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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. If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelssystem.org.

Overview for Request cder_mpl2p_wp017

Request ID: cder_mpl2p_wp017

Request Description: In this report we compared risk of stroke, intracranial hemorrhage, and bleeding outcomes associated with use of dabigatran, rivaroxaban, and apixaban in those aged 65 years or older in the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) and Propensity Score Analysis tools, Version 8.0.3, with additional programming

Data Source: The study period spanned from October 19, 2010 to September 30, 2015. This request was distributed on December 20, 2019. See Appendix A for a list of the latest dates of available data for each Data Partner (DP).

Study Design: We identified individuals with incident use of dabigatran, rivaroxaban, or apixaban and evaluated the occurrence of thromboembolic stroke (stroke), intracranial hemorrhage (ICH), major extracranial bleeding (MEB), and GI bleeding (GIB) outcomes among patients aged 65 years or older. We then conducted a Propensity Score Analysis (PSA) comparing the three NOAC-NOAC comparisons (1:1 (Propensity Score (PS) matching). This study used a retrospective new-user cohort design. It is a Type 2 analysis using the Propensity Score Analysis module in the Query Request Package (QRP)

Exposure and Comparator: We defined exposures of interest as new use of standard dose rivaroxaban (20 mg once daily), dabigatran (150 mg twice daily), and apixaban (5 mg twice daily). The exposure drugs were defined using National Drug Codes (NDCs). For a list of generic names used to define the exposure and comparator drugs, please see Appendix B.

Outcomes of Interest: We defined the following outcomes of interest:

1. MEB was defined as one ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification) diagnosis code from "Major Extracranial Bleeding - List 1"(Appendix C) as primary diagnosis from inpatient encounter AND no code from "Major Extracranial Bleeding - List 3" OR (one ICD-9-CM diagnosis code from "Major Extracranial Bleeding - List 2" (Appendix C) as primary diagnosis from inpatient encounter AND one ICD-9-CM diagnosis code from "Major Extracranial Bleeding - List 1" as secondary or unspecified diagnosis from inpatient encounter on the same day AND no code from "Major Extracranial Bleeding - List 3").
2. GIB was defined as one ICD-9-CM diagnosis code from "Gastrointestinal Bleeding - List 1"(Appendix C) as primary diagnosis from inpatient encounter OR (one ICD-9-CM diagnosis code from "Gastrointestinal Bleeding - List 2" (Appendix C) as primary diagnosis from inpatient encounter AND one ICD-9-CM diagnosis code from "Gastrointestinal Bleeding - List 1" as secondary or unspecified diagnosis from inpatient encounter on the same day).
3. ICH and stroke were defined using ICD-9-CM diagnosis codes flagged as a primary diagnosis in an inpatient encounter.

Patients were excluded from the analysis if they had evidence of the outcome on the day of exposure initiation or in the 183 days preceding exposure initiation. For a list of diagnosis codes used to define the outcomes, please see Appendix C.

Cohort Eligibility Criteria: We required patients aged 65 years or older to be enrolled in plans with both medical and drug coverage for at least 183 days before index dispensing, during which gaps in coverage of up to 45 days were allowed and treated as continuous enrollment. New use was defined as no use of apixaban, dabigatran, edoxaban, rivaroxaban, or warfarin in the 183 days period preceding the index dispensing. We included patients with evidence of atrial fibrillation in the 183 days preceding and including index date. We excluded patients from the cohort if they had evidence of dialysis, kidney replacement, deep vein thrombosis, pulmonary embolism, joint replacement, mitral stenosis, valve replacement or valve repair in the 183 days prior to and including the index date. Dialysis was only assessed in outpatient care settings. Additionally, we excluded patients from the analysis if they had evidence of any other NOAC or an institutional stay encounter on their index date. Inclusion and exclusion criteria were defined using NDCs, ICD-9-CM, and Current Procedural Terminology, Fourth Edition (CPT-4) codes. For a list of specific codes used to define cohort eligibility, please see Appendices D-E.

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Follow-up: We determined follow-up time based on the length of the exposure episodes and censored on prespecified criteria. We created exposure episodes using outpatient pharmacy dispensing data. We bridged together exposure episodes less than three days apart and added three days at the end of each exposure episodes to create continuous treatment episodes. Overlapping days supply of two dispensings were stockpiled up to 33% of the first dispensings days supply. We censored all exposure episodes upon initiation of any other NOAC, low dose of the index NOAC, warfarin or edoxaban dispensing, kidney transplant, dialysis, institutional stay encounter, major extracranial bleed, gastrointestinal bleed, intracranial hemorrhage, or ischemic stroke. Follow-up began on the day after exposure initiation and continued until the first occurrence of any of the following: 1) outcome occurrence; 2) requester-defined censoring criteria; 3) disenrollment; 4) recorded death; 5) end of exposure episode; 6) end of query period; or 7) end of available data. Only the first valid exposure episode that occurred during the study period was included per patient. Please see Appendices D and F for a list of codes used to define censoring criteria.

Baseline Covariates: Please refer to Appendices G-J for a list of covariates, codes, and evaluation windows used to defined covariates.

Propensity Score Estimation: For each of the three NOAC NOAC comparison, we fit a logistic regression model separately for each of the four outcomes (stroke, MEB, GIB, ICH) to estimate the propensity score (PS) based on potential confounders outlined in Appendix J. The matching ratio for the PS was 1:1 and the matching caliper was 0.05. Patients in the exposed and comparator cohorts were nearest neighbor matched without replacement, meaning that each comparator patient was matched one time, at most, to an exposed patient. For each comparison, we used Cox proportional hazards regression model to estimate the adjusted hazard ratio and 95% confidence intervals for the unmatched analyses and unconditional and conditional matched analyses. Subgroup analyses for effect estimation included prior antiplatelet use in 183 days, age categories, sex, CHA₂DS₂-VAsC and HAS-BLED score categories

See Appendices I and J for complete specifications for this request.

Limitations: As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. Algorithms used to define exposures, outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying

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<u>Figure 7c</u>	Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort
<u>Figure 7d</u>	Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort
<u>Figure 7e</u>	Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort
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**Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Module***

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

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

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

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

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

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

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

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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

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

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

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

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

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

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

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

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

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

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

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

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

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

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

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

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

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*all terms may not be used in this report

Table 1a. Baseline Characteristics of New Users of Rivaroxaban and Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

Characteristic ¹	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
Patients (N)	110,113	100.0%	84,473	100.0%	-	-
Demographics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean age (years)	75.5	6.4	76.1	6.6	-0.590	-0.091
Age (years)	Number	Percent	Number	Percent		
65-74	56,862	51.6%	40,695	48.2%	3.465	0.069
75-85	43,527	39.5%	34,508	40.9%	-1.322	-0.027
85+	9,724	8.8%	9,270	11.0%	-2.143	-0.072
Sex						
Female	51,156	46.5%	40,824	48.3%	-1.870	-0.037
Male	58,957	53.5%	43,649	51.7%	1.870	0.037
Race ²						
American Indian or Alaska Native	315	0.3%	224	0.3%	0.021	0.004
Asian	1,440	1.3%	1,361	1.6%	-0.303	-0.025
Black or African American	3,949	3.6%	2,992	3.5%	0.044	0.002
Unknown	3,394	3.1%	2,459	2.9%	0.171	0.010
White	101,015	91.7%	77,437	91.7%	0.067	0.002
Hispanic Origin	1,305	1.2%	1,116	1.3%	-0.136	-0.012
Year						
2010	-	0.0%	1,270	1.5%	-1.503	-
2011	149	0.1%	31,776	37.6%	-37.481	-1.091
2012	13,749	12.5%	23,083	27.3%	-14.840	-0.378
2013	31,382	28.5%	13,927	16.5%	12.013	0.291
2014	38,641	35.1%	9,432	11.2%	23.926	0.592
2015	26,192	23.8%	4,985	5.9%	17.885	0.520
CHA ₂ DS ₂ -VASc						
mean, standard deviation	3.8	1.5	3.9	1.5	-0.103	-0.067
0-1	3,766	3.4%	2,768	3.3%	0.143	0.008
2	18,605	16.9%	12,943	15.3%	1.574	0.043
3	27,766	25.2%	19,794	23.4%	1.784	0.042
4	26,827	24.4%	21,631	25.6%	-1.244	-0.029
5	17,526	15.9%	13,980	16.5%	-0.633	-0.017
>= 6	15,623	14.2%	13,357	15.8%	-1.624	-0.045
HAS-BLED						
mean, standard deviation	2.5	0.9	2.5	0.9	-0.031	-0.034
0-1	10,726	9.7%	7,779	9.2%	0.532	0.018
2	50,401	45.8%	37,972	45.0%	0.820	0.016
3	34,578	31.4%	26,850	31.8%	-0.383	-0.008
>= 4	14,408	13.1%	11,872	14.1%	-0.969	-0.028

Table 1a. Baseline Characteristics of New Users of Rivaroxaban and Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

Recorded History of:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Acute myocardial infarction - Past 0-30 days	1,613	1.5%	1,003	1.2%	0.277	0.024
Acute myocardial infarction - Past 31-183 days	880	0.8%	692	0.8%	-0.020	-0.002
Cardioablation	2,335	2.1%	1,906	2.3%	-0.136	-0.009
Cardioversion	10,129	9.2%	8,099	9.6%	-0.389	-0.013
Coronary revascularization	16,265	14.8%	12,495	14.8%	-0.021	-0.001
Diabetes	35,515	32.3%	28,371	33.6%	-1.333	-0.028
Falls	5,260	4.8%	3,880	4.6%	0.184	0.009
Fractures	1,478	1.3%	1,132	1.3%	0.002	0.000
Heart failure - hospitalized	5,424	4.9%	4,314	5.1%	-0.181	-0.008
Heart failure - outpatient	24,279	22.0%	20,499	24.3%	-2.218	-0.053
Hypercholesterolemia	41,671	37.8%	33,068	39.1%	-1.302	-0.027
Hypertension	94,768	86.1%	73,079	86.5%	-0.447	-0.013
Kidney failure - acute	5,253	4.8%	3,746	4.4%	0.336	0.016
Kidney failure - chronic	9,705	8.8%	8,332	9.9%	-1.050	-0.036
Nicotine dependency	24,121	21.9%	14,997	17.8%	4.152	0.104
Obesity	18,102	16.4%	11,356	13.4%	2.996	0.084
Other ischemic heart disease	48,516	44.1%	38,603	45.7%	-1.638	-0.033
Peptic ulcer disease	411	0.4%	330	0.4%	-0.017	-0.003
Prior hospitalized bleeding	723	0.7%	575	0.7%	-0.024	-0.003
Stroke - past 0-30 days	1,822	1.7%	1,440	1.7%	-0.050	-0.004
Stroke - past 31-183 days	1,343	1.2%	1,190	1.4%	-0.189	-0.017
Syncope	9,786	8.9%	7,432	8.8%	0.089	0.003
Transient ischemic attack	6,700	6.1%	5,568	6.6%	-0.507	-0.021
Walker use	-	0.0%	-	0.0%	0.000	-
History of Use:						
Angiotensin-converting enzyme Inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	65,128	59.1%	50,576	59.9%	-0.726	-0.015
Amiodarone	11,559	10.5%	9,241	10.9%	-0.442	-0.014
Anti-coagulant (injectable)	9,899	9.0%	5,989	7.1%	1.900	0.070
Antiarrhythmics	14,689	13.3%	11,523	13.6%	-0.301	-0.009
Antiplatelets	16,045	14.6%	13,071	15.5%	-0.902	-0.025
Beta blockers	78,479	71.3%	59,939	71.0%	0.315	0.007
Calcium channel blockers	46,764	42.5%	36,204	42.9%	-0.390	-0.008
Digoxin	11,910	10.8%	12,618	14.9%	-4.121	-0.123
Diuretics - loop	25,291	23.0%	21,867	25.9%	-2.918	-0.068
Diuretics - potassium sparing	8,643	7.8%	7,291	8.6%	-0.782	-0.028
Diuretics - thiazide	31,394	28.5%	24,717	29.3%	-0.750	-0.017
Dronedarone	4,259	3.9%	4,709	5.6%	-1.707	-0.081
Estrogen	2,355	2.1%	2,002	2.4%	-0.231	-0.016
Fibrates	4,722	4.3%	3,986	4.7%	-0.430	-0.021

Table 1a. Baseline Characteristics of New Users of Rivaroxaban and Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

History of Use:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
H2-antagonist	5,884	5.3%	4,695	5.6%	-0.214	-0.009
Insulin	6,713	6.1%	5,398	6.4%	-0.294	-0.012
Metformin	17,078	15.5%	12,838	15.2%	0.312	0.009
Nonsteroidal anti-inflammatory drugs (NSAIDs)	16,862	15.3%	12,756	15.1%	0.213	0.006
Nitrates	9,958	9.0%	8,477	10.0%	-0.992	-0.034
Other diabetes medications	6,475	5.9%	5,383	6.4%	-0.492	-0.021
Proton pump inhibitors	30,707	27.9%	22,673	26.8%	1.046	0.023
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	14,878	13.5%	11,401	13.5%	0.015	0.000
Statins	64,665	58.7%	49,288	58.3%	0.378	0.008
Sulfonyureas	9,195	8.4%	7,940	9.4%	-1.049	-0.037
Health Service Utilization Intensity:						
Mean number of ambulatory encounters	12.2	9.1	12.4	9.4	-0.185	-0.020
Mean number of emergency room encounters	0.4	0.8	0.3	0.7	0.043	0.057
Mean number of inpatient hospital encounters	0.5	0.7	0.5	0.7	-0.010	-0.013
Mean number of generics	9.6	4.8	9.7	4.8	-0.072	-0.015

¹Covariates in blue show a standardized difference greater than 0.1.

²Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1b. Baseline Characteristics of New Users of Rivaroxaban and Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

Characteristic ¹	Medical Product				Covariate Balance	
	Rivaroxaban		Dabigatran		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
Patients (N)	82,326	74.8%	82,326	97.5%	-	-
Demographics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean age (years)	76.0	6.5	76.0	6.6	-0.008	-0.001
Age (years)	Number	Percent	Number	Percent		
65-74	39,956	48.5%	40,092	48.7%	-0.165	-0.003
75-85	33,965	41.3%	33,438	40.6%	0.640	0.013
85+	8,405	10.2%	8,796	10.7%	-0.475	-0.016
Sex						
Female	39,426	47.9%	39,491	48.0%	-0.079	-0.002
Male	42,900	52.1%	42,835	52.0%	0.079	0.002
Race ²						
American Indian or Alaska Native	228	0.3%	219	0.3%	0.011	0.002
Asian	1,270	1.5%	1,270	1.5%	0.000	0.000
Black or African American	2,922	3.5%	2,911	3.5%	0.013	0.001
Unknown	2,421	2.9%	2,414	2.9%	0.009	0.001
White	75,485	91.7%	75,512	91.7%	-0.033	-0.001
Hispanic Origin	997	1.2%	1,092	1.3%	-0.115	-0.010
Year						
2010	-	0.0%	1,212	1.5%	-1.472	-
2011	120	0.1%	30,687	37.3%	-37.129	-1.083
2012	10,857	13.2%	22,532	27.4%	-14.181	-0.358
2013	23,986	29.1%	13,682	16.6%	12.516	0.301
2014	28,507	34.6%	9,299	11.3%	23.332	0.577
2015	18,856	22.9%	4,914	6.0%	16.935	0.496
CHA ₂ DS ₂ -VASc						
mean, standard deviation	3.9	1.5	3.9	1.5	0.006	0.004
0-1	2,743	3.3%	2,740	3.3%	0.004	0.000
2	12,769	15.5%	12,831	15.6%	-0.075	-0.002
3	19,566	23.8%	19,585	23.8%	-0.023	-0.001
4	20,955	25.5%	20,996	25.5%	-0.050	-0.001
5	13,590	16.5%	13,506	16.4%	0.102	0.003
>= 6	12,703	15.4%	12,668	15.4%	0.043	0.001
HAS-BLED						
mean, standard deviation	2.5	0.9	2.5	0.9	0.003	0.003
0-1	7,628	9.3%	7,676	9.3%	-0.058	-0.002
2	37,237	45.2%	37,279	45.3%	-0.051	-0.001
3	26,118	31.7%	26,065	31.7%	0.064	0.001
>= 4	11,343	13.8%	11,306	13.7%	0.045	0.001

Table 1b. Baseline Characteristics of New Users of Rivaroxaban and Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

Recorded History of:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Acute myocardial infarction - Past 0-30 days	1,028	1.2%	993	1.2%	0.043	0.004
Acute myocardial infarction - Past 31-183 days	678	0.8%	664	0.8%	0.017	0.002
Cardioablation	1,826	2.2%	1,811	2.2%	0.018	0.001
Cardioversion	7,813	9.5%	7,756	9.4%	0.069	0.002
Coronary revascularization	12,215	14.8%	12,080	14.7%	0.164	0.005
Diabetes	27,451	33.3%	27,349	33.2%	0.124	0.003
Falls	3,816	4.6%	3,784	4.6%	0.039	0.002
Fractures	1,085	1.3%	1,103	1.3%	-0.022	-0.002
Heart failure - hospitalized	4,115	5.0%	4,119	5.0%	-0.005	-0.000
Heart failure - outpatient	19,514	23.7%	19,400	23.6%	0.138	0.003
Hypercholesterolemia	32,178	39.1%	32,046	38.9%	0.160	0.003
Hypertension	71,170	86.4%	71,130	86.4%	0.049	0.001
Kidney failure - acute	3,676	4.5%	3,643	4.4%	0.040	0.002
Kidney failure - chronic	7,906	9.6%	7,842	9.5%	0.078	0.003
Nicotine dependency	14,980	18.2%	14,889	18.1%	0.111	0.003
Obesity	11,335	13.8%	11,285	13.7%	0.061	0.002
Other ischemic heart disease	37,440	45.5%	37,291	45.3%	0.181	0.004
Peptic ulcer disease	309	0.4%	314	0.4%	-0.006	-0.001
Prior hospitalized bleeding	551	0.7%	542	0.7%	0.011	0.001
Stroke - past 0-30 days	1,415	1.7%	1,394	1.7%	0.026	0.002
Stroke - past 31-183 days	1,121	1.4%	1,119	1.4%	0.002	0.000
Syncope	7,168	8.7%	7,197	8.7%	-0.035	-0.001
Transient ischemic attack	5,308	6.4%	5,331	6.5%	-0.028	-0.001
Walker use	-	0.0%	-	0.0%	0.000	-
History of Use:						
Angiotensin-converting enzyme Inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	49,201	59.8%	49,093	59.6%	0.131	0.003
Amiodarone	8,938	10.9%	8,934	10.9%	0.005	0.000
Anti-coagulant (injectable)	5,963	7.2%	5,931	7.2%	0.039	0.002
Antiarrhythmics	11,294	13.7%	11,204	13.6%	0.109	0.003
Antiplatelets	12,540	15.2%	12,506	15.2%	0.041	0.001
Beta blockers	58,429	71.0%	58,347	70.9%	0.100	0.002
Calcium channel blockers	35,304	42.9%	35,230	42.8%	0.090	0.002
Digoxin	11,113	13.5%	11,198	13.6%	-0.103	-0.003
Diuretics - loop	20,847	25.3%	20,652	25.1%	0.237	0.005
Diuretics - potassium sparing	6,935	8.4%	6,972	8.5%	-0.045	-0.002
Diuretics - thiazide	24,015	29.2%	23,965	29.1%	0.061	0.001
Dronedarone	4,048	4.9%	4,057	4.9%	-0.011	-0.001
Estrogen	1,905	2.3%	1,917	2.3%	-0.015	-0.001
Fibrates	3,804	4.6%	3,802	4.6%	0.002	0.000

Table 1b. Baseline Characteristics of New Users of Rivaroxaban and Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

History of Use:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
H2-antagonist	4,523	5.5%	4,513	5.5%	0.012	0.001
Insulin	5,227	6.3%	5,172	6.3%	0.067	0.003
Metformin	12,585	15.3%	12,536	15.2%	0.060	0.002
Nonsteroidal anti-inflammatory drugs (NSAIDs)	12,496	15.2%	12,458	15.1%	0.046	0.001
Nitrates	8,077	9.8%	8,031	9.8%	0.056	0.002
Other diabetes medications	5,153	6.3%	5,153	6.3%	0.000	0.000
Proton pump inhibitors	22,193	27.0%	22,145	26.9%	0.058	0.001
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	11,145	13.5%	11,074	13.5%	0.086	0.003
Statins	48,075	58.4%	48,058	58.4%	0.021	0.000
Sulfonyureas	7,569	9.2%	7,551	9.2%	0.022	0.001
Health Service Utilization Intensity:						
Mean number of ambulatory encounters	12.4	9.2	12.4	9.4	-0.003	-0.000
Mean number of emergency room encounters	0.3	0.7	0.3	0.7	0.003	0.004
Mean number of inpatient hospital encounters	0.5	0.7	0.5	0.7	0.004	0.005
Mean number of generics	9.7	4.8	9.7	4.8	0.015	0.003

¹Covariates in blue show a standardized difference greater than 0.1.

²Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1c. Baseline Characteristics of New Users of Rivaroxaban and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

Characteristic ¹	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
Patients (N)	111,816	100.0%	77,232	100.0%	-	-
Demographics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean age (years)	75.5	6.4	75.7	6.4	-0.288	-0.045
Age (years)	Number	Percent	Number	Percent		
65-74	57,787	51.7%	38,032	49.2%	2.437	0.049
75-85	44,196	39.5%	31,939	41.4%	-1.829	-0.037
85+	9,833	8.8%	7,261	9.4%	-0.608	-0.021
Sex						
Female	51,897	46.4%	37,128	48.1%	-1.660	-0.033
Male	59,919	53.6%	40,104	51.9%	1.660	0.033
Race ²						
American Indian or Alaska Native	323	0.3%	159	0.2%	0.083	0.017
Asian	1,478	1.3%	785	1.0%	0.305	0.028
Black or African American	3,992	3.6%	2,889	3.7%	-0.171	-0.009
Unknown	3,439	3.1%	2,067	2.7%	0.399	0.024
White	102,584	91.7%	71,332	92.4%	-0.617	-0.023
Hispanic Origin	1,323	1.2%	689	0.9%	0.291	0.029
Year						
2010	-	0.0%	-	0.0%	0.000	-
2011	151	0.1%	-	0.0%	0.135	-
2012	13,984	12.5%	-	0.0%	12.506	-
2013	31,948	28.6%	8,722	11.3%	17.279	0.443
2014	39,225	35.1%	30,570	39.6%	-4.502	-0.093
2015	26,508	23.7%	37,940	49.1%	-25.418	-0.548
CHA ₂ DS ₂ -VASc						
mean, standard deviation	3.8	1.5	4.0	1.6	-0.147	-0.096
0-1	3,845	3.4%	2,079	2.7%	0.747	0.043
2	18,983	17.0%	11,656	15.1%	1.885	0.051
3	28,194	25.2%	18,753	24.3%	0.933	0.022
4	27,248	24.4%	18,872	24.4%	-0.067	-0.002
5	17,765	15.9%	13,134	17.0%	-1.118	-0.030
>= 6	15,781	14.1%	12,738	16.5%	-2.380	-0.066
HAS-BLED						
mean, standard deviation	2.5	0.9	2.6	0.9	-0.095	-0.104
0-1	10,937	9.8%	6,486	8.4%	1.383	0.048
2	51,220	45.8%	33,272	43.1%	2.727	0.055
3	35,069	31.4%	25,062	32.5%	-1.087	-0.023
>= 4	14,590	13.0%	12,412	16.1%	-3.023	-0.086

Table 1c. Baseline Characteristics of New Users of Rivaroxaban and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

Recorded History of:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Acute myocardial infarction - Past 0-30 days	1,618	1.4%	1,161	1.5%	-0.056	-0.005
Acute myocardial infarction - Past 31-183 days	886	0.8%	857	1.1%	-0.317	-0.033
Cardioablation	2,384	2.1%	1,870	2.4%	-0.289	-0.019
Cardioversion	10,318	9.2%	8,207	10.6%	-1.399	-0.047
Coronary revascularization	16,459	14.7%	12,836	16.6%	-1.900	-0.052
Diabetes	35,981	32.2%	26,403	34.2%	-2.008	-0.043
Falls	5,335	4.8%	3,750	4.9%	-0.084	-0.004
Fractures	1,497	1.3%	993	1.3%	0.053	0.005
Heart failure - hospitalized	5,481	4.9%	4,542	5.9%	-0.979	-0.043
Heart failure - outpatient	24,600	22.0%	19,092	24.7%	-2.720	-0.064
Hypercholesterolemia	42,317	37.8%	29,286	37.9%	-0.074	-0.002
Hypertension	96,188	86.0%	67,758	87.7%	-1.710	-0.051
Kidney failure - acute	5,305	4.7%	5,444	7.0%	-2.304	-0.098
Kidney failure - chronic	9,834	8.8%	10,601	13.7%	-4.931	-0.156
Nicotine dependency	24,353	21.8%	18,443	23.9%	-2.100	-0.050
Obesity	18,301	16.4%	14,307	18.5%	-2.158	-0.057
Other ischemic heart disease	49,247	44.0%	36,549	47.3%	-3.281	-0.066
Peptic ulcer disease	415	0.4%	348	0.5%	-0.079	-0.012
Prior hospitalized bleeding	733	0.7%	573	0.7%	-0.086	-0.010
Stroke - past 0-30 days	1,843	1.6%	1,376	1.8%	-0.133	-0.010
Stroke - past 31-183 days	1,356	1.2%	1,175	1.5%	-0.309	-0.027
Syncope	9,909	8.9%	7,455	9.7%	-0.791	-0.027
Transient ischemic attack	6,792	6.1%	5,150	6.7%	-0.594	-0.024
Walker use	-	0.0%	-	0.0%	0.000	-
History of Use:						
Angiotensin-converting enzyme Inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	66,064	59.1%	47,305	61.3%	-2.168	-0.044
Amiodarone	11,773	10.5%	8,833	11.4%	-0.908	-0.029
Anti-coagulant (injectable)	10,015	9.0%	7,554	9.8%	-0.824	-0.028
Antiarrhythmics	15,073	13.5%	11,047	14.3%	-0.823	-0.024
Antiplatelets	16,236	14.5%	12,584	16.3%	-1.773	-0.049
Beta blockers	79,641	71.2%	57,149	74.0%	-2.771	-0.062
Calcium channel blockers	47,420	42.4%	33,144	42.9%	-0.506	-0.010
Digoxin	12,136	10.9%	7,163	9.3%	1.579	0.052
Diuretics - loop	25,660	22.9%	20,390	26.4%	-3.453	-0.080
Diuretics - potassium sparing	8,791	7.9%	6,665	8.6%	-0.768	-0.028
Diuretics - thiazide	31,835	28.5%	22,310	28.9%	-0.416	-0.009
Dronedarone	4,398	3.9%	3,182	4.1%	-0.187	-0.010
Estrogen	2,389	2.1%	1,517	2.0%	0.172	0.012
Fibrates	4,790	4.3%	3,599	4.7%	-0.376	-0.018

Table 1c. Baseline Characteristics of New Users of Rivaroxaban and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

History of Use:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
H2-antagonist	5,962	5.3%	4,395	5.7%	-0.359	-0.016
Insulin	6,801	6.1%	5,762	7.5%	-1.378	-0.055
Metformin	17,291	15.5%	12,475	16.2%	-0.689	-0.019
Nonsteroidal anti-inflammatory drugs (NSAIDs)	17,082	15.3%	11,464	14.8%	0.433	0.012
Nitrates	10,074	9.0%	7,925	10.3%	-1.252	-0.042
Other diabetes medications	6,548	5.9%	4,996	6.5%	-0.613	-0.025
Proton pump inhibitors	31,180	27.9%	23,356	30.2%	-2.356	-0.052
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	15,111	13.5%	10,858	14.1%	-0.545	-0.016
Statins	65,614	58.7%	47,889	62.0%	-3.326	-0.068
Sulfonyureas	9,302	8.3%	6,818	8.8%	-0.509	-0.018
Health Service Utilization Intensity:						
Mean number of ambulatory encounters	12.2	9.1	13.0	9.3	-0.763	-0.083
Mean number of emergency room encounters	0.4	0.8	0.4	0.8	-0.022	-0.027
Mean number of inpatient hospital encounters	0.5	0.7	0.5	0.7	-0.007	-0.010
Mean number of generics	9.6	4.8	10.1	4.9	-0.451	-0.092

¹Covariates in blue show a standardized difference greater than 0.1.

²Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1d. Baseline Characteristics of New Users of Rivaroxaban and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

Characteristic ¹	Medical Product				Covariate Balance	
	Rivaroxaban		Apixaban		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
Patients (N)	75,889	67.9%	75,889	98.3%	-	-
Demographics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean age (years)	75.7	6.4	75.7	6.4	-0.018	-0.003
Age (years)	Number	Percent	Number	Percent		
65-74	37,958	50.0%	37,493	49.4%	0.613	0.012
75-85	30,797	40.6%	31,310	41.3%	-0.676	-0.014
85+	7,134	9.4%	7,086	9.3%	0.063	0.002
Sex						
Female	36,498	48.1%	36,424	48.0%	0.098	0.002
Male	39,391	51.9%	39,465	52.0%	-0.098	-0.002
Race ²						
American Indian or Alaska Native	166	0.2%	159	0.2%	0.009	0.002
Asian	815	1.1%	785	1.0%	0.040	0.004
Black or African American	2,775	3.7%	2,797	3.7%	-0.029	-0.002
Unknown	2,082	2.7%	2,053	2.7%	0.038	0.002
White	70,051	92.3%	70,095	92.4%	-0.058	-0.002
Hispanic Origin	847	1.1%	683	0.9%	0.216	0.022
Year						
2010	-	0.0%	-	0.0%	0.000	-
2011	101	0.1%	-	0.0%	0.133	-
2012	9,378	12.4%	-	0.0%	12.358	-
2013	21,524	28.4%	8,609	11.3%	17.018	0.437
2014	26,761	35.3%	30,064	39.6%	-4.352	-0.090
2015	18,125	23.9%	37,216	49.0%	-25.156	-0.541
CHA ₂ DS ₂ -VASc						
mean, standard deviation	3.9	1.5	3.9	1.5	-0.002	-0.001
0-1	2,074	2.7%	2,079	2.7%	-0.007	-0.000
2	11,647	15.3%	11,625	15.3%	0.029	0.001
3	18,587	24.5%	18,612	24.5%	-0.033	-0.001
4	18,652	24.6%	18,657	24.6%	-0.007	-0.000
5	12,749	16.8%	12,801	16.9%	-0.069	-0.002
>= 6	12,180	16.0%	12,115	16.0%	0.086	0.002
HAS-BLED						
mean, standard deviation	2.6	0.9	2.6	0.9	0.001	0.001
0-1	6,472	8.5%	6,485	8.5%	-0.017	-0.001
2	33,239	43.8%	33,236	43.8%	0.004	0.000
3	24,644	32.5%	24,651	32.5%	-0.009	-0.000
>= 4	11,534	15.2%	11,517	15.2%	0.022	0.001

Table 1d. Baseline Characteristics of New Users of Rivaroxaban and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

Recorded History of:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Acute myocardial infarction - Past 0-30 days	1,123	1.5%	1,134	1.5%	-0.014	-0.001
Acute myocardial infarction - Past 31-183 days	772	1.0%	768	1.0%	0.005	0.001
Cardioablation	1,813	2.4%	1,812	2.4%	0.001	0.000
Cardioversion	7,943	10.5%	7,902	10.4%	0.054	0.002
Coronary revascularization	12,400	16.3%	12,316	16.2%	0.111	0.003
Diabetes	25,669	33.8%	25,576	33.7%	0.123	0.003
Falls	3,708	4.9%	3,644	4.8%	0.084	0.004
Fractures	956	1.3%	977	1.3%	-0.028	-0.002
Heart failure - hospitalized	4,252	5.6%	4,233	5.6%	0.025	0.001
Heart failure - outpatient	18,343	24.2%	18,293	24.1%	0.066	0.002
Hypercholesterolemia	28,805	38.0%	28,754	37.9%	0.067	0.001
Hypertension	66,435	87.5%	66,444	87.6%	-0.012	-0.000
Kidney failure - acute	4,716	6.2%	4,731	6.2%	-0.020	-0.001
Kidney failure - chronic	9,308	12.3%	9,347	12.3%	-0.051	-0.002
Nicotine dependency	17,873	23.6%	17,852	23.5%	0.028	0.001
Obesity	13,739	18.1%	13,729	18.1%	0.013	0.000
Other ischemic heart disease	35,517	46.8%	35,550	46.8%	-0.043	-0.001
Peptic ulcer disease	336	0.4%	334	0.4%	0.003	0.000
Prior hospitalized bleeding	540	0.7%	545	0.7%	-0.007	-0.001
Stroke - past 0-30 days	1,353	1.8%	1,336	1.8%	0.022	0.002
Stroke - past 31-183 days	1,093	1.4%	1,121	1.5%	-0.037	-0.003
Syncope	7,267	9.6%	7,232	9.5%	0.046	0.002
Transient ischemic attack	4,984	6.6%	4,996	6.6%	-0.016	-0.001
Walker use	-	0.0%	-	0.0%	0.000	-
History of Use:						
Angiotensin-converting enzyme Inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	46,369	61.1%	46,276	61.0%	0.123	0.003
Amiodarone	8,519	11.2%	8,533	11.2%	-0.018	-0.001
Anti-coagulant (injectable)	7,338	9.7%	7,340	9.7%	-0.003	-0.000
Antiarrhythmics	10,952	14.4%	10,858	14.3%	0.124	0.004
Antiplatelets	12,164	16.0%	12,140	16.0%	0.032	0.001
Beta blockers	55,886	73.6%	55,967	73.7%	-0.107	-0.002
Calcium channel blockers	32,360	42.6%	32,440	42.7%	-0.105	-0.002
Digoxin	7,181	9.5%	7,116	9.4%	0.086	0.003
Diuretics - loop	19,503	25.7%	19,506	25.7%	-0.004	-0.000
Diuretics - potassium sparing	6,485	8.5%	6,440	8.5%	0.059	0.002
Diuretics - thiazide	21,901	28.9%	21,899	28.9%	0.003	0.000
Dronedarone	3,091	4.1%	3,113	4.1%	-0.029	-0.001
Estrogen	1,502	2.0%	1,503	2.0%	-0.001	-0.000
Fibrates	3,486	4.6%	3,474	4.6%	0.016	0.001

Table 1d. Baseline Characteristics of New Users of Rivaroxaban and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

History of Use:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
H2-antagonist	4,314	5.7%	4,280	5.6%	0.045	0.002
Insulin	5,380	7.1%	5,356	7.1%	0.032	0.001
Metformin	12,199	16.1%	12,191	16.1%	0.011	0.000
Nonsteroidal anti-inflammatory drugs (NSAIDs)	11,260	14.8%	11,283	14.9%	-0.030	-0.001
Nitrates	7,604	10.0%	7,586	10.0%	0.024	0.001
Other diabetes medications	4,849	6.4%	4,801	6.3%	0.063	0.003
Proton pump inhibitors	22,770	30.0%	22,696	29.9%	0.098	0.002
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	10,605	14.0%	10,624	14.0%	-0.025	-0.001
Statins	46,822	61.7%	46,778	61.6%	0.058	0.001
Sulfonyureas	6,614	8.7%	6,598	8.7%	0.021	0.001
Health Service Utilization Intensity:						
Mean number of ambulatory encounters	12.9	9.6	12.9	9.1	0.019	0.002
Mean number of emergency room encounters	0.4	0.8	0.4	0.8	0.001	0.002
Mean number of inpatient hospital encounters	0.5	0.7	0.5	0.7	-0.000	-0.000
Mean number of generics	10.0	4.9	10.0	4.9	0.005	0.001

¹Covariates in blue show a standardized difference greater than 0.1.

²Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1e. Baseline Characteristics of New Users of Dabigatran and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

Characteristic ¹	Medical Product				Covariate Balance	
	Dabigatran		Apixaban		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
Patients (N)	84,562	100.0%	76,887	100.0%	-	-
Demographics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean age (years)	76.0	6.6	75.7	6.4	0.303	0.047
Age (years)	Number	Percent	Number	Percent		
65-74	40,753	48.2%	37,862	49.2%	-1.051	-0.021
75-85	34,534	40.8%	31,785	41.3%	-0.501	-0.010
85+	9,275	11.0%	7,240	9.4%	1.552	0.051
Sex						
Female	40,869	48.3%	37,025	48.2%	0.175	0.004
Male	43,693	51.7%	39,862	51.8%	-0.175	-0.004
Race ²						
American Indian or Alaska Native	224	0.3%	156	0.2%	0.062	0.013
(Asian	1,363	1.6%	786	1.0%	0.590	0.052
Black or African American	2,997	3.5%	2,889	3.8%	-0.213	-0.011
Unknown	2,461	2.9%	2,068	2.7%	0.221	0.013
White	77,517	91.7%	70,988	92.3%	-0.659	-0.024
Hispanic Origin	1,116	1.3%	694	0.9%	0.417	0.040
Year						
2010	1,270	1.5%	-	0.0%	1.502	-
2011	31,776	37.6%	-	0.0%	37.577	-
2012	23,085	27.3%	-	0.0%	27.299	-
2013	13,943	16.5%	8,608	11.2%	5.293	0.154
2014	9,463	11.2%	30,302	39.4%	-28.220	-0.686
2015	5,025	5.9%	37,977	49.4%	-43.451	-1.111
CHA ₂ DS ₂ -VASc						
mean, standard deviation	3.9	1.5	4.0	1.6	-0.042	-0.027
0-1	2,775	3.3%	2,050	2.7%	0.615	0.036
2	12,962	15.3%	11,594	15.1%	0.249	0.007
3	19,816	23.4%	18,659	24.3%	-0.834	-0.020
4	21,646	25.6%	18,800	24.5%	1.146	0.026
5	13,991	16.5%	13,112	17.1%	-0.508	-0.014
>= 6	13,372	15.8%	12,672	16.5%	-0.668	-0.018
HAS-BLED						
mean, standard deviation	2.5	0.9	2.6	0.9	-0.064	-0.069
0-1	7,788	9.2%	6,455	8.4%	0.814	0.029
2	38,021	45.0%	33,078	43.0%	1.941	0.039
3	26,875	31.8%	24,997	32.5%	-0.730	-0.016
>= 4	11,878	14.0%	12,357	16.1%	-2.025	-0.057

Table 1e. Baseline Characteristics of New Users of Dabigatran and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

Recorded History of:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Acute myocardial infarction - Past 0-30 days	1,003	1.2%	1,164	1.5%	-0.328	-0.028
Acute myocardial infarction - Past 31-183 days	692	0.8%	857	1.1%	-0.296	-0.030
Cardioablation	1,910	2.3%	1,855	2.4%	-0.154	-0.010
Cardioversion	8,106	9.6%	8,173	10.6%	-1.044	-0.035
Coronary revascularization	12,512	14.8%	12,780	16.6%	-1.826	-0.050
Diabetes	28,398	33.6%	26,301	34.2%	-0.625	-0.013
Falls	3,888	4.6%	3,736	4.9%	-0.261	-0.012
Fractures	1,134	1.3%	992	1.3%	0.051	0.004
Heart failure - hospitalized	4,314	5.1%	4,537	5.9%	-0.799	-0.035
Heart failure - outpatient	20,515	24.3%	19,009	24.7%	-0.463	-0.011
Hypercholesterolemia	33,107	39.2%	29,176	37.9%	1.205	0.025
Hypertension	73,151	86.5%	67,467	87.7%	-1.242	-0.037
Kidney failure - acute	3,747	4.4%	5,426	7.1%	-2.626	-0.113
Kidney failure - chronic	8,336	9.9%	10,550	13.7%	-3.864	-0.120
Nicotine dependency	15,016	17.8%	18,412	23.9%	-6.189	-0.153
Obesity	11,364	13.4%	14,263	18.6%	-5.112	-0.140
Other ischemic heart disease	38,638	45.7%	36,390	47.3%	-1.637	-0.033
Peptic ulcer disease	330	0.4%	342	0.4%	-0.055	-0.008
Prior hospitalized bleeding	574	0.7%	568	0.7%	-0.060	-0.007
Stroke - past 0-30 days	1,440	1.7%	1,358	1.8%	-0.063	-0.005
Stroke - past 31-183 days	1,191	1.4%	1,174	1.5%	-0.118	-0.010
Syncope	7,441	8.8%	7,446	9.7%	-0.885	-0.031
Transient ischemic attack	5,571	6.6%	5,120	6.7%	-0.071	-0.003
Walker use	-	0.0%	-	0.0%	0.000	-
History of Use:						
Angiotensin-converting enzyme Inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	50,619	59.9%	47,103	61.3%	-1.402	-0.029
Amiodarone	9,249	10.9%	8,773	11.4%	-0.473	-0.015
Anti-coagulant (injectable)	5,994	7.1%	7,513	9.8%	-2.683	-0.097
Antiarrhythmics	11,541	13.6%	10,968	14.3%	-0.617	-0.018
Antiplatelets	13,085	15.5%	12,538	16.3%	-0.833	-0.023
Beta blockers	60,003	71.0%	56,894	74.0%	-3.040	-0.068
Calcium channel blockers	36,235	42.9%	33,025	43.0%	-0.102	-0.002
Digoxin	12,638	14.9%	7,146	9.3%	5.651	0.174
Diuretics - loop	21,887	25.9%	20,319	26.4%	-0.544	-0.012
Diuretics - potassium sparing	7,298	8.6%	6,623	8.6%	0.016	0.001
Diuretics - thiazide	24,743	29.3%	22,202	28.9%	0.384	0.008
Dronedarone	4,716	5.6%	3,157	4.1%	1.471	0.069
Estrogen	2,003	2.4%	1,514	2.0%	0.400	0.027
Fibrates	3,986	4.7%	3,581	4.7%	0.056	0.003

Table 1e. Baseline Characteristics of New Users of Dabigatran and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

History of Use:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
H2-antagonist	4,699	5.6%	4,374	5.7%	-0.132	-0.006
Insulin	5,405	6.4%	5,731	7.5%	-1.062	-0.042
Metformin	12,855	15.2%	12,450	16.2%	-0.991	-0.027
Nonsteroidal anti-inflammatory drugs (NSAIDs)	12,763	15.1%	11,423	14.9%	0.236	0.007
Nitrates	8,482	10.0%	7,911	10.3%	-0.259	-0.009
Other diabetes medications	5,392	6.4%	4,970	6.5%	-0.088	-0.004
Proton pump inhibitors	22,700	26.8%	23,243	30.2%	-3.386	-0.075
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	11,409	13.5%	10,822	14.1%	-0.583	-0.017
Statins	49,325	58.3%	47,697	62.0%	-3.705	-0.076
Sulfonyureas	7,949	9.4%	6,794	8.8%	0.564	0.020
Health Service Utilization Intensity:						
Mean number of ambulatory encounters	12.4	9.4	13.0	9.3	-0.578	-0.062
Mean number of emergency room encounters	0.3	0.7	0.4	0.8	-0.064	-0.083
Mean number of inpatient hospital encounters	0.5	0.7	0.5	0.7	0.004	0.005
Mean number of generics	9.7	4.8	10.1	4.9	-0.380	-0.078

¹Covariates in blue show a standardized difference greater than 0.1.

²Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 1f. Baseline Characteristics of New Users of Dabigatran and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

Characteristic ¹	Medical Product				Covariate Balance	
	Dabigatran		Apixaban		Absolute Difference	Standardized Difference
	Number	Percent	Number	Percent		
Patients (N)	69,054	81.7%	69,054	89.8%	-	-
Demographics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean age (years)	75.9	6.6	75.9	6.4	-0.008	-0.001
Age (years)	Number	Percent	Number	Percent		
65-74	33,929	49.1%	33,418	48.4%	0.740	0.015
75-85	27,970	40.5%	28,879	41.8%	-1.316	-0.027
85+	7,155	10.4%	6,757	9.8%	0.576	0.019
Sex						
Female	33,272	48.2%	33,262	48.2%	0.014	0.000
Male	35,782	51.8%	35,792	51.8%	-0.014	-0.000
Race ²						
American Indian or Alaska Native	152	0.2%	150	0.2%	0.003	0.001
Asian	768	1.1%	776	1.1%	-0.012	-0.001
Black or African American	2,506	3.6%	2,469	3.6%	0.054	0.003
Unknown	1,896	2.7%	1,912	2.8%	-0.023	-0.001
White	63,732	92.3%	63,747	92.3%	-0.022	-0.001
Hispanic Origin	853	1.2%	643	0.9%	0.304	0.029
Year						
2010	980	1.4%	-	0.0%	1.419	-
2011	25,133	36.4%	-	0.0%	36.396	-
2012	18,831	27.3%	-	0.0%	27.270	-
2013	11,699	16.9%	7,939	11.5%	5.445	0.156
2014	8,058	11.7%	27,394	39.7%	-28.001	-0.677
2015	4,353	6.3%	33,721	48.8%	-42.529	-1.082
CHA ₂ DS ₂ -VASc						
mean, standard deviation	3.9	1.5	3.9	1.5	-0.007	-0.004
0-1	1,989	2.9%	2,000	2.9%	-0.016	-0.001
2	10,763	15.6%	10,709	15.5%	0.078	0.002
3	16,787	24.3%	16,801	24.3%	-0.020	-0.000
4	17,213	24.9%	17,217	24.9%	-0.006	-0.000
5	11,468	16.6%	11,441	16.6%	0.039	0.001
>= 6	10,834	15.7%	10,886	15.8%	-0.075	-0.002
HAS-BLED						
mean, standard deviation	2.6	0.9	2.6	0.9	-0.002	-0.002
0-1	6,206	9.0%	6,157	8.9%	0.071	0.002
2	30,688	44.4%	30,678	44.4%	0.014	0.000
3	22,122	32.0%	22,164	32.1%	-0.061	-0.001
>= 4	10,038	14.5%	10,055	14.6%	-0.025	-0.001

Table 1f. Baseline Characteristics of New Users of Dabigatran and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

Recorded History of:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Acute myocardial infarction - Past 0-30 days	885	1.3%	922	1.3%	-0.054	-0.005
Acute myocardial infarction - Past 31-183 days	625	0.9%	631	0.9%	-0.009	-0.001
Cardioablation	1,577	2.3%	1,587	2.3%	-0.014	-0.001
Cardioversion	6,905	10.0%	6,950	10.1%	-0.065	-0.002
Coronary revascularization	10,638	15.4%	10,684	15.5%	-0.067	-0.002
Diabetes	22,937	33.2%	23,006	33.3%	-0.100	-0.002
Falls	3,231	4.7%	3,236	4.7%	-0.007	-0.000
Fractures	894	1.3%	882	1.3%	0.017	0.002
Heart failure - hospitalized	3,587	5.2%	3,610	5.2%	-0.033	-0.001
Heart failure - outpatient	16,396	23.7%	16,365	23.7%	0.045	0.001
Hypercholesterolemia	26,405	38.2%	26,392	38.2%	0.019	0.000
Hypertension	60,068	87.0%	60,107	87.0%	-0.056	-0.002
Kidney failure - acute	3,550	5.1%	3,562	5.2%	-0.017	-0.001
Kidney failure - chronic	7,686	11.1%	7,776	11.3%	-0.130	-0.004
Nicotine dependency	13,911	20.1%	13,958	20.2%	-0.068	-0.002
Obesity	10,680	15.5%	10,786	15.6%	-0.154	-0.004
Other ischemic heart disease	31,807	46.1%	31,805	46.1%	0.003	0.000
Peptic ulcer disease	283	0.4%	282	0.4%	0.001	0.000
Prior hospitalized bleeding	465	0.7%	474	0.7%	-0.013	-0.002
Stroke - past 0-30 days	1,196	1.7%	1,184	1.7%	0.017	0.001
Stroke - past 31-183 days	996	1.4%	1,008	1.5%	-0.017	-0.001
Syncope	6,327	9.2%	6,349	9.2%	-0.032	-0.001
Transient ischemic attack	4,554	6.6%	4,525	6.6%	0.042	0.002
Walker use	-	0.0%	-	0.0%	0.000	-
History of Use:						
Angiotensin-converting enzyme Inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	41,771	60.5%	41,805	60.5%	-0.049	-0.001
Amiodarone	7,592	11.0%	7,594	11.0%	-0.003	-0.000
Anti-coagulant (injectable)	5,586	8.1%	5,653	8.2%	-0.097	-0.004
Antiarrhythmics	9,783	14.2%	9,815	14.2%	-0.046	-0.001
Antiplatelets	10,793	15.6%	10,789	15.6%	0.006	0.000
Beta blockers	50,352	72.9%	50,278	72.8%	0.107	0.002
Calcium channel blockers	29,479	42.7%	29,454	42.7%	0.036	0.001
Digoxin	6,998	10.1%	7,046	10.2%	-0.070	-0.002
Diuretics - loop	17,596	25.5%	17,655	25.6%	-0.085	-0.002
Diuretics - potassium sparing	5,881	8.5%	5,802	8.4%	0.114	0.004
Diuretics - thiazide	20,011	29.0%	20,067	29.1%	-0.081	-0.002
Dronedarone	2,998	4.3%	3,059	4.4%	-0.088	-0.004
Estrogen	1,437	2.1%	1,433	2.1%	0.006	0.000
Fibrates	3,127	4.5%	3,149	4.6%	-0.032	-0.002

Table 1f. Baseline Characteristics of New Users of Dabigatran and Apixaban in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

History of Use:	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
H2-antagonist	3,804	5.5%	3,808	5.5%	-0.006	-0.000
Insulin	4,636	6.7%	4,657	6.7%	-0.030	-0.001
Metformin	10,751	15.6%	10,795	15.6%	-0.064	-0.002
Nonsteroidal anti-inflammatory drugs (NSAIDs)	10,288	14.9%	10,335	15.0%	-0.068	-0.002
Nitrates	6,819	9.9%	6,870	9.9%	-0.074	-0.002
Other diabetes medications	4,315	6.2%	4,378	6.3%	-0.091	-0.004
Proton pump inhibitors	19,645	28.4%	19,736	28.6%	-0.132	-0.003
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	9,485	13.7%	9,454	13.7%	0.045	0.001
Statins	41,792	60.5%	41,826	60.6%	-0.049	-0.001
Sulfonyureas	6,048	8.8%	6,093	8.8%	-0.065	-0.002
Health Service Utilization Intensity:						
Mean number of ambulatory encounters	12.7	9.6	12.7	9.1	-0.009	-0.001
Mean number of emergency room encounters	0.4	0.8	0.4	0.7	-0.002	-0.003
Mean number of inpatient hospital encounters	0.5	0.7	0.5	0.7	-0.000	-0.000
Mean number of generics	9.8	4.9	9.8	4.8	-0.014	-0.003

¹Covariates in blue show a standardized difference greater than 0.1.

²Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

Table 2. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	110,113	37,287.25	123.68	0.34	292	7.83	2.65	-1.29	-0.25	0.87 (0.74, 1.03)	0.114
Dabigatran	84,473	26,858.70	116.13	0.32	245	9.12	2.9				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	82,326	12,020.37	53.33	0.15	142	11.81	1.72	-1.33	-0.19	0.90 (0.72, 1.13)	0.356
Dabigatran	82,326	12,020.37	53.33	0.15	158	13.14	1.92				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	82,326	27,774.62	123.23	0.34	221	7.96	2.68	-1.11	-0.21	0.89 (0.74, 1.07)	0.205
Dabigatran	82,326	26,242.22	116.43	0.32	238	9.07	2.89				

¹Conditional analysis includes informative events and person-time.

Table 3. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	94,068	31,920.44	123.94	0.34	233	7.3	2.48				
Dabigatran	71,402	22,722.51	116.23	0.32	187	8.23	2.62	-0.93	-0.14	0.90 (0.75, 1.10)	0.303
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	69,758	10,226.98	53.55	0.15	116	11.34	1.66				
Dabigatran	69,758	10,226.98	53.55	0.15	123	12.03	1.76	-0.68	-0.1	0.94 (0.73, 1.22)	0.651
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	69,758	23,594.14	123.54	0.34	173	7.33	2.48				
Dabigatran	69,758	22,245.22	116.48	0.32	182	8.18	2.61	-0.85	-0.13	0.91 (0.74, 1.12)	0.375
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,045	5,366.81	122.17	0.33	59	10.99	3.68				
Dabigatran	13,071	4,136.20	115.58	0.32	58	14.02	4.44	-3.03	-0.76	0.79 (0.55, 1.13)	0.199
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,416	1,791.59	52.7	0.14	29	16.19	2.34				
Dabigatran	12,416	1,791.59	52.7	0.14	35	19.54	2.82	-3.35	-0.48	0.83 (0.51, 1.36)	0.454
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,416	4,137.37	121.71	0.33	48	11.6	3.87				
Dabigatran	12,416	3,953.22	116.29	0.32	56	14.17	4.51	-2.56	-0.64	0.82 (0.56, 1.21)	0.317

¹Conditional analysis includes informative events and person-time.

Table 4. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	58,957	19,586.52	121.34	0.33	131	6.69	2.22				
Dabigatran	43,649	13,750.04	115.06	0.32	110	8	2.52	-1.31	-0.3	0.84 (0.65, 1.08)	0.182
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	42,684	6,223.10	53.25	0.15	57	9.16	1.34				
Dabigatran	42,684	6,223.10	53.25	0.15	73	11.73	1.71	-2.57	-0.37	0.78 (0.55, 1.10)	0.162
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	42,684	14,091.00	120.58	0.33	90	6.39	2.11				
Dabigatran	42,684	13,457.06	115.15	0.32	108	8.03	2.53	-1.64	-0.42	0.80 (0.60, 1.06)	0.116
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,156	17,700.73	126.38	0.35	161	9.1	3.15				
Dabigatran	40,824	13,108.67	117.28	0.32	135	10.3	3.31	-1.2	-0.16	0.91 (0.72, 1.14)	0.394
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,269	5,728.64	53.28	0.15	85	14.84	2.16				
Dabigatran	39,269	5,728.64	53.28	0.15	92	16.06	2.34	-1.22	-0.18	0.92 (0.69, 1.24)	0.599
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,269	13,558.25	126.11	0.35	129	9.51	3.29				
Dabigatran	39,269	12,651.02	117.67	0.32	130	10.28	3.31	-0.76	-0.03	0.95 (0.74, 1.21)	0.65

¹Conditional analysis includes informative events and person-time.

Table 5. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Users by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	56,862	19,632.17	126.11	0.35	114	5.81	2	-1.12	-0.23	0.86 (0.65, 1.13)	0.274
Dabigatran	40,695	13,143.72	117.97	0.32	91	6.92	2.24				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,926	5,941.38	54.35	0.15	46	7.74	1.15	-2.36	-0.35	0.77 (0.52, 1.13)	0.175
Dabigatran	39,926	5,941.38	54.35	0.15	60	10.1	1.5				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,926	13,763.29	125.91	0.34	85	6.18	2.13	-0.56	-0.05	0.94 (0.70, 1.27)	0.683
Dabigatran	39,926	12,914.53	118.14	0.32	87	6.74	2.18				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	43,527	14,753.69	123.8	0.34	140	9.49	3.22	-0.78	-0.09	0.94 (0.73, 1.20)	0.596
Dabigatran	34,508	11,097.34	117.46	0.32	114	10.27	3.3				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,403	4,890.12	53.47	0.15	66	13.5	1.98	-1.02	-0.15	0.93 (0.66, 1.30)	0.669
Dabigatran	33,403	4,890.12	53.47	0.15	71	14.52	2.13				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,403	11,304.40	123.61	0.34	100	8.85	2.99	-1.65	-0.39	0.85 (0.65, 1.11)	0.234
Dabigatran	33,403	10,763.47	117.69	0.32	113	10.5	3.38				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,724	2,901.39	108.98	0.3	38	13.1	3.91	-2.18	-0.41	0.85 (0.55, 1.33)	0.485
Dabigatran	9,270	2,617.65	103.14	0.28	40	15.28	4.31				

Table 5. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Users by Analysis Type and Age Group

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	8,388	1,075.86	46.85	0.13	19	17.66	2.27	-2.79	-0.36	0.86 (0.47, 1.60)	0.64
Dabigatran	8,388	1,075.86	46.85	0.13	22	20.45	2.62				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	8,388	2,516.20	109.57	0.3	33	13.12	3.93	-1.58	-0.24	0.89 (0.55, 1.44)	0.637
Dabigatran	8,388	2,382.12	103.73	0.28	35	14.69	4.17				

¹Conditional analysis includes informative events and person-time.

Table 6. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,766	1,229.68	119.26	0.33	*****	*****	*****				
Dabigatran	2,768	859.06	113.36	0.31	*****	*****	*****	-0.24	-0.02	0.91 (0.20, 4.07)	0.902
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,726	395.41	52.98	0.15	*****	*****	*****				
Dabigatran	2,726	395.41	52.98	0.15	*****	*****	*****	-2.53	-0.37	0.50 (0.05, 5.51)	0.571
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,726	888.59	119.06	0.33	*****	*****	*****				
Dabigatran	2,726	849.07	113.76	0.31	*****	*****	*****	0.97	0.37	1.24 (0.28, 5.54)	0.779
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,605	6,550.83	128.6	0.35	*****	*****	*****				
Dabigatran	12,943	4,148.21	117.06	0.32	*****	*****	*****	-0.52	-0.05	0.93 (0.51, 1.72)	0.827
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,668	1,959.70	56.5	0.15	*****	*****	*****				
Dabigatran	12,668	1,959.70	56.5	0.15	*****	*****	*****	-1.53	-0.24	0.73 (0.29, 1.81)	0.493
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,668	4,454.51	128.43	0.35	*****	*****	*****				
Dabigatran	12,668	4,065.50	117.22	0.32	*****	*****	*****	-1.28	-0.32	0.76 (0.38, 1.52)	0.432
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,766	9,689.18	127.46	0.35	46	4.75	1.66				
Dabigatran	19,794	6,483.95	119.65	0.33	45	6.94	2.27	-2.19	-0.62	0.69 (0.45, 1.04)	0.073

Table 6. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsC Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	19,542	2,938.95	54.93	0.15	16	5.44	0.82				
Dabigatran	19,542	2,938.95	54.93	0.15	31	10.55	1.59	-5.1	-0.77	0.52 (0.28, 0.94)	0.032
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	19,542	6,769.98	126.53	0.35	32	4.73	1.64				
Dabigatran	19,542	6,390.96	119.45	0.33	44	6.88	2.25	-2.16	-0.61	0.68 (0.43, 1.08)	0.103
CHA₂DS₂-VAsC Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	26,827	9,260.57	126.08	0.35	71	7.67	2.65				
Dabigatran	21,631	7,101.32	119.91	0.33	61	8.59	2.82	-0.92	-0.17	0.90 (0.64, 1.27)	0.546
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	20,835	3,121.17	54.72	0.15	39	12.5	1.87				
Dabigatran	20,835	3,121.17	54.72	0.15	42	13.46	2.02	-0.96	-0.14	0.93 (0.60, 1.44)	0.739
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	20,835	7,191.33	126.07	0.35	54	7.51	2.59				
Dabigatran	20,835	6,870.31	120.44	0.33	57	8.3	2.74	-0.79	-0.14	0.91 (0.63, 1.32)	0.62
CHA₂DS₂-VAsC Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,526	5,714.86	119.1	0.33	61	10.67	3.48				
Dabigatran	13,980	4,323.18	112.95	0.31	47	10.87	3.36	-0.2	0.12	0.99 (0.68, 1.45)	0.97
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	13,481	1,890.25	51.21	0.14	31	16.4	2.3				
Dabigatran	13,481	1,890.25	51.21	0.14	27	14.28	2	2.12	0.3	1.15 (0.69, 1.92)	0.6
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	13,481	4,390.11	118.94	0.33	46	10.48	3.41				
Dabigatran	13,481	4,188.73	113.49	0.31	46	10.98	3.41	-0.5	0	0.96 (0.64, 1.45)	0.857

Table 6. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASC Score

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
CHA₂DS₂-VASC Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,623	4,842.13	113.2	0.31	85	17.55	5.44				
Dabigatran	13,357	3,942.98	107.82	0.3	71	18.01	5.32	-0.45	0.13	0.98 (0.72, 1.35)	0.916
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,542	1,656.93	48.25	0.13	46	27.76	3.67				
Dabigatran	12,542	1,656.93	48.25	0.13	48	28.97	3.83	-1.21	-0.16	0.96 (0.64, 1.44)	0.837
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,542	3,905.66	113.74	0.31	70	17.92	5.58				
Dabigatran	12,542	3,708.01	107.99	0.3	67	18.07	5.34	-0.15	0.24	1.01 (0.72, 1.41)	0.965

¹Conditional analysis includes informative events and person-time.

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

Table 7. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,726	3,711.82	126.4	0.35	21	5.66	1.96	*****	*****	1.77 (0.78, 4.00)	0.17
Dabigatran	7,779	2,451.25	115.09	0.32	*****	*****	*****	*****	*****		
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,582	1,118.93	53.9	0.15	*****	*****	*****	2.68	0.4	1.60 (0.52, 4.89)	0.41
Dabigatran	7,582	1,118.93	53.9	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,582	2,591.50	124.84	0.34	13	5.02	1.71	*****	*****	1.51 (0.62, 3.64)	0.361
Dabigatran	7,582	2,390.63	115.16	0.32	*****	*****	*****	*****	*****		
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	50,401	17,982.00	130.31	0.36	94	5.23	1.87	-1.77	-0.48	0.76 (0.57, 1.02)	0.069
Dabigatran	37,972	12,723.87	122.39	0.34	89	6.99	2.34				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,179	5,705.52	56.05	0.15	47	8.24	1.26	-2.28	-0.35	0.78 (0.53, 1.15)	0.21
Dabigatran	37,179	5,705.52	56.05	0.15	60	10.52	1.61				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,179	13,245.00	130.12	0.36	67	5.06	1.8	-1.91	-0.54	0.74 (0.54, 1.02)	0.064
Dabigatran	37,179	12,478.69	122.59	0.34	87	6.97	2.34				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	34,578	11,415.89	120.59	0.33	116	10.16	3.35	-0.11	0.19	1.01 (0.76, 1.33)	0.969
Dabigatran	26,850	8,275.39	112.57	0.31	85	10.27	3.17				

Table 7. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	25,923	3,678.69	51.83	0.14	54	14.68	2.08	0	0	1.00 (0.69, 1.46)	1
Dabigatran	25,923	3,678.69	51.83	0.14	54	14.68	2.08				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	25,923	8,530.15	120.19	0.33	92	10.79	3.55	0.65	0.42	1.08 (0.80, 1.46)	0.616
Dabigatran	25,923	7,989.80	112.57	0.31	81	10.14	3.12				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,408	4,177.54	105.9	0.29	61	14.6	4.23	*****	*****	0.78 (0.55, 1.11)	0.167
Dabigatran	11,872	3,408.19	104.86	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,241	1,440.71	46.81	0.13	*****	*****	*****	-2.08	-0.27	0.93 (0.59, 1.45)	0.733
Dabigatran	11,241	1,440.71	46.81	0.13	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,241	3,264.82	106.08	0.29	48	14.7	4.27	*****	*****	0.78 (0.54, 1.15)	0.211
Dabigatran	11,241	3,248.88	105.56	0.29	*****	*****	*****				

¹Conditional analysis includes informative events and person-time.

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

Table 8. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	111,816	37,792.24	123.45	0.34	298	7.89	2.67	-1.29	0.15	0.94 (0.79, 1.13)	0.532
Apixaban	77,232	21,151.93	100.03	0.27	194	9.17	2.51				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	75,889	10,853.49	52.24	0.14	127	11.7	1.67	0.09	0.01	1.01 (0.79, 1.29)	0.95
Apixaban	75,889	10,853.49	52.24	0.14	126	11.61	1.66				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	75,889	25,335.44	121.94	0.33	212	8.37	2.79	-0.74	0.29	1.00 (0.82, 1.22)	0.987
Apixaban	75,889	20,856.28	100.38	0.27	190	9.11	2.5				

¹Conditional analysis includes informative events and person-time.

Table 9. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	95,580	32,365.36	123.68	0.34	238	7.35	2.49	-0.89	0.22	0.98 (0.80, 1.21)	0.872
Apixaban	64,648	17,827.12	100.72	0.28	147	8.25	2.27				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	63,624	9,121.46	52.36	0.14	105	11.51	1.65	1.32	0.19	1.13 (0.85, 1.49)	0.394
Apixaban	63,624	9,121.46	52.36	0.14	93	10.2	1.46				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	63,624	21,305.34	122.31	0.33	168	7.89	2.64	-0.35	0.36	1.04 (0.83, 1.30)	0.719
Apixaban	63,624	17,596.51	101.02	0.28	145	8.24	2.28				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,236	5,426.88	122.08	0.33	60	11.06	3.7	-3.08	-0.04	0.84 (0.57, 1.24)	0.389
Apixaban	12,584	3,324.81	96.5	0.26	47	14.14	3.73				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,067	1,679.34	50.83	0.14	28	16.67	2.32	-0.6	-0.08	0.97 (0.57, 1.62)	0.895
Apixaban	12,067	1,679.34	50.83	0.14	29	17.27	2.4				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,067	3,968.32	120.12	0.33	43	10.84	3.56	-3.2	-0.17	0.83 (0.55, 1.27)	0.398
Apixaban	12,067	3,207.14	97.08	0.27	45	14.03	3.73				

¹Conditional analysis includes informative events and person-time.

Table 10. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	59,919	19,861.98	121.07	0.33	135	6.8	2.25	-1.5	-0.02	0.90 (0.69, 1.17)	0.429
Apixaban	40,104	10,966.23	99.88	0.27	91	8.3	2.27				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,359	5,660.85	52.53	0.14	57	10.07	1.45	0.18	0.03	1.02 (0.70, 1.47)	0.925
Apixaban	39,359	5,660.85	52.53	0.14	56	9.89	1.42				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,359	12,870.32	119.44	0.33	85	6.6	2.16	-1.55	-0.08	0.88 (0.65, 1.19)	0.403
Apixaban	39,359	10,795.76	100.18	0.27	88	8.15	2.24				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,897	17,930.26	126.19	0.35	163	9.09	3.14	-1.02	0.37	0.99 (0.77, 1.27)	0.936
Apixaban	37,128	10,185.70	100.2	0.27	103	10.11	2.77				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	36,358	5,215.49	52.39	0.14	75	14.38	2.06	2.3	0.33	1.19 (0.85, 1.66)	0.308
Apixaban	36,358	5,215.49	52.39	0.14	63	12.08	1.73				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	36,358	12,417.29	124.74	0.34	126	10.15	3.47	0.16	0.72	1.11 (0.85, 1.44)	0.45
Apixaban	36,358	10,013.53	100.6	0.28	100	9.99	2.75				

¹Conditional analysis includes informative events and person-time.

Table 11. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	57,787	19,909.37	125.84	0.34	116	5.83	2.01	-0.91	0.14	0.96 (0.71, 1.29)	0.788
Apixaban	38,032	10,540.22	101.23	0.28	71	6.74	1.87				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,491	5,480.65	53.39	0.15	47	8.58	1.25	-0.73	-0.11	0.92 (0.62, 1.37)	0.686
Apixaban	37,491	5,480.65	53.39	0.15	51	9.31	1.36				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,491	12,780.59	124.51	0.34	79	6.18	2.11	-0.63	0.21	1.01 (0.73, 1.39)	0.963
Apixaban	37,491	10,423.04	101.54	0.28	71	6.81	1.89				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	44,196	14,954.61	123.59	0.34	144	9.63	3.26	-0.84	0.38	1.00 (0.77, 1.30)	0.986
Apixaban	31,939	8,784.27	100.46	0.28	92	10.47	2.88				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	30,797	4,378.82	51.93	0.14	67	15.3	2.18	3.65	0.52	1.31 (0.91, 1.89)	0.142
Apixaban	30,797	4,378.82	51.93	0.14	51	11.65	1.66				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	30,797	10,287.68	122.01	0.33	107	10.4	3.47	-0.06	0.58	1.07 (0.80, 1.41)	0.662
Apixaban	30,797	8,504.11	100.86	0.28	89	10.47	2.89				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,833	2,928.27	108.77	0.3	38	12.98	3.86	-3.99	-0.4	0.82 (0.51, 1.32)	0.42
Apixaban	7,261	1,827.44	91.93	0.25	31	16.96	4.27				

Table 11. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,020	898.42	46.74	0.13	14	15.58	1.99	-7.79	-1	0.67 (0.34, 1.31)	0.24
Apixaban	7,020	898.42	46.74	0.13	21	23.37	2.99				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,020	2,078.32	108.13	0.3	25	12.03	3.56	-4.27	-0.57	0.78 (0.46, 1.34)	0.376
Apixaban	7,020	1,779.64	92.59	0.25	29	16.3	4.13				

¹Conditional analysis includes informative events and person-time.

Table 12. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsC Score

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
CHA₂DS₂-VAsC Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,845	1,253.20	119.05	0.33	*****	*****	*****	-1.92	-0.4	0.71 (0.16, 3.16)	0.649
Apixaban	2,079	586.61	103.06	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,044	303.26	54.19	0.15	*****	*****	*****	-3.3	-0.49	0.50 (0.05, 5.51)	0.571
Apixaban	2,044	303.26	54.19	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,044	650.49	116.24	0.32	*****	*****	*****	-0.38	0	0.99 (0.14, 7.02)	0.991
Apixaban	2,044	578.58	103.39	0.28	*****	*****	*****				
CHA₂DS₂-VAsC Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,983	6,664.10	128.22	0.35	*****	*****	*****	-0.05	0.22	1.07 (0.56, 2.04)	0.846
Apixaban	11,656	3,412.18	106.92	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,587	1,764.71	55.63	0.15	*****	*****	*****	0.57	0.09	1.10 (0.47, 2.59)	0.827
Apixaban	11,587	1,764.71	55.63	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,587	4,053.59	127.78	0.35	*****	*****	*****	-1.16	-0.17	0.77 (0.36, 1.68)	0.518
Apixaban	11,587	3,397.62	107.1	0.29	*****	*****	*****				
CHA₂DS₂-VAsC Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	28,194	9,822.58	127.25	0.35	47	4.78	1.67	0.33	0.39	1.17 (0.71, 1.91)	0.535
Apixaban	18,753	5,384.17	104.87	0.29	24	4.46	1.28				

Table 12. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,534	2,789.63	54.98	0.15	22	7.89	1.19	2.15	0.32	1.37 (0.72, 2.62)	0.332
Apixaban	18,534	2,789.63	54.98	0.15	16	5.74	0.86				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,534	6,379.88	125.73	0.34	37	5.8	2	1.3	0.7	1.38 (0.82, 2.31)	0.224
Apixaban	18,534	5,333.47	105.11	0.29	24	4.5	1.29				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,248	9,387.62	125.84	0.34	74	7.88	2.72	-0.83	0.33	0.99 (0.68, 1.44)	0.966
Apixaban	18,872	5,161.97	99.91	0.27	45	8.72	2.38				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,616	2,684.04	52.66	0.14	29	10.8	1.56	0.37	0.05	1.04 (0.62, 1.74)	0.895
Apixaban	18,616	2,684.04	52.66	0.14	28	10.43	1.5				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,616	6,338.77	124.37	0.34	46	7.26	2.47	-1.56	0.05	0.89 (0.59, 1.34)	0.571
Apixaban	18,616	5,102.06	100.1	0.27	45	8.82	2.42				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,765	5,772.68	118.69	0.32	61	10.57	3.43	-2.35	0.01	0.89 (0.61, 1.31)	0.559
Apixaban	13,134	3,482.85	96.86	0.27	45	12.92	3.43				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,727	1,739.85	49.93	0.14	27	15.52	2.12	2.3	0.31	1.17 (0.67, 2.05)	0.572
Apixaban	12,727	1,739.85	49.93	0.14	23	13.22	1.81				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,727	4,083.95	117.2	0.32	45	11.02	3.54	-1.07	0.31	0.99 (0.65, 1.51)	0.965
Apixaban	12,727	3,392.42	97.36	0.27	41	12.09	3.22				

Table 12. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsC Score

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
CHA₂DS₂-VAsC Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,781	4,892.05	113.23	0.31	85	17.38	5.39				
Apixaban	12,738	3,124.16	89.58	0.25	63	20.17	4.95	-2.79	0.44	0.96 (0.69, 1.34)	0.817
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,024	1,533.47	46.58	0.13	39	25.43	3.24				
Apixaban	12,024	1,533.47	46.58	0.13	43	28.04	3.58	-2.61	-0.33	0.91 (0.59, 1.40)	0.659
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,024	3,714.25	112.83	0.31	69	18.58	5.74				
Apixaban	12,024	2,977.02	90.43	0.25	59	19.82	4.91	-1.24	0.83	1.04 (0.73, 1.48)	0.828

¹Conditional analysis includes informative events and person-time.

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

Table 13. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,937	3,780.12	126.24	0.35	23	6.08	2.1	*****	*****	1.81 (0.77, 4.21)	0.171
Apixaban	6,486	1,848.42	104.09	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	6,472	974.13	54.98	0.15	*****	*****	*****	1.03	0.15	1.25 (0.34, 4.65)	0.739
Apixaban	6,472	974.13	54.98	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	6,472	2,221.82	125.39	0.34	*****	*****	*****	-0.2	0.15	1.04 (0.37, 2.86)	0.947
Apixaban	6,472	1,843.56	104.04	0.28	*****	*****	*****				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,220	18,227.38	129.98	0.36	97	5.32	1.89	-1.96	-0.21	0.79 (0.58, 1.08)	0.137
Apixaban	33,272	9,611.59	105.51	0.29	70	7.28	2.1				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,228	4,987.09	54.82	0.15	47	9.42	1.41	-0.4	-0.06	0.96 (0.64, 1.43)	0.838
Apixaban	33,228	4,987.09	54.82	0.15	49	9.83	1.47				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,228	11,741.85	129.07	0.35	72	6.13	2.17	-1.16	0.06	0.90 (0.64, 1.25)	0.517
Apixaban	33,228	9,602.88	105.56	0.29	70	7.29	2.11				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	35,069	11,549.72	120.29	0.33	116	10.04	3.31	1.1	0.91	1.22 (0.89, 1.67)	0.214
Apixaban	25,062	6,708.68	97.77	0.27	60	8.94	2.39				

Table 13. Effect Estimates for Risk of Thromboembolic Stroke among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	24,588	3,454.66	51.32	0.14	45	13.03	1.83	1.74	0.24	1.15 (0.75, 1.77)	0.513
Apixaban	24,588	3,454.66	51.32	0.14	39	11.29	1.59				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	24,588	8,043.89	119.49	0.33	81	10.07	3.29	0.97	0.85	1.21 (0.86, 1.69)	0.271
Apixaban	24,588	6,594.90	97.97	0.27	60	9.1	2.44				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,590	4,235.01	106.02	0.29	62	14.64	4.25	*****	*****	0.85 (0.59, 1.22)	0.374
Apixaban	12,412	2,983.24	87.79	0.24	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,496	1,409.49	44.78	0.12	*****	*****	*****	-4.97	-0.61	0.82 (0.51, 1.31)	0.4
Apixaban	11,496	1,409.49	44.78	0.12	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,496	3,293.70	104.65	0.29	*****	*****	*****	-3.17	-0.09	0.91 (0.62, 1.35)	0.646
Apixaban	11,496	2,787.01	88.55	0.24	*****	*****	*****				

¹Conditional analysis includes informative events and person-time.

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

Table 14. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	84,562	26,877.42	116.09	0.32	246	9.15	2.91	0.11	0.44	1.11 (0.92, 1.34)	0.292
Apixaban	76,887	21,016.72	99.84	0.27	190	9.04	2.47				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Dabigatran	69,054	9,442.44	49.94	0.14	130	13.77	1.88	2.01	0.28	1.17 (0.91, 1.51)	0.221
Apixaban	69,054	9,442.44	49.94	0.14	111	11.76	1.61				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	69,054	21,886.65	115.77	0.32	208	9.5	3.01	0.5	0.54	1.15 (0.93, 1.40)	0.191
Apixaban	69,054	19,001.49	100.51	0.28	171	9	2.48				

¹Conditional analysis includes informative events and person-time.

Table 15. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	71,477	22,739.81	116.2	0.32	188	8.27	2.63	0.19	0.41	1.12 (0.90, 1.40)	0.292
Apixaban	64,349	17,708.30	100.51	0.28	143	8.08	2.22				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	58,127	7,954.50	49.98	0.14	105	13.2	1.81	2.14	0.29	1.19 (0.90, 1.58)	0.222
Apixaban	58,127	7,954.50	49.98	0.14	88	11.06	1.51				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	58,127	18,436.38	115.85	0.32	161	8.73	2.77	0.46	0.48	1.15 (0.92, 1.45)	0.226
Apixaban	58,127	16,084.70	101.07	0.28	133	8.27	2.29				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,085	4,137.62	115.5	0.32	58	14.02	4.43	-0.19	0.68	1.07 (0.72, 1.57)	0.743
Apixaban	12,538	3,308.42	96.38	0.26	47	14.21	3.75				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,645	1,416.73	48.61	0.13	31	21.88	2.91	4.94	0.66	1.29 (0.76, 2.20)	0.347
Apixaban	10,645	1,416.73	48.61	0.13	24	16.94	2.25				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,645	3,350.41	114.96	0.31	46	13.73	4.32	0.71	0.85	1.12 (0.72, 1.73)	0.621
Apixaban	10,645	2,842.50	97.53	0.27	37	13.02	3.48				

¹Conditional analysis includes informative events and person-time.

Table 16. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	43,693	13,759.20	115.02	0.31	110	7.99	2.52	-0.01	0.34	1.09 (0.82, 1.45)	0.54
Apixaban	39,862	10,869.87	99.6	0.27	87	8	2.18				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	35,590	4,924.68	50.54	0.14	61	12.39	1.71	1.02	0.14	1.09 (0.76, 1.57)	0.644
Apixaban	35,590	4,924.68	50.54	0.14	56	11.37	1.57				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	35,590	11,231.79	115.27	0.32	93	8.28	2.61	0.2	0.39	1.11 (0.82, 1.50)	0.488
Apixaban	35,590	9,775.76	100.33	0.27	79	8.08	2.22				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,869	13,118.22	117.24	0.32	136	10.37	3.33	0.22	0.55	1.12 (0.87, 1.45)	0.389
Apixaban	37,025	10,146.86	100.1	0.27	103	10.15	2.78				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,046	4,469.73	49.4	0.14	78	17.45	2.36	4.92	0.67	1.39 (0.99, 1.96)	0.059
Apixaban	33,046	4,469.73	49.4	0.14	56	12.53	1.69				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,046	10,520.50	116.28	0.32	114	10.84	3.45	0.73	0.67	1.16 (0.88, 1.53)	0.284
Apixaban	33,046	9,104.61	100.63	0.28	92	10.1	2.78				

¹Conditional analysis includes informative events and person-time.

