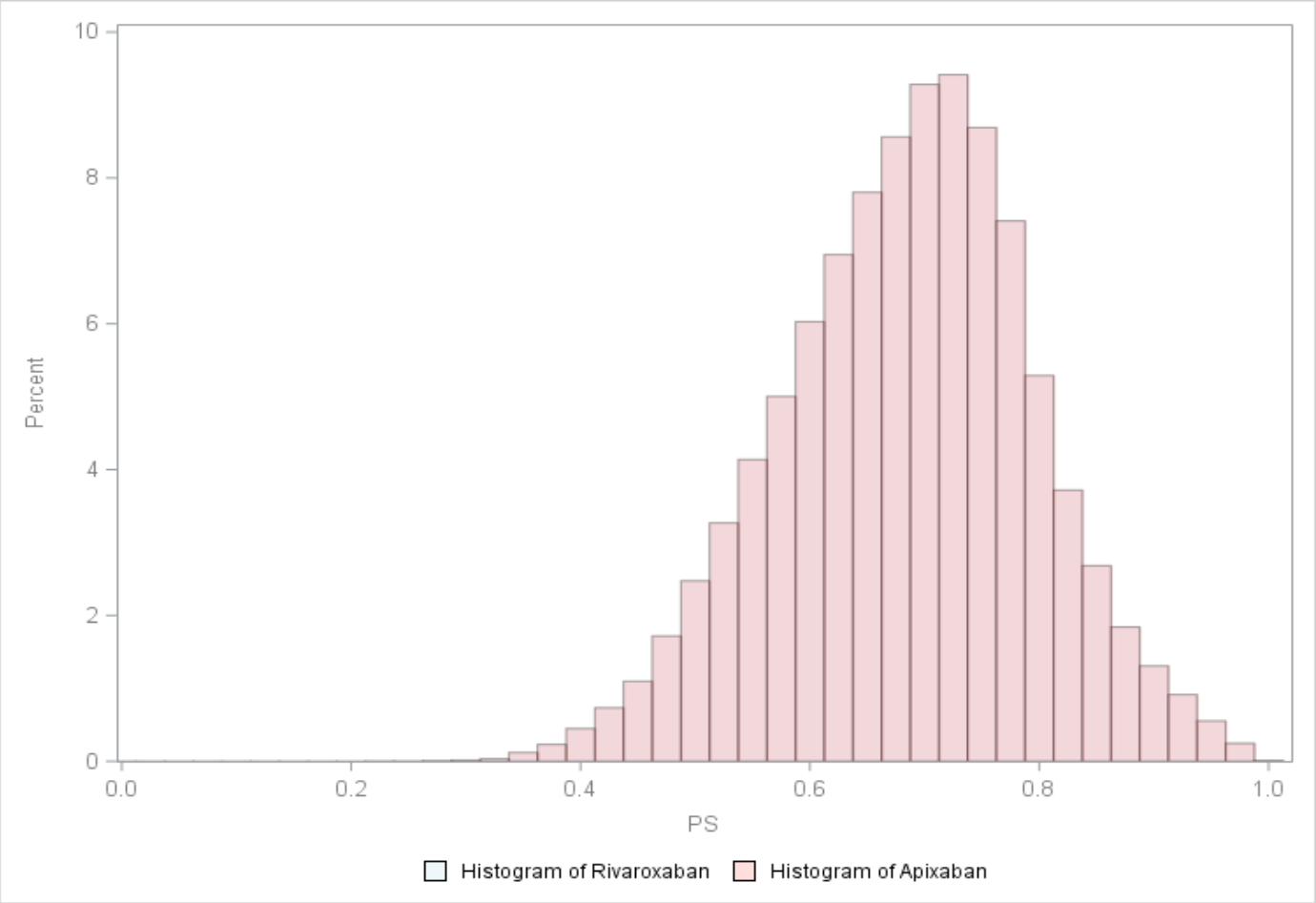


Figure 1m. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

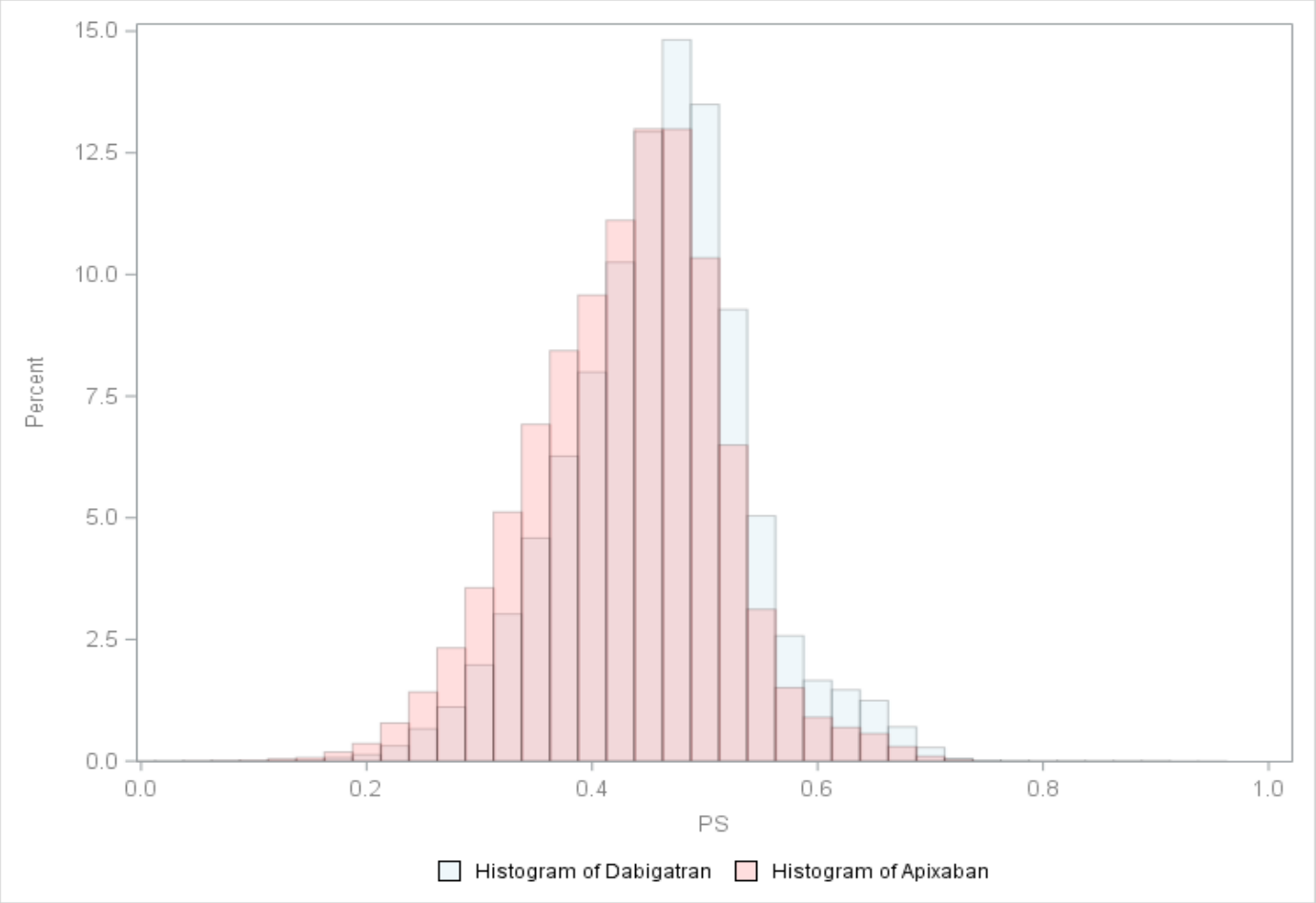


Figure 1n. Histograms Depicting Propensity Score Distributions, Dabigatran and Apixaban, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