Table 17. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,753	13,154.60	117.9	0.32	92	6.99	2.26	0.31	0.41	1.14 (0.84, 1.56)	0.403
Apixaban	37,862	10,478.49	101.08	0.28	70	6.68	1.85				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,356	4,660.42	51.03	0.14	57	12.23	1.71	3.22	0.45	1.36 (0.91, 2.02)	0.133
Apixaban	33,356	4,660.42	51.03	0.14	42	9.01	1.26				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,356	10,747.87	117.69	0.32	79	7.35	2.37	0.49	0.45	1.15 (0.83, 1.61)	0.397
Apixaban	33,356	9,328.57	102.15	0.28	64	6.86	1.92				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	34,534	11,104.31	117.45	0.32	114	10.27	3.3	0.06	0.5	1.12 (0.85, 1.48)	0.433
Apixaban	31,785	8,721.71	100.22	0.27	89	10.2	2.8				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	27,960	3,842.44	50.19	0.14	62	16.14	2.22	3.64	0.5	1.29 (0.89, 1.88)	0.183
Apixaban	27,960	3,842.44	50.19	0.14	48	12.49	1.72				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	27,960	8,966.28	117.13	0.32	97	10.82	3.47	0.84	0.72	1.20 (0.89, 1.62)	0.23
Apixaban	27,960	7,715.29	100.79	0.28	77	9.98	2.75				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	9,275	2,618.52	103.12	0.28	40	15.28	4.31	-1.79	0.03	0.94 (0.58, 1.50)	0.788
Apixaban	7,240	1,816.52	91.64	0.25	31	17.07	4.28				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,751	810.25	43.84	0.12	14	17.28	2.07	-3.7	-0.44	0.82 (0.41, 1.67)	0.591
Apixaban	6,751	810.25	43.84	0.12	17	20.98	2.52				

Table 17. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,751	1,880.79	101.76	0.28	28	14.89	4.15	-2.19	-0.15	0.89 (0.52, 1.49)	0.649
Apixaban	6,751	1,698.15	91.87	0.25	29	17.08	4.3				

¹Conditional analysis includes informative events and person-time.

Table 18. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	2,775	860.22	113.22	0.31	*****	*****	*****	-1.68	-0.38	0.74 (0.15, 3.68)	0.714
Apixaban	2,050	581.06	103.53	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	1,959	269.58	50.26	0.14	*****	*****	*****	-3.71	-0.51	0.50 (0.05, 5.51)	0.571
Apixaban	1,959	269.58	50.26	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	1,959	611.11	113.94	0.31	*****	*****	*****	-2.1	-0.51	0.66 (0.11, 3.98)	0.655
Apixaban	1,959	558.56	104.14	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	12,962	4,152.11	117	0.32	*****	*****	*****	0.19	0.18	1.04 (0.51, 2.12)	0.906
Apixaban	11,594	3,380.86	106.51	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,670	1,535.13	52.55	0.14	*****	*****	*****	1.95	0.28	1.37 (0.55, 3.42)	0.493
Apixaban	10,670	1,535.13	52.55	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,670	3,418.60	117.02	0.32	*****	*****	*****	0.81	0.37	1.18 (0.57, 2.46)	0.659
Apixaban	10,670	3,120.74	106.83	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	19,816	6,490.63	119.64	0.33	45	6.93	2.27	2.82	1.09	1.85 (1.11, 3.08)	0.019
Apixaban	18,659	5,353.49	104.79	0.29	22	4.11	1.18				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	16,641	2,371.64	52.05	0.14	28	11.81	1.68	6.75	0.96	2.33 (1.19, 4.59)	0.014
Apixaban	16,641	2,371.64	52.05	0.14	12	5.06	0.72				

Table 18. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	16,641	5,439.00	119.38	0.33	37	6.8	2.22	2.21	0.9	1.65 (0.97, 2.79)	0.065
Apixaban	16,641	4,792.91	105.2	0.29	22	4.59	1.32				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	21,646	7,105.08	119.89	0.33	61	8.59	2.82	-0.39	0.37	1.07 (0.73, 1.57)	0.735
Apixaban	18,800	5,123.62	99.54	0.27	46	8.98	2.45				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	17,117	2,367.47	50.52	0.14	38	16.05	2.22	5.49	0.76	1.52 (0.92, 2.52)	0.104
Apixaban	17,117	2,367.47	50.52	0.14	25	10.56	1.46				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	17,117	5,626.09	120.05	0.33	54	9.6	3.15	1.28	0.88	1.28 (0.84, 1.94)	0.244
Apixaban	17,117	4,688.69	100.05	0.27	39	8.32	2.28				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,991	4,324.43	112.89	0.31	48	11.1	3.43	-1.59	0.08	0.96 (0.64, 1.46)	0.864
Apixaban	13,112	3,467.30	96.59	0.26	44	12.69	3.36				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	11,373	1,507.72	48.42	0.13	27	17.91	2.37	1.99	0.26	1.12 (0.65, 1.95)	0.675
Apixaban	11,373	1,507.72	48.42	0.13	24	15.92	2.11				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	11,373	3,491.79	112.14	0.31	37	10.6	3.25	-2.23	-0.18	0.90 (0.57, 1.41)	0.636
Apixaban	11,373	3,039.75	97.62	0.27	39	12.83	3.43				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,372	3,944.95	107.75	0.3	71	18	5.31	-1.61	0.5	1.02 (0.72, 1.44)	0.913
Apixaban	12,672	3,110.39	89.65	0.25	61	19.61	4.81				

Table 18. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,805	1,339.38	45.28	0.12	38	28.37	3.52	0.75	0.09	1.03 (0.65, 1.62)	0.908
Apixaban	10,805	1,339.38	45.28	0.12	37	27.62	3.42				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,805	3,158.75	106.78	0.29	60	18.99	5.55	-1.21	0.56	1.03 (0.71, 1.50)	0.858
Apixaban	10,805	2,672.77	90.35	0.25	54	20.2	5				

¹Conditional analysis includes informative events and person-time.

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

Table 19. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	7,788	2,453.26	115.06	0.32	*****	*****	*****	-0.54	-0.06	0.85 (0.30, 2.37)	0.749
Apixaban	6,455	1,841.15	104.18	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,098	859.78	51.5	0.14	*****	*****	*****	-2.33	-0.33	0.33 (0.03, 3.20)	0.341
Apixaban	6,098	859.78	51.5	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,098	1,924.61	115.28	0.32	*****	*****	*****	-1.42	-0.33	0.66 (0.21, 2.12)	0.488
Apixaban	6,098	1,742.89	104.39	0.29	*****	*****	*****				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	38,021	12,735.60	122.34	0.33	90	7.07	2.37	-0.07	0.31	1.09 (0.79, 1.50)	0.59
Apixaban	33,078	9,534.18	105.28	0.29	68	7.13	2.06				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	30,531	4,396.15	52.59	0.14	51	11.6	1.67	2.27	0.33	1.24 (0.82, 1.88)	0.298
Apixaban	30,531	4,396.15	52.59	0.14	41	9.33	1.34				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	30,531	10,198.85	122.01	0.33	72	7.06	2.36	-0.2	0.26	1.06 (0.76, 1.49)	0.729
Apixaban	30,531	8,811.10	105.41	0.29	64	7.26	2.1				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	26,875	8,280.22	112.53	0.31	85	10.27	3.16	1.28	0.76	1.24 (0.89, 1.73)	0.199
Apixaban	24,997	6,675.35	97.54	0.27	60	8.99	2.4				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	22,081	2,971.20	49.15	0.13	48	16.16	2.17	3.7	0.5	1.30 (0.84, 1.99)	0.234
Apixaban	22,081	2,971.20	49.15	0.13	37	12.45	1.68				

Table 19. Effect Estimates for Risk of Thromboembolic Stroke among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	22,081	6,800.57	112.49	0.31	77	11.32	3.49	2.04	1	1.32 (0.93, 1.87)	0.119
Apixaban	22,081	5,923.91	97.99	0.27	55	9.28	2.49				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	11,878	3,408.34	104.81	0.29	*****	*****	*****				
Apixaban	12,357	2,966.03	87.67	0.24	*****	*****	*****	-0.06	0.85	1.11 (0.77, 1.59)	0.584
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	9,997	1,222.69	44.67	0.12	*****	*****	*****				
Apixaban	9,997	1,222.69	44.67	0.12	*****	*****	*****	0.82	0.1	1.03 (0.63, 1.69)	0.9
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	9,997	2,859.68	104.48	0.29	*****	*****	*****				
Apixaban	9,997	2,438.17	89.08	0.24	*****	*****	*****	0.43	0.9	1.11 (0.75, 1.66)	0.594

¹Conditional analysis includes informative events and person-time.

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

Table 20. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	110,113	37,287.25	123.68	0.34	1,687	45.24	15.32	5.07	2.55	1.14 (1.05, 1.23)	<0.001
Dabigatran	84,473	26,858.70	116.13	0.32	1,079	40.17	12.77				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	82,326	12,020.37	53.33	0.15	764	63.56	9.28	7.49	1.09	1.13 (1.02, 1.26)	0.018
Dabigatran	82,326	12,020.37	53.33	0.15	674	56.07	8.19				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	82,326	27,774.62	123.23	0.34	1,312	47.24	15.94	7.95	3.41	1.21 (1.12, 1.32)	<0.001
Dabigatran	82,326	26,242.22	116.43	0.32	1,031	39.29	12.52				

¹Conditional analysis includes informative events and person-time.

Table 21. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	94,068	31,920.44	123.94	0.34	1,275	39.94	13.55	4.91	2.41	1.15 (1.05, 1.25)	0.002
Dabigatran	71,402	22,722.51	116.23	0.32	796	35.03	11.15				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	69,758	10,226.98	53.55	0.15	584	57.1	8.37	7.72	1.13	1.16 (1.03, 1.30)	0.017
Dabigatran	69,758	10,226.98	53.55	0.15	505	49.38	7.24				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	69,758	23,594.14	123.54	0.34	982	41.62	14.08	7.19	3.1	1.21 (1.10, 1.33)	<0.001
Dabigatran	69,758	22,245.22	116.48	0.32	766	34.43	10.98				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,045	5,366.81	122.17	0.33	412	76.77	25.68	8.35	4.03	1.15 (0.99, 1.34)	0.076
Dabigatran	13,071	4,136.20	115.58	0.32	283	68.42	21.65				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,416	1,791.59	52.7	0.14	191	106.61	15.38	13.4	1.93	1.14 (0.93, 1.41)	0.205
Dabigatran	12,416	1,791.59	52.7	0.14	167	93.21	13.45				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,416	4,137.37	121.71	0.33	328	79.28	26.42	13	5.32	1.22 (1.04, 1.44)	0.017
Dabigatran	12,416	3,953.22	116.29	0.32	262	66.28	21.1				

¹Conditional analysis includes informative events and person-time.

Table 22. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	58,957	19,586.52	121.34	0.33	764	39.01	12.96	5.84	2.51	1.19 (1.06, 1.34)	0.003
Dabigatran	43,649	13,750.04	115.06	0.32	456	33.16	10.45				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	42,684	6,223.10	53.25	0.15	320	51.42	7.5	6.27	0.91	1.14 (0.97, 1.34)	0.112
Dabigatran	42,684	6,223.10	53.25	0.15	281	45.15	6.58				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	42,684	14,091.00	120.58	0.33	566	40.17	13.26	7.32	2.91	1.23 (1.09, 1.40)	<0.001
Dabigatran	42,684	13,457.06	115.15	0.32	442	32.85	10.36				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,156	17,700.73	126.38	0.35	923	52.14	18.04	4.62	2.78	1.11 (1.00, 1.23)	0.048
Dabigatran	40,824	13,108.67	117.28	0.32	623	47.53	15.26				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,269	5,728.64	53.28	0.15	434	75.76	11.05	13.96	2.04	1.23 (1.07, 1.41)	0.004
Dabigatran	39,269	5,728.64	53.28	0.15	354	61.79	9.01				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,269	13,558.25	126.11	0.35	741	54.65	18.87	9.04	4.18	1.21 (1.08, 1.35)	<0.001
Dabigatran	39,269	12,651.02	117.67	0.32	577	45.61	14.69				

¹Conditional analysis includes informative events and person-time.

Table 23. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	56,862	19,632.17	126.11	0.35	628	31.99	11.04	8.56	3.48	1.39 (1.21, 1.59)	<0.001
Dabigatran	40,695	13,143.72	117.97	0.32	308	23.43	7.57				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,926	5,941.38	54.35	0.15	276	46.45	6.91	12.46	1.85	1.37 (1.14, 1.64)	<0.001
Dabigatran	39,926	5,941.38	54.35	0.15	202	34	5.06				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,926	13,763.29	125.91	0.34	455	33.06	11.4	10.22	4.01	1.47 (1.27, 1.70)	<0.001
Dabigatran	39,926	12,914.53	118.14	0.32	295	22.84	7.39				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	43,527	14,753.69	123.8	0.34	813	55.1	18.68	8.16	3.58	1.18 (1.05, 1.31)	0.004
Dabigatran	34,508	11,097.34	117.46	0.32	521	46.95	15.1				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,403	4,890.12	53.47	0.15	385	78.73	11.53	14.31	2.1	1.22 (1.05, 1.42)	0.008
Dabigatran	33,403	4,890.12	53.47	0.15	315	64.42	9.43				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,403	11,304.40	123.61	0.34	633	56	18.95	9.45	3.95	1.20 (1.07, 1.35)	0.002
Dabigatran	33,403	10,763.47	117.69	0.32	501	46.55	15				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,724	2,901.39	108.98	0.3	246	84.79	25.3	-10.72	-1.67	0.90 (0.75, 1.07)	0.231
Dabigatran	9,270	2,617.65	103.14	0.28	250	95.51	26.97				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	8,388	1,075.86	46.85	0.13	113	105.03	13.47	-16.73	-2.15	0.86 (0.67, 1.11)	0.25
Dabigatran	8,388	1,075.86	46.85	0.13	131	121.76	15.62				

Table 23. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

Medical Product	Number of New Users	Person Years at Risk	Average	Average	Number of Events	Incidence	Risk per 1,000 New Users	Incidence	Difference in Risk per 1,000 New Users	Hazard Ratio	Wald P-Value
			Person Days at Risk	Person Years at Risk		Rate per 1,000 Person-Years		Rate Difference per 1,000 Person-Years		(95% Confidence Interval)	
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	8,388	2,516.20	109.57	0.3	213	84.65	25.39	-8.12	-0.95	0.92 (0.76, 1.11)	0.405
Dabigatran	8,388	2,382.12	103.73	0.28	221	92.77	26.35				

¹Conditional analysis includes informative events and person-time.

Table 24. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,766	1,229.68	119.26	0.33	*****	*****	*****	-1.88	-0.43	0.82 (0.36, 1.90)	0.648
Dabigatran	2,768	859.06	113.36	0.31	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,726	395.41	52.98	0.15	*****	*****	*****	5.06	0.73	1.33 (0.46, 3.84)	0.594
Dabigatran	2,726	395.41	52.98	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,726	888.59	119.06	0.33	*****	*****	*****	-0.52	0	0.94 (0.39, 2.25)	0.885
Dabigatran	2,726	849.07	113.76	0.31	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,605	6,550.83	128.6	0.35	*****	*****	*****	3.32	1.67	1.25 (0.93, 1.68)	0.146
Dabigatran	12,943	4,148.21	117.06	0.32	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,668	1,959.70	56.5	0.15	*****	*****	*****	3.57	0.55	1.18 (0.77, 1.81)	0.448
Dabigatran	12,668	1,959.70	56.5	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,668	4,454.51	128.43	0.35	*****	*****	*****	2.46	1.34	1.20 (0.86, 1.67)	0.285
Dabigatran	12,668	4,065.50	117.22	0.32	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,766	9,689.18	127.46	0.35	301	31.07	10.84	2.69	1.54	1.10 (0.92, 1.33)	0.29
Dabigatran	19,794	6,483.95	119.65	0.33	184	28.38	9.3				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	19,542	2,938.95	54.93	0.15	131	44.57	6.7	7.49	1.13	1.20 (0.93, 1.55)	0.156
Dabigatran	19,542	2,938.95	54.93	0.15	109	37.09	5.58				

Table 24. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	19,542	6,769.98	126.53	0.35	217	32.05	11.1	3.89	1.89	1.14 (0.94, 1.39)	0.188
Dabigatran	19,542	6,390.96	119.45	0.33	180	28.16	9.21				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	26,827	9,260.57	126.08	0.35	428	46.22	15.95	9.46	3.89	1.27 (1.09, 1.49)	0.002
Dabigatran	21,631	7,101.32	119.91	0.33	261	36.75	12.07				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	20,835	3,121.17	54.72	0.15	201	64.4	9.65	18.58	2.78	1.41 (1.13, 1.74)	0.002
Dabigatran	20,835	3,121.17	54.72	0.15	143	45.82	6.86				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	20,835	7,191.33	126.07	0.35	333	46.31	15.98	10.65	4.22	1.31 (1.11, 1.55)	0.001
Dabigatran	20,835	6,870.31	120.44	0.33	245	35.66	11.76				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,526	5,714.86	119.1	0.33	407	71.22	23.22	14.08	5.55	1.25 (1.07, 1.47)	0.005
Dabigatran	13,980	4,323.18	112.95	0.31	247	57.13	17.67				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	13,481	1,890.25	51.21	0.14	177	93.64	13.13	11.64	1.63	1.14 (0.92, 1.42)	0.228
Dabigatran	13,481	1,890.25	51.21	0.14	155	82	11.5				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	13,481	4,390.11	118.94	0.33	323	73.57	23.96	17.23	6.45	1.31 (1.11, 1.55)	0.002
Dabigatran	13,481	4,188.73	113.49	0.31	236	56.34	17.51				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,623	4,842.13	113.2	0.31	413	85.29	26.44	6.42	3.15	1.08 (0.93, 1.25)	0.318
Dabigatran	13,357	3,942.98	107.82	0.3	311	78.87	23.28				

Table 24. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASC Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,542	1,656.93	48.25	0.13	200	120.71	15.95	4.83	0.64	1.04 (0.85, 1.27)	0.686
Dabigatran	12,542	1,656.93	48.25	0.13	192	115.88	15.31				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,542	3,905.66	113.74	0.31	340	87.05	27.11	8.04	3.75	1.10 (0.94, 1.29)	0.218
Dabigatran	12,542	3,708.01	107.99	0.3	293	79.02	23.36				

¹Conditional analysis includes informative events and person-time.

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

Table 25. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,726	3,711.82	126.4	0.35	68	18.32	6.34				
Dabigatran	7,779	2,451.25	115.09	0.32	45	18.36	5.78	-0.04	0.55	1.01 (0.69, 1.47)	0.968
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,582	1,118.93	53.9	0.15	25	22.34	3.3				
Dabigatran	7,582	1,118.93	53.9	0.15	25	22.34	3.3	0	0	1.00 (0.57, 1.74)	1
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,582	2,591.50	124.84	0.34	47	18.14	6.2				
Dabigatran	7,582	2,390.63	115.16	0.32	44	18.41	5.8	-0.27	0.4	0.98 (0.65, 1.48)	0.932
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	50,401	17,982.00	130.31	0.36	549	30.53	10.89				
Dabigatran	37,972	12,723.87	122.39	0.34	331	26.01	8.72	4.52	2.18	1.18 (1.03, 1.36)	0.016
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,179	5,705.52	56.05	0.15	256	44.87	6.89				
Dabigatran	37,179	5,705.52	56.05	0.15	197	34.53	5.3	10.34	1.59	1.30 (1.08, 1.56)	0.006
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,179	13,245.00	130.12	0.36	418	31.56	11.24				
Dabigatran	37,179	12,478.69	122.59	0.34	319	25.56	8.58	6	2.66	1.24 (1.07, 1.44)	0.004
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	34,578	11,415.89	120.59	0.33	635	55.62	18.36				
Dabigatran	26,850	8,275.39	112.57	0.31	408	49.3	15.2	6.32	3.17	1.14 (1.01, 1.29)	0.036
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	25,923	3,678.69	51.83	0.14	292	79.38	11.26				
Dabigatran	25,923	3,678.69	51.83	0.14	245	66.6	9.45	12.78	1.81	1.19 (1.01, 1.41)	0.043

Table 25. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	25,923	8,530.15	120.19	0.33	498	58.38	19.21	9.57	4.17	1.21 (1.06, 1.38)	0.005
Dabigatran	25,923	7,989.80	112.57	0.31	390	48.81	15.04				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,408	4,177.54	105.9	0.29	435	104.13	30.19	17.57	5.34	1.20 (1.03, 1.39)	0.016
Dabigatran	11,872	3,408.19	104.86	0.29	295	86.56	24.85				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,241	1,440.71	46.81	0.13	205	142.29	18.24	15.96	2.05	1.13 (0.92, 1.38)	0.243
Dabigatran	11,241	1,440.71	46.81	0.13	182	126.33	16.19				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,241	3,264.82	106.08	0.29	343	105.06	30.51	19.8	5.87	1.23 (1.05, 1.44)	0.012
Dabigatran	11,241	3,248.88	105.56	0.29	277	85.26	24.64				

¹Conditional analysis includes informative events and person-time.

Table 26. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	111,816	37,792.24	123.45	0.34	1,705	45.12	15.25	21.57	8.8	2.10 (1.90, 2.32)	<0.001
Apixaban	77,232	21,151.93	100.03	0.27	498	23.54	6.45				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	75,889	10,853.49	52.24	0.14	733	67.54	9.66	38.51	5.51	2.33 (2.04, 2.66)	<0.001
Apixaban	75,889	10,853.49	52.24	0.14	315	29.02	4.15				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	75,889	25,335.44	121.94	0.33	1,234	48.71	16.26	25.6	9.91	2.29 (2.06, 2.55)	<0.001
Apixaban	75,889	20,856.28	100.38	0.27	482	23.11	6.35				

¹Conditional analysis includes informative events and person-time.

Table 27. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	95,580	32,365.36	123.68	0.34	1,289	39.83	13.49	19.13	7.78	2.09 (1.86, 2.35)	<0.001
Apixaban	64,648	17,827.12	100.72	0.28	369	20.7	5.71				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	63,624	9,121.46	52.36	0.14	529	58	8.31	32.89	4.72	2.31 (1.98, 2.70)	<0.001
Apixaban	63,624	9,121.46	52.36	0.14	229	25.11	3.6				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	63,624	21,305.34	122.31	0.33	899	42.2	14.13	22.02	8.55	2.26 (2.00, 2.56)	<0.001
Apixaban	63,624	17,596.51	101.02	0.28	355	20.17	5.58				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,236	5,426.88	122.08	0.33	416	76.66	25.62	37.86	15.37	2.23 (1.83, 2.72)	<0.001
Apixaban	12,584	3,324.81	96.5	0.26	129	38.8	10.25				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,067	1,679.34	50.83	0.14	210	125.05	17.4	76.82	10.69	2.59 (2.01, 3.35)	<0.001
Apixaban	12,067	1,679.34	50.83	0.14	81	48.23	6.71				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,067	3,968.32	120.12	0.33	331	83.41	27.43	45.37	17.32	2.44 (1.98, 3.01)	<0.001
Apixaban	12,067	3,207.14	97.08	0.27	122	38.04	10.11				

¹Conditional analysis includes informative events and person-time.

Table 28. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	59,919	19,861.98	121.07	0.33	774	38.97	12.92	19.27	7.53	2.14 (1.84, 2.49)	<0.001
Apixaban	40,104	10,966.23	99.88	0.27	216	19.7	5.39				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,359	5,660.85	52.53	0.14	332	58.65	8.44	31.8	4.57	2.18 (1.80, 2.65)	<0.001
Apixaban	39,359	5,660.85	52.53	0.14	152	26.85	3.86				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,359	12,870.32	119.44	0.33	549	42.66	13.95	23.2	8.61	2.35 (2.01, 2.76)	<0.001
Apixaban	39,359	10,795.76	100.18	0.27	210	19.45	5.34				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,897	17,930.26	126.19	0.35	931	51.92	17.94	24.24	10.34	2.08 (1.82, 2.38)	<0.001
Apixaban	37,128	10,185.70	100.2	0.27	282	27.69	7.6				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	36,358	5,215.49	52.39	0.14	406	77.85	11.17	44.87	6.44	2.36 (1.97, 2.82)	<0.001
Apixaban	36,358	5,215.49	52.39	0.14	172	32.98	4.73				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	36,358	12,417.29	124.74	0.34	683	55	18.79	28.04	11.36	2.25 (1.95, 2.59)	<0.001
Apixaban	36,358	10,013.53	100.6	0.28	270	26.96	7.43				

¹Conditional analysis includes informative events and person-time.

Table 29. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	57,787	19,909.37	125.84	0.34	632	31.74	10.94	13.91	5.99	1.95 (1.65, 2.29)	<0.001
Apixaban	38,032	10,540.22	101.23	0.28	188	17.84	4.94				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,491	5,480.65	53.39	0.15	257	46.89	6.85	23.9	3.49	2.04 (1.65, 2.52)	<0.001
Apixaban	37,491	5,480.65	53.39	0.15	126	22.99	3.36				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,491	12,780.59	124.51	0.34	441	34.51	11.76	16.76	6.83	2.10 (1.77, 2.50)	<0.001
Apixaban	37,491	10,423.04	101.54	0.28	185	17.75	4.93				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	44,196	14,954.61	123.59	0.34	825	55.17	18.67	28.07	11.22	2.24 (1.94, 2.59)	<0.001
Apixaban	31,939	8,784.27	100.46	0.28	238	27.09	7.45				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	30,797	4,378.82	51.93	0.14	358	81.76	11.62	45.67	6.49	2.27 (1.88, 2.73)	<0.001
Apixaban	30,797	4,378.82	51.93	0.14	158	36.08	5.13				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	30,797	10,287.68	122.01	0.33	598	58.13	19.42	32.02	12.21	2.44 (2.09, 2.85)	<0.001
Apixaban	30,797	8,504.11	100.86	0.28	222	26.11	7.21				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,833	2,928.27	108.77	0.3	248	84.69	25.22	45.29	15.31	2.28 (1.75, 2.97)	<0.001
Apixaban	7,261	1,827.44	91.93	0.25	72	39.4	9.92				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,020	898.42	46.74	0.13	99	110.19	14.1	64.56	8.26	2.41 (1.68, 3.47)	<0.001
Apixaban	7,020	898.42	46.74	0.13	41	45.64	5.84				

Table 29. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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		Hazard Ratio (95% Confidence Interval)	Wald P-Value
								per 1,000 Person-Years	Risk per 1,000 New Users		
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,020	2,078.32	108.13	0.3	180	86.61	25.64	47.27	15.67	2.33 (1.76, 3.07)	<0.001
Apixaban	7,020	1,779.64	92.59	0.25	70	39.33	9.97				

¹Conditional analysis includes informative events and person-time.

Table 30. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,845	1,253.20	119.05	0.33	13	10.37	3.38	*****	*****	3.35 (0.76, 14.84)	0.112
Apixaban	2,079	586.61	103.06	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,044	303.26	54.19	0.15	*****	*****	*****	9.89	1.47	4.00 (0.45, 35.79)	0.215
Apixaban	2,044	303.26	54.19	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,044	650.49	116.24	0.32	*****	*****	*****	8.84	2.94	3.81 (0.81, 17.95)	0.091
Apixaban	2,044	578.58	103.39	0.28	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,983	6,664.10	128.22	0.35	127	19.06	6.69	*****	*****	2.33 (1.56, 3.47)	<0.001
Apixaban	11,656	3,412.18	106.92	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,587	1,764.71	55.63	0.15	*****	*****	*****	14.17	2.16	2.14 (1.29, 3.54)	0.003
Apixaban	11,587	1,764.71	55.63	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,587	4,053.59	127.78	0.35	*****	*****	*****	10.41	4.14	2.34 (1.54, 3.57)	<0.001
Apixaban	11,587	3,397.62	107.1	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	28,194	9,822.58	127.25	0.35	302	30.75	10.71	17	6.77	2.41 (1.87, 3.11)	<0.001
Apixaban	18,753	5,384.17	104.87	0.29	74	13.74	3.95				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,534	2,789.63	54.98	0.15	111	39.79	5.99	23.66	3.56	2.47 (1.74, 3.49)	<0.001
Apixaban	18,534	2,789.63	54.98	0.15	45	16.13	2.43				

Table 30. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,534	6,379.88	125.73	0.34	198	31.04	10.68	17.54	6.8	2.41 (1.84, 3.16)	<0.001
Apixaban	18,534	5,333.47	105.11	0.29	72	13.5	3.88				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,248	9,387.62	125.84	0.34	435	46.34	15.96	23.48	9.71	2.23 (1.82, 2.74)	<0.001
Apixaban	18,872	5,161.97	99.91	0.27	118	22.86	6.25				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,616	2,684.04	52.66	0.14	191	71.16	10.26	43.22	6.23	2.55 (1.95, 3.33)	<0.001
Apixaban	18,616	2,684.04	52.66	0.14	75	27.94	4.03				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,616	6,338.77	124.37	0.34	314	49.54	16.87	26.8	10.64	2.40 (1.94, 2.97)	<0.001
Apixaban	18,616	5,102.06	100.1	0.27	116	22.74	6.23				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,765	5,772.68	118.69	0.32	410	71.02	23.08	34.85	13.49	2.15 (1.76, 2.63)	<0.001
Apixaban	13,134	3,482.85	96.86	0.27	126	36.18	9.59				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,727	1,739.85	49.93	0.14	189	108.63	14.85	62.07	8.49	2.33 (1.80, 3.03)	<0.001
Apixaban	12,727	1,739.85	49.93	0.14	81	46.56	6.36				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,727	4,083.95	117.2	0.32	302	73.95	23.73	37.69	14.06	2.23 (1.80, 2.75)	<0.001
Apixaban	12,727	3,392.42	97.36	0.27	123	36.26	9.66				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,781	4,892.05	113.23	0.31	418	85.44	26.49	38.07	14.87	2.00 (1.66, 2.42)	<0.001
Apixaban	12,738	3,124.16	89.58	0.25	148	47.37	11.62				

Table 30. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,024	1,533.47	46.58	0.13	193	125.86	16.05	65.86	8.4	2.10 (1.64, 2.69)	<0.001
Apixaban	12,024	1,533.47	46.58	0.13	92	59.99	7.65				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,024	3,714.25	112.83	0.31	328	88.31	27.28	42.29	15.88	2.12 (1.74, 2.59)	<0.001
Apixaban	12,024	2,977.02	90.43	0.25	137	46.02	11.39				

¹Conditional analysis includes informative events and person-time.

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

Table 31. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,937	3,780.12	126.24	0.35	71	18.78	6.49	7.96	3.41	1.85 (1.13, 3.05)	0.015
Apixaban	6,486	1,848.42	104.09	0.28	20	10.82	3.08				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	6,472	974.13	54.98	0.15	30	30.8	4.64	15.4	2.32	2.00 (1.08, 3.72)	0.028
Apixaban	6,472	974.13	54.98	0.15	15	15.4	2.32				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	6,472	2,221.82	125.39	0.34	42	18.9	6.49	8.05	3.4	1.90 (1.11, 3.23)	0.019
Apixaban	6,472	1,843.56	104.04	0.28	20	10.85	3.09				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,220	18,227.38	129.98	0.36	554	30.39	10.82	16.87	6.91	2.46 (2.03, 2.98)	<0.001
Apixaban	33,272	9,611.59	105.51	0.29	130	13.53	3.91				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,228	4,987.09	54.82	0.15	206	41.31	6.2	23.26	3.49	2.29 (1.79, 2.93)	<0.001
Apixaban	33,228	4,987.09	54.82	0.15	90	18.05	2.71				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,228	11,741.85	129.07	0.35	360	30.66	10.83	17.12	6.92	2.46 (2.01, 3.01)	<0.001
Apixaban	33,228	9,602.88	105.56	0.29	130	13.54	3.91				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	35,069	11,549.72	120.29	0.33	640	55.41	18.25	27.69	10.83	2.17 (1.84, 2.56)	<0.001
Apixaban	25,062	6,708.68	97.77	0.27	186	27.73	7.42				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	24,588	3,454.66	51.32	0.14	270	78.16	10.98	43.71	6.14	2.27 (1.83, 2.81)	<0.001
Apixaban	24,588	3,454.66	51.32	0.14	119	34.45	4.84				

Table 31. Effect Estimates for Risk of Major Extracranial Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	24,588	8,043.89	119.49	0.33	458	56.94	18.63	29.04	11.14	2.20 (1.85, 2.61)	<0.001
Apixaban	24,588	6,594.90	97.97	0.27	184	27.9	7.48				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,590	4,235.01	106.02	0.29	440	103.9	30.16	49.59	17.11	2.09 (1.75, 2.51)	<0.001
Apixaban	12,412	2,983.24	87.79	0.24	162	54.3	13.05				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,496	1,409.49	44.78	0.12	212	150.41	18.44	83.01	10.18	2.23 (1.75, 2.84)	<0.001
Apixaban	11,496	1,409.49	44.78	0.12	95	67.4	8.26				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,496	3,293.70	104.65	0.29	370	112.34	32.19	59.23	19.31	2.30 (1.90, 2.79)	<0.001
Apixaban	11,496	2,787.01	88.55	0.24	148	53.1	12.87				

¹Conditional analysis includes informative events and person-time.

Table 32. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	84,562	26,877.42	116.09	0.32	1,079	40.15	12.76	16.45	6.28	1.84 (1.65, 2.05)	<0.001
Apixaban	76,887	21,016.72	99.84	0.27	498	23.7	6.48				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Dabigatran	69,054	9,442.44	49.94	0.14	539	57.08	7.81	30.08	4.11	2.11 (1.82, 2.45)	<0.001
Apixaban	69,054	9,442.44	49.94	0.14	255	27.01	3.69				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	69,054	21,886.65	115.77	0.32	894	40.85	12.95	18.43	6.78	1.96 (1.75, 2.20)	<0.001
Apixaban	69,054	19,001.49	100.51	0.28	426	22.42	6.17				

¹Conditional analysis includes informative events and person-time.

Table 33. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	71,477	22,739.81	116.2	0.32	796	35	11.14	14.17	5.4	1.83 (1.62, 2.07)	<0.001
Apixaban	64,349	17,708.30	100.51	0.28	369	20.84	5.73				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	58,127	7,954.50	49.98	0.14	388	48.78	6.68	25.77	3.53	2.12 (1.78, 2.53)	<0.001
Apixaban	58,127	7,954.50	49.98	0.14	183	23.01	3.15				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	58,127	18,436.38	115.85	0.32	645	34.99	11.1	15.09	5.59	1.90 (1.66, 2.18)	<0.001
Apixaban	58,127	16,084.70	101.07	0.28	320	19.89	5.51				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,085	4,137.62	115.5	0.32	283	68.4	21.63	29.41	11.34	1.90 (1.54, 2.34)	<0.001
Apixaban	12,538	3,308.42	96.38	0.26	129	38.99	10.29				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,645	1,416.73	48.61	0.13	156	110.11	14.65	63.53	8.45	2.36 (1.77, 3.15)	<0.001
Apixaban	10,645	1,416.73	48.61	0.13	66	46.59	6.2				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,645	3,350.41	114.96	0.31	242	72.23	22.73	37.05	13.34	2.19 (1.73, 2.77)	<0.001
Apixaban	10,645	2,842.50	97.53	0.27	100	35.18	9.39				

¹Conditional analysis includes informative events and person-time.

Table 34. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	43,693	13,759.20	115.02	0.31	456	33.14	10.44	13.18	4.99	1.77 (1.51, 2.09)	<0.001
Apixaban	39,862	10,869.87	99.6	0.27	217	19.96	5.44				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	35,590	4,924.68	50.54	0.14	241	48.94	6.77	25.59	3.54	2.10 (1.68, 2.62)	<0.001
Apixaban	35,590	4,924.68	50.54	0.14	115	23.35	3.23				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	35,590	11,231.79	115.27	0.32	379	33.74	10.65	15.43	5.62	1.96 (1.64, 2.34)	<0.001
Apixaban	35,590	9,775.76	100.33	0.27	179	18.31	5.03				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,869	13,118.22	117.24	0.32	623	47.49	15.24	19.8	7.65	1.89 (1.64, 2.18)	<0.001
Apixaban	37,025	10,146.86	100.1	0.27	281	27.69	7.59				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,046	4,469.73	49.4	0.14	296	66.22	8.96	33.34	4.51	2.01 (1.65, 2.45)	<0.001
Apixaban	33,046	4,469.73	49.4	0.14	147	32.89	4.45				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,046	10,520.50	116.28	0.32	513	48.76	15.52	22.18	8.2	2.00 (1.72, 2.33)	<0.001
Apixaban	33,046	9,104.61	100.63	0.28	242	26.58	7.32				

¹Conditional analysis includes informative events and person-time.

Table 35. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,753	13,154.60	117.9	0.32	308	23.41	7.56	5.47	2.59	1.41 (1.18, 1.70)	<0.001
Apixaban	37,862	10,478.49	101.08	0.28	188	17.94	4.97				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,356	4,660.42	51.03	0.14	158	33.9	4.74	11.37	1.59	1.50 (1.18, 1.93)	0.001
Apixaban	33,356	4,660.42	51.03	0.14	105	22.53	3.15				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,356	10,747.87	117.69	0.32	250	23.26	7.49	6.75	2.88	1.52 (1.24, 1.86)	<0.001
Apixaban	33,356	9,328.57	102.15	0.28	154	16.51	4.62				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	34,534	11,104.31	117.45	0.32	521	46.92	15.09	19.75	7.63	1.90 (1.63, 2.22)	<0.001
Apixaban	31,785	8,721.71	100.22	0.27	237	27.17	7.46				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	27,960	3,842.44	50.19	0.14	259	67.41	9.26	36.17	4.97	2.16 (1.74, 2.68)	<0.001
Apixaban	27,960	3,842.44	50.19	0.14	120	31.23	4.29				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	27,960	8,966.28	117.13	0.32	444	49.52	15.88	24.11	8.87	2.12 (1.79, 2.51)	<0.001
Apixaban	27,960	7,715.29	100.79	0.28	196	25.4	7.01				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	9,275	2,618.52	103.12	0.28	250	95.47	26.95	55.29	16.87	2.50 (1.92, 3.24)	<0.001
Apixaban	7,240	1,816.52	91.64	0.25	73	40.19	10.08				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,751	810.25	43.84	0.12	102	125.89	15.11	76.52	9.18	2.55 (1.77, 3.68)	<0.001
Apixaban	6,751	810.25	43.84	0.12	40	49.37	5.93				

Table 35. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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 in	Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Difference per 1,000 Person-Years	Risk per 1,000 New Users		
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,751	1,880.79	101.76	0.28	183	97.3	27.11	57.84	17.18	2.55 (1.92, 3.38)	<0.001
Apixaban	6,751	1,698.15	91.87	0.25	67	39.45	9.92				

¹Conditional analysis includes informative events and person-time.

Table 36. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	2,775	860.22	113.22	0.31	*****	*****	*****	8.18	2.63	3.65 (0.80, 16.69)	0.094
Apixaban	2,050	581.06	103.53	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	1,959	269.58	50.26	0.14	*****	*****	*****	14.84	2.04	5.00 (0.58, 42.80)	0.142
Apixaban	1,959	269.58	50.26	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	1,959	611.11	113.94	0.31	*****	*****	*****	8.03	2.55	5.84 (0.70, 48.54)	0.103
Apixaban	1,959	558.56	104.14	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	12,962	4,152.11	117	0.32	*****	*****	*****	7.02	2.5	1.83 (1.18, 2.83)	0.007
Apixaban	11,594	3,380.86	106.51	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,670	1,535.13	52.55	0.14	*****	*****	*****	13.03	1.87	2.11 (1.20, 3.70)	0.009
Apixaban	10,670	1,535.13	52.55	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,670	3,418.60	117.02	0.32	*****	*****	*****	7.46	2.62	1.91 (1.19, 3.07)	0.007
Apixaban	10,670	3,120.74	106.83	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	19,816	6,490.63	119.64	0.33	184	28.35	9.29	14.53	5.32	2.21 (1.68, 2.89)	<0.001
Apixaban	18,659	5,353.49	104.79	0.29	74	13.82	3.97				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	16,641	2,371.64	52.05	0.14	90	37.95	5.41	22.77	3.24	2.50 (1.70, 3.68)	<0.001
Apixaban	16,641	2,371.64	52.05	0.14	36	15.18	2.16				

Table 36. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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	Difference in	Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Rate	Risk per		
								per 1,000 Person-Years	1,000 New Users		
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	16,641	5,439.00	119.38	0.33	154	28.31	9.25	14.96	5.41	2.29 (1.71, 3.07)	<0.001
Apixaban	16,641	4,792.91	105.2	0.29	64	13.35	3.85				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	21,646	7,105.08	119.89	0.33	261	36.73	12.06	13.31	5.67	1.69 (1.36, 2.10)	<0.001
Apixaban	18,800	5,123.62	99.54	0.27	120	23.42	6.38				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	17,117	2,367.47	50.52	0.14	122	51.53	7.13	22.39	3.1	1.77 (1.32, 2.38)	<0.001
Apixaban	17,117	2,367.47	50.52	0.14	69	29.15	4.03				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	17,117	5,626.09	120.05	0.33	215	38.21	12.56	15.61	6.37	1.80 (1.42, 2.28)	<0.001
Apixaban	17,117	4,688.69	100.05	0.27	106	22.61	6.19				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,991	4,324.43	112.89	0.31	247	57.12	17.65	21.35	8.2	1.75 (1.41, 2.18)	<0.001
Apixaban	13,112	3,467.30	96.59	0.26	124	35.76	9.46				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	11,373	1,507.72	48.42	0.13	113	74.95	9.94	31.17	4.13	1.71 (1.26, 2.32)	<0.001
Apixaban	11,373	1,507.72	48.42	0.13	66	43.77	5.8				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	11,373	3,491.79	112.14	0.31	207	59.28	18.2	25.07	9.06	1.87 (1.47, 2.36)	<0.001
Apixaban	11,373	3,039.75	97.62	0.27	104	34.21	9.14				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,372	3,944.95	107.75	0.3	311	78.83	23.26	31.25	11.58	1.87 (1.53, 2.27)	<0.001
Apixaban	12,672	3,110.39	89.65	0.25	148	47.58	11.68				

Table 36. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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 in	Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Difference per 1,000 Person-Years	Risk per 1,000 New Users		
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,805	1,339.38	45.28	0.12	157	117.22	14.53	58.98	7.31	2.01 (1.53, 2.64)	<0.001
Apixaban	10,805	1,339.38	45.28	0.12	78	58.24	7.22				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,805	3,158.75	106.78	0.29	255	80.73	23.6	35.46	12.4	1.98 (1.59, 2.46)	<0.001
Apixaban	10,805	2,672.77	90.35	0.25	121	45.27	11.2				

¹Conditional analysis includes informative events and person-time.

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

Table 37. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	7,788	2,453.26	115.06	0.32	45	18.34	5.78	7.48	2.68	1.81 (1.07, 3.07)	0.027
Apixaban	6,455	1,841.15	104.18	0.29	20	10.86	3.1				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,098	859.78	51.5	0.14	17	19.77	2.79	*****	*****	2.12 (0.92, 4.92)	0.079
Apixaban	6,098	859.78	51.5	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,098	1,924.61	115.28	0.32	35	18.19	5.74	7.86	2.79	1.91 (1.08, 3.37)	0.026
Apixaban	6,098	1,742.89	104.39	0.29	18	10.33	2.95				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	38,021	12,735.60	122.34	0.33	331	25.99	8.71	12.25	4.75	2.04 (1.67, 2.51)	<0.001
Apixaban	33,078	9,534.18	105.28	0.29	131	13.74	3.96				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	30,531	4,396.15	52.59	0.14	157	35.71	5.14	*****	*****	2.12 (1.61, 2.80)	<0.001
Apixaban	30,531	4,396.15	52.59	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	30,531	10,198.85	122.01	0.33	259	25.4	8.48	11.89	4.59	2.03 (1.63, 2.52)	<0.001
Apixaban	30,531	8,811.10	105.41	0.29	119	13.51	3.9				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	26,875	8,280.22	112.53	0.31	408	49.27	15.18	21.56	7.78	1.91 (1.60, 2.27)	<0.001
Apixaban	24,997	6,675.35	97.54	0.27	185	27.71	7.4				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	22,081	2,971.20	49.15	0.13	198	66.64	8.97	36.35	4.89	2.20 (1.71, 2.82)	<0.001
Apixaban	22,081	2,971.20	49.15	0.13	90	30.29	4.08				

Table 37. Effect Estimates for Risk of Major Extracranial Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	22,081	6,800.57	112.49	0.31	333	48.97	15.08	22.13	7.88	1.93 (1.60, 2.34)	<0.001
Apixaban	22,081	5,923.91	97.99	0.27	159	26.84	7.2				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	11,878	3,408.34	104.81	0.29	295	86.55	24.84	31.93	11.73	1.77 (1.46, 2.15)	<0.001
Apixaban	12,357	2,966.03	87.67	0.24	162	54.62	13.11				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	9,997	1,222.69	44.67	0.12	186	152.12	18.61	86.69	10.6	2.32 (1.79, 3.02)	<0.001
Apixaban	9,997	1,222.69	44.67	0.12	80	65.43	8				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	9,997	2,859.68	104.48	0.29	261	91.27	26.11	39.18	13.4	1.93 (1.56, 2.39)	<0.001
Apixaban	9,997	2,438.17	89.08	0.24	127	52.09	12.7				

¹Conditional analysis includes informative events and person-time.

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

Table 38. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	110,113	37,287.25	123.68	0.34	1,510	40.5	13.71	3.19	1.85	1.10 (1.01, 1.19)	0.023
Dabigatran	84,473	26,858.70	116.13	0.32	1,002	37.31	11.86				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	82,326	12,020.37	53.33	0.15	689	57.32	8.37	5.41	0.79	1.10 (0.99, 1.23)	0.073
Dabigatran	82,326	12,020.37	53.33	0.15	624	51.91	7.58				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	82,326	27,774.62	123.23	0.34	1,178	42.41	14.31	6.02	2.71	1.17 (1.08, 1.28)	<0.001
Dabigatran	82,326	26,242.22	116.43	0.32	955	36.39	11.6				

¹Conditional analysis includes informative events and person-time.

Table 39. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	94,068	31,920.44	123.94	0.34	1,137	35.62	12.09	3.01	1.71	1.10 (1.00, 1.21)	0.047
Dabigatran	71,402	22,722.51	116.23	0.32	741	32.61	10.38				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	69,758	10,226.98	53.55	0.15	523	51.14	7.5	4.99	0.73	1.11 (0.98, 1.25)	0.106
Dabigatran	69,758	10,226.98	53.55	0.15	472	46.15	6.77				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	69,758	23,594.14	123.54	0.34	883	37.42	12.66	5.42	2.45	1.17 (1.06, 1.29)	0.002
Dabigatran	69,758	22,245.22	116.48	0.32	712	32.01	10.21				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,045	5,366.81	122.17	0.33	373	69.5	23.25	6.4	3.28	1.13 (0.96, 1.32)	0.137
Dabigatran	13,071	4,136.20	115.58	0.32	261	63.1	19.97				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,416	1,791.59	52.7	0.14	174	97.12	14.01	12.84	1.85	1.15 (0.93, 1.43)	0.202
Dabigatran	12,416	1,791.59	52.7	0.14	151	84.28	12.16				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,416	4,137.37	121.71	0.33	293	70.82	23.6	10.11	4.27	1.19 (1.00, 1.41)	0.045
Dabigatran	12,416	3,953.22	116.29	0.32	240	60.71	19.33				

¹Conditional analysis includes informative events and person-time.

Table 40. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	58,957	19,586.52	121.34	0.33	685	34.97	11.62	3.7	1.77	1.13 (1.01, 1.28)	0.041
Dabigatran	43,649	13,750.04	115.06	0.32	430	31.27	9.85				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	42,684	6,223.10	53.25	0.15	287	46.12	6.72	4.34	0.63	1.10 (0.93, 1.31)	0.249
Dabigatran	42,684	6,223.10	53.25	0.15	260	41.78	6.09				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	42,684	14,091.00	120.58	0.33	510	36.19	11.95	5.28	2.2	1.18 (1.04, 1.35)	0.012
Dabigatran	42,684	13,457.06	115.15	0.32	416	30.91	9.75				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,156	17,700.73	126.38	0.35	825	46.61	16.13	2.97	2.12	1.08 (0.97, 1.20)	0.171
Dabigatran	40,824	13,108.67	117.28	0.32	572	43.64	14.01				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,269	5,728.64	53.28	0.15	388	67.73	9.88	11	1.6	1.19 (1.03, 1.38)	0.018
Dabigatran	39,269	5,728.64	53.28	0.15	325	56.73	8.28				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,269	13,558.25	126.11	0.35	664	48.97	16.91	7.24	3.46	1.18 (1.05, 1.32)	0.004
Dabigatran	39,269	12,651.02	117.67	0.32	528	41.74	13.45				

¹Conditional analysis includes informative events and person-time.

Table 41. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	56,862	19,632.17	126.11	0.35	563	28.68	9.9	7.45	3.05	1.38 (1.19, 1.59)	<0.001
Dabigatran	40,695	13,143.72	117.97	0.32	279	21.23	6.86				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,926	5,941.38	54.35	0.15	253	42.58	6.34	12.96	1.93	1.44 (1.19, 1.74)	<0.001
Dabigatran	39,926	5,941.38	54.35	0.15	176	29.62	4.41				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,926	13,763.29	125.91	0.34	412	29.93	10.32	9.34	3.66	1.48 (1.27, 1.73)	<0.001
Dabigatran	39,926	12,914.53	118.14	0.32	266	20.6	6.66				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	43,527	14,753.69	123.8	0.34	724	49.07	16.63	4.83	2.4	1.11 (0.99, 1.24)	0.08
Dabigatran	34,508	11,097.34	117.46	0.32	491	44.24	14.23				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,403	4,890.12	53.47	0.15	344	70.35	10.3	10.02	1.47	1.17 (1.00, 1.36)	0.053
Dabigatran	33,403	4,890.12	53.47	0.15	295	60.33	8.83				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,403	11,304.40	123.61	0.34	566	50.07	16.94	6.31	2.84	1.14 (1.01, 1.29)	0.037
Dabigatran	33,403	10,763.47	117.69	0.32	471	43.76	14.1				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,724	2,901.39	108.98	0.3	223	76.86	22.93	-11.77	-2.09	0.88 (0.73, 1.06)	0.171
Dabigatran	9,270	2,617.65	103.14	0.28	232	88.63	25.03				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	8,388	1,075.86	46.85	0.13	101	93.88	12.04	-19.52	-2.5	0.83 (0.64, 1.08)	0.16
Dabigatran	8,388	1,075.86	46.85	0.13	122	113.4	14.54				

Table 41. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	8,388	2,516.20	109.57	0.3	193	76.7	23.01	-9.35	-1.43	0.90 (0.74, 1.10)	0.316
Dabigatran	8,388	2,382.12	103.73	0.28	205	86.06	24.44				

¹Conditional analysis includes informative events and person-time.

Table 42. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,766	1,229.68	119.26	0.33	*****	*****	*****	-2.34	-0.6	0.76 (0.31, 1.88)	0.559
Dabigatran	2,768	859.06	113.36	0.31	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,726	395.41	52.98	0.15	*****	*****	*****	2.53	0.37	1.17 (0.39, 3.47)	0.782
Dabigatran	2,726	395.41	52.98	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,726	888.59	119.06	0.33	*****	*****	*****	-0.47	0	0.94 (0.37, 2.37)	0.895
Dabigatran	2,726	849.07	113.76	0.31	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,605	6,550.83	128.6	0.35	*****	*****	*****	1.97	1.18	1.17 (0.86, 1.59)	0.321
Dabigatran	12,943	4,148.21	117.06	0.32	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,668	1,959.70	56.5	0.15	*****	*****	*****	3.06	0.47	1.17 (0.75, 1.82)	0.497
Dabigatran	12,668	1,959.70	56.5	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,668	4,454.51	128.43	0.35	*****	*****	*****	0.93	0.79	1.10 (0.78, 1.55)	0.587
Dabigatran	12,668	4,065.50	117.22	0.32	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,766	9,689.18	127.46	0.35	271	27.97	9.76	1.29	1.02	1.06 (0.87, 1.28)	0.575
Dabigatran	19,794	6,483.95	119.65	0.33	173	26.68	8.74				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	19,542	2,938.95	54.93	0.15	121	41.17	6.19	5.78	0.87	1.16 (0.90, 1.51)	0.258
Dabigatran	19,542	2,938.95	54.93	0.15	104	35.39	5.32				

Table 42. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	19,542	6,769.98	126.53	0.35	199	29.39	10.18	2.95	1.54	1.11 (0.91, 1.37)	0.302
Dabigatran	19,542	6,390.96	119.45	0.33	169	26.44	8.65				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	26,827	9,260.57	126.08	0.35	382	41.25	14.24	7.31	3.1	1.23 (1.04, 1.44)	0.013
Dabigatran	21,631	7,101.32	119.91	0.33	241	33.94	11.14				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	20,835	3,121.17	54.72	0.15	177	56.71	8.5	15.06	2.26	1.36 (1.09, 1.71)	0.008
Dabigatran	20,835	3,121.17	54.72	0.15	130	41.65	6.24				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	20,835	7,191.33	126.07	0.35	303	42.13	14.54	9.38	3.74	1.29 (1.09, 1.54)	0.004
Dabigatran	20,835	6,870.31	120.44	0.33	225	32.75	10.8				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,526	5,714.86	119.1	0.33	376	65.79	21.45	12.36	4.93	1.24 (1.05, 1.46)	0.01
Dabigatran	13,980	4,323.18	112.95	0.31	231	53.43	16.52				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	13,481	1,890.25	51.21	0.14	166	87.82	12.31	10.58	1.48	1.14 (0.91, 1.42)	0.258
Dabigatran	13,481	1,890.25	51.21	0.14	146	77.24	10.83				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	13,481	4,390.11	118.94	0.33	300	68.34	22.25	15.57	5.86	1.30 (1.09, 1.55)	0.003
Dabigatran	13,481	4,188.73	113.49	0.31	221	52.76	16.39				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,623	4,842.13	113.2	0.31	357	73.73	22.85	1.7	1.59	1.02 (0.87, 1.19)	0.795
Dabigatran	13,357	3,942.98	107.82	0.3	284	72.03	21.26				

Table 42. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,542	1,656.93	48.25	0.13	169	102	13.47	-2.41	-0.32	0.98 (0.79, 1.21)	0.829
Dabigatran	12,542	1,656.93	48.25	0.13	173	104.41	13.79				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,542	3,905.66	113.74	0.31	287	73.48	22.88	1.75	1.67	1.03 (0.87, 1.21)	0.764
Dabigatran	12,542	3,708.01	107.99	0.3	266	71.74	21.21				

¹Conditional analysis includes informative events and person-time.

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

Table 43. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,726	3,711.82	126.4	0.35	63	16.97	5.87	-0.16	0.47	1.00 (0.68, 1.48)	0.985
Dabigatran	7,779	2,451.25	115.09	0.32	42	17.13	5.4				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,582	1,118.93	53.9	0.15	23	20.56	3.03	0.89	0.13	1.05 (0.58, 1.88)	0.882
Dabigatran	7,582	1,118.93	53.9	0.15	22	19.66	2.9				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,582	2,591.50	124.84	0.34	44	16.98	5.8	-0.17	0.4	0.99 (0.65, 1.51)	0.959
Dabigatran	7,582	2,390.63	115.16	0.32	41	17.15	5.41				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	50,401	17,982.00	130.31	0.36	483	26.86	9.58	3.2	1.66	1.14 (0.99, 1.32)	0.074
Dabigatran	37,972	12,723.87	122.39	0.34	301	23.66	7.93				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,179	5,705.52	56.05	0.15	227	39.79	6.11	7.89	1.21	1.25 (1.03, 1.52)	0.026
Dabigatran	37,179	5,705.52	56.05	0.15	182	31.9	4.9				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,179	13,245.00	130.12	0.36	375	28.31	10.09	5.07	2.29	1.22 (1.05, 1.42)	0.01
Dabigatran	37,179	12,478.69	122.59	0.34	290	23.24	7.8				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	34,578	11,415.89	120.59	0.33	573	50.19	16.57	3.55	2.2	1.09 (0.96, 1.24)	0.185
Dabigatran	26,850	8,275.39	112.57	0.31	386	46.64	14.38				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	25,923	3,678.69	51.83	0.14	263	71.49	10.15	8.16	1.16	1.13 (0.95, 1.35)	0.178
Dabigatran	25,923	3,678.69	51.83	0.14	233	63.34	8.99				

Table 43. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	25,923	8,530.15	120.19	0.33	449	52.64	17.32	6.58	3.12	1.16 (1.01, 1.33)	0.039
Dabigatran	25,923	7,989.80	112.57	0.31	368	46.06	14.2				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,408	4,177.54	105.9	0.29	391	93.6	27.14	13.49	4.14	1.17 (1.00, 1.36)	0.053
Dabigatran	11,872	3,408.19	104.86	0.29	273	80.1	23				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,241	1,440.71	46.81	0.13	185	128.41	16.46	17.35	2.22	1.16 (0.94, 1.43)	0.179
Dabigatran	11,241	1,440.71	46.81	0.13	160	111.06	14.23				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,241	3,264.82	106.08	0.29	304	93.11	27.04	14.63	4.36	1.18 (1.00, 1.39)	0.051
Dabigatran	11,241	3,248.88	105.56	0.29	255	78.49	22.68				

¹Conditional analysis includes informative events and person-time.

Table 44. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	111,816	37,792.24	123.45	0.34	1,527	40.41	13.66	19.41	7.91	2.11 (1.90, 2.35)	<0.001
Apixaban	77,232	21,151.93	100.03	0.27	444	20.99	5.75				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	75,889	10,853.49	52.24	0.14	661	60.9	8.71	34.09	4.88	2.27 (1.98, 2.61)	<0.001
Apixaban	75,889	10,853.49	52.24	0.14	291	26.81	3.83				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	75,889	25,335.44	121.94	0.33	1,112	43.89	14.65	23.23	8.97	2.32 (2.07, 2.59)	<0.001
Apixaban	75,889	20,856.28	100.38	0.27	431	20.67	5.68				

¹Conditional analysis includes informative events and person-time.

Table 45. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	95,580	32,365.36	123.68	0.34	1,150	35.53	12.03	17.02	6.93	2.09 (1.85, 2.36)	<0.001
Apixaban	64,648	17,827.12	100.72	0.28	330	18.51	5.1				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	63,624	9,121.46	52.36	0.14	472	51.75	7.42	28.39	4.07	2.22 (1.88, 2.61)	<0.001
Apixaban	63,624	9,121.46	52.36	0.14	213	23.35	3.35				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	63,624	21,305.34	122.31	0.33	811	38.07	12.75	19.94	7.73	2.27 (1.99, 2.59)	<0.001
Apixaban	63,624	17,596.51	101.02	0.28	319	18.13	5.01				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,236	5,426.88	122.08	0.33	377	69.47	23.22	35.18	14.16	2.30 (1.86, 2.83)	<0.001
Apixaban	12,584	3,324.81	96.5	0.26	114	34.29	9.06				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,067	1,679.34	50.83	0.14	191	113.74	15.83	69.07	9.61	2.55 (1.95, 3.33)	<0.001
Apixaban	12,067	1,679.34	50.83	0.14	75	44.66	6.22				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,067	3,968.32	120.12	0.33	297	74.84	24.61	41.17	15.66	2.49 (2.00, 3.11)	<0.001
Apixaban	12,067	3,207.14	97.08	0.27	108	33.67	8.95				

¹Conditional analysis includes informative events and person-time.

Table 46. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	59,919	19,861.98	121.07	0.33	695	34.99	11.6	17.3	6.76	2.15 (1.83, 2.52)	<0.001
Apixaban	40,104	10,966.23	99.88	0.27	194	17.69	4.84				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,359	5,660.85	52.53	0.14	304	53.7	7.72	29.5	4.24	2.22 (1.81, 2.71)	<0.001
Apixaban	39,359	5,660.85	52.53	0.14	137	24.2	3.48				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,359	12,870.32	119.44	0.33	497	38.62	12.63	21.11	7.83	2.38 (2.01, 2.81)	<0.001
Apixaban	39,359	10,795.76	100.18	0.27	189	17.51	4.8				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,897	17,930.26	126.19	0.35	832	46.4	16.03	21.86	9.3	2.10 (1.83, 2.42)	<0.001
Apixaban	37,128	10,185.70	100.2	0.27	250	24.54	6.73				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	36,358	5,215.49	52.39	0.14	364	69.79	10.01	39.11	5.61	2.27 (1.89, 2.74)	<0.001
Apixaban	36,358	5,215.49	52.39	0.14	160	30.68	4.4				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	36,358	12,417.29	124.74	0.34	613	49.37	16.86	25.3	10.23	2.27 (1.95, 2.63)	<0.001
Apixaban	36,358	10,013.53	100.6	0.28	241	24.07	6.63				

¹Conditional analysis includes informative events and person-time.

Table 47. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	57,787	19,909.37	125.84	0.34	567	28.48	9.81	12.54	5.39	1.96 (1.65, 2.33)	<0.001
Apixaban	38,032	10,540.22	101.23	0.28	168	15.94	4.42				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,491	5,480.65	53.39	0.15	236	43.06	6.29	21.71	3.17	2.02 (1.62, 2.52)	<0.001
Apixaban	37,491	5,480.65	53.39	0.15	117	21.35	3.12				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,491	12,780.59	124.51	0.34	398	31.14	10.62	15.21	6.19	2.12 (1.77, 2.55)	<0.001
Apixaban	37,491	10,423.04	101.54	0.28	166	15.93	4.43				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	44,196	14,954.61	123.59	0.34	735	49.15	16.63	25.01	9.99	2.25 (1.93, 2.62)	<0.001
Apixaban	31,939	8,784.27	100.46	0.28	212	24.13	6.64				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	30,797	4,378.82	51.93	0.14	320	73.08	10.39	40.65	5.78	2.25 (1.85, 2.75)	<0.001
Apixaban	30,797	4,378.82	51.93	0.14	142	32.43	4.61				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	30,797	10,287.68	122.01	0.33	536	52.1	17.4	28.82	10.98	2.46 (2.09, 2.90)	<0.001
Apixaban	30,797	8,504.11	100.86	0.28	198	23.28	6.43				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,833	2,928.27	108.77	0.3	225	76.84	22.88	41.82	14.07	2.32 (1.76, 3.07)	<0.001
Apixaban	7,261	1,827.44	91.93	0.25	64	35.02	8.81				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,020	898.42	46.74	0.13	88	97.95	12.54	57.88	7.41	2.44 (1.66, 3.60)	<0.001
Apixaban	7,020	898.42	46.74	0.13	36	40.07	5.13				

Table 47. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,020	2,078.32	108.13	0.3	165	79.39	23.5	44.55	14.67	2.40 (1.79, 3.22)	<0.001
Apixaban	7,020	1,779.64	92.59	0.25	62	34.84	8.83				

¹Conditional analysis includes informative events and person-time.

Table 48. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,845	1,253.20	119.05	0.33	11	8.78	2.86	*****	*****	2.82 (0.62, 12.73)	0.178
Apixaban	2,079	586.61	103.06	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,044	303.26	54.19	0.15	*****	*****	*****	9.89	1.47	4.00 (0.45, 35.79)	0.215
Apixaban	2,044	303.26	54.19	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,044	650.49	116.24	0.32	*****	*****	*****	7.3	2.45	3.32 (0.69, 15.98)	0.135
Apixaban	2,044	578.58	103.39	0.28	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,983	6,664.10	128.22	0.35	115	17.26	6.06	*****	*****	2.44 (1.59, 3.74)	<0.001
Apixaban	11,656	3,412.18	106.92	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,587	1,764.71	55.63	0.15	*****	*****	*****	13.6	2.07	2.26 (1.32, 3.88)	0.003
Apixaban	11,587	1,764.71	55.63	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,587	4,053.59	127.78	0.35	*****	*****	*****	9.86	3.88	2.46 (1.57, 3.86)	<0.001
Apixaban	11,587	3,397.62	107.1	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	28,194	9,822.58	127.25	0.35	272	27.69	9.65	15.25	6.07	2.41 (1.84, 3.15)	<0.001
Apixaban	18,753	5,384.17	104.87	0.29	67	12.44	3.57				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,534	2,789.63	54.98	0.15	101	36.21	5.45	20.43	3.08	2.30 (1.61, 3.27)	<0.001
Apixaban	18,534	2,789.63	54.98	0.15	44	15.77	2.37				

Table 48. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,534	6,379.88	125.73	0.34	180	28.21	9.71	15.84	6.15	2.41 (1.81, 3.20)	<0.001
Apixaban	18,534	5,333.47	105.11	0.29	66	12.37	3.56				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,248	9,387.62	125.84	0.34	388	41.33	14.24	20.41	8.52	2.17 (1.76, 2.69)	<0.001
Apixaban	18,872	5,161.97	99.91	0.27	108	20.92	5.72				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,616	2,684.04	52.66	0.14	170	63.34	9.13	38.75	5.59	2.58 (1.94, 3.42)	<0.001
Apixaban	18,616	2,684.04	52.66	0.14	66	24.59	3.55				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,616	6,338.77	124.37	0.34	283	44.65	15.2	23.67	9.45	2.35 (1.88, 2.93)	<0.001
Apixaban	18,616	5,102.06	100.1	0.27	107	20.97	5.75				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,765	5,772.68	118.69	0.32	379	65.65	21.33	33.78	12.88	2.27 (1.83, 2.80)	<0.001
Apixaban	13,134	3,482.85	96.86	0.27	111	31.87	8.45				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,727	1,739.85	49.93	0.14	179	102.88	14.06	62.07	8.49	2.52 (1.92, 3.32)	<0.001
Apixaban	12,727	1,739.85	49.93	0.14	71	40.81	5.58				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,727	4,083.95	117.2	0.32	282	69.05	22.16	37.22	13.67	2.38 (1.90, 2.97)	<0.001
Apixaban	12,727	3,392.42	97.36	0.27	108	31.84	8.49				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,781	4,892.05	113.23	0.31	362	74	22.94	32.39	12.73	1.98 (1.62, 2.42)	<0.001
Apixaban	12,738	3,124.16	89.58	0.25	130	41.61	10.21				

Table 48. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASC Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,024	1,533.47	46.58	0.13	162	105.64	13.47	52.82	6.74	2.00 (1.53, 2.61)	<0.001
Apixaban	12,024	1,533.47	46.58	0.13	81	52.82	6.74				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,024	3,714.25	112.83	0.31	283	76.19	23.54	35.88	13.56	2.09 (1.69, 2.59)	<0.001
Apixaban	12,024	2,977.02	90.43	0.25	120	40.31	9.98				

¹Conditional analysis includes informative events and person-time.

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

Table 49. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,937	3,780.12	126.24	0.35	66	17.46	6.03	8.8	3.57	2.15 (1.24, 3.72)	0.006
Apixaban	6,486	1,848.42	104.09	0.28	16	8.66	2.47				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	6,472	974.13	54.98	0.15	29	29.77	4.48	17.45	2.63	2.42 (1.23, 4.74)	0.01
Apixaban	6,472	974.13	54.98	0.15	12	12.32	1.85				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	6,472	2,221.82	125.39	0.34	40	18	6.18	9.32	3.71	2.25 (1.26, 4.03)	0.006
Apixaban	6,472	1,843.56	104.04	0.28	16	8.68	2.47				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,220	18,227.38	129.98	0.36	487	26.72	9.51	14.23	5.9	2.35 (1.92, 2.87)	<0.001
Apixaban	33,272	9,611.59	105.51	0.29	120	12.48	3.61				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,228	4,987.09	54.82	0.15	184	36.9	5.54	20.05	3.01	2.19 (1.69, 2.84)	<0.001
Apixaban	33,228	4,987.09	54.82	0.15	84	16.84	2.53				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,228	11,741.85	129.07	0.35	320	27.25	9.63	14.76	6.02	2.37 (1.92, 2.93)	<0.001
Apixaban	33,228	9,602.88	105.56	0.29	120	12.5	3.61				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	35,069	11,549.72	120.29	0.33	578	50.04	16.48	25.45	9.9	2.21 (1.86, 2.63)	<0.001
Apixaban	25,062	6,708.68	97.77	0.27	165	24.6	6.58				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	24,588	3,454.66	51.32	0.14	248	71.79	10.09	40.81	5.73	2.32 (1.85, 2.91)	<0.001
Apixaban	24,588	3,454.66	51.32	0.14	107	30.97	4.35				

Table 49. Effect Estimates for Risk of Gastrointestinal Bleeding among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	24,588	8,043.89	119.49	0.33	415	51.59	16.88	26.88	10.25	2.25 (1.88, 2.70)	<0.001
Apixaban	24,588	6,594.90	97.97	0.27	163	24.72	6.63				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,590	4,235.01	106.02	0.29	396	93.51	27.14	45.57	15.62	2.14 (1.77, 2.60)	<0.001
Apixaban	12,412	2,983.24	87.79	0.24	143	47.93	11.52				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,496	1,409.49	44.78	0.12	189	134.09	16.44	72.37	8.87	2.17 (1.69, 2.80)	<0.001
Apixaban	11,496	1,409.49	44.78	0.12	87	61.72	7.57				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,496	3,293.70	104.65	0.29	333	101.1	28.97	53.74	17.48	2.33 (1.90, 2.85)	<0.001
Apixaban	11,496	2,787.01	88.55	0.24	132	47.36	11.48				

¹Conditional analysis includes informative events and person-time.

Table 50. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	84,562	26,877.42	116.09	0.32	1,002	37.28	11.85	16.15	6.07	1.91 (1.71, 2.14)	<0.001
Apixaban	76,887	21,016.72	99.84	0.27	444	21.13	5.77				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Dabigatran	69,054	9,442.44	49.94	0.14	504	53.38	7.3	28.7	3.92	2.16 (1.85, 2.53)	<0.001
Apixaban	69,054	9,442.44	49.94	0.14	233	24.68	3.37				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	69,054	21,886.65	115.77	0.32	833	38.06	12.06	18.01	6.55	2.04 (1.81, 2.31)	<0.001
Apixaban	69,054	19,001.49	100.51	0.28	381	20.05	5.52				

¹Conditional analysis includes informative events and person-time.

Table 51. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	71,477	22,739.81	116.2	0.32	741	32.59	10.37	13.95	5.24	1.91 (1.67, 2.17)	<0.001
Apixaban	64,349	17,708.30	100.51	0.28	330	18.64	5.13				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	58,127	7,954.50	49.98	0.14	366	46.01	6.3	24.77	3.39	2.17 (1.80, 2.60)	<0.001
Apixaban	58,127	7,954.50	49.98	0.14	169	21.25	2.91				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	58,127	18,436.38	115.85	0.32	602	32.65	10.36	14.87	5.44	1.99 (1.73, 2.29)	<0.001
Apixaban	58,127	16,084.70	101.07	0.28	286	17.78	4.92				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,085	4,137.62	115.5	0.32	261	63.08	19.95	28.62	10.85	1.96 (1.57, 2.45)	<0.001
Apixaban	12,538	3,308.42	96.38	0.26	114	34.46	9.09				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,645	1,416.73	48.61	0.13	145	102.35	13.62	59.29	7.89	2.38 (1.76, 3.21)	<0.001
Apixaban	10,645	1,416.73	48.61	0.13	61	43.06	5.73				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,645	3,350.41	114.96	0.31	225	67.16	21.14	35.85	12.78	2.27 (1.77, 2.91)	<0.001
Apixaban	10,645	2,842.50	97.53	0.27	89	31.31	8.36				

¹Conditional analysis includes informative events and person-time.

Table 52. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	43,693	13,759.20	115.02	0.31	430	31.25	9.84	13.31	4.95	1.86 (1.57, 2.20)	<0.001
Apixaban	39,862	10,869.87	99.6	0.27	195	17.94	4.89				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	35,590	4,924.68	50.54	0.14	225	45.69	6.32	24.37	3.37	2.14 (1.70, 2.70)	<0.001
Apixaban	35,590	4,924.68	50.54	0.14	105	21.32	2.95				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	35,590	11,231.79	115.27	0.32	357	31.78	10.03	15.11	5.45	2.02 (1.68, 2.43)	<0.001
Apixaban	35,590	9,775.76	100.33	0.27	163	16.67	4.58				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,869	13,118.22	117.24	0.32	572	43.6	14	19.06	7.27	1.96 (1.69, 2.28)	<0.001
Apixaban	37,025	10,146.86	100.1	0.27	249	24.54	6.73				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,046	4,469.73	49.4	0.14	273	61.08	8.26	31.55	4.27	2.07 (1.68, 2.55)	<0.001
Apixaban	33,046	4,469.73	49.4	0.14	132	29.53	3.99				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,046	10,520.50	116.28	0.32	475	45.15	14.37	21.65	7.9	2.09 (1.78, 2.46)	<0.001
Apixaban	33,046	9,104.61	100.63	0.28	214	23.5	6.48				

¹Conditional analysis includes informative events and person-time.

Table 53. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,753	13,154.60	117.9	0.32	279	21.21	6.85	5.18	2.41	1.43 (1.18, 1.73)	<0.001
Apixaban	37,862	10,478.49	101.08	0.28	168	16.03	4.44				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,356	4,660.42	51.03	0.14	142	30.47	4.26	9.66	1.35	1.46 (1.13, 1.90)	0.004
Apixaban	33,356	4,660.42	51.03	0.14	97	20.81	2.91				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,356	10,747.87	117.69	0.32	229	21.31	6.87	6.19	2.64	1.51 (1.22, 1.87)	<0.001
Apixaban	33,356	9,328.57	102.15	0.28	141	15.11	4.23				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	34,534	11,104.31	117.45	0.32	491	44.22	14.22	20.02	7.58	2.02 (1.71, 2.37)	<0.001
Apixaban	31,785	8,721.71	100.22	0.27	211	24.19	6.64				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	27,960	3,842.44	50.19	0.14	245	63.76	8.76	36.7	5.04	2.36 (1.87, 2.96)	<0.001
Apixaban	27,960	3,842.44	50.19	0.14	104	27.07	3.72				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	27,960	8,966.28	117.13	0.32	419	46.73	14.99	24.44	8.83	2.28 (1.91, 2.73)	<0.001
Apixaban	27,960	7,715.29	100.79	0.28	172	22.29	6.15				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	9,275	2,618.52	103.12	0.28	232	88.6	25.01	52.82	16.04	2.59 (1.96, 3.41)	<0.001
Apixaban	7,240	1,816.52	91.64	0.25	65	35.78	8.98				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,751	810.25	43.84	0.12	95	117.25	14.07	69.11	8.3	2.44 (1.68, 3.54)	<0.001
Apixaban	6,751	810.25	43.84	0.12	39	48.13	5.78				

Table 53. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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 in	Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Difference per 1,000 Person-Years	Risk per 1,000 New Users		
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,751	1,880.79	101.76	0.28	168	89.32	24.89	53.99	16	2.60 (1.93, 3.50)	<0.001
Apixaban	6,751	1,698.15	91.87	0.25	60	35.33	8.89				

¹Conditional analysis includes informative events and person-time.

Table 54. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsC Score

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
CHA₂DS₂-VAsC Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	2,775	860.22	113.22	0.31	*****	*****	*****	7.02	2.27	3.30 (0.71, 15.27)	0.127
Apixaban	2,050	581.06	103.53	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	1,959	269.58	50.26	0.14	*****	*****	*****	14.84	2.04	5.00 (0.58, 42.80)	0.142
Apixaban	1,959	269.58	50.26	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	1,959	611.11	113.94	0.31	*****	*****	*****	8.03	2.55	5.84 (0.70, 48.54)	0.103
Apixaban	1,959	558.56	104.14	0.29	*****	*****	*****				
CHA₂DS₂-VAsC Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	12,962	4,152.11	117	0.32	*****	*****	*****	7.72	2.69	2.03 (1.28, 3.22)	0.003
Apixaban	11,594	3,380.86	106.51	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,670	1,535.13	52.55	0.14	*****	*****	*****	13.03	1.87	2.25 (1.25, 4.05)	0.007
Apixaban	10,670	1,535.13	52.55	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,670	3,418.60	117.02	0.32	*****	*****	*****	7.52	2.62	1.99 (1.22, 3.25)	0.006
Apixaban	10,670	3,120.74	106.83	0.29	*****	*****	*****				
CHA₂DS₂-VAsC Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	19,816	6,490.63	119.64	0.33	173	26.65	8.73	14.14	5.14	2.28 (1.72, 3.03)	<0.001
Apixaban	18,659	5,353.49	104.79	0.29	67	12.52	3.59				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	16,641	2,371.64	52.05	0.14	87	36.68	5.23	21.93	3.12	2.49 (1.68, 3.68)	<0.001
Apixaban	16,641	2,371.64	52.05	0.14	35	14.76	2.1				

Table 54. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsC Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	16,641	5,439.00	119.38	0.33	148	27.21	8.89	15.32	5.47	2.47 (1.82, 3.35)	<0.001
Apixaban	16,641	4,792.91	105.2	0.29	57	11.89	3.43				
CHA₂DS₂-VAsC Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	21,646	7,105.08	119.89	0.33	241	33.92	11.13	12.45	5.28	1.71 (1.36, 2.14)	<0.001
Apixaban	18,800	5,123.62	99.54	0.27	110	21.47	5.85				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	17,117	2,367.47	50.52	0.14	112	47.31	6.54	20.7	2.86	1.78 (1.31, 2.42)	<0.001
Apixaban	17,117	2,367.47	50.52	0.14	63	26.61	3.68				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	17,117	5,626.09	120.05	0.33	197	35.02	11.51	14.11	5.78	1.79 (1.40, 2.29)	<0.001
Apixaban	17,117	4,688.69	100.05	0.27	98	20.9	5.73				
CHA₂DS₂-VAsC Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,991	4,324.43	112.89	0.31	231	53.42	16.51	21.98	8.2	1.85 (1.47, 2.33)	<0.001
Apixaban	13,112	3,467.30	96.59	0.26	109	31.44	8.31				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	11,373	1,507.72	48.42	0.13	109	72.29	9.58	31.84	4.22	1.79 (1.31, 2.44)	<0.001
Apixaban	11,373	1,507.72	48.42	0.13	61	40.46	5.36				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	11,373	3,491.79	112.14	0.31	197	56.42	17.32	26.15	9.23	1.99 (1.55, 2.56)	<0.001
Apixaban	11,373	3,039.75	97.62	0.27	92	30.27	8.09				
CHA₂DS₂-VAsC Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,372	3,944.95	107.75	0.3	284	71.99	21.24	30.2	10.98	1.95 (1.58, 2.40)	<0.001
Apixaban	12,672	3,110.39	89.65	0.25	130	41.8	10.26				

Table 54. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsc Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,805	1,339.38	45.28	0.12	138	103.03	12.77	50.77	6.29	1.97 (1.48, 2.63)	<0.001
Apixaban	10,805	1,339.38	45.28	0.12	70	52.26	6.48				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,805	3,158.75	106.78	0.29	230	72.81	21.29	33.53	11.57	2.06 (1.64, 2.60)	<0.001
Apixaban	10,805	2,672.77	90.35	0.25	105	39.29	9.72				

¹Conditional analysis includes informative events and person-time.