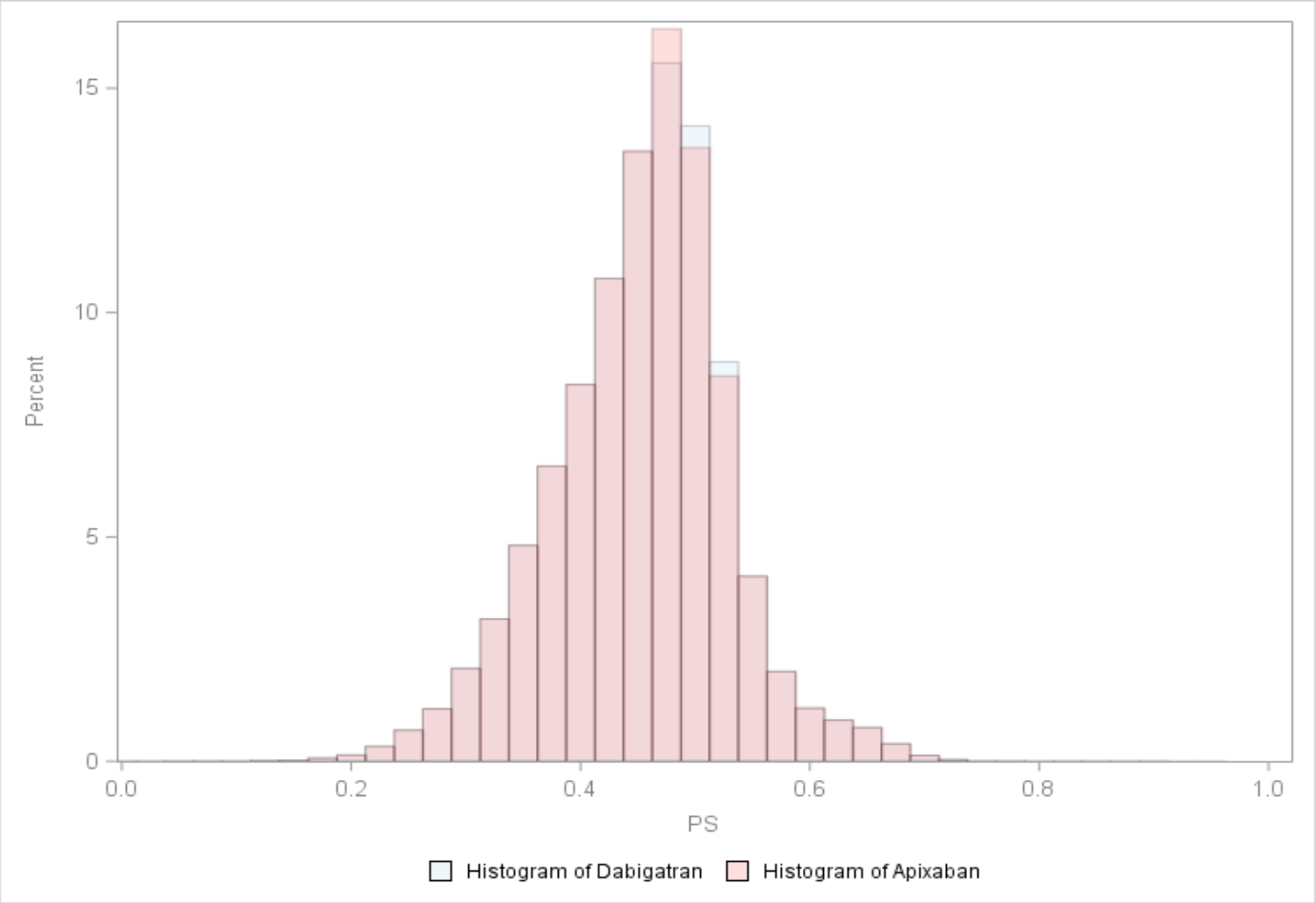


Figure 1o. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Unmatched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

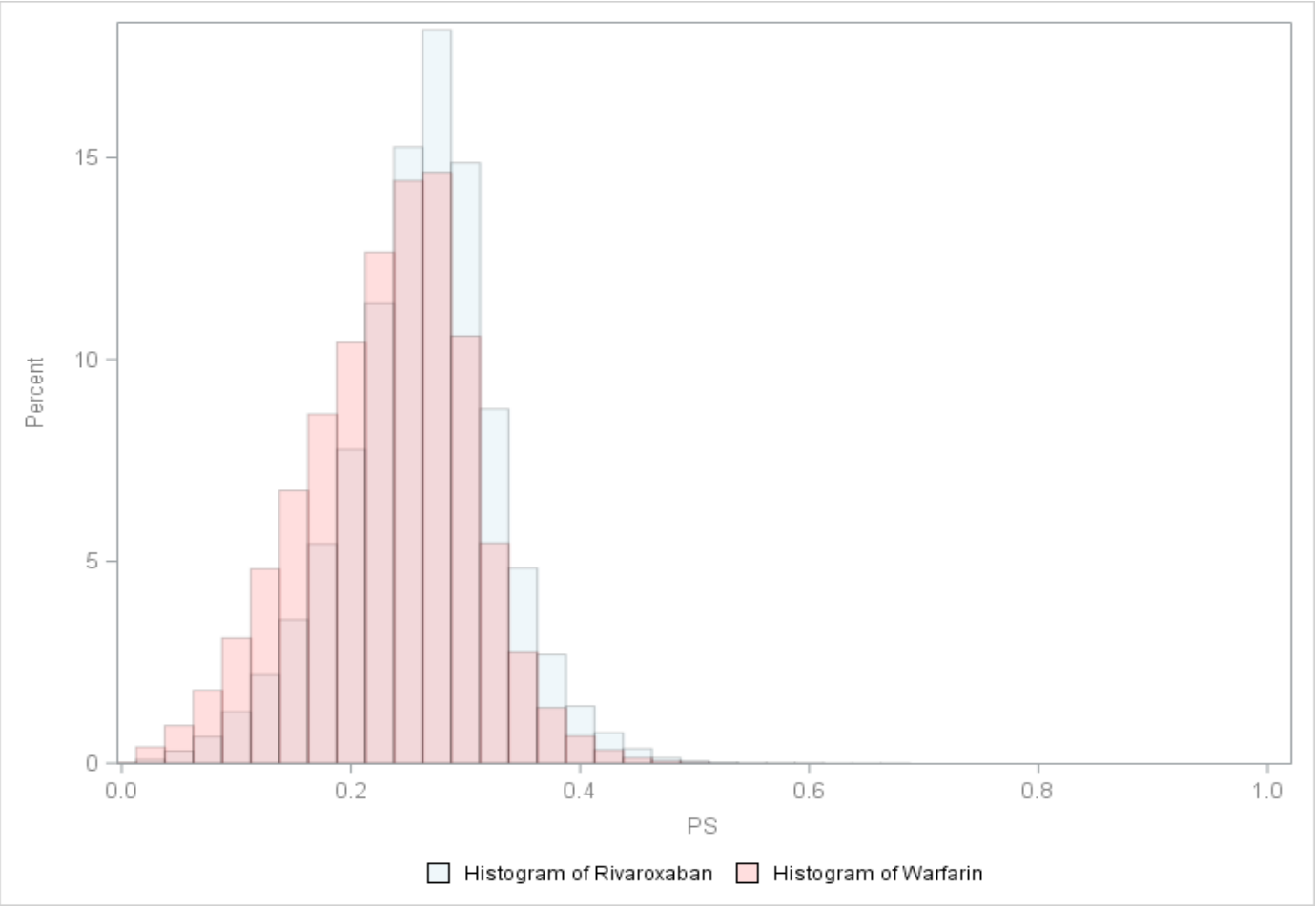


Figure 1p. Histograms Depicting Propensity Score Distributions, Rivaroxaban and Warfarin, Severe Uterine Bleed (SUB) Defined by Transfusion Management (Matched, Aggregated) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Ratio: 1:1, Caliper: 0.05

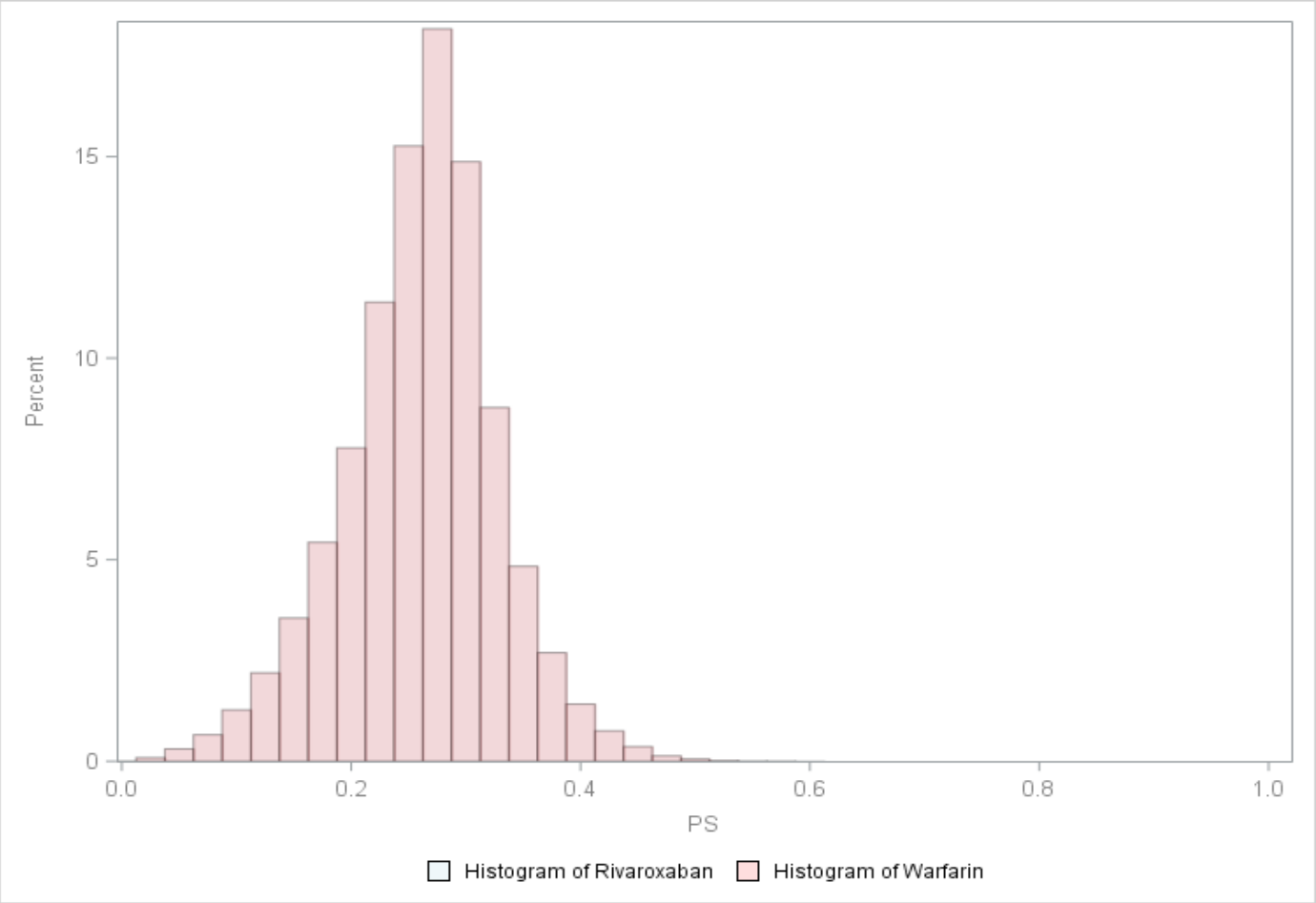


Figure 2a. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Rivaroxaban and Dabigatran, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

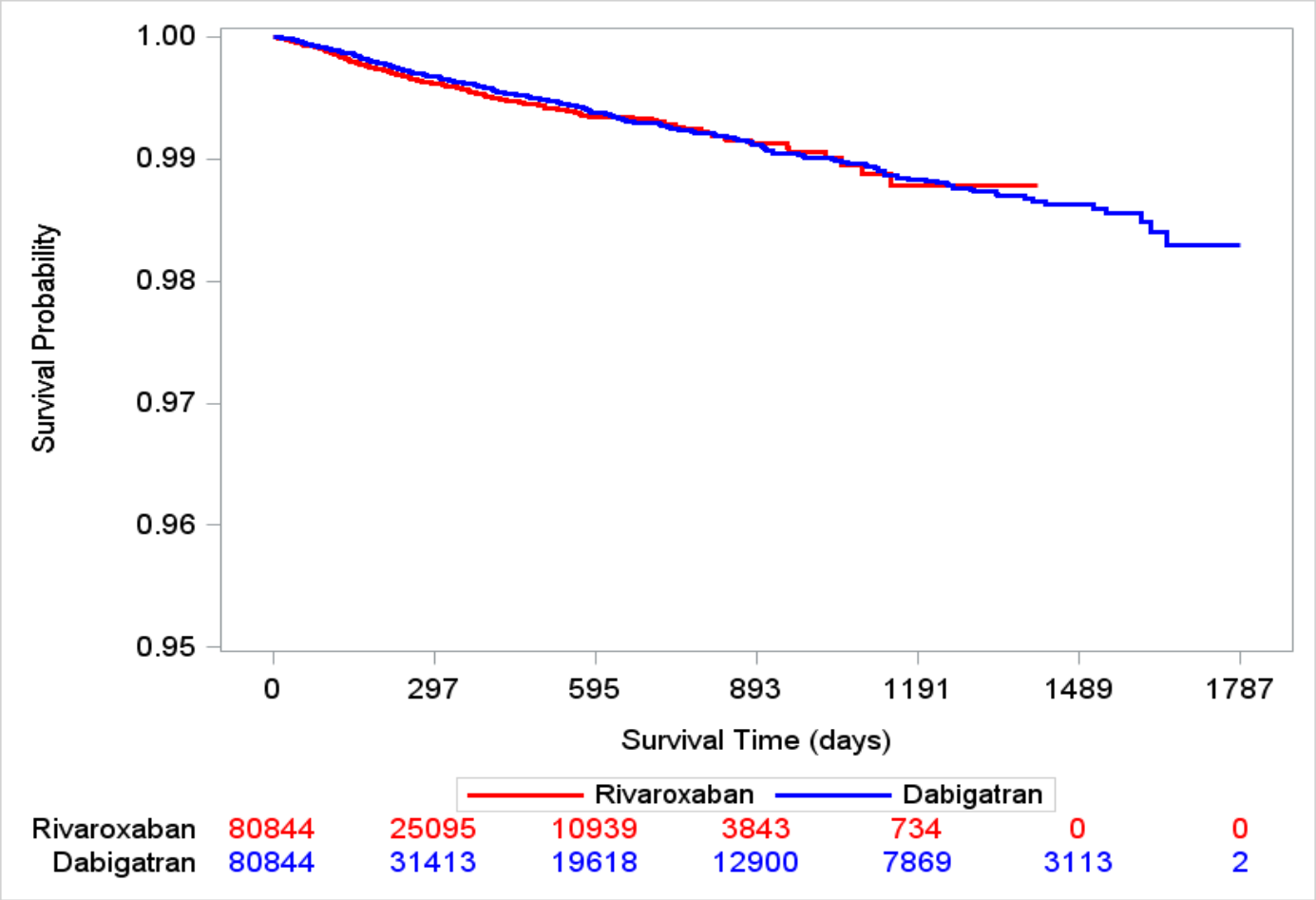


Figure 2b. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Rivaroxaban and Apixaban, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

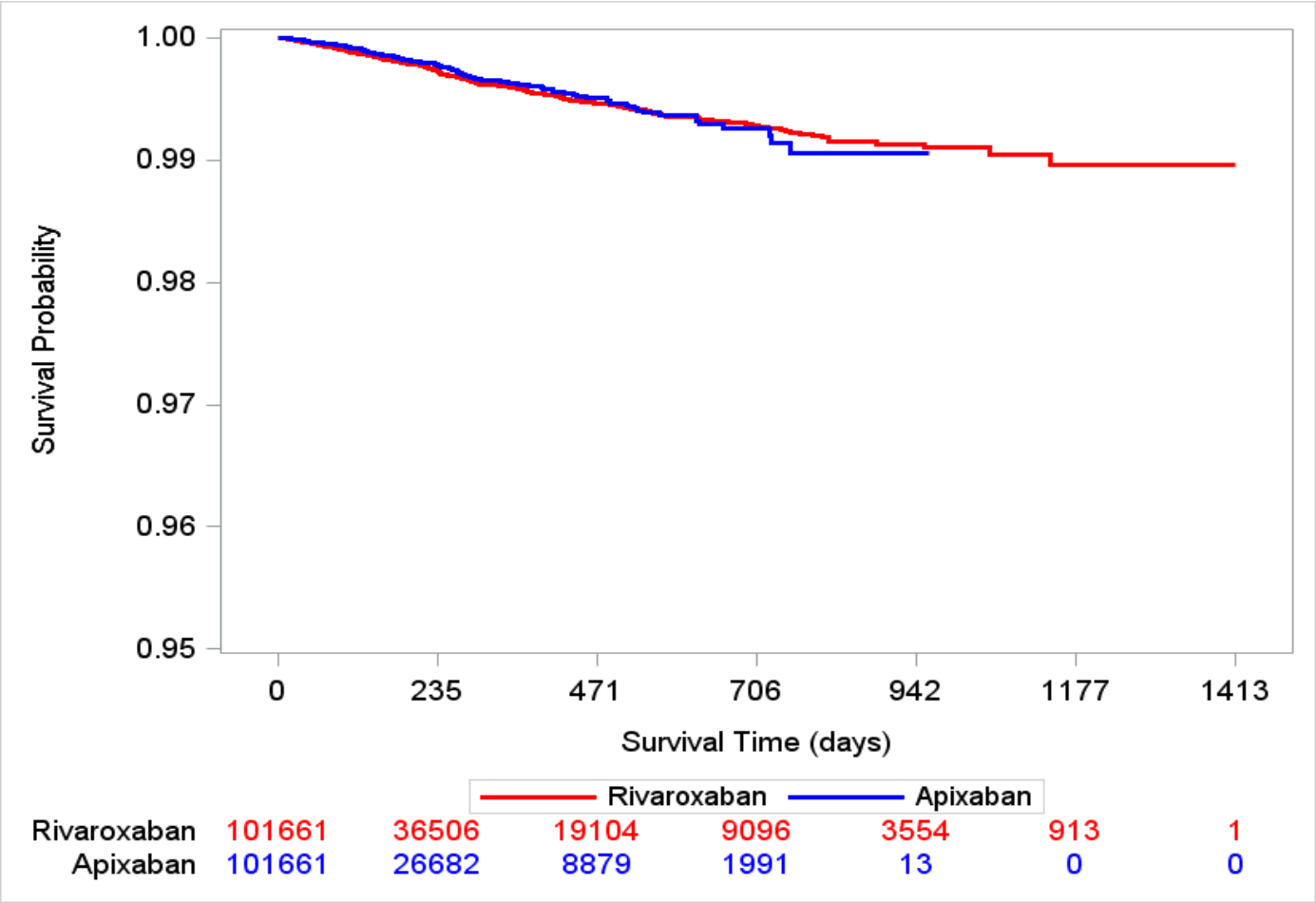


Figure 2c. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Dabigatran and Apixaban, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

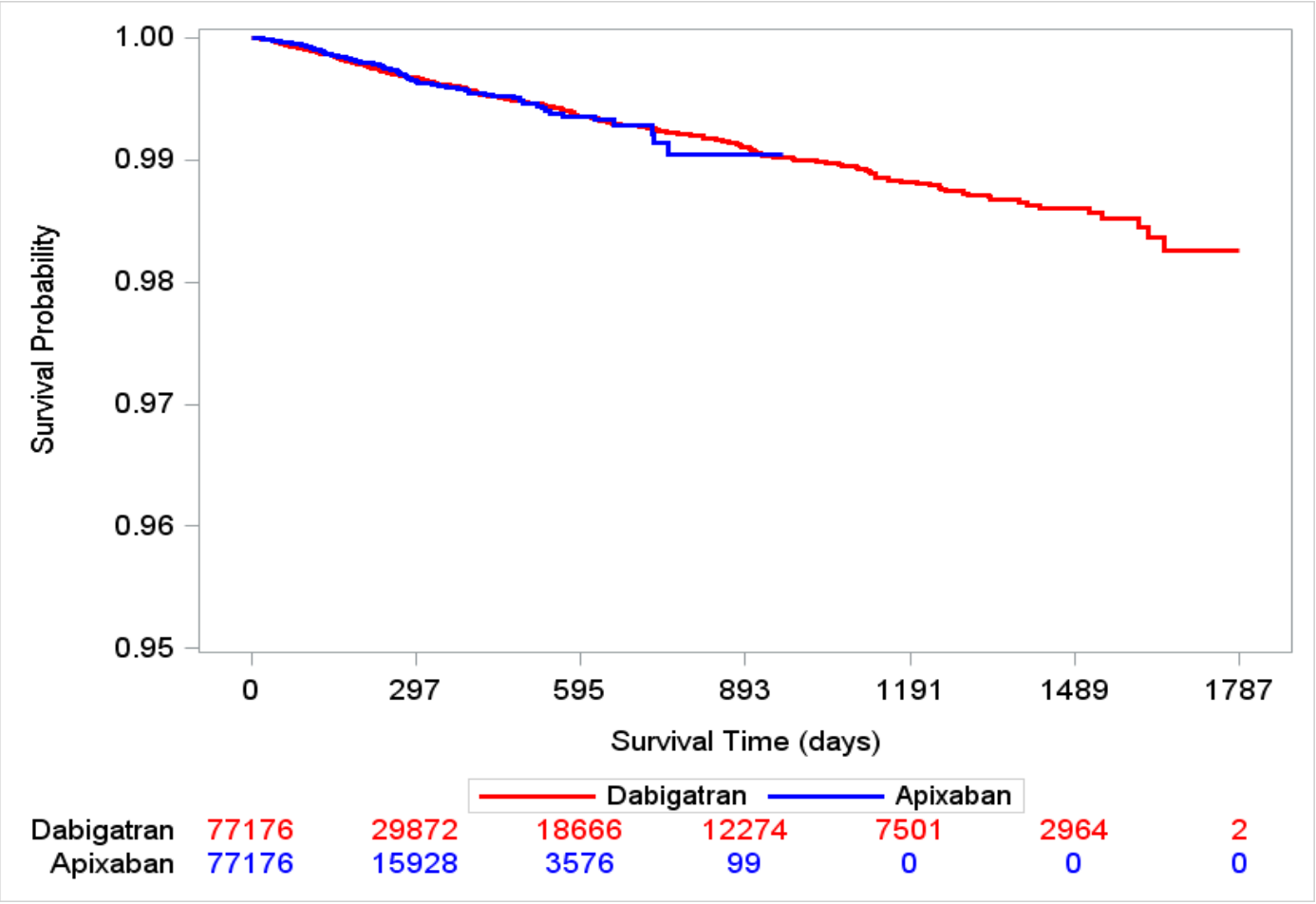


Figure 2d. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Surgical Management, Rivaroxaban and Warfarin, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