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

Table 55. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	7,788	2,453.26	115.06	0.32	42	17.12	5.39	8.43	2.91	2.09 (1.17, 3.72)	0.013
Apixaban	6,455	1,841.15	104.18	0.29	16	8.69	2.48				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,098	859.78	51.5	0.14	16	18.61	2.62	*****	*****	2.67 (1.04, 6.81)	0.04
Apixaban	6,098	859.78	51.5	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,098	1,924.61	115.28	0.32	32	16.63	5.25	8.02	2.79	2.08 (1.13, 3.85)	0.019
Apixaban	6,098	1,742.89	104.39	0.29	15	8.61	2.46				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	38,021	12,735.60	122.34	0.33	301	23.63	7.92	10.94	4.26	2.02 (1.63, 2.49)	<0.001
Apixaban	33,078	9,534.18	105.28	0.29	121	12.69	3.66				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	30,531	4,396.15	52.59	0.14	149	33.89	4.88	*****	*****	2.10 (1.58, 2.78)	<0.001
Apixaban	30,531	4,396.15	52.59	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	30,531	10,198.85	122.01	0.33	241	23.63	7.89	11.15	4.29	2.05 (1.63, 2.57)	<0.001
Apixaban	30,531	8,811.10	105.41	0.29	110	12.48	3.6				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	26,875	8,280.22	112.53	0.31	386	46.62	14.36	22.05	7.8	2.03 (1.69, 2.44)	<0.001
Apixaban	24,997	6,675.35	97.54	0.27	164	24.57	6.56				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	22,081	2,971.20	49.15	0.13	192	64.62	8.7	35.68	4.8	2.23 (1.73, 2.88)	<0.001
Apixaban	22,081	2,971.20	49.15	0.13	86	28.94	3.89				

Table 55. Effect Estimates for Risk of Gastrointestinal Bleeding among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	22,081	6,800.57	112.49	0.31	315	46.32	14.27	22.69	7.93	2.07 (1.69, 2.53)	<0.001
Apixaban	22,081	5,923.91	97.99	0.27	140	23.63	6.34				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	11,878	3,408.34	104.81	0.29	273	80.1	22.98	31.89	11.41	1.85 (1.51, 2.27)	<0.001
Apixaban	12,357	2,966.03	87.67	0.24	143	48.21	11.57				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	9,997	1,222.69	44.67	0.12	168	137.4	16.81	76.06	9.3	2.24 (1.71, 2.94)	<0.001
Apixaban	9,997	1,222.69	44.67	0.12	75	61.34	7.5				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	9,997	2,859.68	104.48	0.29	240	83.93	24.01	37.17	12.6	1.98 (1.58, 2.47)	<0.001
Apixaban	9,997	2,438.17	89.08	0.24	114	46.76	11.4				

¹Conditional analysis includes informative events and person-time.

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

Table 56. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	110,113	37,287.25	123.68	0.34	194	5.2	1.76	1.67	0.64	1.49 (1.16, 1.90)	0.002
Dabigatran	84,473	26,858.70	116.13	0.32	95	3.54	1.12				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	82,326	12,020.37	53.33	0.15	67	5.57	0.81	1.16	0.17	1.26 (0.88, 1.81)	0.202
Dabigatran	82,326	12,020.37	53.33	0.15	53	4.41	0.64				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	82,326	27,774.62	123.23	0.34	157	5.65	1.91	2.22	0.81	1.67 (1.29, 2.17)	<0.001
Dabigatran	82,326	26,242.22	116.43	0.32	90	3.43	1.09				

¹Conditional analysis includes informative events and person-time.

Table 57. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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	Difference in	Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Rate Difference per 1,000 Person-Years	Risk per 1,000 New Users		
No Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	94,068	31,920.44	123.94	0.34	153	4.79	1.63	1.18	0.48	1.34 (1.03, 1.76)	0.032
Dabigatran	71,402	22,722.51	116.23	0.32	82	3.61	1.15				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	69,758	10,226.98	53.55	0.15	54	5.28	0.77	*****	*****	1.23 (0.82, 1.83)	0.313
Dabigatran	69,758	10,226.98	53.55	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	69,758	23,594.14	123.54	0.34	122	5.17	1.75	1.71	0.65	1.52 (1.14, 2.02)	0.004
Dabigatran	69,758	22,245.22	116.48	0.32	77	3.46	1.1				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,045	5,366.81	122.17	0.33	41	7.64	2.56	4.5	1.56	2.43 (1.30, 4.54)	0.005
Dabigatran	13,071	4,136.20	115.58	0.32	13	3.14	0.99				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,416	1,791.59	52.7	0.14	16	8.93	1.29	*****	*****	2.67 (1.04, 6.81)	0.04
Dabigatran	12,416	1,791.59	52.7	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,416	4,137.37	121.71	0.33	35	8.46	2.82	5.17	1.77	2.58 (1.36, 4.89)	0.004
Dabigatran	12,416	3,953.22	116.29	0.32	13	3.29	1.05				

¹Conditional analysis includes informative events and person-time.

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

Table 58. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	58,957	19,586.52	121.34	0.33	109	5.57	1.85				
Dabigatran	43,649	13,750.04	115.06	0.32	49	3.56	1.12	2	0.73	1.56 (1.11, 2.19)	0.01
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	42,684	6,223.10	53.25	0.15	38	6.11	0.89				
Dabigatran	42,684	6,223.10	53.25	0.15	27	4.34	0.63	1.77	0.26	1.41 (0.86, 2.30)	0.175
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	42,684	14,091.00	120.58	0.33	87	6.17	2.04				
Dabigatran	42,684	13,457.06	115.15	0.32	48	3.57	1.12	2.61	0.91	1.73 (1.22, 2.46)	0.002
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,156	17,700.73	126.38	0.35	85	4.8	1.66				
Dabigatran	40,824	13,108.67	117.28	0.32	46	3.51	1.13	1.29	0.53	1.40 (0.97, 2.01)	0.07
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,269	5,728.64	53.28	0.15	29	5.06	0.74				
Dabigatran	39,269	5,728.64	53.28	0.15	24	4.19	0.61	0.87	0.13	1.21 (0.70, 2.08)	0.493
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,269	13,558.25	126.11	0.35	69	5.09	1.76				
Dabigatran	39,269	12,651.02	117.67	0.32	42	3.32	1.07	1.77	0.69	1.58 (1.07, 2.32)	0.021

¹Conditional analysis includes informative events and person-time.

Table 59. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	56,862	19,632.17	126.11	0.35	72	3.67	1.27	0.93	0.38	1.33 (0.89, 1.98)	0.168
Dabigatran	40,695	13,143.72	117.97	0.32	36	2.74	0.88				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,926	5,941.38	54.35	0.15	22	3.7	0.55	*****	*****	1.37 (0.72, 2.62)	0.332
Dabigatran	39,926	5,941.38	54.35	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,926	13,763.29	125.91	0.34	52	3.78	1.3	1.07	0.43	1.39 (0.90, 2.13)	0.137
Dabigatran	39,926	12,914.53	118.14	0.32	35	2.71	0.88				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	43,527	14,753.69	123.8	0.34	92	6.24	2.11	2.27	0.84	1.59 (1.11, 2.27)	0.012
Dabigatran	34,508	11,097.34	117.46	0.32	44	3.96	1.28				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,403	4,890.12	53.47	0.15	34	6.95	1.02	1.23	0.18	1.21 (0.74, 2.00)	0.447
Dabigatran	33,403	4,890.12	53.47	0.15	28	5.73	0.84				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,403	11,304.40	123.61	0.34	78	6.9	2.34	3.09	1.11	1.83 (1.25, 2.67)	0.002
Dabigatran	33,403	10,763.47	117.69	0.32	41	3.81	1.23				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,724	2,901.39	108.98	0.3	30	10.34	3.09	4.61	1.47	1.88 (1.00, 3.52)	0.049
Dabigatran	9,270	2,617.65	103.14	0.28	15	5.73	1.62				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	8,388	1,075.86	46.85	0.13	13	12.08	1.55	*****	*****	2.17 (0.82, 5.70)	0.117
Dabigatran	8,388	1,075.86	46.85	0.13	*****	*****	*****				

Table 59. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	8,388	2,516.20	109.57	0.3	27	10.73	3.22	6.11	1.91	2.46 (1.21, 5.01)	0.013
Dabigatran	8,388	2,382.12	103.73	0.28	11	4.62	1.31				

¹Conditional analysis includes informative events and person-time.

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

Table 60. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsc Score

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
CHA₂DS₂-VAsc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,766	1,229.68	119.26	0.33	*****	*****	*****	1.74	0.61	1.64 (0.32, 8.48)	0.553
Dabigatran	2,768	859.06	113.36	0.31	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,726	395.41	52.98	0.15	0	0	0	0	0	-	-
Dabigatran	2,726	395.41	52.98	0.15	0	0	0				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,726	888.59	119.06	0.33	*****	*****	*****	2.15	0.73	1.80 (0.33, 9.83)	0.499
Dabigatran	2,726	849.07	113.76	0.31	*****	*****	*****				
CHA₂DS₂-VAsc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,605	6,550.83	128.6	0.35	*****	*****	*****	1.37	0.53	1.78 (0.75, 4.21)	0.189
Dabigatran	12,943	4,148.21	117.06	0.32	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,668	1,959.70	56.5	0.15	*****	*****	*****	2.04	0.32	2.33 (0.60, 9.02)	0.22
Dabigatran	12,668	1,959.70	56.5	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,668	4,454.51	128.43	0.35	*****	*****	*****	2.34	0.87	2.55 (1.00, 6.47)	0.049
Dabigatran	12,668	4,065.50	117.22	0.32	*****	*****	*****				
CHA₂DS₂-VAsc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,766	9,689.18	127.46	0.35	46	4.75	1.66	0.74	0.34	1.19 (0.74, 1.93)	0.476
Dabigatran	19,794	6,483.95	119.65	0.33	26	4.01	1.31				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	19,542	2,938.95	54.93	0.15	12	4.08	0.61	-1.02	-0.15	0.80 (0.37, 1.71)	0.565
Dabigatran	19,542	2,938.95	54.93	0.15	15	5.1	0.77				

Table 60. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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		Hazard Ratio (95% Confidence Interval)	Wald P-Value
								per 1,000 Person-Years	Difference in Risk per 1,000 New Users		
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	19,542	6,769.98	126.53	0.35	38	5.61	1.94	1.7	0.67	1.45 (0.87, 2.40)	0.15
Dabigatran	19,542	6,390.96	119.45	0.33	25	3.91	1.28				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	26,827	9,260.57	126.08	0.35	51	5.51	1.9	2.27	0.84	1.68 (1.03, 2.75)	0.039
Dabigatran	21,631	7,101.32	119.91	0.33	23	3.24	1.06				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	20,835	3,121.17	54.72	0.15	15	4.81	0.72	-0.32	-0.05	0.94 (0.46, 1.90)	0.857
Dabigatran	20,835	3,121.17	54.72	0.15	16	5.13	0.77				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	20,835	7,191.33	126.07	0.35	39	5.42	1.87	2.37	0.86	1.76 (1.04, 3.00)	0.037
Dabigatran	20,835	6,870.31	120.44	0.33	21	3.06	1.01				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,526	5,714.86	119.1	0.33	24	4.2	1.37	-0.43	-0.06	0.97 (0.53, 1.76)	0.909
Dabigatran	13,980	4,323.18	112.95	0.31	20	4.63	1.43				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	13,481	1,890.25	51.21	0.14	*****	*****	*****	1.06	0.15	1.22 (0.51, 2.95)	0.655
Dabigatran	13,481	1,890.25	51.21	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	13,481	4,390.11	118.94	0.33	17	3.87	1.26	-0.9	-0.22	0.86 (0.45, 1.66)	0.656
Dabigatran	13,481	4,188.73	113.49	0.31	20	4.77	1.48				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,623	4,842.13	113.2	0.31	48	9.91	3.07	5.6	1.8	2.29 (1.32, 3.99)	0.003
Dabigatran	13,357	3,942.98	107.82	0.3	17	4.31	1.27				

Table 60. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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		Hazard Ratio (95% Confidence Interval)	Wald P-Value
								per 1,000 Person-Years	Difference in Risk per 1,000 New Users		
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,542	1,656.93	48.25	0.13	*****	*****	*****	3.62	0.48	1.67 (0.73, 3.81)	0.226
Dabigatran	12,542	1,656.93	48.25	0.13	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,542	3,905.66	113.74	0.31	39	9.99	3.11	5.94	1.91	2.46 (1.35, 4.46)	0.003
Dabigatran	12,542	3,708.01	107.99	0.3	15	4.05	1.2				

¹Conditional analysis includes informative events and person-time.

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

Table 61. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,726	3,711.82	126.4	0.35	17	4.58	1.58	*****	*****	1.14 (0.52, 2.50)	0.735
Dabigatran	7,779	2,451.25	115.09	0.32	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,582	1,118.93	53.9	0.15	*****	*****	*****	0.89	0.13	1.20 (0.37, 3.93)	0.763
Dabigatran	7,582	1,118.93	53.9	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,582	2,591.50	124.84	0.34	12	4.63	1.58	*****	*****	1.15 (0.50, 2.66)	0.746
Dabigatran	7,582	2,390.63	115.16	0.32	*****	*****	*****				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	50,401	17,982.00	130.31	0.36	71	3.95	1.41	1.12	0.46	1.41 (0.94, 2.11)	0.095
Dabigatran	37,972	12,723.87	122.39	0.34	36	2.83	0.95				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,179	5,705.52	56.05	0.15	30	5.26	0.81	1.75	0.27	1.50 (0.85, 2.64)	0.16
Dabigatran	37,179	5,705.52	56.05	0.15	20	3.51	0.54				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,179	13,245.00	130.12	0.36	59	4.45	1.59	1.65	0.65	1.60 (1.05, 2.44)	0.028
Dabigatran	37,179	12,478.69	122.59	0.34	35	2.8	0.94				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	34,578	11,415.89	120.59	0.33	65	5.69	1.88	1.22	0.5	1.27 (0.85, 1.91)	0.245
Dabigatran	26,850	8,275.39	112.57	0.31	37	4.47	1.38				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	25,923	3,678.69	51.83	0.14	22	5.98	0.85	1.09	0.15	1.22 (0.66, 2.28)	0.528
Dabigatran	25,923	3,678.69	51.83	0.14	18	4.89	0.69				

Table 61. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	25,923	8,530.15	120.19	0.33	49	5.74	1.89	1.61	0.62	1.40 (0.90, 2.19)	0.132
Dabigatran	25,923	7,989.80	112.57	0.31	33	4.13	1.27				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,408	4,177.54	105.9	0.29	41	9.81	2.85	*****	*****	2.94 (1.52, 5.69)	0.001
Dabigatran	11,872	3,408.19	104.86	0.29	*****	*****	*****	*****	*****		
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,241	1,440.71	46.81	0.13	*****	*****	*****	7.64	0.98	3.75 (1.24, 11.30)	0.019
Dabigatran	11,241	1,440.71	46.81	0.13	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,241	3,264.82	106.08	0.29	36	11.03	3.2	*****	*****	3.15 (1.61, 6.15)	<0.001
Dabigatran	11,241	3,248.88	105.56	0.29	*****	*****	*****				

¹Conditional analysis includes informative events and person-time.

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

Table 62. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	111,816	37,792.24	123.45	0.34	196	5.19	1.75	0.74	0.54	1.17 (0.92, 1.50)	0.204
Apixaban	77,232	21,151.93	100.03	0.27	94	4.44	1.22				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Rivaroxaban	75,889	10,853.49	52.24	0.14	65	5.99	0.86	1.66	0.24	1.38 (0.95, 2.01)	0.09
Apixaban	75,889	10,853.49	52.24	0.14	47	4.33	0.62				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Rivaroxaban	75,889	25,335.44	121.94	0.33	144	5.68	1.9	1.18	0.66	1.28 (0.99, 1.67)	0.063
Apixaban	75,889	20,856.28	100.38	0.27	94	4.51	1.24				

¹Conditional analysis includes informative events and person-time.

Table 63. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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	Difference in	Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Rate	Risk per		
No Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	95,580	32,365.36	123.68	0.34	155	4.79	1.62	0.58	0.46	1.15 (0.87, 1.52)	0.319
Apixaban	64,648	17,827.12	100.72	0.28	75	4.21	1.16				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	63,624	9,121.46	52.36	0.14	59	6.47	0.93	2.08	0.3	1.47 (0.99, 2.20)	0.058
Apixaban	63,624	9,121.46	52.36	0.14	40	4.39	0.63				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	63,624	21,305.34	122.31	0.33	112	5.26	1.76	0.99	0.58	1.27 (0.94, 1.70)	0.116
Apixaban	63,624	17,596.51	101.02	0.28	75	4.26	1.18				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	16,236	5,426.88	122.08	0.33	41	7.55	2.53	1.84	1.02	1.31 (0.75, 2.27)	0.34
Apixaban	12,584	3,324.81	96.5	0.26	19	5.71	1.51				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,067	1,679.34	50.83	0.14	14	8.34	1.16	1.19	0.17	1.17 (0.54, 2.52)	0.695
Apixaban	12,067	1,679.34	50.83	0.14	12	7.15	0.99				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,067	3,968.32	120.12	0.33	31	7.81	2.57	1.89	0.99	1.30 (0.73, 2.31)	0.382
Apixaban	12,067	3,207.14	97.08	0.27	19	5.92	1.57				

¹Conditional analysis includes informative events and person-time.

Table 64. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	59,919	19,861.98	121.07	0.33	110	5.54	1.84	0.8	0.54	1.17 (0.84, 1.63)	0.351
Apixaban	40,104	10,966.23	99.88	0.27	52	4.74	1.3				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	39,359	5,660.85	52.53	0.14	33	5.83	0.84	1.41	0.2	1.32 (0.79, 2.22)	0.295
Apixaban	39,359	5,660.85	52.53	0.14	25	4.42	0.64				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	39,359	12,870.32	119.44	0.33	77	5.98	1.96	1.17	0.64	1.25 (0.88, 1.79)	0.212
Apixaban	39,359	10,795.76	100.18	0.27	52	4.82	1.32				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,897	17,930.26	126.19	0.35	86	4.8	1.66	0.67	0.53	1.17 (0.81, 1.70)	0.397
Apixaban	37,128	10,185.70	100.2	0.27	42	4.12	1.13				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	36,358	5,215.49	52.39	0.14	35	6.71	0.96	3.07	0.44	1.84 (1.05, 3.22)	0.032
Apixaban	36,358	5,215.49	52.39	0.14	19	3.64	0.52				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	36,358	12,417.29	124.74	0.34	67	5.4	1.84	1.2	0.69	1.32 (0.89, 1.95)	0.161
Apixaban	36,358	10,013.53	100.6	0.28	42	4.19	1.16				

¹Conditional analysis includes informative events and person-time.

Table 65. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	57,787	19,909.37	125.84	0.34	73	3.67	1.26	0.25	0.32	1.10 (0.73, 1.64)	0.649
Apixaban	38,032	10,540.22	101.23	0.28	36	3.42	0.95				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	37,491	5,480.65	53.39	0.15	27	4.93	0.72	*****	*****	1.69 (0.91, 3.13)	0.097
Apixaban	37,491	5,480.65	53.39	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	37,491	12,780.59	124.51	0.34	58	4.54	1.55	1.08	0.59	1.37 (0.90, 2.08)	0.139
Apixaban	37,491	10,423.04	101.54	0.28	36	3.45	0.96				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	44,196	14,954.61	123.59	0.34	93	6.22	2.1	2.12	0.98	1.52 (1.03, 2.23)	0.035
Apixaban	31,939	8,784.27	100.46	0.28	36	4.1	1.13				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	30,797	4,378.82	51.93	0.14	28	6.39	0.91	2.51	0.36	1.65 (0.90, 3.01)	0.105
Apixaban	30,797	4,378.82	51.93	0.14	17	3.88	0.55				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	30,797	10,287.68	122.01	0.33	59	5.74	1.92	1.5	0.75	1.36 (0.89, 2.06)	0.152
Apixaban	30,797	8,504.11	100.86	0.28	36	4.23	1.17				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	9,833	2,928.27	108.77	0.3	30	10.24	3.05	-1.79	0.02	0.84 (0.48, 1.46)	0.525
Apixaban	7,261	1,827.44	91.93	0.25	22	12.04	3.03				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	7,020	898.42	46.74	0.13	13	14.47	1.85	*****	*****	2.60 (0.93, 7.29)	0.069
Apixaban	7,020	898.42	46.74	0.13	*****	*****	*****				

Table 65. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	7,020	2,078.32	108.13	0.3	27	12.99	3.85	0.63	0.71	1.04 (0.59, 1.83)	0.898
Apixaban	7,020	1,779.64	92.59	0.25	22	12.36	3.13				

¹Conditional analysis includes informative events and person-time.

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

Table 66. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	3,845	1,253.20	119.05	0.33	*****	*****	*****	2.29	0.82	2.34 (0.27, 20.18)	0.438
Apixaban	2,079	586.61	103.06	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	2,044	303.26	54.19	0.15	*****	*****	*****	3.3	0.49	2.00 (0.18, 22.06)	0.571
Apixaban	2,044	303.26	54.19	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	2,044	650.49	116.24	0.32	*****	*****	*****	4.42	1.47	3.82 (0.43, 34.23)	0.23
Apixaban	2,044	578.58	103.39	0.28	*****	*****	*****				
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	18,983	6,664.10	128.22	0.35	*****	*****	*****	1.24	0.54	1.68 (0.67, 4.20)	0.269
Apixaban	11,656	3,412.18	106.92	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,587	1,764.71	55.63	0.15	*****	*****	*****	2.83	0.43	3.50 (0.73, 16.85)	0.118
Apixaban	11,587	1,764.71	55.63	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,587	4,053.59	127.78	0.35	*****	*****	*****	1.93	0.78	2.06 (0.80, 5.34)	0.136
Apixaban	11,587	3,397.62	107.1	0.29	*****	*****	*****				
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	28,194	9,822.58	127.25	0.35	46	4.68	1.63	0.97	0.57	1.18 (0.70, 2.01)	0.534
Apixaban	18,753	5,384.17	104.87	0.29	20	3.71	1.07				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,534	2,789.63	54.98	0.15	12	4.3	0.65	*****	*****	2.00 (0.75, 5.33)	0.166
Apixaban	18,534	2,789.63	54.98	0.15	*****	*****	*****				

Table 66. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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		Hazard Ratio (95% Confidence Interval)	Wald P-Value
								Difference per 1,000 Person-Years	Difference in Risk per 1,000 New Users		
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,534	6,379.88	125.73	0.34	29	4.55	1.56	0.8	0.49	1.13 (0.63, 2.01)	0.679
Apixaban	18,534	5,333.47	105.11	0.29	20	3.75	1.08				
CHA₂DS₂-VASc Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	27,248	9,387.62	125.84	0.34	53	5.65	1.95	0.8	0.62	1.21 (0.75, 1.95)	0.435
Apixaban	18,872	5,161.97	99.91	0.27	25	4.84	1.32				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	18,616	2,684.04	52.66	0.14	23	8.57	1.24	2.61	0.38	1.44 (0.76, 2.72)	0.265
Apixaban	18,616	2,684.04	52.66	0.14	16	5.96	0.86				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	18,616	6,338.77	124.37	0.34	40	6.31	2.15	1.41	0.81	1.37 (0.83, 2.25)	0.224
Apixaban	18,616	5,102.06	100.1	0.27	25	4.9	1.34				
CHA₂DS₂-VASc Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	17,765	5,772.68	118.69	0.32	*****	*****	*****	-1.3	-0.1	0.79 (0.43, 1.46)	0.456
Apixaban	13,134	3,482.85	96.86	0.27	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,727	1,739.85	49.93	0.14	*****	*****	*****	0	0	1.00 (0.42, 2.40)	1
Apixaban	12,727	1,739.85	49.93	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,727	4,083.95	117.2	0.32	*****	*****	*****	-0.21	0.24	1.00 (0.54, 1.86)	0.991
Apixaban	12,727	3,392.42	97.36	0.27	*****	*****	*****				
CHA₂DS₂-VASc Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	15,781	4,892.05	113.23	0.31	48	9.81	3.04	2.45	1.24	1.38 (0.83, 2.27)	0.211
Apixaban	12,738	3,124.16	89.58	0.25	23	7.36	1.81				

Table 66. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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		Hazard Ratio (95% Confidence Interval)	Wald P-Value
								per 1,000 Person-Years	Difference in Risk per 1,000 New Users		
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	12,024	1,533.47	46.58	0.13	16	10.43	1.33	*****	*****	2.29 (0.94, 5.56)	0.068
Apixaban	12,024	1,533.47	46.58	0.13	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	12,024	3,714.25	112.83	0.31	34	9.15	2.83	1.43	0.91	1.23 (0.72, 2.10)	0.449
Apixaban	12,024	2,977.02	90.43	0.25	23	7.73	1.91				

¹Conditional analysis includes informative events and person-time.

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

Table 67. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	10,937	3,780.12	126.24	0.35	17	4.5	1.55	*****	*****	1.56 (0.57, 4.27)	0.385
Apixaban	6,486	1,848.42	104.09	0.28	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	6,472	974.13	54.98	0.15	*****	*****	*****	0	0	1.00 (0.20, 4.95)	1
Apixaban	6,472	974.13	54.98	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	6,472	2,221.82	125.39	0.34	*****	*****	*****	1.34	0.62	1.50 (0.50, 4.52)	0.471
Apixaban	6,472	1,843.56	104.04	0.28	*****	*****	*****				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	51,220	18,227.38	129.98	0.36	73	4	1.43	*****	*****	1.12 (0.75, 1.69)	0.576
Apixaban	33,272	9,611.59	105.51	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	33,228	4,987.09	54.82	0.15	*****	*****	*****	3.41	0.51	2.55 (1.27, 5.11)	0.009
Apixaban	33,228	4,987.09	54.82	0.15	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	33,228	11,741.85	129.07	0.35	*****	*****	*****	1.23	0.66	1.33 (0.86, 2.04)	0.197
Apixaban	33,228	9,602.88	105.56	0.29	*****	*****	*****				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	35,069	11,549.72	120.29	0.33	65	5.63	1.85	0.41	0.46	1.09 (0.72, 1.65)	0.682
Apixaban	25,062	6,708.68	97.77	0.27	35	5.22	1.4				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	24,588	3,454.66	51.32	0.14	23	6.66	0.94	-0.29	-0.04	0.96 (0.54, 1.70)	0.884
Apixaban	24,588	3,454.66	51.32	0.14	24	6.95	0.98				

Table 67. Effect Estimates for Risk of Intracranial Hemorrhage among Rivaroxaban vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	24,588	8,043.89	119.49	0.33	50	6.22	2.03	0.91	0.61	1.20 (0.78, 1.86)	0.411
Apixaban	24,588	6,594.90	97.97	0.27	35	5.31	1.42				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Rivaroxaban	14,590	4,235.01	106.02	0.29	41	9.68	2.81	2.98	1.2	1.50 (0.87, 2.56)	0.142
Apixaban	12,412	2,983.24	87.79	0.24	20	6.7	1.61				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Rivaroxaban	11,496	1,409.49	44.78	0.12	12	8.51	1.04	-0.71	-0.09	0.92 (0.42, 2.02)	0.842
Apixaban	11,496	1,409.49	44.78	0.12	13	9.22	1.13				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Rivaroxaban	11,496	3,293.70	104.65	0.29	29	8.8	2.52	1.63	0.78	1.29 (0.73, 2.28)	0.385
Apixaban	11,496	2,787.01	88.55	0.24	20	7.18	1.74				

¹Conditional analysis includes informative events and person-time.

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

Table 68. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type

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	84,562	26,877.42	116.09	0.32	95	3.53	1.12	-0.94	-0.1	0.79 (0.59, 1.05)	0.107
Apixaban	76,887	21,016.72	99.84	0.27	94	4.47	1.22				
1:1 Matched Conditional Analysis; Caliper= 0.05¹											
Dabigatran	69,054	9,442.44	49.94	0.14	39	4.13	0.56	-0.74	-0.1	0.85 (0.55, 1.30)	0.448
Apixaban	69,054	9,442.44	49.94	0.14	46	4.87	0.67				
1:1 Matched Unconditional Analysis; Caliper= 0.05											
Dabigatran	69,054	21,886.65	115.77	0.32	75	3.43	1.09	-1.1	-0.16	0.75 (0.55, 1.03)	0.079
Apixaban	69,054	19,001.49	100.51	0.28	86	4.53	1.25				

¹Conditional analysis includes informative events and person-time.

Table 69. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Antiplatelet Use

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 Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	71,477	22,739.81	116.2	0.32	82	3.61	1.15	-0.63	-0.02	0.83 (0.61, 1.15)	0.267
Apixaban	64,349	17,708.30	100.51	0.28	75	4.24	1.17				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	58,127	7,954.50	49.98	0.14	*****	*****	*****	0	0	1.00 (0.62, 1.62)	1
Apixaban	58,127	7,954.50	49.98	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	58,127	18,436.38	115.85	0.32	*****	*****	*****	-0.7	-0.05	0.82 (0.58, 1.16)	0.258
Apixaban	58,127	16,084.70	101.07	0.28	68	4.23	1.17				
Antiplatelets											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,085	4,137.62	115.5	0.32	13	3.14	0.99	-2.6	-0.52	0.60 (0.29, 1.21)	0.154
Apixaban	12,538	3,308.42	96.38	0.26	19	5.74	1.52				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,645	1,416.73	48.61	0.13	*****	*****	*****	-4.24	-0.56	0.33 (0.09, 1.23)	0.099
Apixaban	10,645	1,416.73	48.61	0.13	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,645	3,350.41	114.96	0.31	*****	*****	*****	*****	*****	0.45 (0.20, 1.02)	0.055
Apixaban	10,645	2,842.50	97.53	0.27	18	6.33	1.69				

¹Conditional analysis includes informative events and person-time.

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

Table 70. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Sex

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
Sex: Male											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	43,693	13,759.20	115.02	0.31	49	3.56	1.12	-1.22	-0.18	0.75 (0.50, 1.11)	0.147
Apixaban	39,862	10,869.87	99.6	0.27	52	4.78	1.3				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	35,590	4,924.68	50.54	0.14	26	5.28	0.73	1.02	0.14	1.24 (0.70, 2.20)	0.467
Apixaban	35,590	4,924.68	50.54	0.14	21	4.26	0.59				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	35,590	11,231.79	115.27	0.32	42	3.74	1.18	-0.86	-0.08	0.81 (0.53, 1.24)	0.326
Apixaban	35,590	9,775.76	100.33	0.27	45	4.6	1.26				
Sex: Female											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,869	13,118.22	117.24	0.32	46	3.51	1.13	-0.63	-0.01	0.84 (0.55, 1.29)	0.43
Apixaban	37,025	10,146.86	100.1	0.27	42	4.14	1.13				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,046	4,469.73	49.4	0.14	15	3.36	0.45	0.22	0.03	1.07 (0.52, 2.22)	0.853
Apixaban	33,046	4,469.73	49.4	0.14	14	3.13	0.42				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,046	10,520.50	116.28	0.32	33	3.14	1	-1.37	-0.24	0.70 (0.44, 1.11)	0.132
Apixaban	33,046	9,104.61	100.63	0.28	41	4.5	1.24				

¹Conditional analysis includes informative events and person-time.

Table 71. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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: 65-74											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	40,753	13,154.60	117.9	0.32	36	2.74	0.88	-0.7	-0.07	0.78 (0.49, 1.24)	0.294
Apixaban	37,862	10,478.49	101.08	0.28	36	3.44	0.95				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	33,356	4,660.42	51.03	0.14	*****	*****	*****	*****	*****	0.73 (0.34, 1.60)	0.435
Apixaban	33,356	4,660.42	51.03	0.14	15	3.22	0.45				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	33,356	10,747.87	117.69	0.32	*****	*****	*****	*****	*****	0.83 (0.50, 1.38)	0.464
Apixaban	33,356	9,328.57	102.15	0.28	31	3.32	0.93				
Age Group: 75-84											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	34,534	11,104.31	117.45	0.32	44	3.96	1.27	-0.17	0.14	0.99 (0.63, 1.54)	0.949
Apixaban	31,785	8,721.71	100.22	0.27	36	4.13	1.13				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	27,960	3,842.44	50.19	0.14	20	5.21	0.72	0.52	0.07	1.11 (0.59, 2.10)	0.746
Apixaban	27,960	3,842.44	50.19	0.14	18	4.68	0.64				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	27,960	8,966.28	117.13	0.32	36	4.02	1.29	-0.26	0.11	0.94 (0.58, 1.53)	0.814
Apixaban	27,960	7,715.29	100.79	0.28	33	4.28	1.18				
Age Group: 85+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	9,275	2,618.52	103.12	0.28	15	5.73	1.62	-6.38	-1.42	0.46 (0.23, 0.90)	0.022
Apixaban	7,240	1,816.52	91.64	0.25	22	12.11	3.04				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,751	810.25	43.84	0.12	*****	*****	*****	*****	*****	0.33 (0.11, 1.03)	0.057
Apixaban	6,751	810.25	43.84	0.12	12	14.81	1.78				

Table 71. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and Age Group

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,751	1,880.79	101.76	0.28	*****	*****	*****	*****	*****	0.39 (0.18, 0.86)	0.019
Apixaban	6,751	1,698.15	91.87	0.25	21	12.37	3.11				

¹Conditional analysis includes informative events and person-time.

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

Table 72. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
CHA₂DS₂-VASc Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	2,775	860.22	113.22	0.31	*****	*****	*****				
Apixaban	2,050	581.06	103.53	0.28	*****	*****	*****	0.6	0.23	1.48 (0.13, 16.29)	0.751
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	1,959	269.58	50.26	0.14	0	0	0	0	0	-	-
Apixaban	1,959	269.58	50.26	0.14	0	0	0				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	1,959	611.11	113.94	0.31	*****	*****	*****				
Apixaban	1,959	558.56	104.14	0.29	*****	*****	*****	-0.15	0	1.03 (0.06, 16.42)	0.985
CHA₂DS₂-VASc Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	12,962	4,152.11	117	0.32	*****	*****	*****				
Apixaban	11,594	3,380.86	106.51	0.29	*****	*****	*****	-0.09	0.02	0.79 (0.26, 2.44)	0.686
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,670	1,535.13	52.55	0.14	*****	*****	*****				
Apixaban	10,670	1,535.13	52.55	0.14	*****	*****	*****	0	0	1.00 (0.14, 7.10)	1
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,670	3,418.60	117.02	0.32	*****	*****	*****				
Apixaban	10,670	3,120.74	106.83	0.29	*****	*****	*****	-0.14	0	0.80 (0.22, 2.89)	0.736
CHA₂DS₂-VASc Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	19,816	6,490.63	119.64	0.33	26	4.01	1.31				
Apixaban	18,659	5,353.49	104.79	0.29	20	3.74	1.07	0.27	0.24	1.07 (0.59, 1.93)	0.827
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	16,641	2,371.64	52.05	0.14	14	5.9	0.84				
Apixaban	16,641	2,371.64	52.05	0.14	*****	*****	*****	*****	*****	2.00 (0.81, 4.96)	0.134

Table 72. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VAsC Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	16,641	5,439.00	119.38	0.33	23	4.23	1.38	0.89	0.42	1.24 (0.65, 2.38)	0.507
Apixaban	16,641	4,792.91	105.2	0.29	16	3.34	0.96				
CHA₂DS₂-VAsC Score: 4											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	21,646	7,105.08	119.89	0.33	23	3.24	1.06	-1.64	-0.27	0.70 (0.40, 1.24)	0.221
Apixaban	18,800	5,123.62	99.54	0.27	25	4.88	1.33				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	17,117	2,367.47	50.52	0.14	12	5.07	0.7	-0.42	-0.06	0.92 (0.42, 2.02)	0.842
Apixaban	17,117	2,367.47	50.52	0.14	13	5.49	0.76				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	17,117	5,626.09	120.05	0.33	18	3.2	1.05	-1.71	-0.29	0.68 (0.36, 1.26)	0.217
Apixaban	17,117	4,688.69	100.05	0.27	23	4.91	1.34				
CHA₂DS₂-VAsC Score: 5											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,991	4,324.43	112.89	0.31	20	4.62	1.43	-0.85	-0.02	0.77 (0.40, 1.47)	0.428
Apixaban	13,112	3,467.30	96.59	0.26	19	5.48	1.45				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	11,373	1,507.72	48.42	0.13	*****	*****	*****	-5.31	-0.7	0.27 (0.08, 0.98)	0.046
Apixaban	11,373	1,507.72	48.42	0.13	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	11,373	3,491.79	112.14	0.31	14	4.01	1.23	-1.91	-0.35	0.62 (0.30, 1.28)	0.198
Apixaban	11,373	3,039.75	97.62	0.27	18	5.92	1.58				
CHA₂DS₂-VAsC Score: 6+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	13,372	3,944.95	107.75	0.3	17	4.31	1.27	-3.09	-0.54	0.64 (0.34, 1.21)	0.171
Apixaban	12,672	3,110.39	89.65	0.25	23	7.39	1.82				

Table 72. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and CHA₂DS₂-VASc Score

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
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	10,805	1,339.38	45.28	0.12	*****	*****	*****	*****	*****	0.67 (0.27, 1.63)	0.374
Apixaban	10,805	1,339.38	45.28	0.12	12	8.96	1.11				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	10,805	3,158.75	106.78	0.29	*****	*****	*****				
Apixaban	10,805	2,672.77	90.35	0.25	*****	*****	*****	-4.12	-0.83	0.55 (0.28, 1.09)	0.086

¹Conditional analysis includes informative events and person-time.

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Table 73. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
HAS-BLED Score: 0-1											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	7,788	2,453.26	115.06	0.32	*****	*****	*****	1.36	0.51	1.26 (0.42, 3.80)	0.683
Apixaban	6,455	1,841.15	104.18	0.29	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	6,098	859.78	51.5	0.14	*****	*****	*****	2.33	0.33	2.00 (0.37, 10.92)	0.423
Apixaban	6,098	859.78	51.5	0.14	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	6,098	1,924.61	115.28	0.32	*****	*****	*****	0.77	0.33	1.08 (0.33, 3.55)	0.896
Apixaban	6,098	1,742.89	104.39	0.29	*****	*****	*****				
HAS-BLED Score: 2											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	38,021	12,735.60	122.34	0.33	36	2.83	0.95	-0.74	-0.08	0.78 (0.48, 1.25)	0.302
Apixaban	33,078	9,534.18	105.28	0.29	34	3.57	1.03				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	30,531	4,396.15	52.59	0.14	*****	*****	*****	*****	*****	1.18 (0.53, 2.64)	0.683
Apixaban	30,531	4,396.15	52.59	0.14	11	2.5	0.36				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	30,531	10,198.85	122.01	0.33	28	2.75	0.92	-0.89	-0.13	0.73 (0.43, 1.22)	0.226
Apixaban	30,531	8,811.10	105.41	0.29	32	3.63	1.05				
HAS-BLED Score: 3											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	26,875	8,280.22	112.53	0.31	37	4.47	1.38	-0.77	-0.02	0.90 (0.57, 1.44)	0.666
Apixaban	24,997	6,675.35	97.54	0.27	35	5.24	1.4				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	22,081	2,971.20	49.15	0.13	17	5.72	0.77	-1.01	-0.14	0.85 (0.45, 1.62)	0.622
Apixaban	22,081	2,971.20	49.15	0.13	20	6.73	0.91				

Table 73. Effect Estimates for Risk of Intracranial Hemorrhage among Dabigatran vs. Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, by Analysis Type and HAS-BLED Score

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
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	22,081	6,800.57	112.49	0.31	28	4.12	1.27	-1.28	-0.18	0.80 (0.48, 1.33)	0.382
Apixaban	22,081	5,923.91	97.99	0.27	32	5.4	1.45				
HAS-BLED Score: 4+											
<i>Unmatched Analysis (Site-adjusted only)</i>											
Dabigatran	11,878	3,408.34	104.81	0.29	*****	*****	*****	-3.22	-0.61	0.50 (0.24, 1.05)	0.068
Apixaban	12,357	2,966.03	87.67	0.24	*****	*****	*****				
<i>1:1 Matched Conditional Analysis; Caliper= 0.05¹</i>											
Dabigatran	9,997	1,222.69	44.67	0.12	*****	*****	*****	-4.91	-0.6	0.45 (0.16, 1.31)	0.144
Apixaban	9,997	1,222.69	44.67	0.12	*****	*****	*****				
<i>1:1 Matched Unconditional Analysis; Caliper= 0.05</i>											
Dabigatran	9,997	2,859.68	104.48	0.29	*****	*****	*****	-3.13	-0.6	0.57 (0.26, 1.23)	0.154
Apixaban	9,997	2,438.17	89.08	0.24	*****	*****	*****				

¹Conditional analysis includes informative events and person-time.

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

Figure 1a. Histogram Depicting Propensity Score Distributions of Rivaroxaban and Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

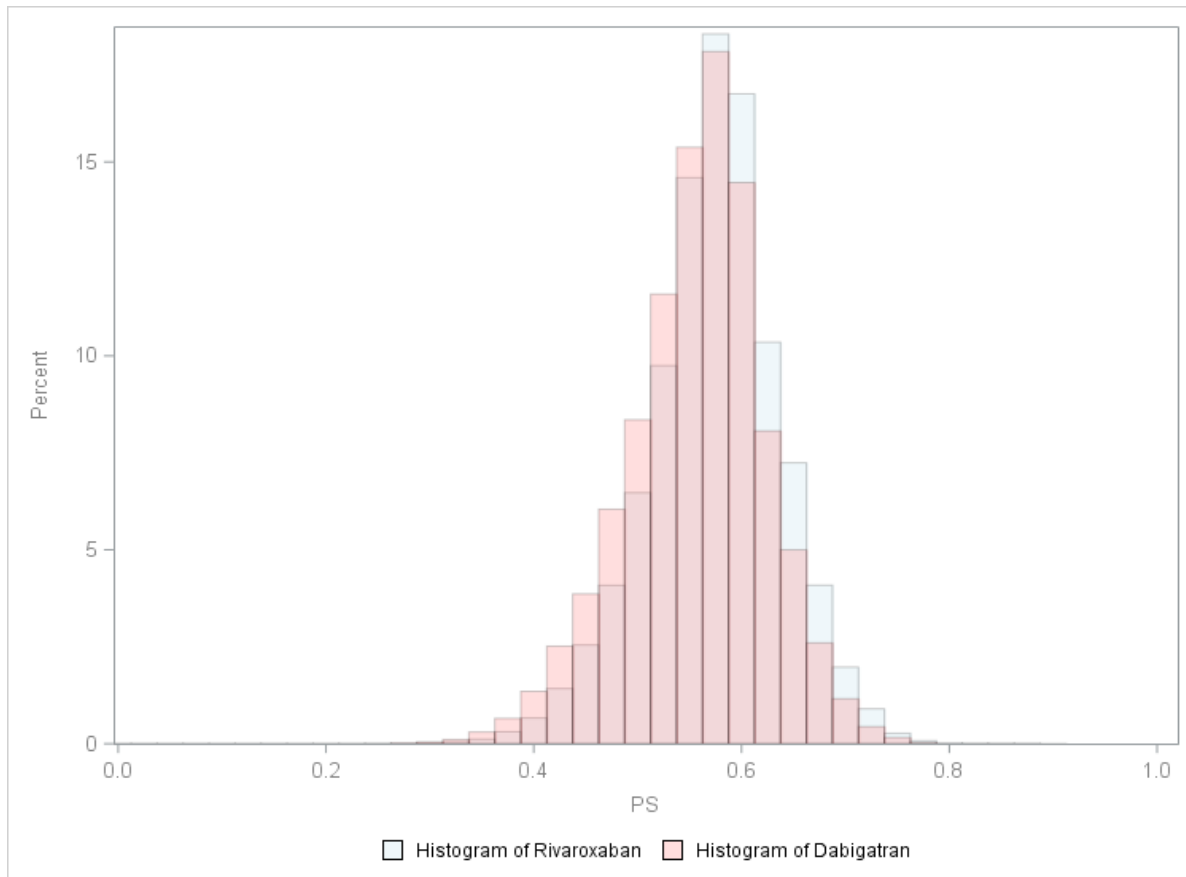


Figure 1b. Histogram Depicting Propensity Score Distributions of Rivaroxaban and Dabigatran Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

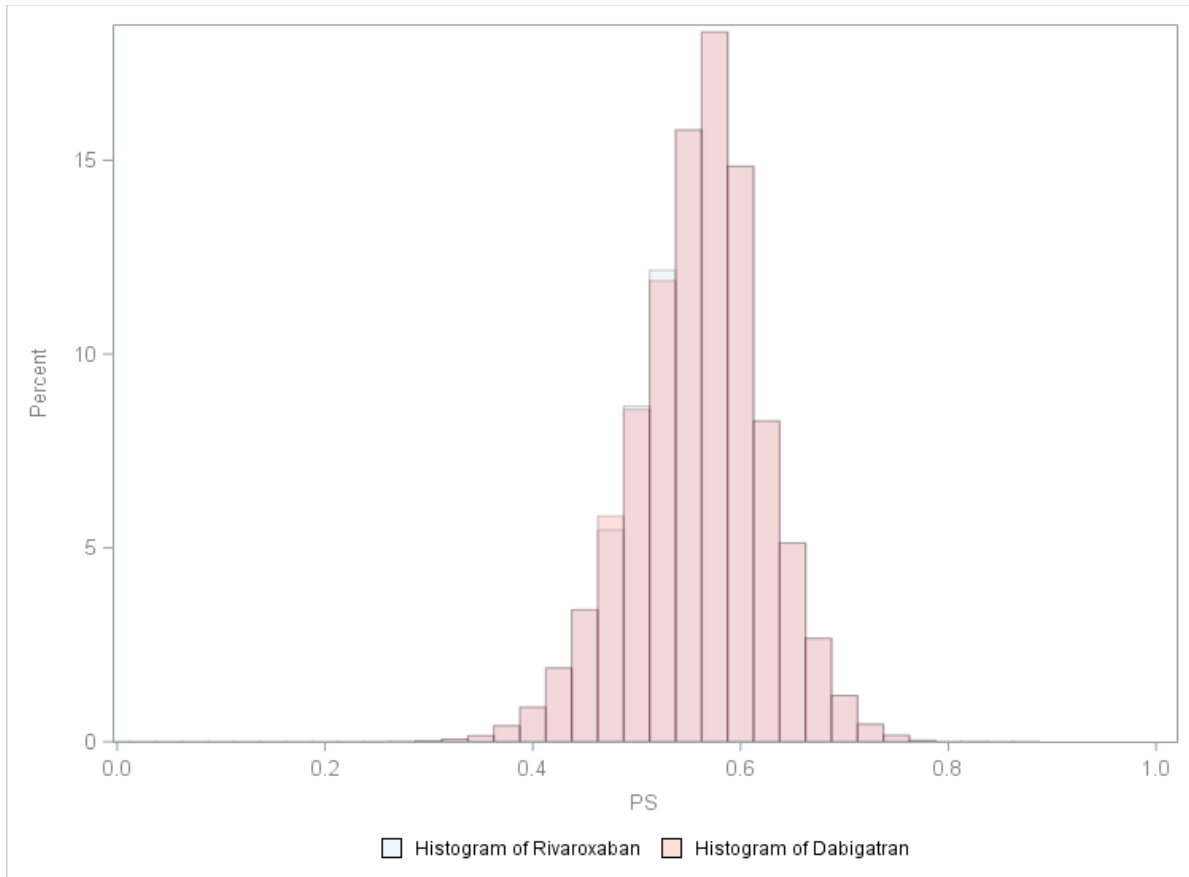


Figure 2a. Histogram Depicting Propensity Score Distributions of Rivaroxaban and Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

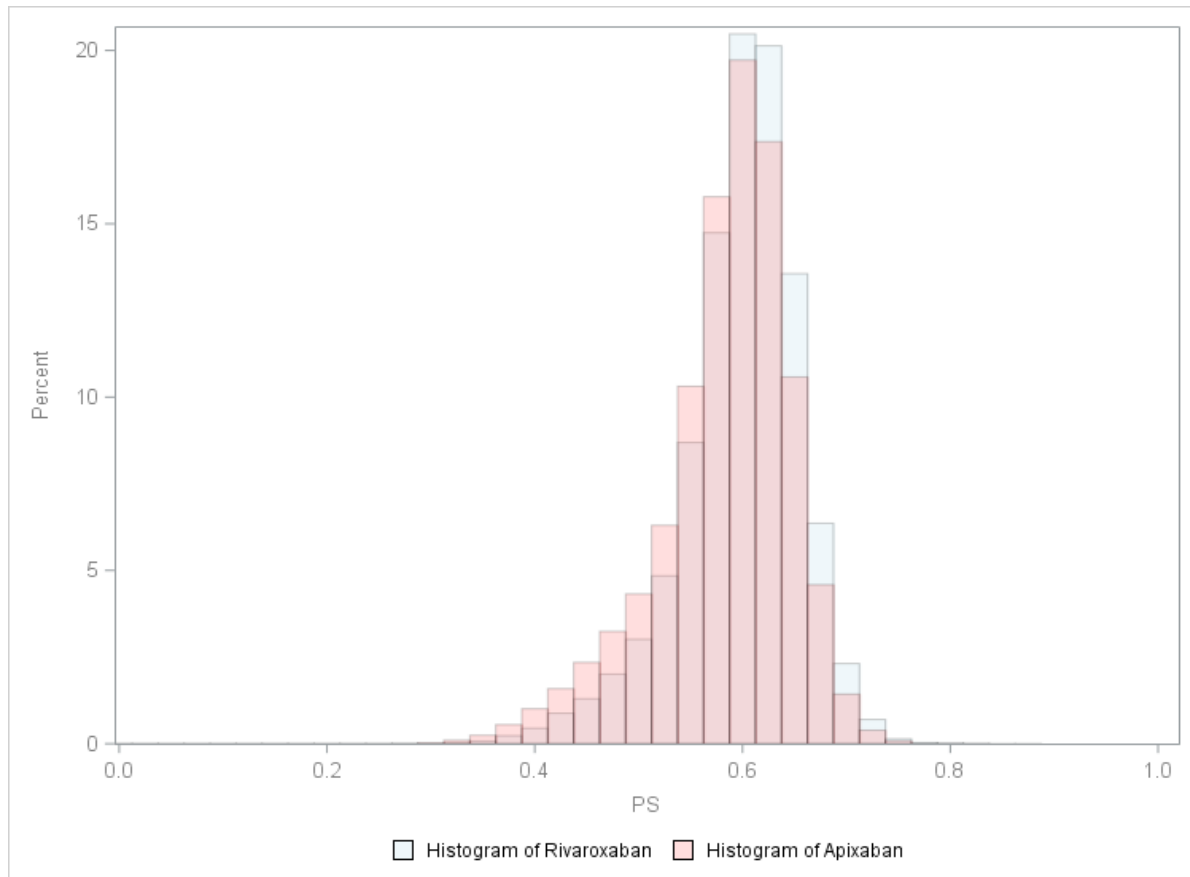


Figure 2b. Histogram Depicting Propensity Score Distributions of Rivaroxaban and Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

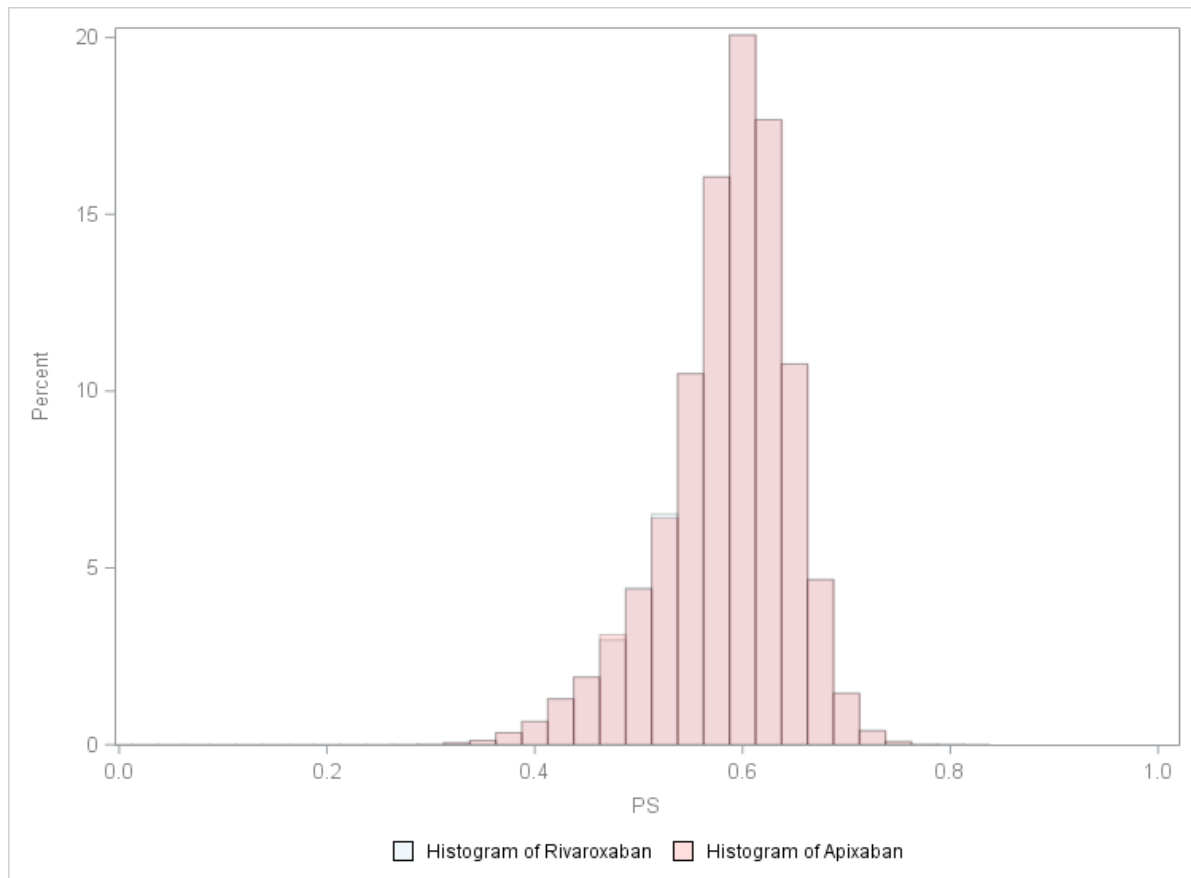


Figure 3a. Histogram Depicting Propensity Score Distributions of Dabigatran and Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Before Matching

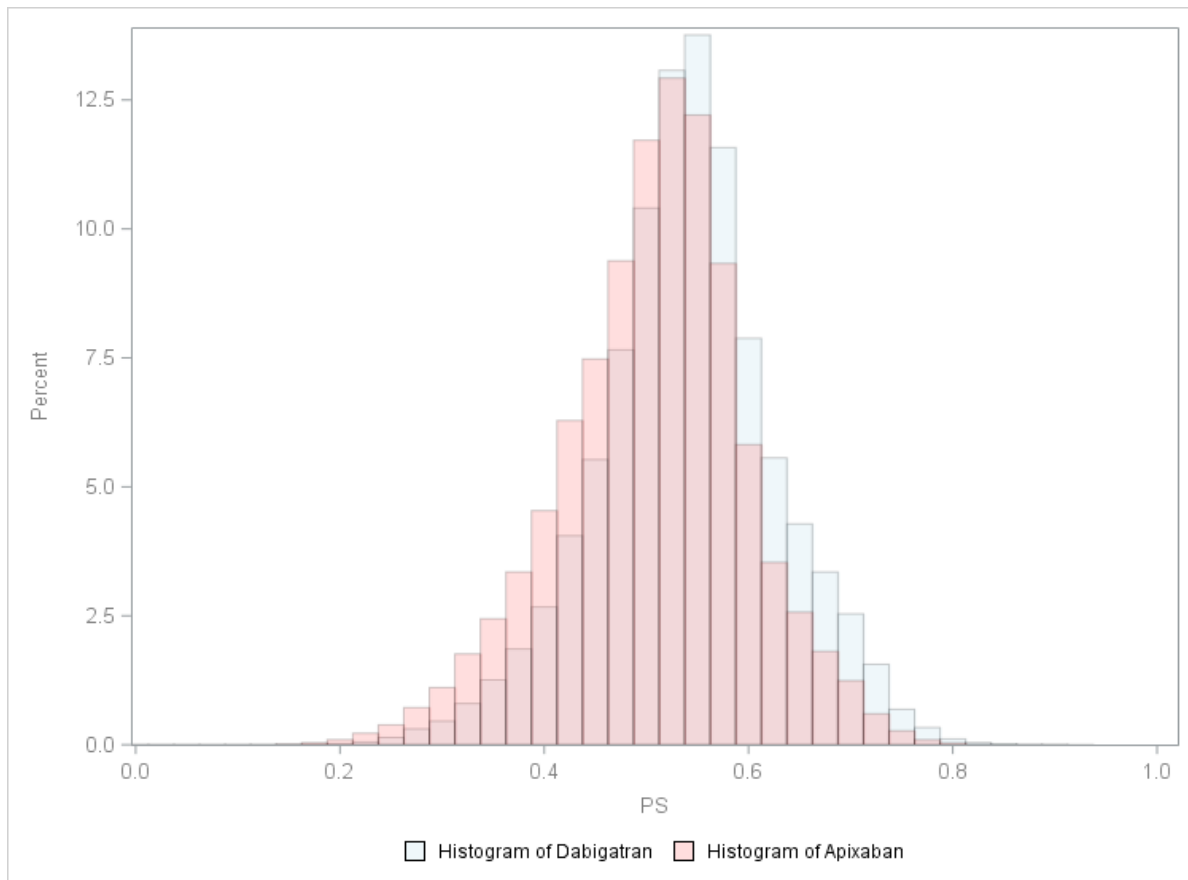


Figure 3b. Histogram Depicting Propensity Score Distributions of Dabigatran and Apixaban Users in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, After Matching

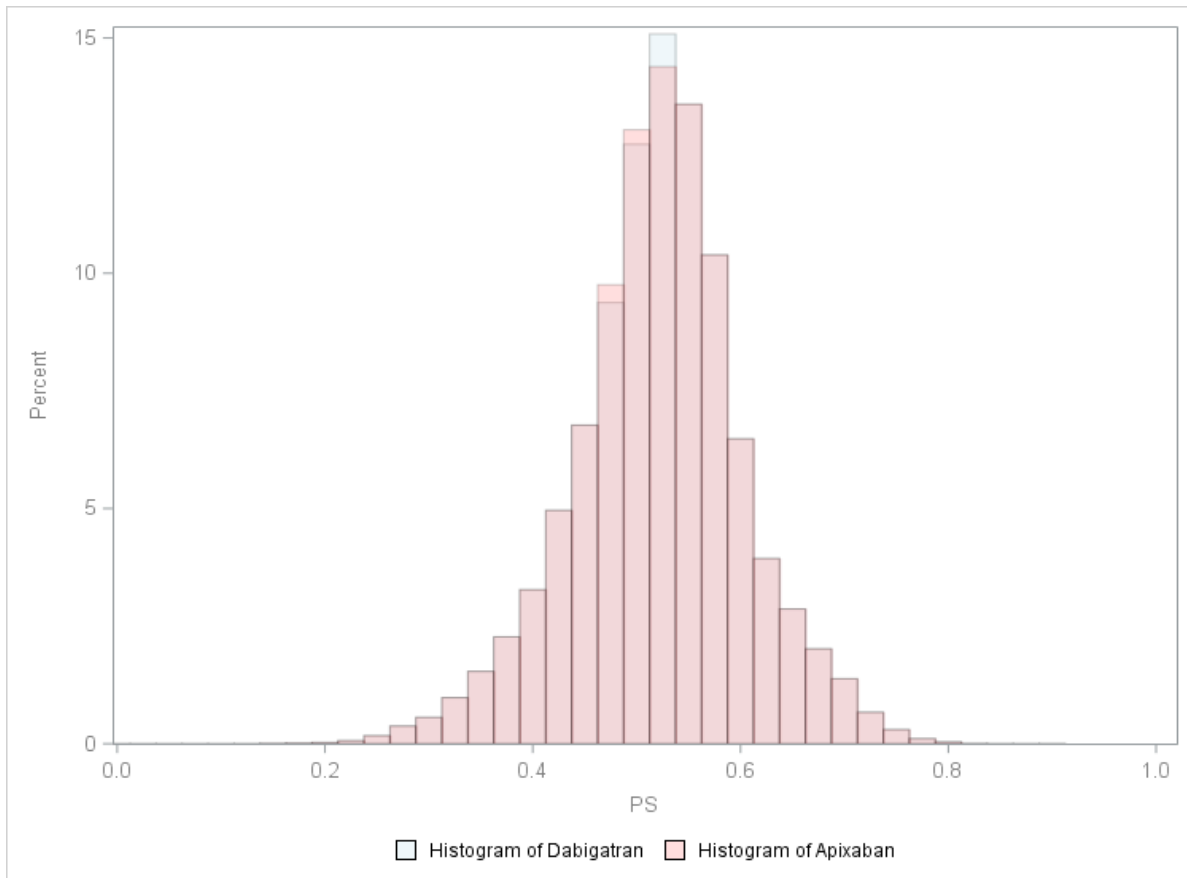


Figure 4a. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Thromboembolic Stroke, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

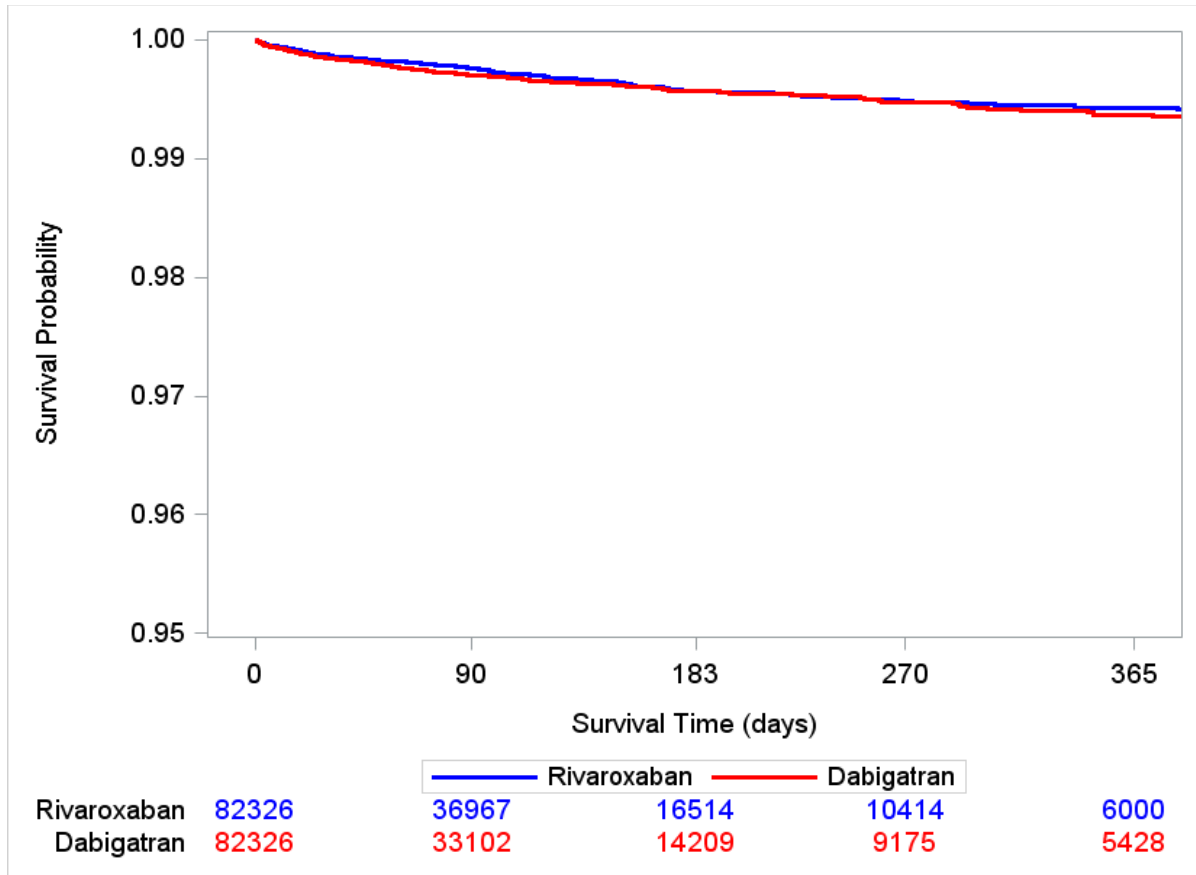


Figure 4b. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for for Rivaroxaban and Dabigatran and Risk of Thromboembolic Stroke, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

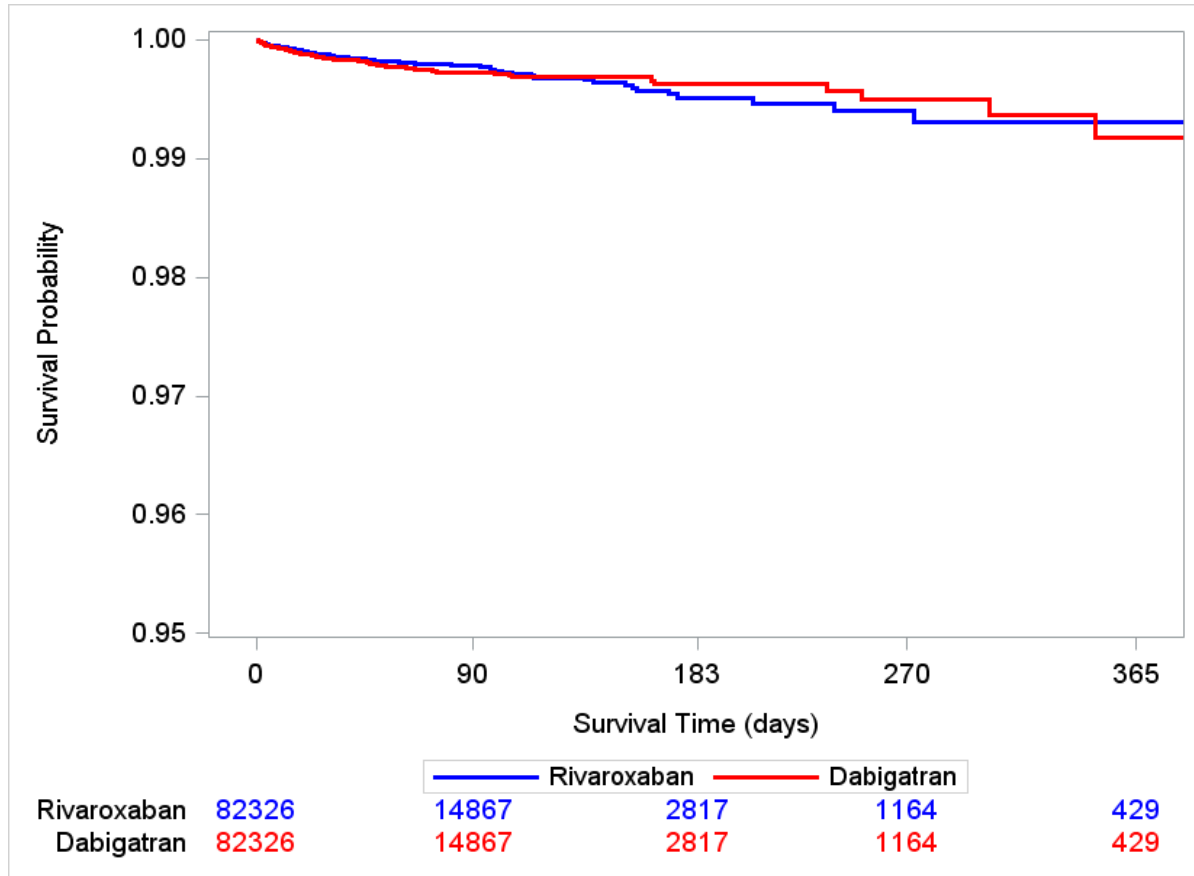


Figure 4c. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Thromboembolic Stroke, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

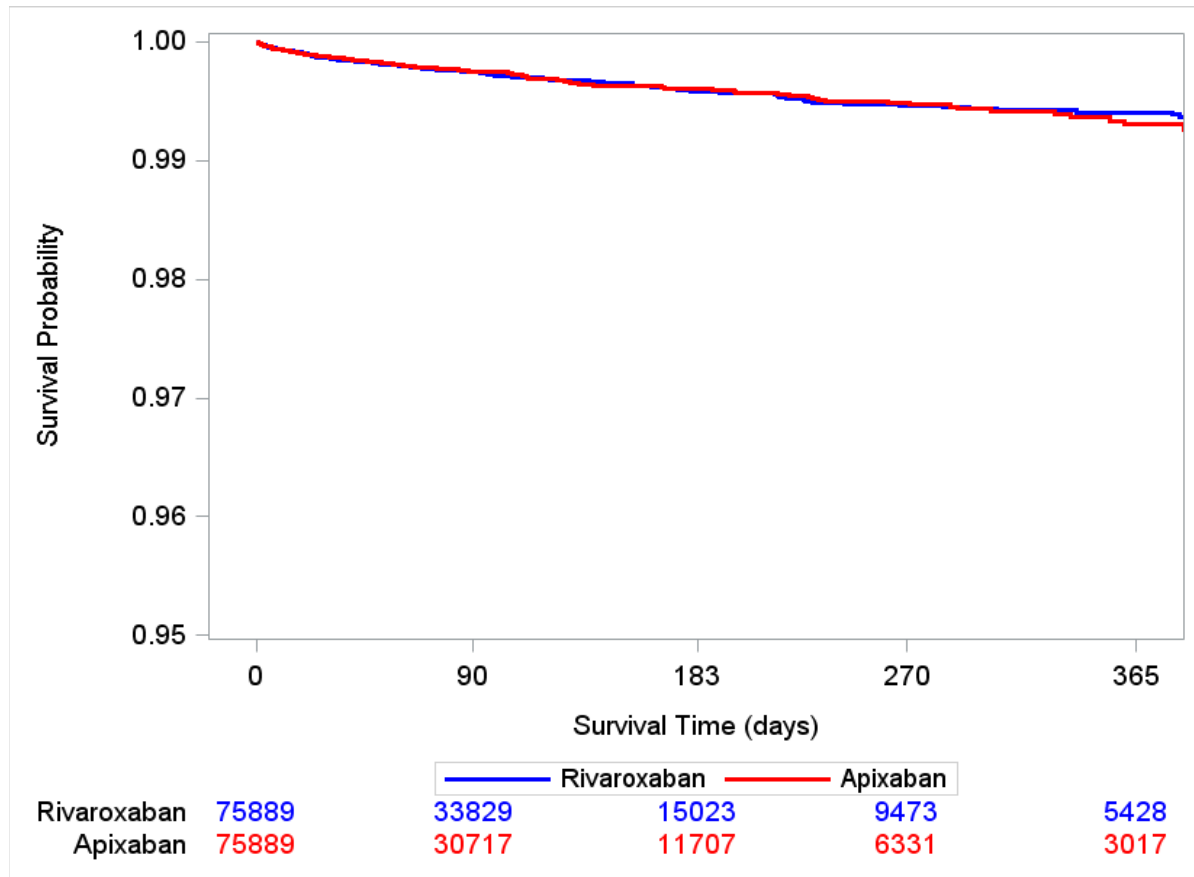


Figure 4d. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for for Rivaroxaban and Apixaban and Risk of Thromboembolic Stroke, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

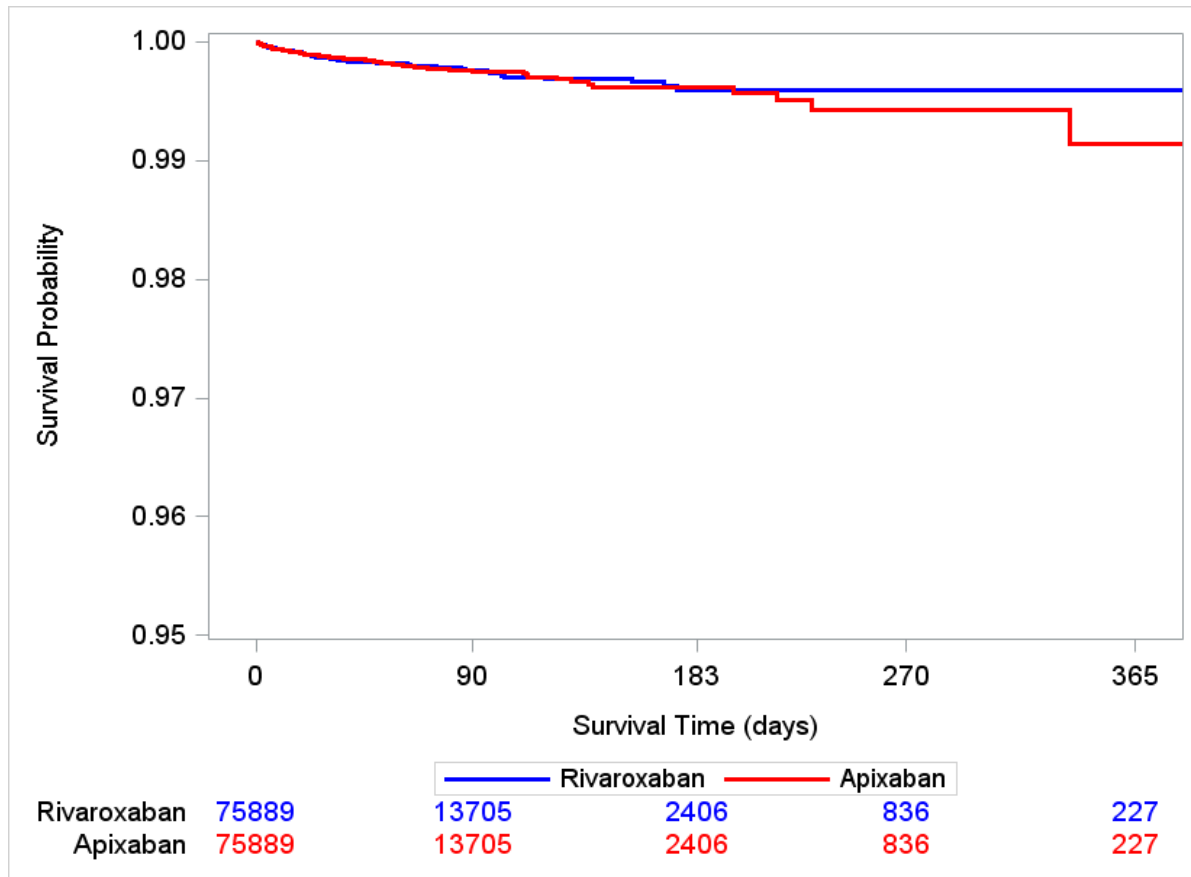


Figure 4e. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Thromboembolic Stroke, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

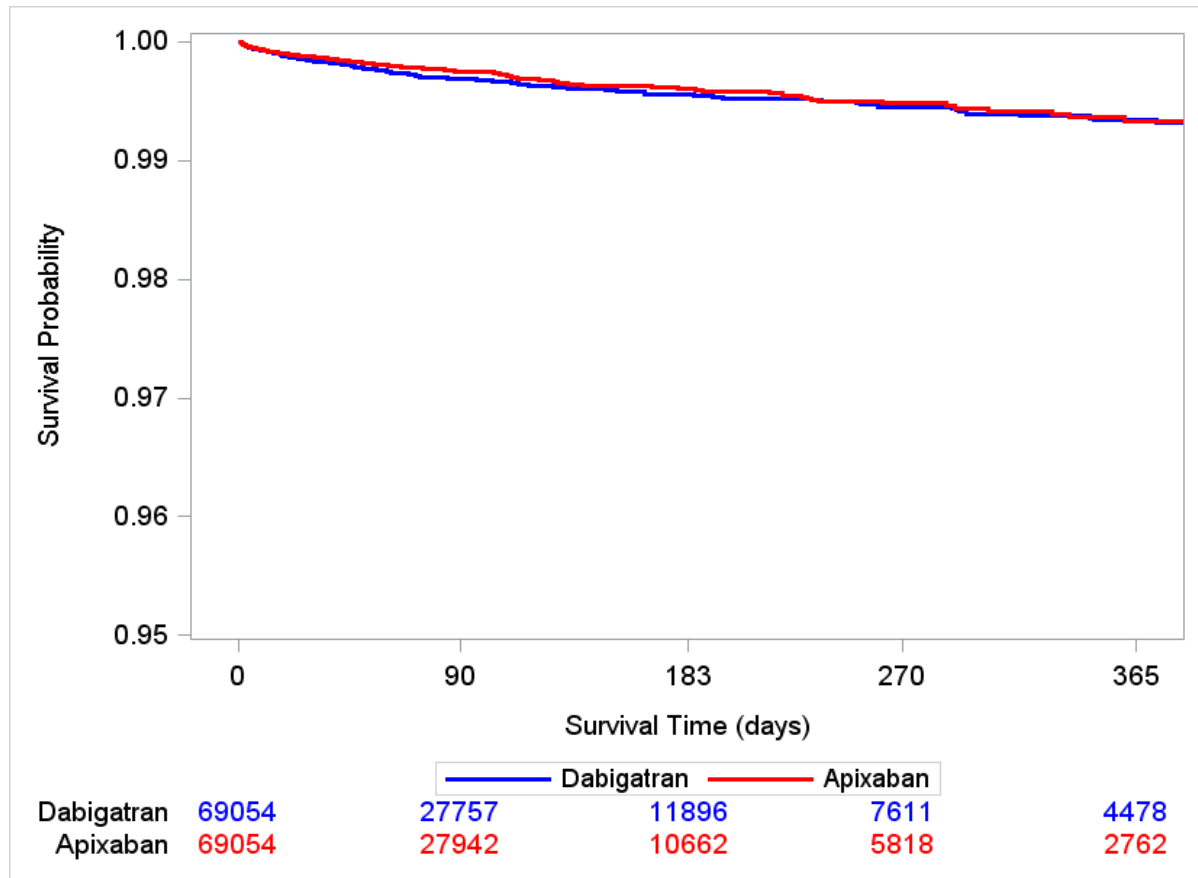


Figure 4f. Kaplan Meier Survival Curves of Informative Events and Follow-up Time for for Dabigatran and Apixaban and Risk of Thromboembolic Stroke, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