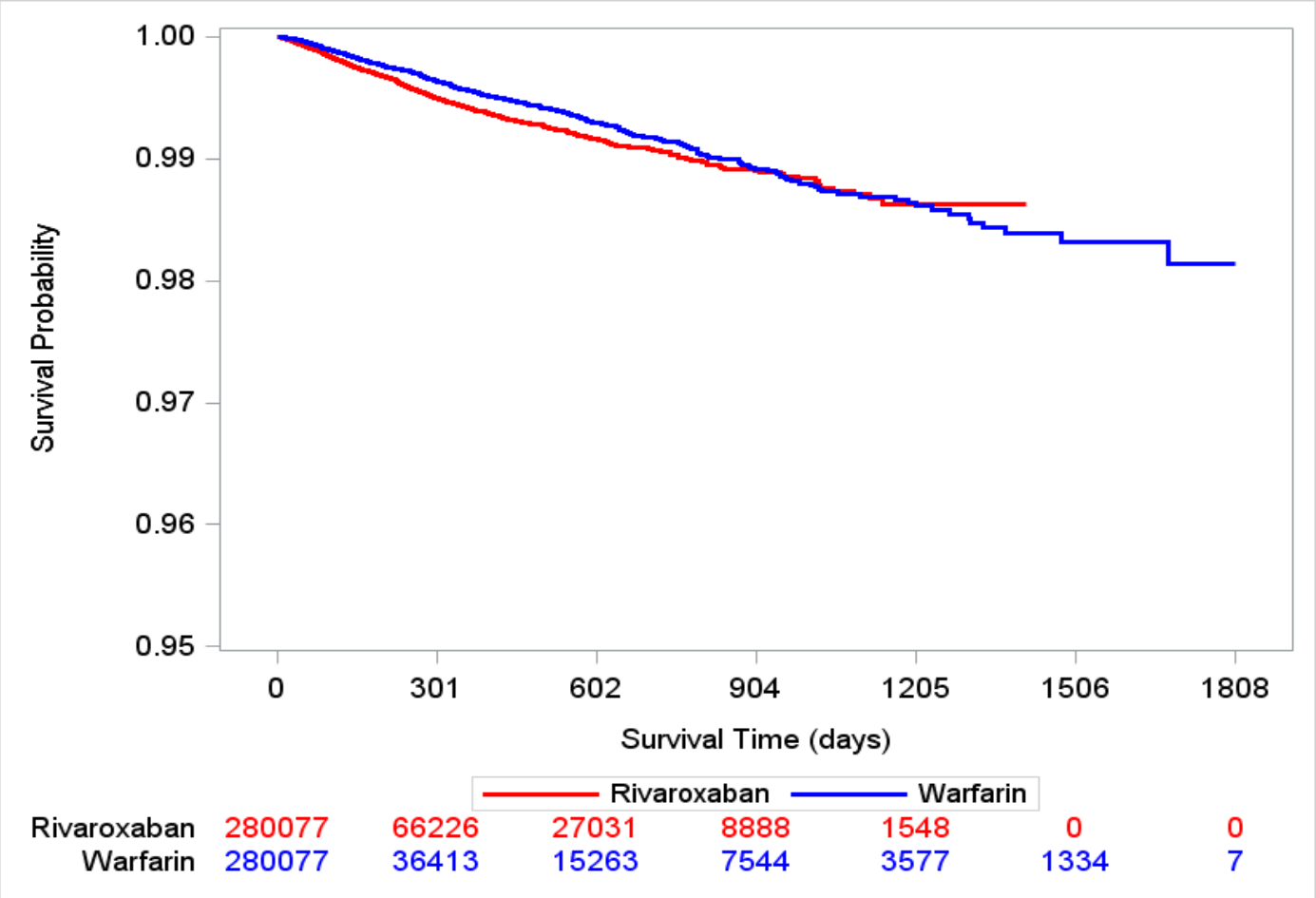


Figure 2e. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Rivaroxaban and Dabigatran, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

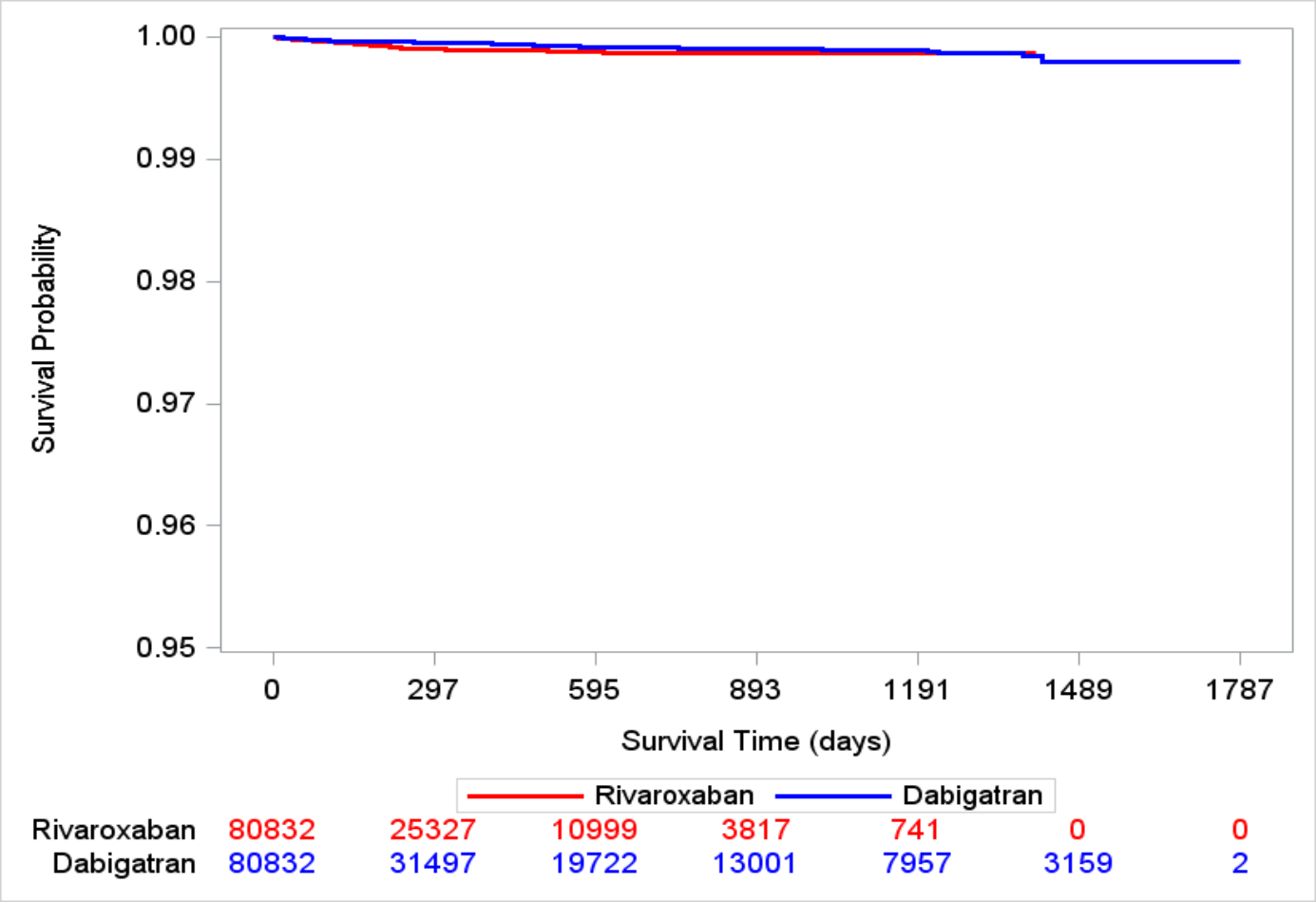


Figure 2f. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Rivaroxaban and Apixaban, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched