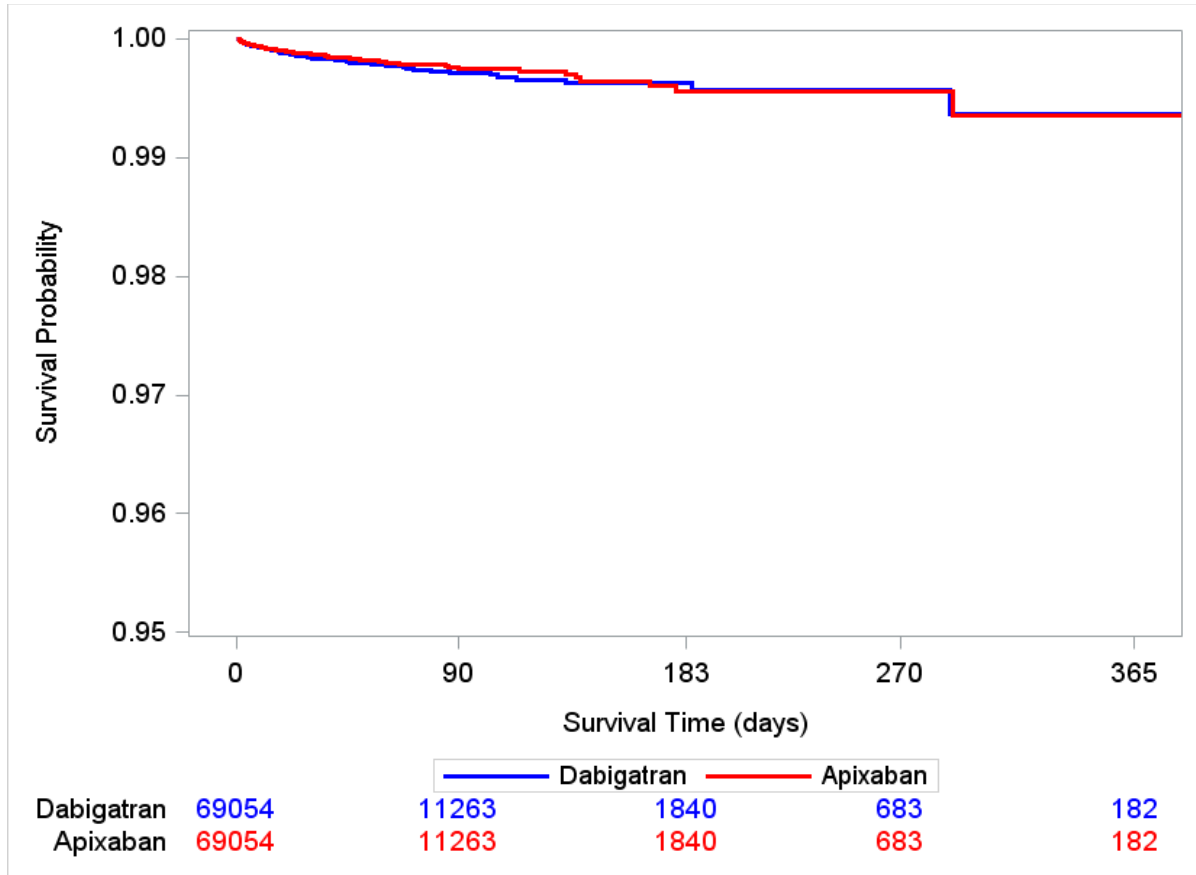


Figure 5a. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Major Extracranial Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

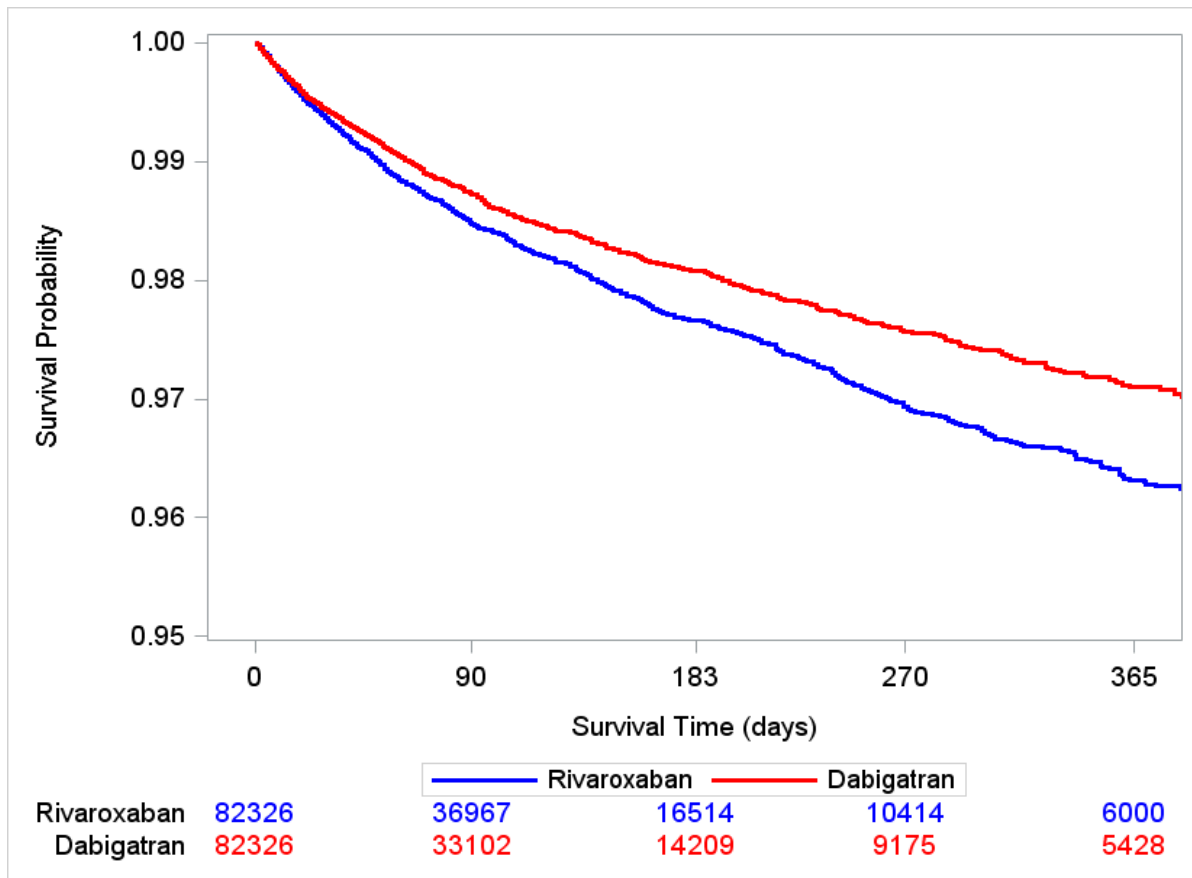


Figure 5b. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Major Extracranial Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

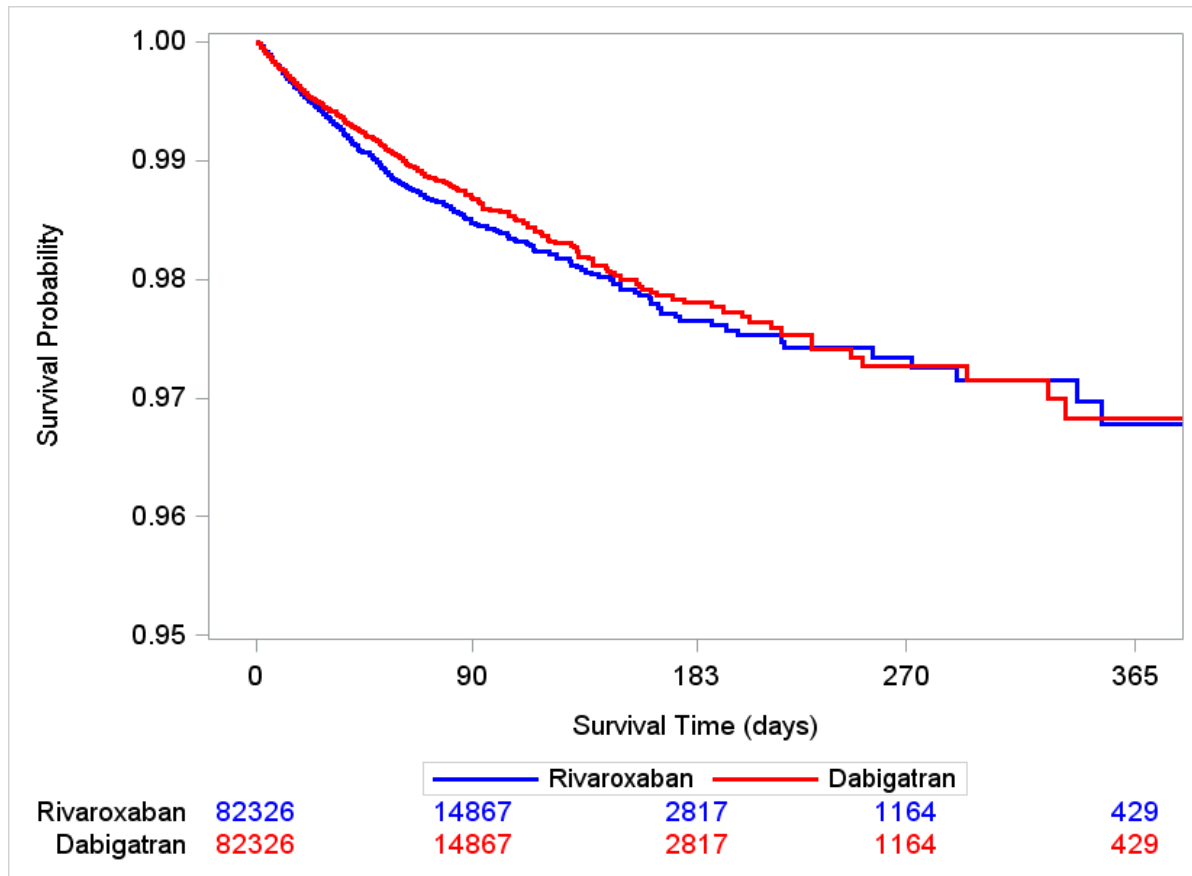


Figure 5c. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Major Extracranial Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

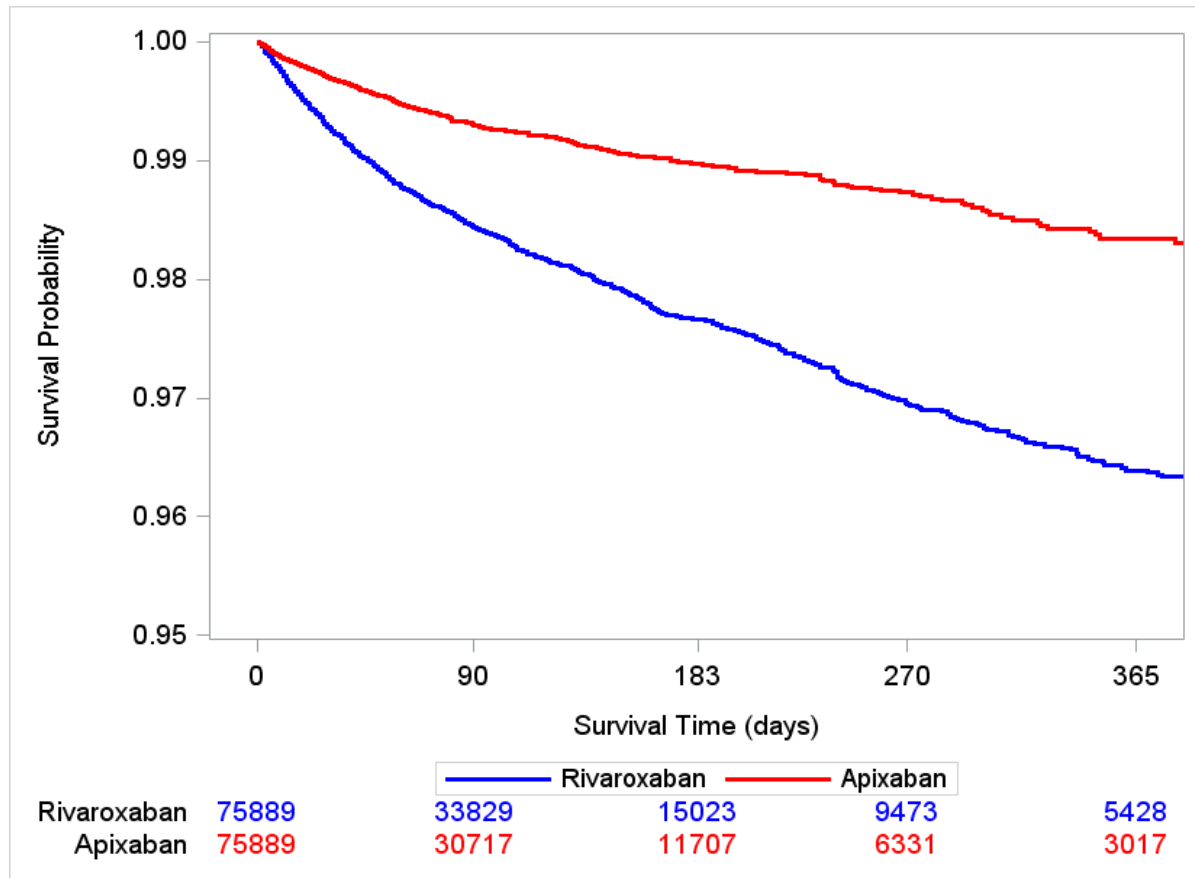


Figure 5d. Kaplan Meier Survival Curves of Events and Follow-up Time for Apixaban and Dabigatran and Risk of Major Extracranial Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

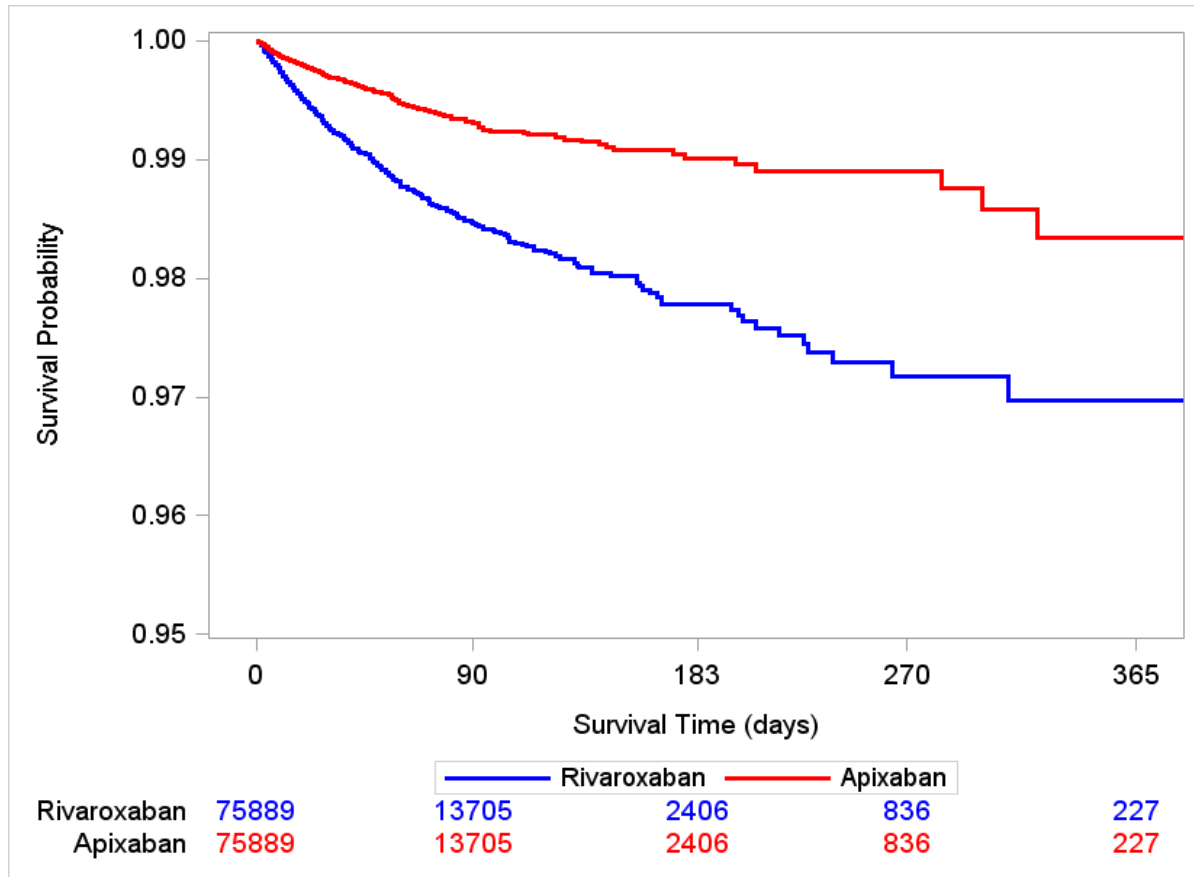


Figure 5e. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Major Extracranial Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

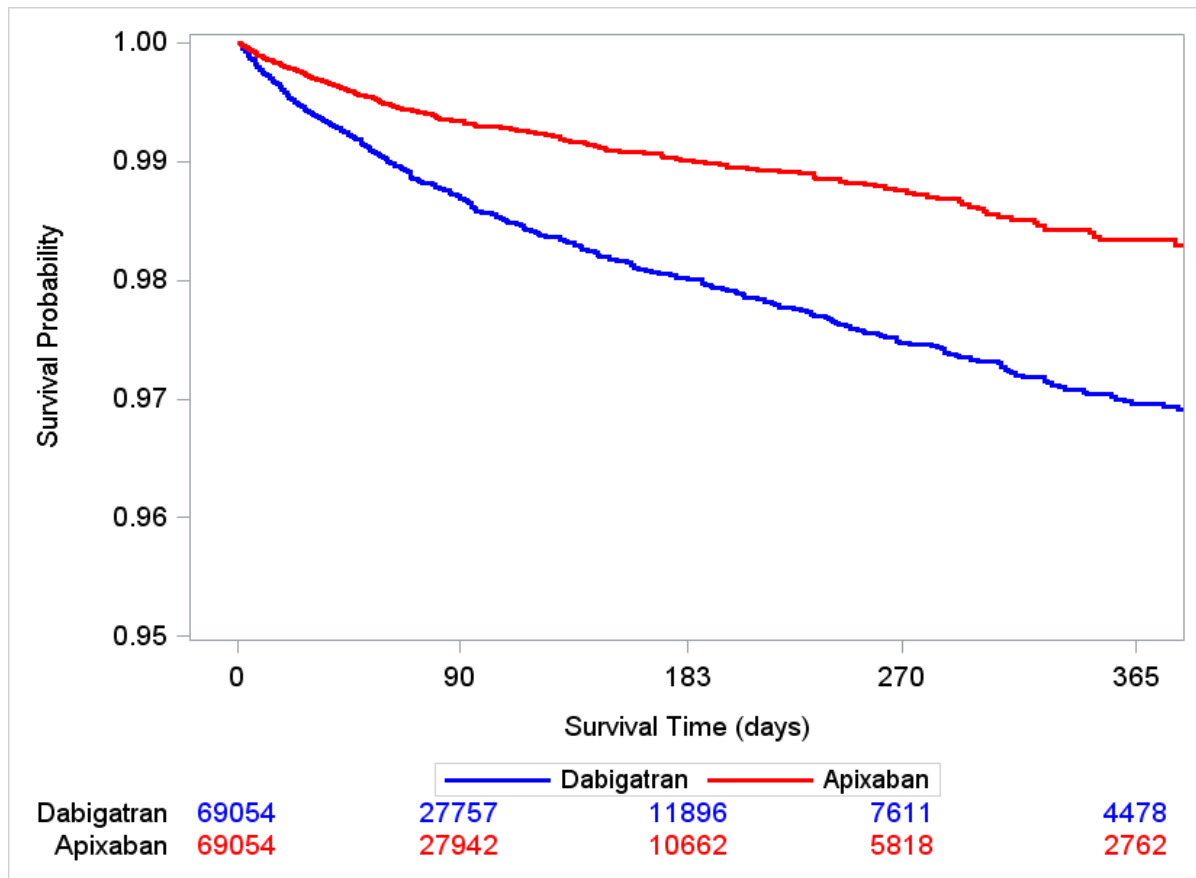


Figure 5f. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Dabigatran and Risk of Major Extracranial Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

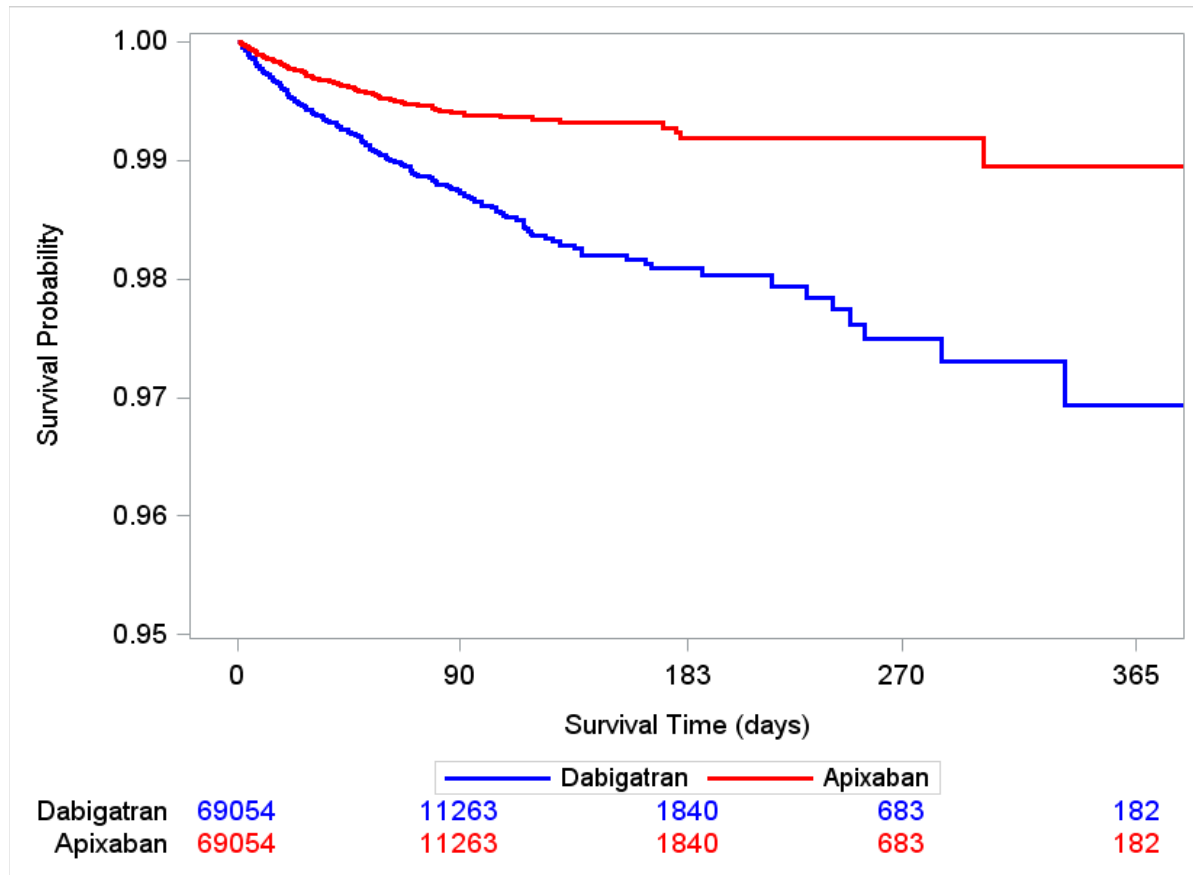


Figure 6a. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Gastrointestinal Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

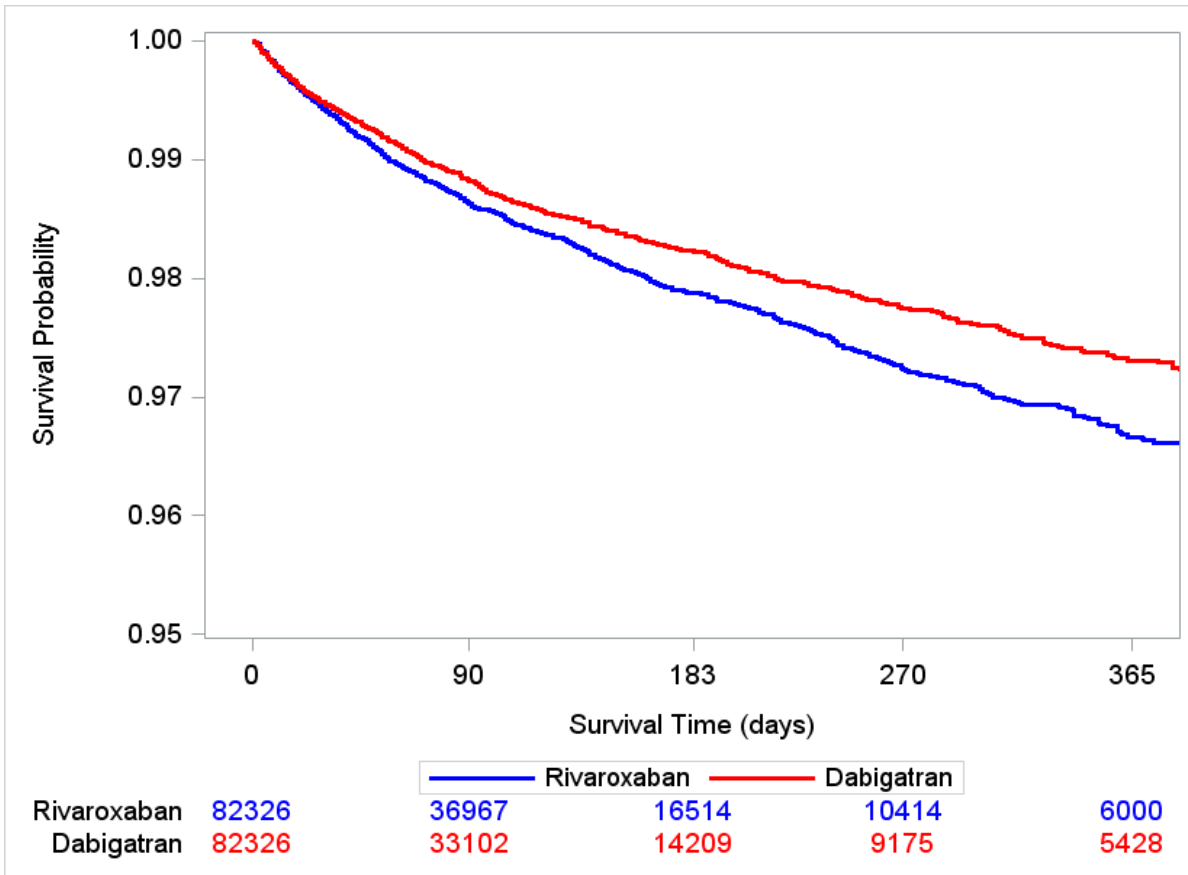


Figure 6b. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Gastrointestinal Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

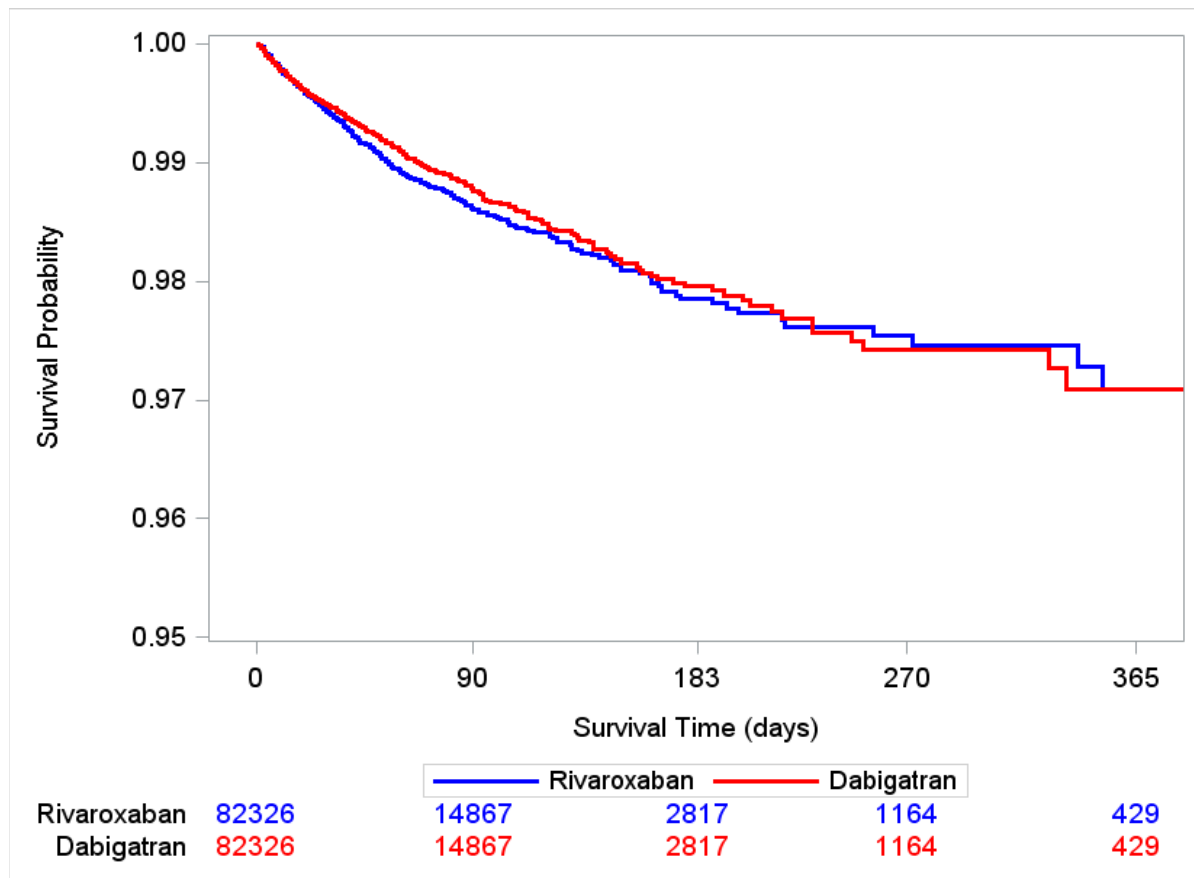


Figure 6c. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Gastrointestinal Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

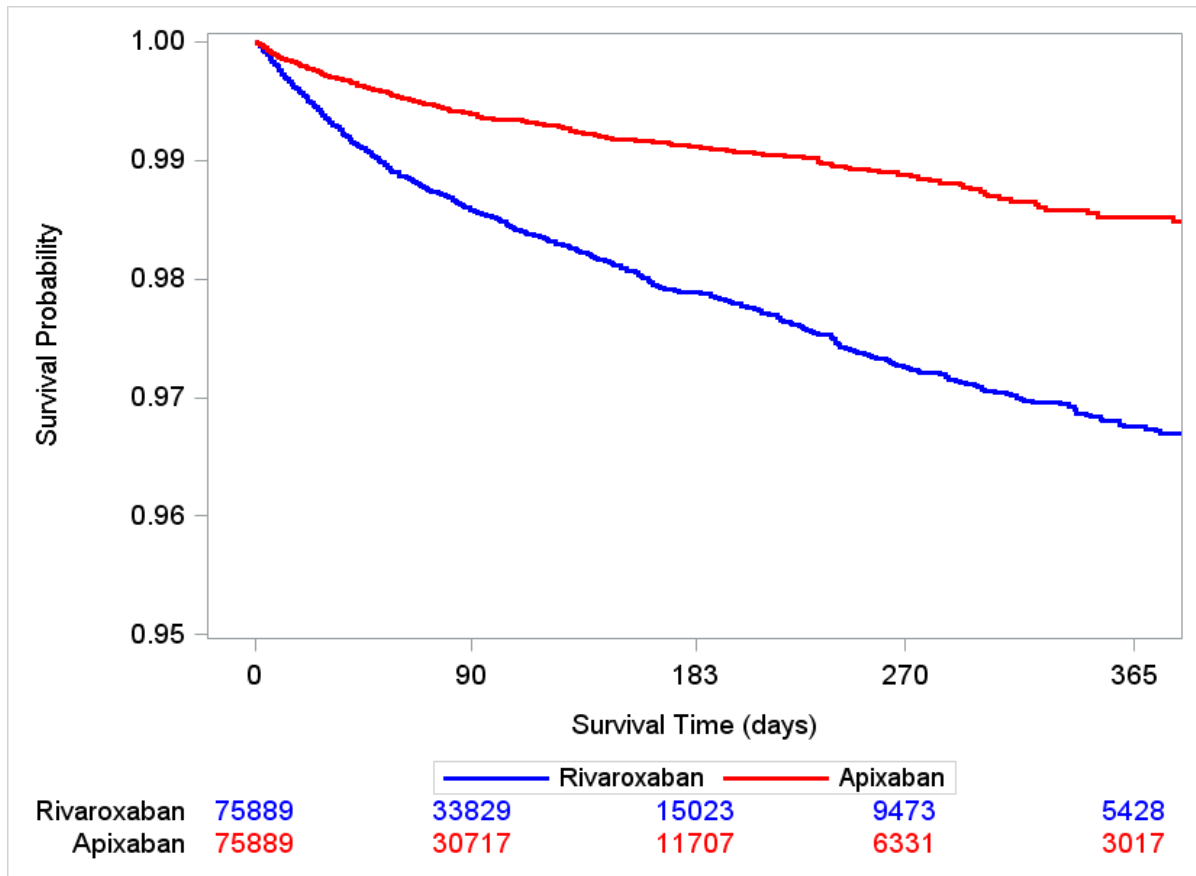


Figure 6d. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Gastrointestinal Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

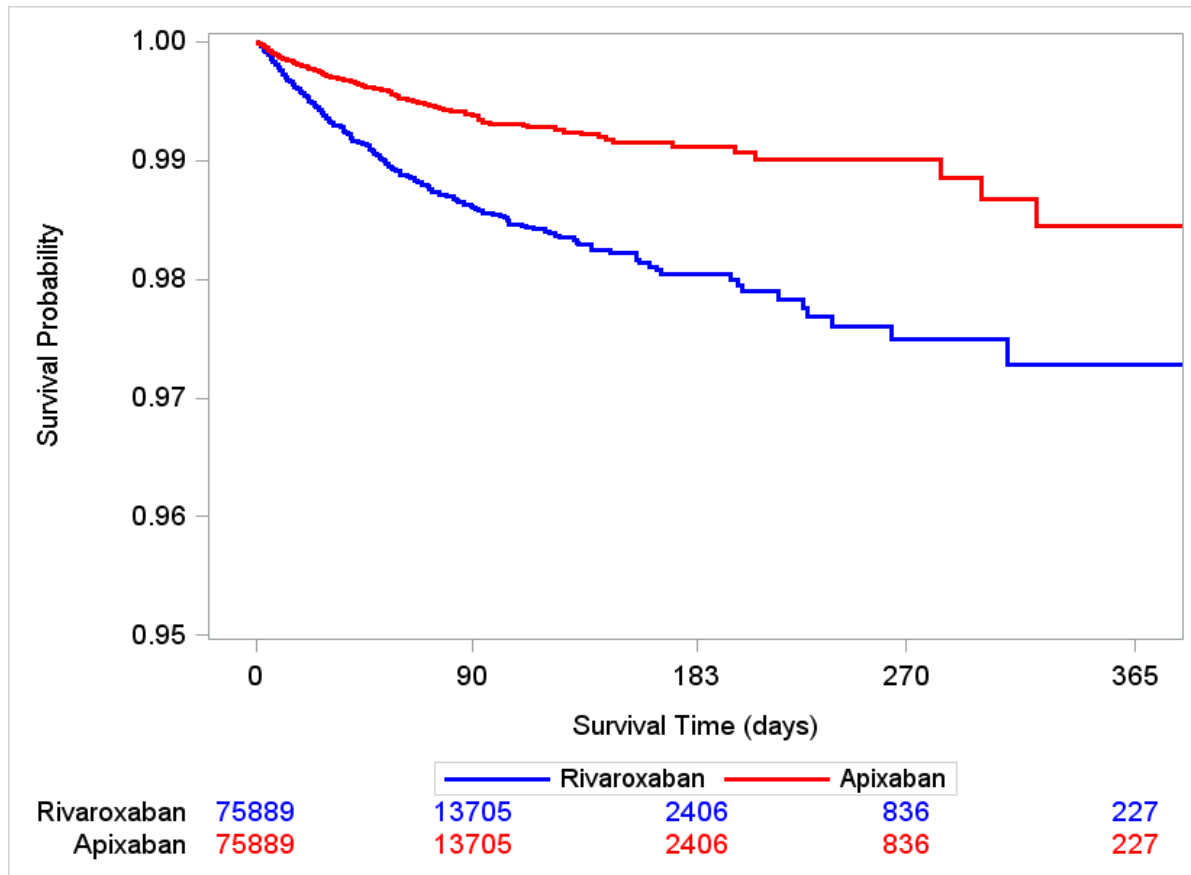


Figure 6e. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Gastrointestinal Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

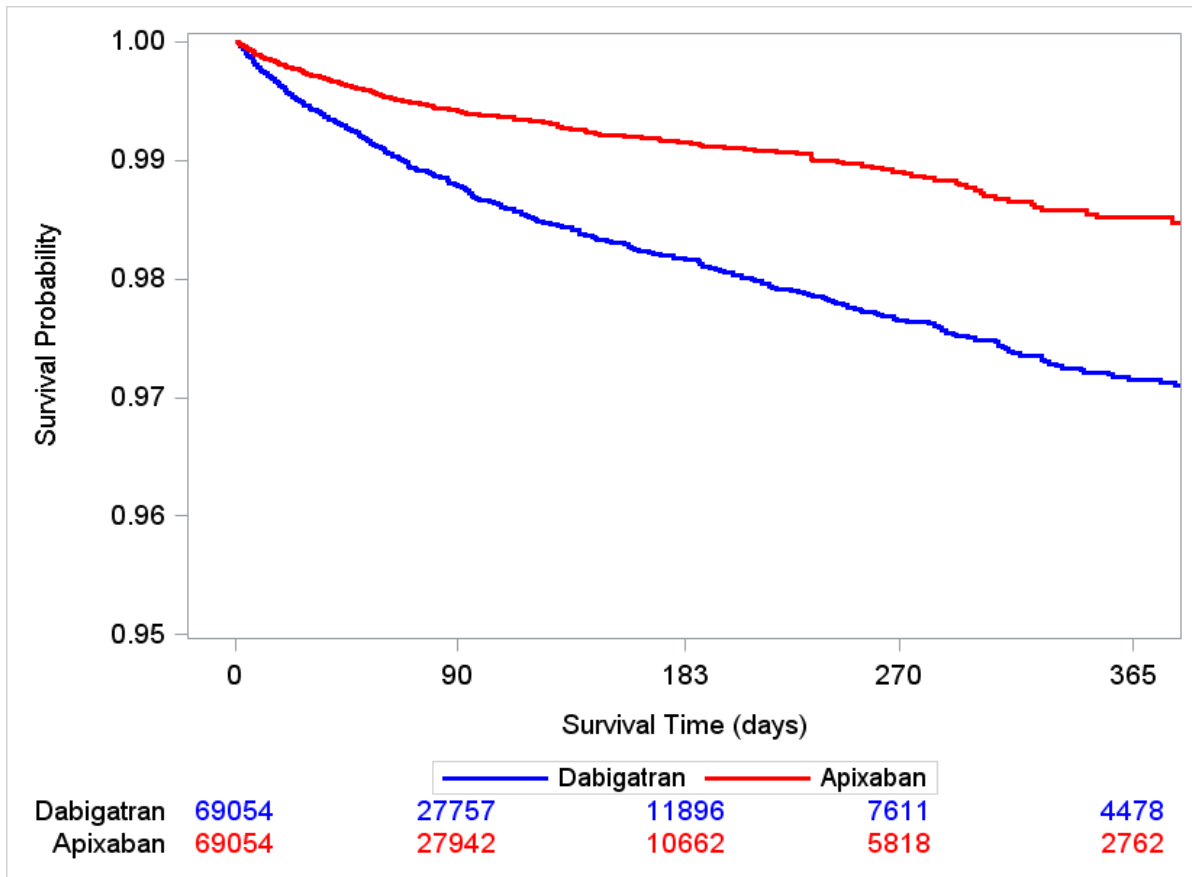


Figure 6f. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Gastrointestinal Bleeding, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