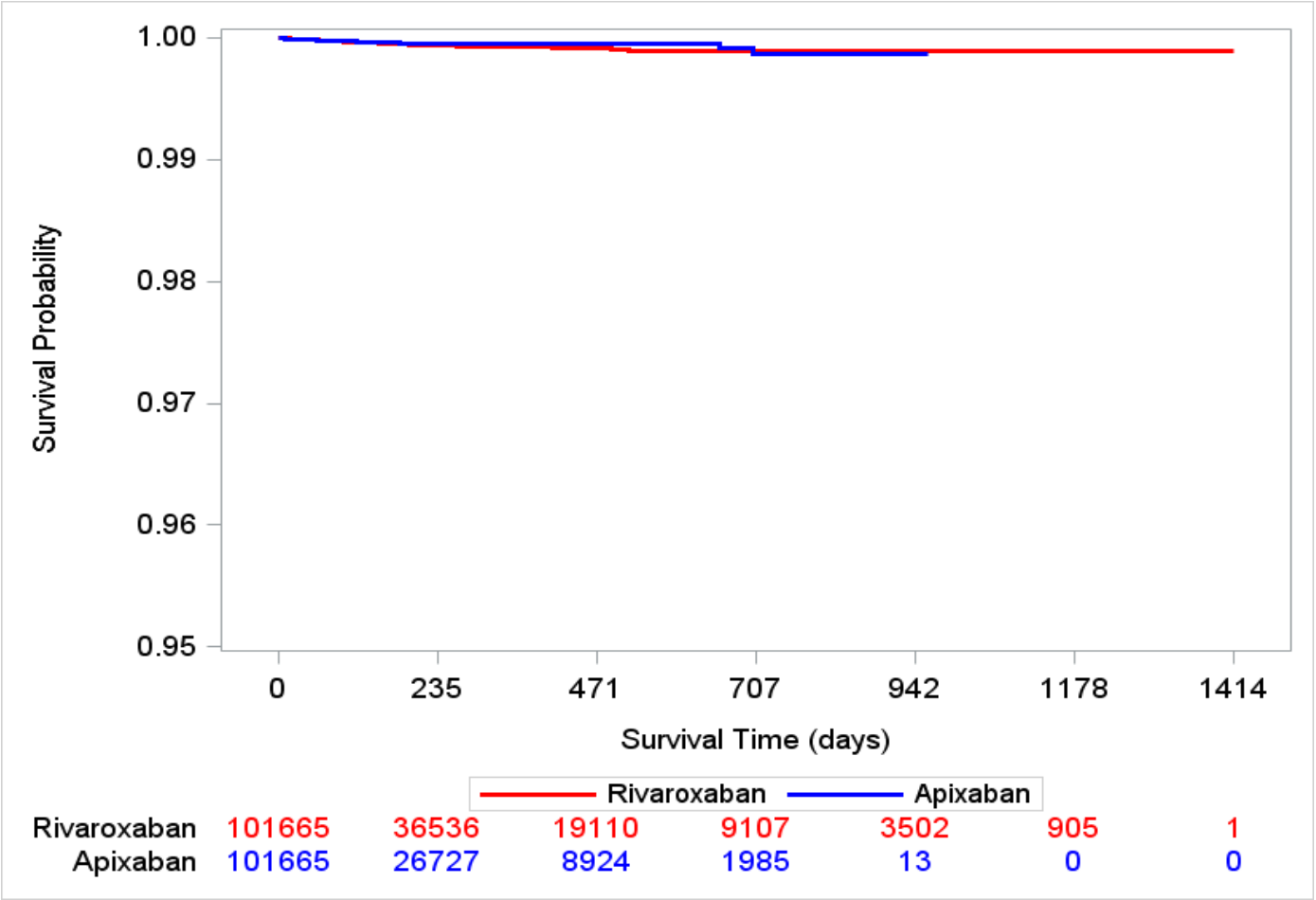


Figure 2g. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Dabigatran and Apixaban, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched

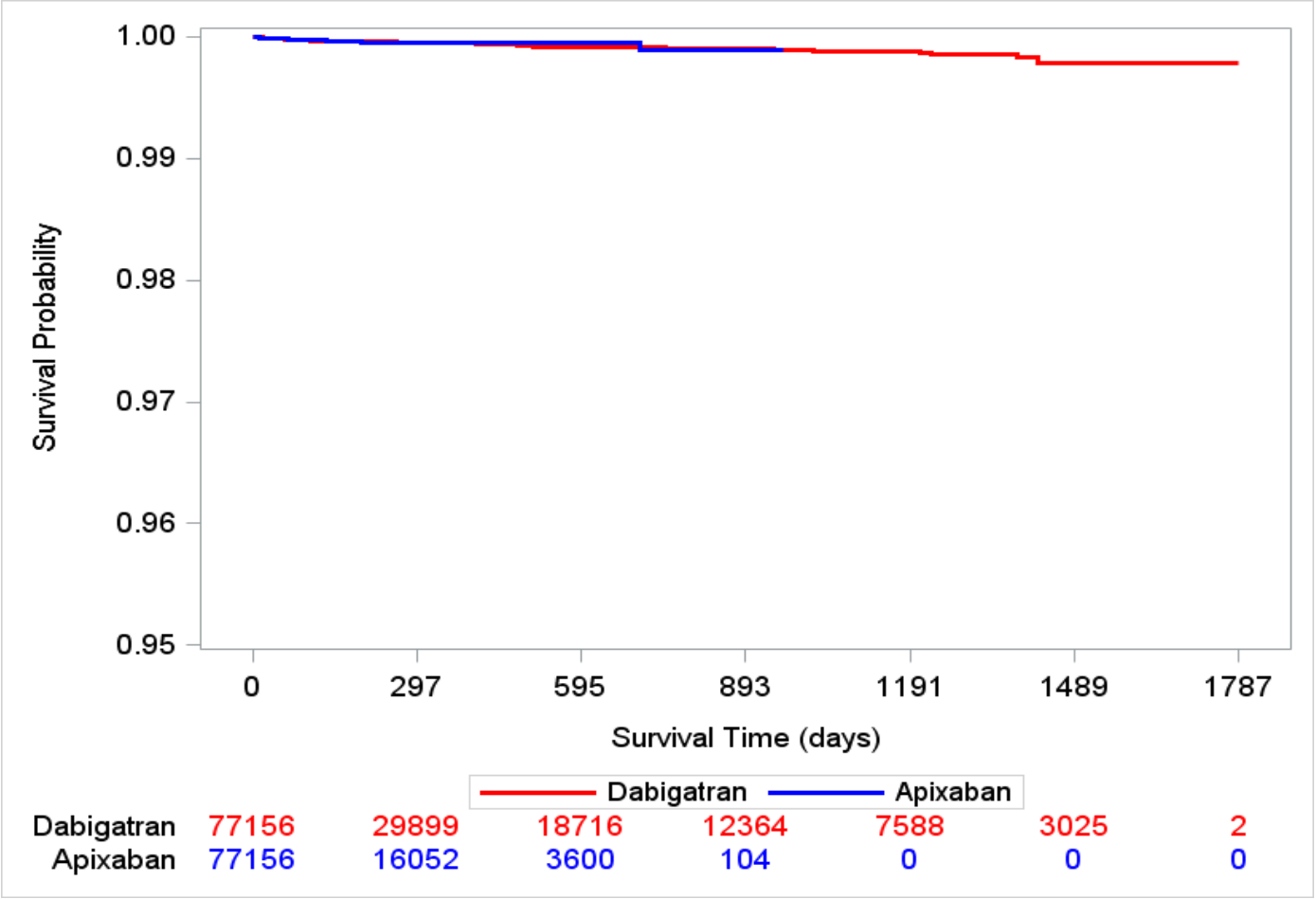
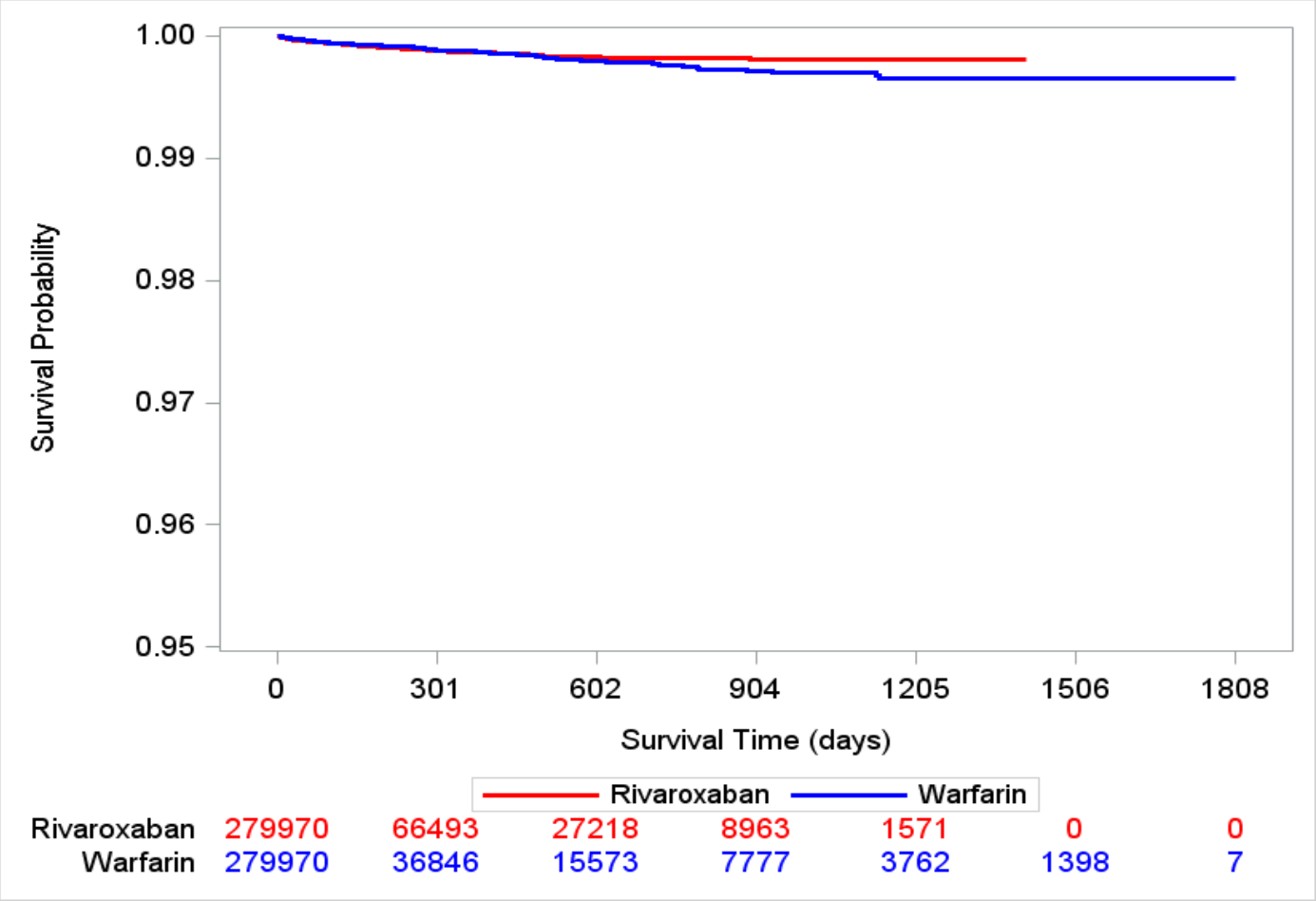


Figure 2h. Kaplan Meier Survival Curves for Severe Uterine Bleed Defined by Transfusion Management, Rivaroxaban and Warfarin, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched



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

Data Partner (Masked)	Start Date	End Date
DP01	01/01/2008	09/30/2015
DP02	01/01/2010	09/30/2015
DP03	01/01/2008	09/30/2015
DP04	01/01/2006	09/30/2015
DP05	06/01/2007	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 Drugs by Generic and Brand Medical Product Names Used to Define Oral Anti-Coagulants in this Request

Generic Name	Brand Name
Novel Oral Anti-Coagulants (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
453.71	Chronic venous embolism and thrombosis of superficial veins of upper extremity	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
453.72	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
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee 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
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	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
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

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
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

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
68.4	Total abdominal hysterectomy	ICD-9-CM	Procedure
68.41	Laparoscopic total abdominal hysterectomy	ICD-9-CM	Procedure
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 Drugs by Generic and Brand Medical Product Names Used to Define Inclusion and Exclusion Criteria in this

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 medical product names for medical management.	
Novel Oral Anti-Coagulants (NOACs)	
See Appendix B for generic and brand medical product names for NOACs.	
Vaginal Bleed	
See Appendix E for diagnosis codes for vaginal bleed.	

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 (RE) 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	RE	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
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

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 (RE) Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
	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
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

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 (RE) Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
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 (RE) 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-3 (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

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 (RE) Codes Diagnosis and Procedure Codes Used to Define Transfusion or Surgical Managements in this Request

Code	Description	Code Type	Code Category
	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
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

[A]Myomectomy diagnosis codes

[B]Myomectomy procedure codes are used in combination to detect myomectomy

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	CPT-4	Procedure
96.14	Vaginal packing	ICD-9-CM	Procedure

Appendix H. List of Drugs by Generic and Brand Medical Product Names 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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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)

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

Generic Name	Brand Name
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
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)

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

Generic Name	Brand Name
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)
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)

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

Generic Name	Brand Name
norgestrel-ethinyl estradiol	Ovral (21)
norgestrel-ethinyl estradiol	Ovral (28)

Appendix I. List of International Classification of Diseases, Ninth Revision (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Fourth Editions (CPT-4), and Revenue Center (RE) codes Diagnosis 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	ICD-9-CM	Diagnosis
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as	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
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	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	ICD-9-CM	Diagnosis
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
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
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	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 recommendation of footwear, and (4) patient education	HCPCS	Procedure

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

Code	Description	Code Type	Code Category
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 education	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
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

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Code	Description	Code Type	Code Category
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
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

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Code	Description	Code Type	Code Category
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
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		

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Code	Description	Code Type	Code Category
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
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

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

Code	Description	Code Type	Code Category
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
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

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Code	Description	Code Type	Code Category
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
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

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Code	Description	Code Type	Code Category
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
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

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Code	Description	Code Type	Code Category
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 vessel	CPT-4	Procedure
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

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Code	Description	Code Type	Code Category
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
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 primary procedure)	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

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Code	Description	Code Type	Code Category
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
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		

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Code	Description	Code Type	Code Category
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
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

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

Code	Description	Code Type	Code Category
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
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

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Code	Description	Code Type	Code Category
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
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

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Code	Description	Code Type	Code Category
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		
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	RE	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

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Code	Description	Code Type	Code Category
	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
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

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Code	Description	Code Type	Code Category
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 Drugs by Generic and Brand Medical Product Names 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

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Generic Name	Brand Name
Aldosterone Receptor Antagonists (ARAs)	
eplerenone	Inspra
eplerenone	Eplerenone
spironolactone	CaroSpir
spironolactone	Aldactone
spironolactone	Spironolactone
spironolactone/hydrochlorothiazide	Aldactazide
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

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Generic Name	Brand Name
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
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)

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Generic Name	Brand Name
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
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)

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Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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Generic Name	Brand Name
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
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

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Generic Name	Brand Name
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
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 besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besylate/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

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Generic Name	Brand Name
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
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

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Generic Name	Brand Name
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
niacin	Niacin
Oral Antidiabetic Agents	
acarbose	Precose
acarbose	Acarbose
alogliptin benzoate	Alogliptin
alogliptin benzoate	Nesina

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Generic Name	Brand Name
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
mifepristone	Korlym
miglitol	Glyset
miglitol	Miglitol

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Generic Name	Brand Name
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

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Generic Name	Brand Name
mecamylamine hcl	Vecamyl
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

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Generic Name	Brand Name
Medications that Increase Bleeding Risk Without Interaction with Warfarin or Novel Oral Anti-Coagulants (NOACs)	
Antiplatelet Agents	
abciximab	Reopro
anagrelide hcl	Anagrelide
anagrelide hcl	Agrylin
aspirin	Durlaza
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

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Generic Name	Brand Name
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
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)

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

Generic Name	Brand Name
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
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)

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

Generic Name	Brand Name
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
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
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

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

Generic Name	Brand Name
diclofenac sodium	Voltaren
diclofenac sodium/capsaicin	Flexipak
diclofenac sodium/capsaicin	Nudiclo TabPAK
diclofenac sodium/capsicum oleoresin	Inflammacin
diclofenac sodium/capsicum oleoresin	Dermasilkrx DicloPAK
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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 Anti-Coagulants (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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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
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 Anti-Coagulants (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

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

Generic Name	Brand Name
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
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

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

Generic Name	Brand Name
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 Anti-Coagulant (High Dose)	
See Appendix B for generic and brand medical product names for NOACs.	

Appendix K. Specifications Defining Parameters Used in this Request

The request executed the Cohort Identification and Descriptive Analysis (CIDA) tool to perform a risk assessment of serious uterine bleeding (SUB) among users of oral anticoagulants (rivaroxaban vs. dabigatran, rivaroxaban vs. apixaban, dabigatran vs. apixaban, rivaroxaban vs. warfarin).

Query Period: October 19, 2010 to Septemer 30, 2015
Coverage Requirement: Medical and Drug
Pre-exposure Enrollment: 183 days
Post-index enrollment requirement: 0 day
Enrollment Gap: 45 days
Sex: Female
Stratifications Age: 00-49; 50+ years
Index-defining Novel Oral Anticoagulant (NOAC) Dose: low; high
Any gynecological disorder: see Appendix L
Age*dose: <50, low; <50, high; 50+, low; 50+, high
Return: Aggregate-level, index code distribution, censoring table
Envelope Macro Use: On
Frozen Data: Yes
Notes: Default stockpiling specifications will be used; stockpiling will be done by generic name only

	Drug/Exposure								
Comparison	**Exposure**	**Exposure Episode Truncation Criteria**	**Incident with respect to:**	**Washout (days)**	**Cohort Definition**	**Exposure Episode Gap (Days)**	**Exposure Extension Period (Days)**	**Minimum Episode Duration (Days)**	**Minimum Days Supplied**
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							

Appendix K. Specifications Defining Parameters Used in this Request

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

Appendix K. Specifications Defining Parameters Used in this Request

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

Appendix K. Specifications Defining Parameters Used in this Request

	Inclusion/Exclusion Criteria				Event/Outcome				
Comparison	Conditions	Include or Exclude	Care Setting/ Diagnosis Position	Lookback Period	Event/Outcome[1]	Event Time	Care Setting/ Diagnosis Position	Event Washout (days)	Blackout Period
1	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see Appendix F and Appendix M, Figure 2)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Apixaban, edoxaban, warfarin	Exclusion	NA	(0, 0)					
2	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see Appendix F and Appendix M, Figure 2)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Dabigatran, edoxaban, warfarin	Exclusion	NA	(0, 0)					
3	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see Appendix F and Appendix M, Figure 2)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Rivaroxaban, edoxaban, warfarin	Exclusion	NA	(0, 0)					

Appendix K. Specifications Defining Parameters Used in this Request

	Inclusion/Exclusion Criteria				Event/Outcome				
Comparison	Conditions	Include or Exclude	Care Setting/ Diagnosis Position	Lookback Period	Event/Outcome[1]	Event Time	Care Setting/ Diagnosis Position	Event Washout (days)	Blackout Period
4	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Surgical Management Outcome (see Appendix F and Appendix M, Figure 2)	Surgery Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (VB); surgical management for Severe Uterine Bleed (SUB); medical managements for SUB	Exclusion	Any	(-183, 0)					
	Dabigatran, apixaban, edoxaban	Exclusion	NA	(0, 0)					
5	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see Appendix F and Appendix M, Figure 1)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (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	NA	(0, 0)					
6	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see Appendix F and Appendix M, Figure 1)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (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	NA	(0, 0)					

Appendix K. Specifications Defining Parameters Used in this Request

	Inclusion/Exclusion Criteria				Event/Outcome				
Comparison	Conditions	Include or Exclude	Care Setting/ Diagnosis Position	Lookback Period	Event/Outcome[1]	Event Time	Care Setting/ Diagnosis Position	Event Washout (days)	Blackout Period
7	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see Appendix F and Appendix M, Figure 1)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (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	NA	(0, 0)					
8	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter; joint replacement surgery (knee or hip)	Inclusion	Any	(-183, 0)	Transfusion Management Outcome (see Appendix F and Appendix M, Figure 1)	Transfusion Date	IP*, ED*, AV*, or OA*	0	0
	Hysterectomy; vaginal bleeding (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	NA	(0, 0)					

Appendix K. Specifications Defining Parameters Used in this Request

	Baseline Covariates				Propensity Score Analysis				
Comparison	Covariates	Care Setting/ Diagnosis Position	Covariate evaluation window (days)	Comorbidity Score evaluation window (days)	Perform HDPS Analysis	Matching Ratio	Matching Caliper Settings	Subgroup	Matching reperformed within subgroups
1	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Index-Defining NOAC Dose (low; high) Age*Dose (<50, low; <50, high; 50+, low; 50+, high) Gynecological disorders (Yes; No)	Test: Matched population Use for final analysis
2	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Index-Defining NOAC Dose (low; high) Age*Dose (<50, low; <50, high; 50+, low; 50+, high) Gynecological disorders (Yes; No)	Matched population
3	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Index-Defining NOAC Dose (low; high) Age*Dose (<50, low; <50, high; 50+, low; 50+, high) Gynecological disorders (Yes; No)	Matched population

Appendix K. Specifications Defining Parameters Used in this Request

	Baseline Covariates				PS Analysis				
Comparison	Covariates	Care Setting/ Diagnosis Position	Covariate evaluation window (days)	Comorbidity Score evaluation window (days)	Perform HDPS Analysis	Matching Ratio	Matching Caliper Settings	Subgroup	Matching reperformed within subgroups
4	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Gynecological disorders (Yes; No)	Matched population
5	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Index-Defining NOAC Dose (low; high) Age*Dose (<50, low; <50, high; 50+, low; 50+, high) Gynecological disorders (Yes; No)	Matched population
6	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Index-Defining NOAC Dose (low; high) Age*Dose (<50, low; <50, high; 50+, low; 50+, high) Gynecological disorders (Yes; No)	Matched population

Appendix K. Specifications Defining Parameters Used in this Request

	Baseline Covariates				PS Analysis				
Comparison	Covariates	Care Setting/ Diagnosis Position	Covariate evaluation window (days)	Comorbidity Score evaluation window (days)	Perform HDPS Analysis	Matching Ratio	Matching Caliper Settings	Subgroup	Matching reperformed within subgroups
7	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Index-Defining NOAC Dose (low; high) Age*Dose (<50, low; <50, high; 50+, low; 50+, high) Gynecological disorders (Yes; No)	Matched population
8	(See Appendix L tab)	(See Appendix L tab)	(-183, 0)	(-183, 0)	No	1:1	0.05	Age (00-49; 50+) Gynecological disorders (Yes; No)	Matched population

Appendix L. List and Definition of Covariates Appearing in Table 1, Propensity Score Model (PSM), or Subgroup Definition in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PSM Covariate	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	NA	(-183, 0)	N	N	N
	Non-statin lipid lowering agents	NA	(-183, 0)	N	N	N
	ACE inhibitors	NA	(-183, 0)	N	N	N
	Angiotensin receptor blockers	NA	(-183, 0)	N	N	N
	Anti-arrhythmic agents	NA	(-183, 0)	N	N	N
	Aldosterone receptor antagonists	NA	(-183, 0)	N	N	N
	Beta blockers	NA	(-183, 0)	N	N	N
	Calcium channel blockers	NA	(-183, 0)	N	N	N
	Diuretics	NA	(-183, 0)	N	N	N
	Other antihypertensives	NA	(-183, 0)	N	N	N
	Antianginal vasodilators	NA	(-183, 0)	N	N	N
	Oral antidiabetic agents	NA	(-183, 0)	N	N	N
	Insulin	NA	(-183, 0)	N	N	N
	All cardiovascular and antidiabetic agents	NA	(-183, 0)	Y	Y	N

Appendix L. List and Definition of Covariates Appearing in Table 1, Propensity Score Model (PSM), or Subgroup Definition in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PSM Covariate	Subgroup
Medications that increase bleeding risk without interaction with warfarin or NOACs	Aspirin	NA	(-183, 0)	N	N	N
	Antiplatelet agents	NA	(-183, 0)	N	N	N
	Prescription NSAIDs	NA	(-183, 0)	N	N	N
	COX-2 inhibitors	NA	(-183, 0)	N	N	N
	SSRIs	NA	(-183, 0)	N	N	N
	SNRIs	NA	(-183, 0)	N	N	N
	Heparin, low molecular weight heparin, fondaparinux	NA	(-183, 0)	N	N	N
	Cephalosporins	NA	(-183, 0)	N	N	N
	All medications that increase bleeding risk	NA	(-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)	NA	(-183, 0)	N	N	N
	Fibrates	NA	(-183, 0)	N	N	N
	Statins	NA	(-183, 0)	N	N	N
	Other medications that inhibit CYP3A4, P-gp, CYP2C9, or CYP1A2 (amiodarone, cimetidine, ciprofloxacin, clopidogrel, co-trimoxazole (trimethoprim), erythromycin, clarithromycin)	NA	(-183, 0)	N	N	N
	All medications listed on label as having clinically significant interactions with warfarin or NOACs (inhibitors and substrates)	NA	(-183, 0)	Y	Y	N
Medications that induce metabolism of warfarin or NOACs and decrease bleeding risk	CYP3A4 and P-gp inducers (rifampin, phenytoin, carbamazepine, omacetaxine)	NA	(-183, 0)	N	N	N
	CYP2C9 inducers (bosentan, phenobarbital)	NA	(-183, 0)	N	N	N
	CYP1A2 inducers (montelukast, omeprazole)	NA	(-183, 0)	N	N	N
	All medications listed on label as having clinically significant interactions with warfarin or NOACs (inducers)	NA	(-183, 0)	Y	Y	N

Appendix L. List and Definition of Covariates Appearing in Table 1, Propensity Score Model (PSM), or Subgroup Definition in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PSM Covariate	Subgroup
Severe anemia (RBC Transfusion)	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
Treatment dose	High dosage (rivaroxaban, apixaban)	NA	(0, 0)	Y	N	Y
	High dosage (rivaroxaban, dabigatran)	NA	(0, 0)	Y	N	Y
	High dosage (dabigatran, apixaban)	NA	(0, 0)	Y	N	Y
Demographics	Race/ethnicity	NA	NA	Y	N	N
	Continuous age	NA	NA	Y	Y	N
	Age groups <50 and 50+ years	NA	NA	Y	N	Y
	Calendar year	NA	NA	Y	N	N
Comorbidity	Comorbidity Score	NA	(-183, 0)	Y	Y	N
Health care / medical utilization	Number of inpatient hospital stays	NA	(-183, 0)	Y	Y	N
	Number of non-acute institutional stays	NA	(-183, 0)	Y	Y	N
	Number of emergency department visits	NA	(-183, 0)	Y	Y	N
	Number of ambulatory visits	NA	(-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)	NA	(-183, 0)	Y	Y	N
Drug utilization	Number of dispensings	NA	(-183, 0)	Y	Y	N
	Number of unique generics dispensed	NA	(-183, 0)	Y	Y	N
	Number of unique drug classes dispensed	NA	(-183, 0)	Y	Y	N

Appendix L. List and Definition of Covariates Appearing in Table 1, Propensity Score Model (PSM), or Subgroup Definition in this Request

Covariate	Group	Care Setting	Covariate Window	Table 1 Entry	PSM Covariate	Subgroup
Additional reporting	Vaginal bleed (VB)	IP*, ED*, AV*, or OA*	(1, end of enrollment)	Y	N	N
	Insertion of intrauterine system device	IP*, ED*, AV*, or OA*	(VB date, Severe Uterine Bleeding (SUB)/censoring)	N	N	N
	Initiation of contraception (combined oral contraceptives and progestin-only contraceptives)	NA	(VB date, SUB/censoring)	N	N	N
	Vaginal packing	IP*, ED*, AV*, or OA*	(VB date, SUB/censoring)	N	N	N
	Initiation of an antifibrinolytic drug (tranexamic acid, aminocaproic acid, aprotinin, desmopressin)	NA	(VB date, SUB/censoring)	N	N	N
	Any medical management	IP*, ED*, AV*, or OA*	(VB date, SUB/censoring)	N	N	N

*Inpatient Hospital Stay (IP), Emergency Department (ED), Ambulatory Visit (AV), Other Ambulatory Visit (OA)

Appendix M. Pictorial Summary of Outcome Assessment

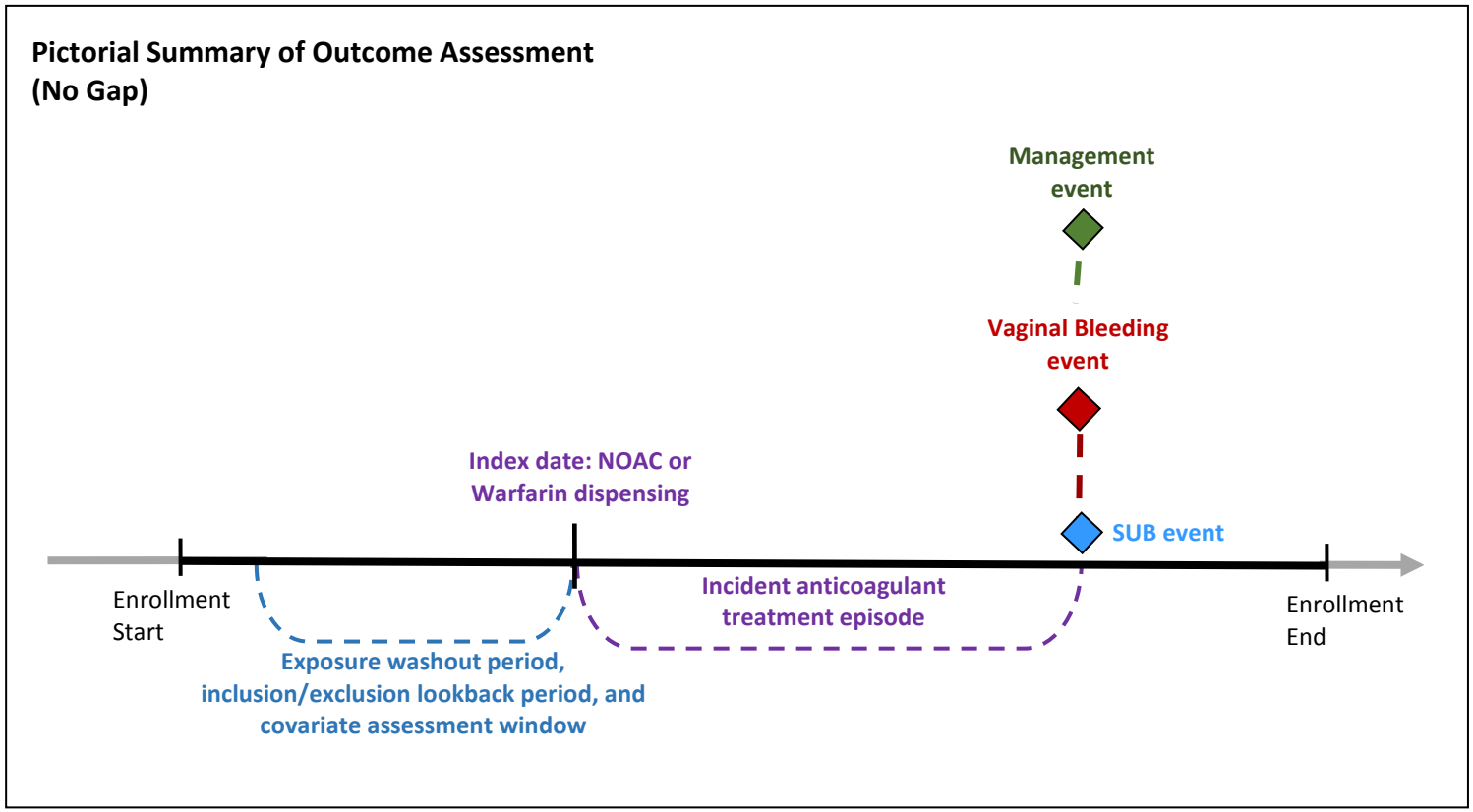
Note 1: The maximum allowable gap was 60 days.

Note 2: The exposure episode ended if one of the following occurs: 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) the outcome of interest; or 6) dispensing of any oral anti-coagulant that did not define the exposure of each respective cohort.

Note 3: Vaginal Bleeding event date was the date a patient was diagnosed with vaginal bleed. Tthe date of Severe Uterine Bleeding (SUB) was taken to be the date of the SUB management.

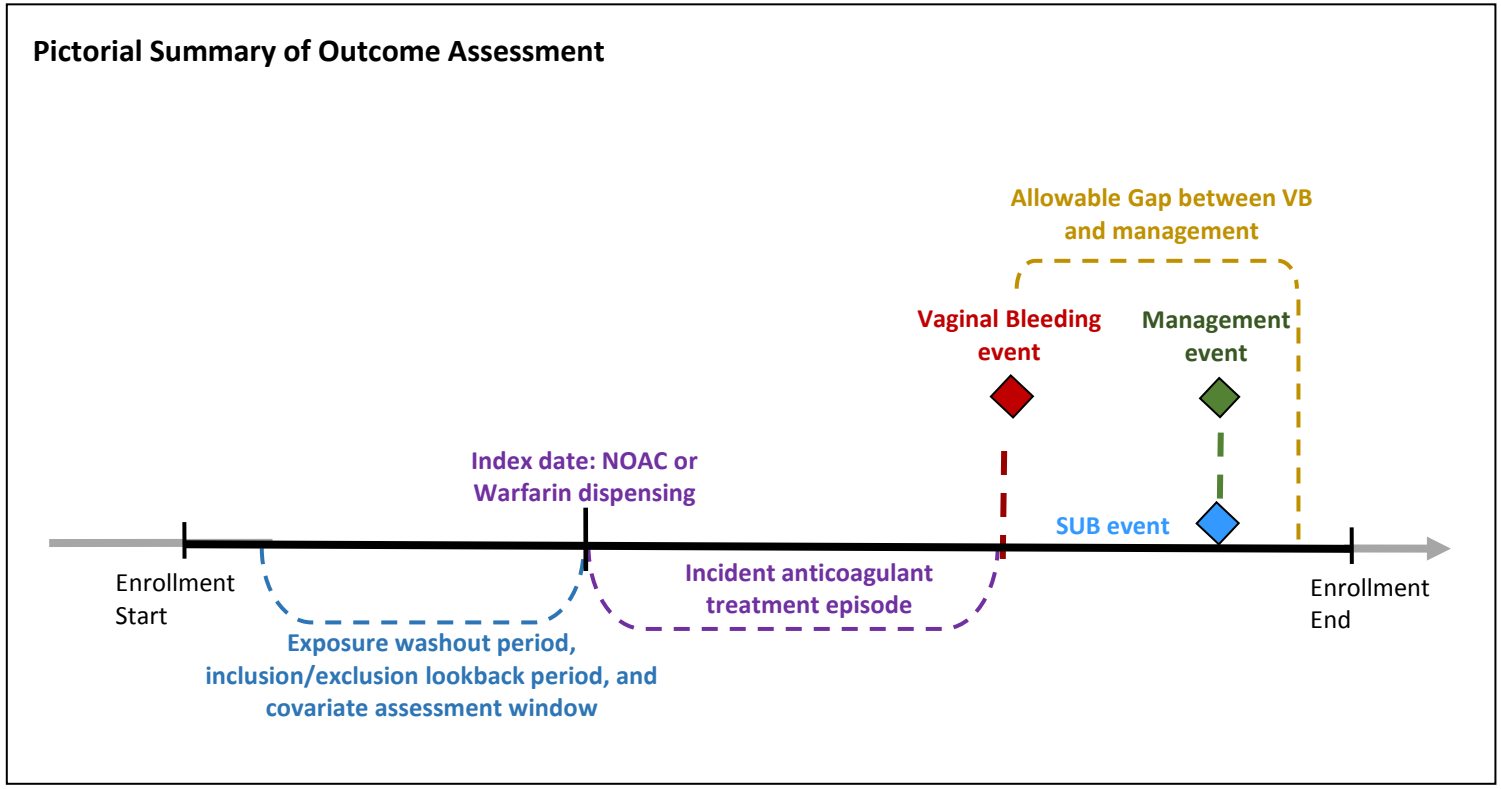
Note 4: SUB event date was taken as the date of health outcome of interest (HOI).

Figure 1.



Appendix M. Pictorial Summary of Outcome Assessment

Figure 2.



Appendix M. Pictorial Summary of Outcome Assessment

Figure 4

Post-Index Medical Management Window Definition with Surgical Management Severe Uterine Bleed Definition

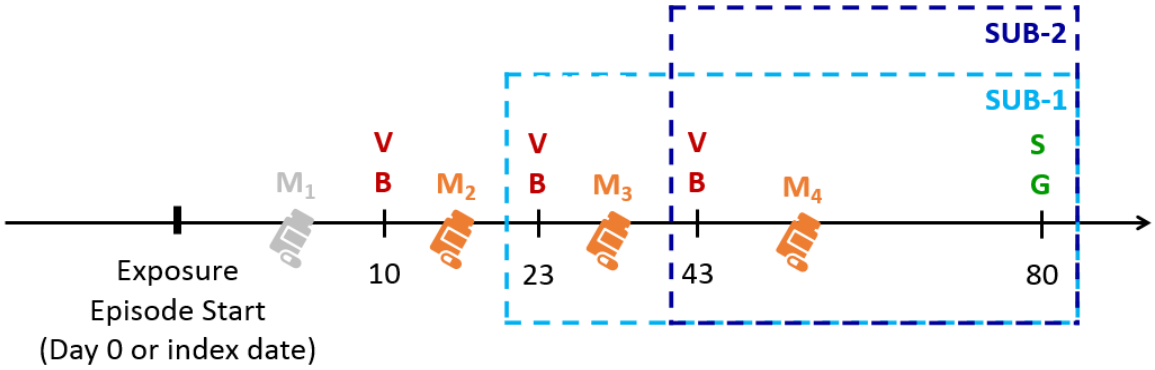
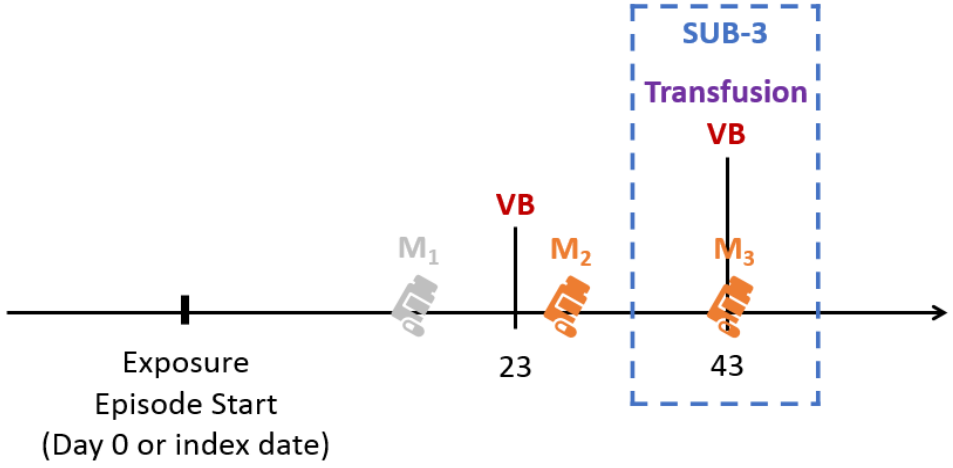


Figure 5

Post-Index Medical Management Window Definition with Transfusion Management Severe Uterine Bleed Definition



Appendix M. Pictorial Summary of Outcome Assessment

Figure 6

Post-Index Medical Management Window Definition without Severe Uterine Bleed