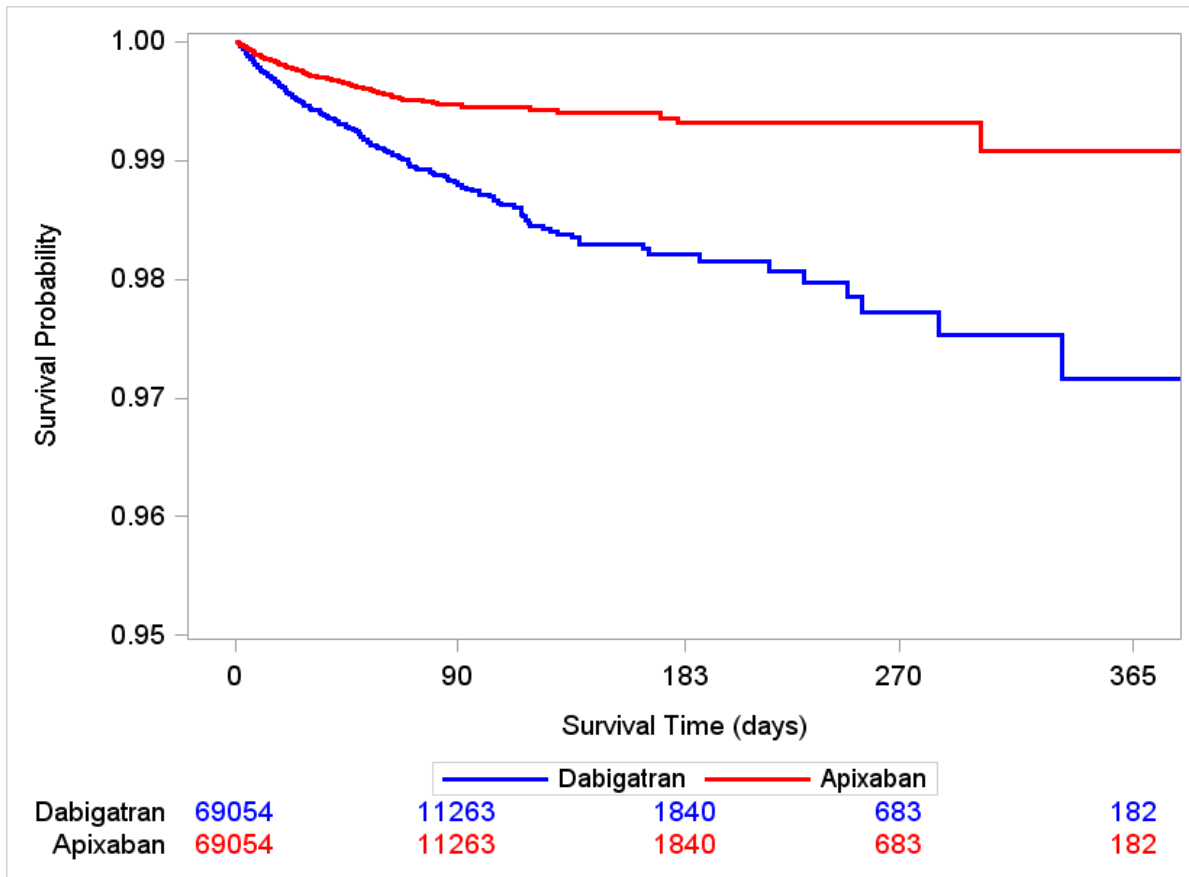


Figure 7a. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

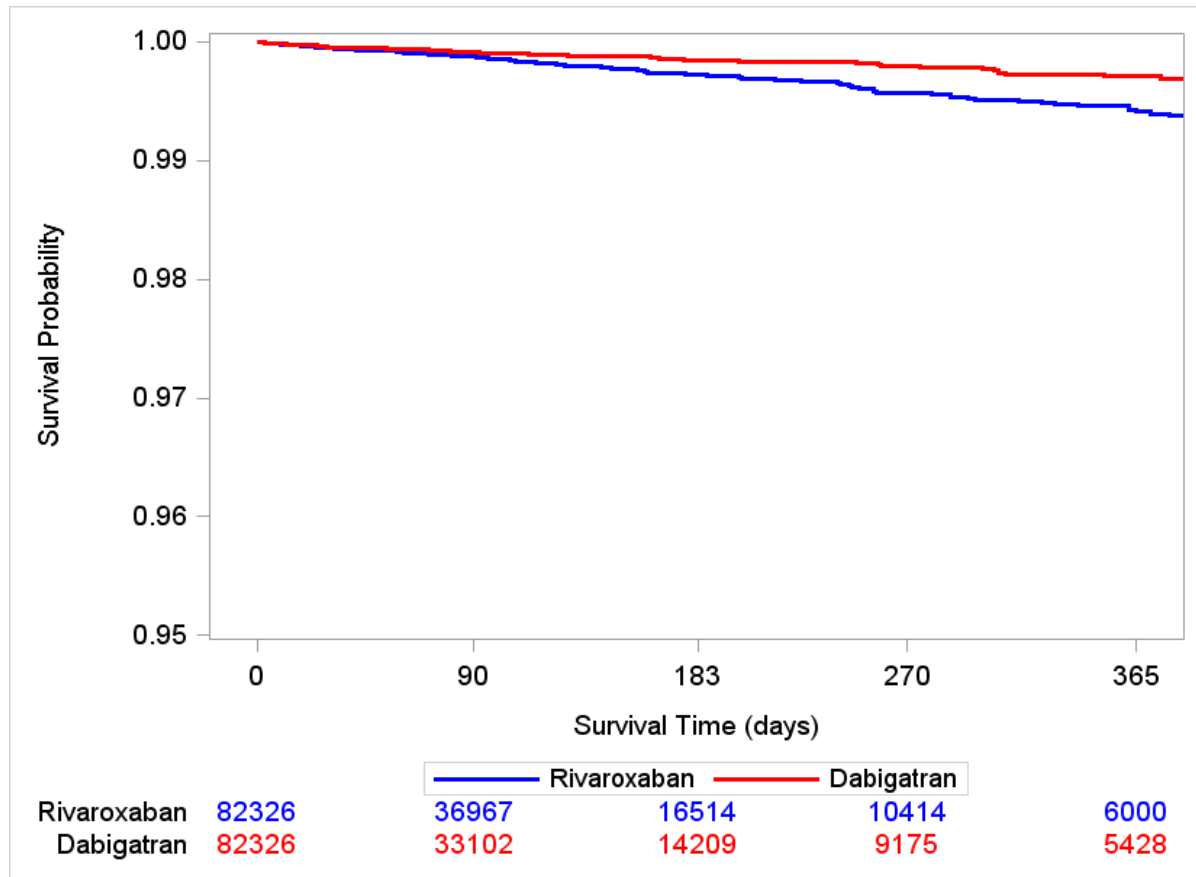


Figure 7b. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Dabigatran and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

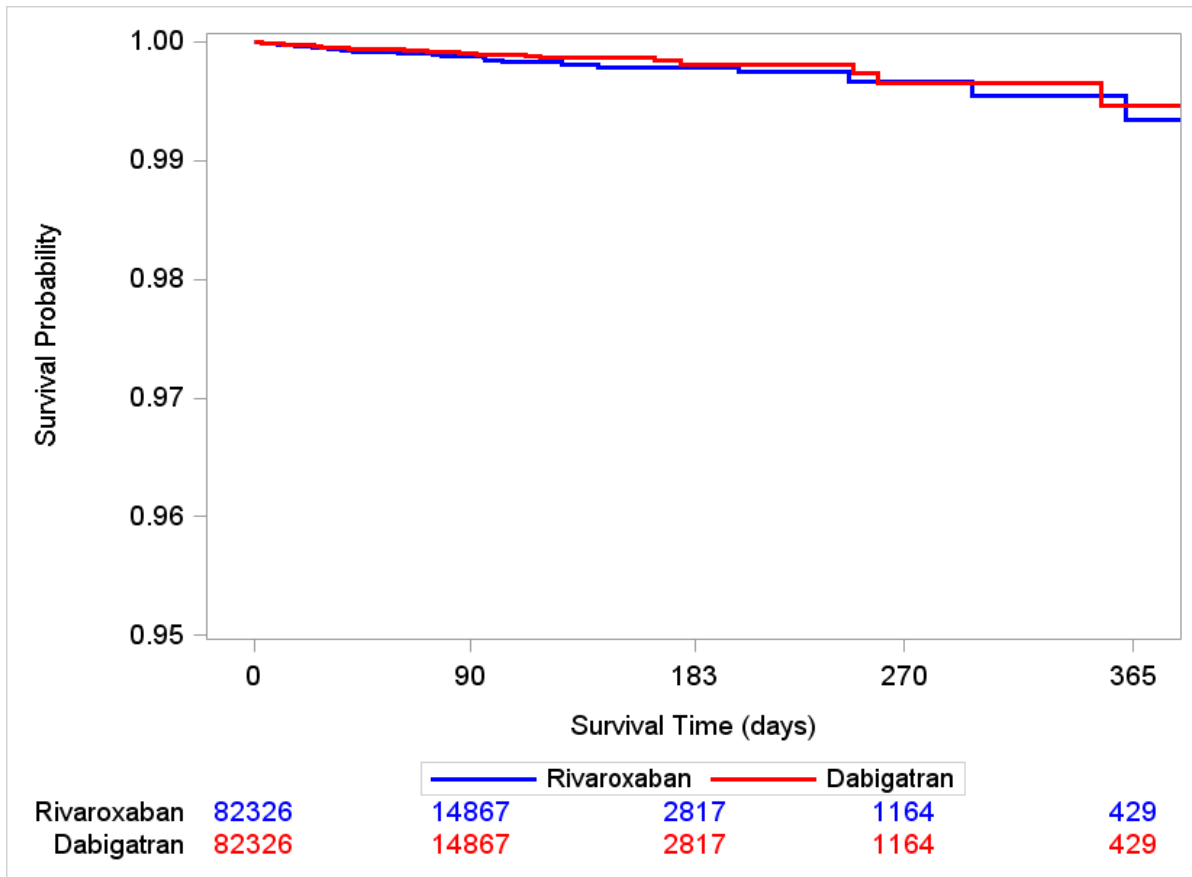


Figure 7c. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

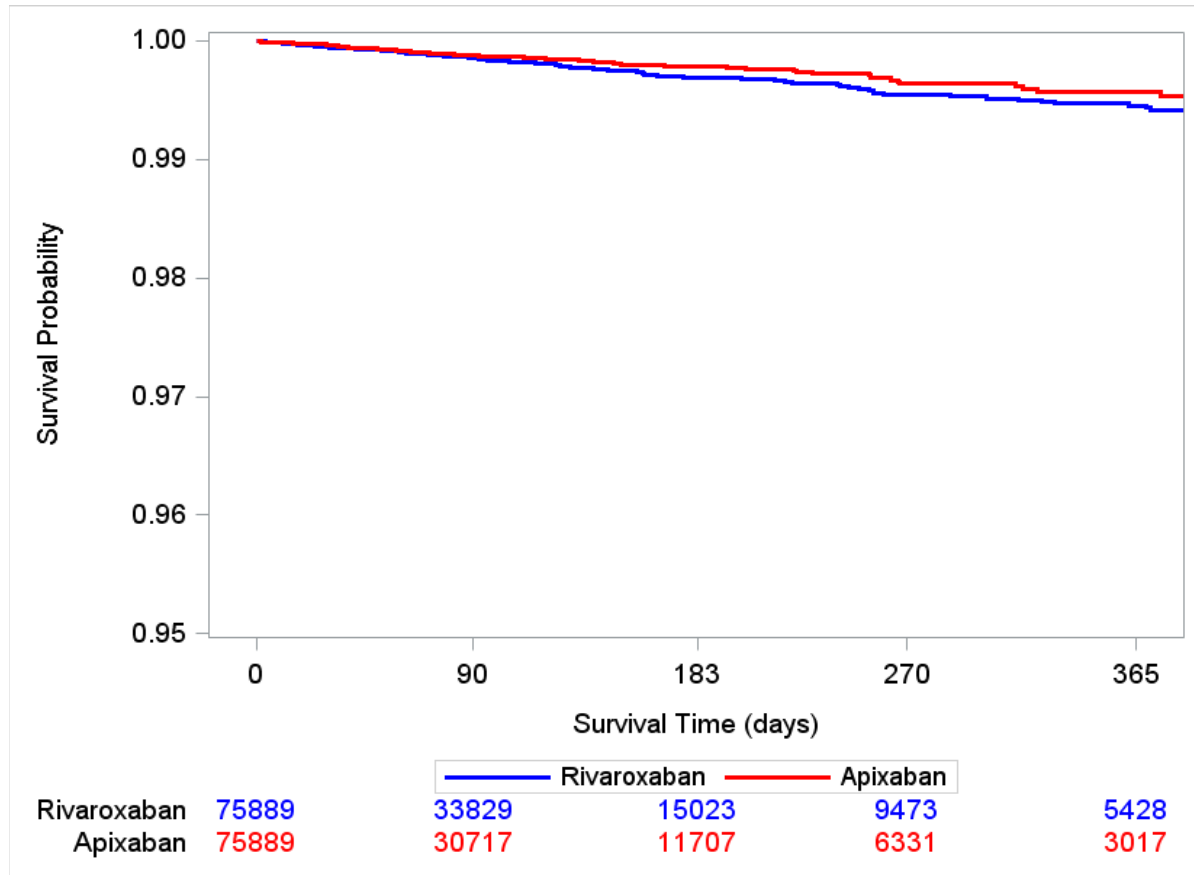


Figure 7d. Kaplan Meier Survival Curves of Events and Follow-up Time for Rivaroxaban and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort

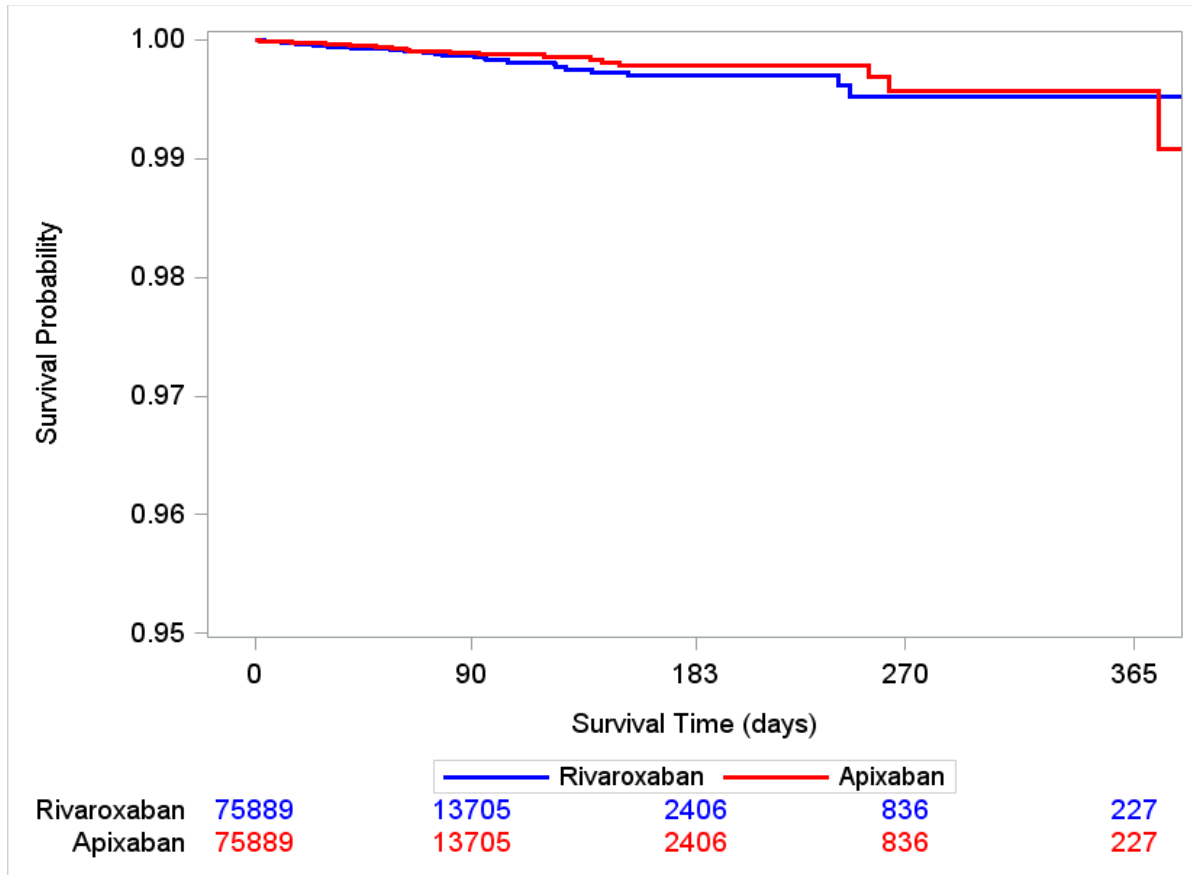


Figure 7e. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Unconditional Matched Cohort

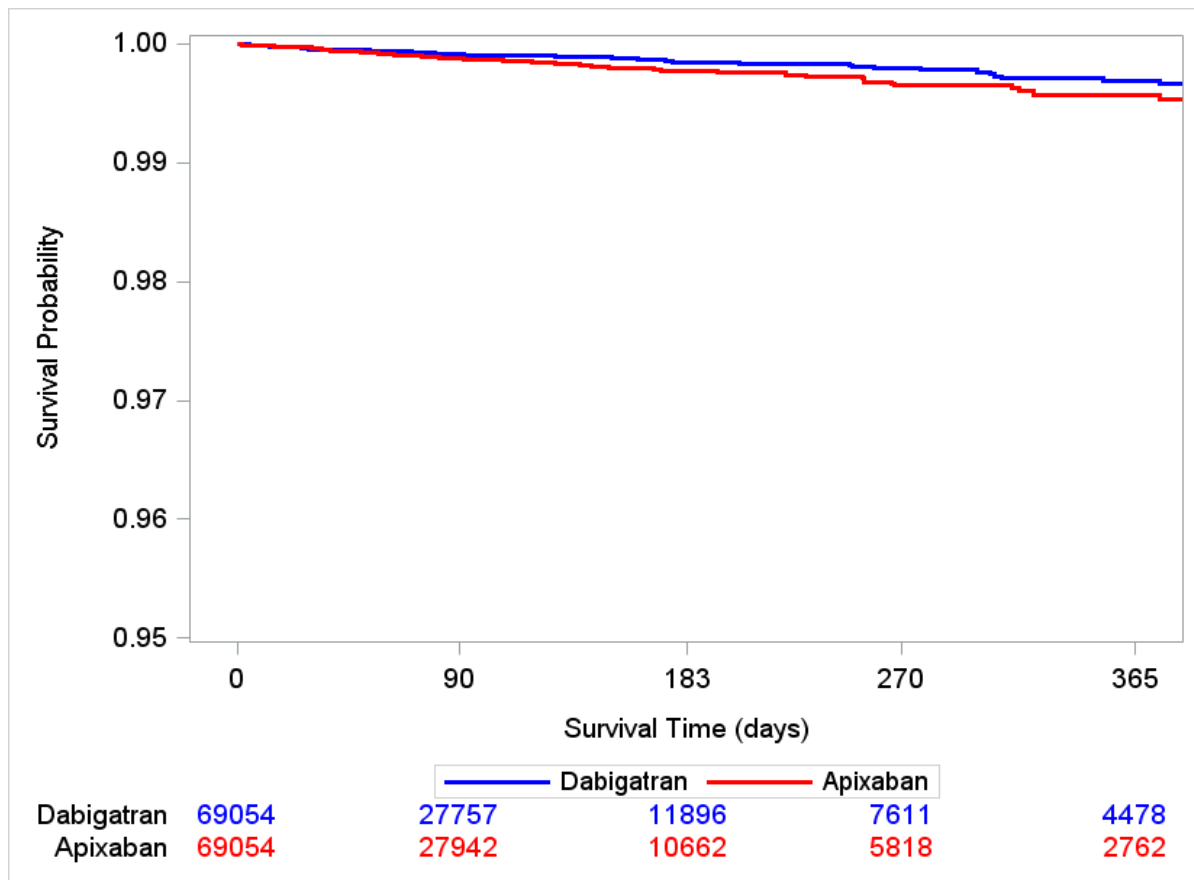
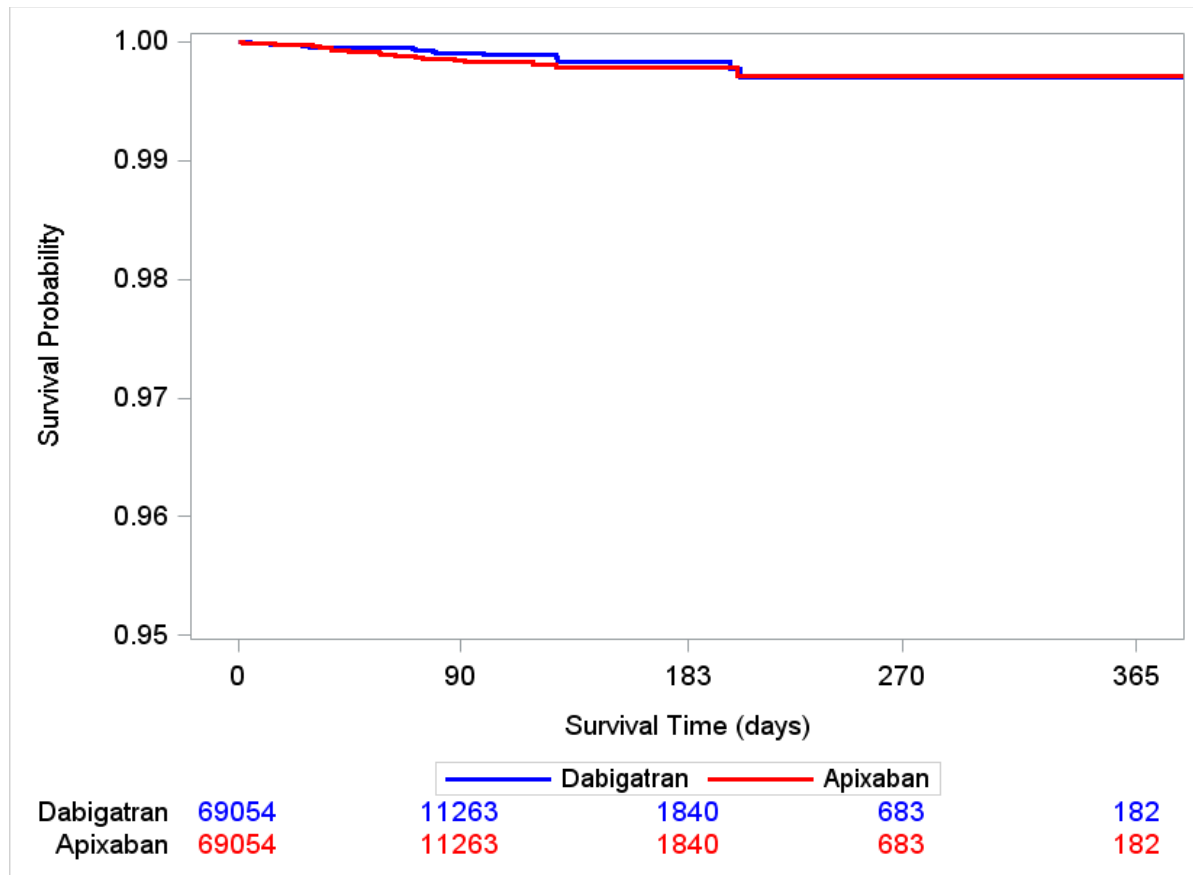


Figure 7f. Kaplan Meier Survival Curves of Events and Follow-up Time for Dabigatran and Apixaban and Risk of Intracranial Hemorrhage, in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015, Conditional Matched Cohort



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

Data Partner (Masked)	Start Date	End Date
DP01	01/01/2010	09/30/2015

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

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

Generic Name	Brand Name
	Apixaban
apixaban	Eliquis
	Dabigatran
dabigatran etexilate mesylate	Pradaxa
	Rivaroxaban
rivaroxaban	Xarelto

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

Code	Description	Code Type	Code Category
Ischemic Stroke			
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
Intracranial Hemorrhage			
430	Subarachnoid hemorrhage	ICD-9-CM	Diagnosis
431	Intracerebral hemorrhage	ICD-9-CM	Diagnosis
432	Other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
432.0	Nontraumatic extradural hemorrhage	ICD-9-CM	Diagnosis
432.1	Subdural hemorrhage	ICD-9-CM	Diagnosis
432.9	Unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
852.0	Subarachnoid hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.00	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.01	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.02	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
852.03	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.04	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.05	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.06	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.09	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
852.2	Subdural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.20	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.21	Subdural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.22	Subdural hemorrhage following injury, without mention of open intracranial wound, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
852.23	Subdural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.24	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.25	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.26	Subdural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.29	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
852.4	Extradural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.40	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.41	Extradural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.42	Extradural hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
852.43	Extradural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.44	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.45	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.46	Extradural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.49	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
853.0	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound	ICD-9-CM	Diagnosis
853.00	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
853.01	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
853.02	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
853.03	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
853.04	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to preexisting conscious level	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
853.05	Other and unspecified intracranial hemorrhage following injury. Without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
853.06	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
853.09	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
Gastrointestinal Bleeding - List 1			
455.2	Internal hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.5	External hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM	Diagnosis
456.0	Esophageal varices with bleeding	ICD-9-CM	Diagnosis
456.20	Esophageal varices with bleeding in diseases classified elsewhere	ICD-9-CM	Diagnosis
459.0	Unspecified hemorrhage	ICD-9-CM	Diagnosis
530.7	Gastroesophageal laceration-hemorrhage syndrome	ICD-9-CM	Diagnosis
530.82	Esophageal hemorrhage	ICD-9-CM	Diagnosis
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
535.01	Acute gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.11	Atrophic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.21	Gastric mucosal hypertrophy with hemorrhage	ICD-9-CM	Diagnosis
535.31	Alcoholic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.41	Other specified gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.51	Unspecified gastritis and gastroduodenitis with hemorrhage	ICD-9-CM	Diagnosis
535.61	Duodenitis with hemorrhage	ICD-9-CM	Diagnosis
537.83	Angiodysplasia of stomach and duodenum with hemorrhage	ICD-9-CM	Diagnosis
562.02	Diverticulosis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.03	Diverticulitis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.12	Diverticulosis of colon with hemorrhage	ICD-9-CM	Diagnosis
562.13	Diverticulitis of colon with hemorrhage	ICD-9-CM	Diagnosis
568.81	Hemoperitoneum (nontraumatic)	ICD-9-CM	Diagnosis
569.3	Hemorrhage of rectum and anus	ICD-9-CM	Diagnosis
569.85	Angiodysplasia of intestine with hemorrhage	ICD-9-CM	Diagnosis
578.0	Hematemesis	ICD-9-CM	Diagnosis
578.1	Blood in stool	ICD-9-CM	Diagnosis
578.9	Hemorrhage of gastrointestinal tract, unspecified	ICD-9-CM	Diagnosis
Gastrointestinal Bleeding - List 2			
455.0	Internal hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.1	Internal thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.3	External hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.4	External thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.6	Unspecified hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.7	Unspecified thrombosed hemorrhoids	ICD-9-CM	Diagnosis
531.1	Acute gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.3	Acute gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.5	Chronic or unspecified gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.7	Chronic gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.9	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.1	Acute duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.3	Acute duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.5	Chronic or unspecified duodenal ulcer with perforation	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
532.7	Chronic duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.9	Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.1	Acute peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.3	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation	ICD-9-CM	Diagnosis
533.5	Chronic or unspecified peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.7	Chronic peptic ulcer, unspecified site, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.9	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.1	Acute gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.3	Acute gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.5	Chronic or unspecified gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.7	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.9	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
535.00	Acute gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.10	Atrophic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.20	Gastric mucosal hypertrophy without mention of hemorrhage	ICD-9-CM	Diagnosis
535.30	Alcoholic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.40	Other specified gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.50	Unspecified gastritis and gastroduodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.60	Duodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
562.00	Diverticulosis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.01	Diverticulitis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.10	Diverticulosis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.11	Diverticulitis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
530.1	Esophagitis	ICD-9-CM	Diagnosis
Major Extracranial Bleeding - List 1			
423.0	Hemopericardium	ICD-9-CM	Diagnosis
455.2	Internal hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.5	External hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM	Diagnosis
456.0	Esophageal varices with bleeding	ICD-9-CM	Diagnosis
456.20	Esophageal varices with bleeding in diseases classified elsewhere	ICD-9-CM	Diagnosis
459.0	Unspecified hemorrhage	ICD-9-CM	Diagnosis
530.7	Gastroesophageal laceration-hemorrhage syndrome	ICD-9-CM	Diagnosis
530.82	Esophageal hemorrhage	ICD-9-CM	Diagnosis
531.0	Acute gastric ulcer with hemorrhage	ICD-9-CM	Diagnosis
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.2	Acute gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.4	Chronic or unspecified gastric ulcer with hemorrhage	ICD-9-CM	Diagnosis
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.6	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.0	Acute duodenal ulcer with hemorrhage	ICD-9-CM	Diagnosis
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.2	Acute duodenal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.4	Chronic or unspecified duodenal ulcer with hemorrhage	ICD-9-CM	Diagnosis
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.6	Chronic or unspecified duodenal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.0	Acute peptic ulcer, unspecified site, with hemorrhage	ICD-9-CM	Diagnosis
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.2	Acute peptic ulcer, unspecified site, with hemorrhage and perforation	ICD-9-CM	Diagnosis
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.4	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage	ICD-9-CM	Diagnosis
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.6	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation	ICD-9-CM	Diagnosis
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.0	Acute gastrojejunal ulcer with hemorrhage	ICD-9-CM	Diagnosis
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.2	Acute gastrojejunal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage	ICD-9-CM	Diagnosis
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
534.6	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
535.01	Acute gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.11	Atrophic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.21	Gastric mucosal hypertrophy with hemorrhage	ICD-9-CM	Diagnosis
535.31	Alcoholic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.41	Other specified gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.51	Unspecified gastritis and gastroduodenitis with hemorrhage	ICD-9-CM	Diagnosis
535.61	Duodenitis with hemorrhage	ICD-9-CM	Diagnosis
537.83	Angiodysplasia of stomach and duodenum with hemorrhage	ICD-9-CM	Diagnosis
562.02	Diverticulosis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.03	Diverticulitis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.12	Diverticulosis of colon with hemorrhage	ICD-9-CM	Diagnosis
562.13	Diverticulitis of colon with hemorrhage	ICD-9-CM	Diagnosis
568.81	Hemoperitoneum (nontraumatic)	ICD-9-CM	Diagnosis
569.3	Hemorrhage of rectum and anus	ICD-9-CM	Diagnosis
569.85	Angiodysplasia of intestine with hemorrhage	ICD-9-CM	Diagnosis
578.0	Hematemesis	ICD-9-CM	Diagnosis
578.1	Blood in stool	ICD-9-CM	Diagnosis
578.9	Hemorrhage of gastrointestinal tract, unspecified	ICD-9-CM	Diagnosis
593.81	Vascular disorders of kidney	ICD-9-CM	Diagnosis
599.7	Hematuria	ICD-9-CM	Diagnosis
623.8	Other specified noninflammatory disorder of vagina	ICD-9-CM	Diagnosis
626.2	Excessive or frequent menstruation	ICD-9-CM	Diagnosis
626.6	Metrorrhagia	ICD-9-CM	Diagnosis
719.1	Hemarthrosis	ICD-9-CM	Diagnosis
719.10	Hemarthrosis, site unspecified	ICD-9-CM	Diagnosis
719.11	Hemarthrosis, shoulder region	ICD-9-CM	Diagnosis
719.12	Hemarthrosis, upper arm	ICD-9-CM	Diagnosis
719.13	Hemarthrosis, forearm	ICD-9-CM	Diagnosis
719.14	Hemarthrosis, hand	ICD-9-CM	Diagnosis
719.15	Hemarthrosis, pelvic region and thigh	ICD-9-CM	Diagnosis
719.16	Hemarthrosis, lower leg	ICD-9-CM	Diagnosis
719.17	Hemarthrosis, ankle and foot	ICD-9-CM	Diagnosis
719.18	Hemarthrosis, other specified site	ICD-9-CM	Diagnosis
719.19	Hemarthrosis, multiple sites	ICD-9-CM	Diagnosis
784.7	Epistaxis	ICD-9-CM	Diagnosis
784.8	Hemorrhage from throat	ICD-9-CM	Diagnosis
786.3	Hemoptysis	ICD-9-CM	Diagnosis
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
Major Extracranial Bleeding - List 2			
280.0	Iron deficiency anemia secondary to blood loss (chronic)	ICD-9-CM	Diagnosis
285.1	Acute posthemorrhagic anemia	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
285.9	Unspecified anemia	ICD-9-CM	Diagnosis
455.0	Internal hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.1	Internal thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.2	Internal hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.3	External hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.4	External thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.5	External hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.6	Unspecified hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.7	Unspecified thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.9	Residual hemorrhoidal skin tags	ICD-9-CM	Diagnosis
530.1	Esophagitis	ICD-9-CM	Diagnosis
531.1	Acute gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.3	Acute gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.5	Chronic or unspecified gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.7	Chronic gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.9	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.1	Acute duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.3	Acute duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.5	Chronic or unspecified duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.7	Chronic duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.9	Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.1	Acute peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.3	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation	ICD-9-CM	Diagnosis
533.5	Chronic or unspecified peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.7	Chronic peptic ulcer, unspecified site, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.9	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.1	Acute gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.3	Acute gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.5	Chronic or unspecified gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.7	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.9	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
535.00	Acute gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.10	Atrophic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.20	Gastric mucosal hypertrophy without mention of hemorrhage	ICD-9-CM	Diagnosis
535.30	Alcoholic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.40	Other specified gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.50	Unspecified gastritis and gastroduodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.60	Duodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
562.00	Diverticulosis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.01	Diverticulitis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
562.10	Diverticulosis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.11	Diverticulitis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
790.92	Abnormal coagulation profile	ICD-9-CM	Diagnosis
Major Extracranial Bleeding - List 3			
62000	Elevation of depressed skull fracture; simple, extradural	CPT-4	Procedure
62005	Elevation of depressed skull fracture; compound or comminuted, extradural	CPT-4	Procedure
62010	Elevation of depressed skull fracture; with repair of dura and/or debridement of brain	CPT-4	Procedure
800	Fracture of vault of skull	ICD-9-CM	Diagnosis
800.0	Closed fracture of vault of skull without mention of intracranial injury	ICD-9-CM	Diagnosis
800.00	Closed fracture of vault of skull without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.01	Closed fracture of vault of skull without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
800.02	Closed fracture of vault of skull without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.03	Closed fracture of vault of skull without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.04	Closed fracture of vault of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.05	Closed fracture of vault of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.06	Closed fracture of vault of skull without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.09	Closed fracture of vault of skull without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
800.1	Closed fracture of vault of skull with cerebral laceration and contusion	ICD-9-CM	Diagnosis
800.10	Closed fracture of vault of skull with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.11	Closed fracture of vault of skull with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
800.12	Closed fracture of vault of skull with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.13	Closed fracture of vault of skull with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.14	Closed fracture of vault of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.15	Closed fracture of vault of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.16	Closed fracture of vault of skull with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.19	Closed fracture of vault of skull with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
800.2	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis
800.20	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
800.21	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
800.22	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.23	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.24	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.25	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.26	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.29	Closed fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
800.3	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
800.30	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.31	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
800.32	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.33	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.34	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.35	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.36	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.39	Closed fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
800.4	Closed fracture of vault of skull with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
800.40	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.41	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis
800.42	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.43	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
800.44	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.45	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.46	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.49	Closed fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
800.5	Open fracture of vault of skull without mention of intracranial injury	ICD-9-CM	Diagnosis
800.50	Open fracture of vault of skull without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.51	Open fracture of vault of skull without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
800.52	Open fracture of vault of skull without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.53	Open fracture of vault of skull without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.54	Open fracture of vault of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.55	Open fracture of vault of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.56	Open fracture of vault of skull without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.59	Open fracture of vault of skull without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
800.6	Open fracture of vault of skull with cerebral laceration and contusion	ICD-9-CM	Diagnosis
800.60	Open fracture of vault of skull with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.61	Open fracture of vault of skull with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
800.62	Open fracture of vault of skull with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.63	Open fracture of vault of skull with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.64	Open fracture of vault of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.65	Open fracture of vault of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.66	Open fracture of vault of skull with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.69	Open fracture of vault of skull with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
800.7	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
800.70	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.71	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
800.72	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.73	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.74	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.75	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.76	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.79	Open fracture of vault of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
800.8	Open fracture of vault of skull with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
800.80	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.81	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
800.82	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
800.83	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.84	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.85	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.86	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.89	Open fracture of vault of skull with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
800.9	Open fracture of vault of skull with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
800.90	Open fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
800.91	Open fracture of vault of skull with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis
800.92	Open fracture of vault of skull with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
800.93	Open fracture of vault of skull with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
800.94	Open fracture of vault of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.95	Open fracture of vault of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
800.96	Open fracture of vault of skull with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
800.99	Open fracture of vault of skull with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
801	Fracture of base of skull	ICD-9-CM	Diagnosis
801.0	Closed fracture of base of skull without mention of intracranial injury	ICD-9-CM	Diagnosis
801.00	Closed fracture of base of skull without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.01	Closed fracture of base of skull without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
801.02	Closed fracture of base of skull without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.03	Closed fracture of base of skull without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.04	Closed fracture of base of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.05	Closed fracture of base of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.06	Closed fracture of base of skull without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.09	Closed fracture of base of skull without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
801.1	Closed fracture of base of skull with cerebral laceration and contusion	ICD-9-CM	Diagnosis
801.10	Closed fracture of base of skull with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.11	Closed fracture of base of skull with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
801.12	Closed fracture of base of skull with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.13	Closed fracture of base of skull with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.14	Closed fracture of base of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.15	Closed fracture of base of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.16	Closed fracture of base of skull with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
801.19	Closed fracture of base of skull with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
801.2	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis
801.20	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.21	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
801.22	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.23	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.24	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.25	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.26	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.29	Closed fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
801.3	Closed fracture of base of skull with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
801.30	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.31	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
801.32	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.33	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.34	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.35	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.36	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.39	Closed fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
801.4	Closed fracture of base of skull with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
801.40	Closed fracture of base of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.41	Closed fracture of base of skull with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
801.42	Closed fracture of base of skull with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.43	Closed fracture of base of skull with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.44	Closed fracture of base of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.45	Closed fracture of base of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.46	Closed fracture of base of skull with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.49	Closed fracture of base of skull with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
801.5	Open fracture of base of skull without mention of intracranial injury	ICD-9-CM	Diagnosis
801.50	Open fracture of base of skull without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.51	Open fracture of base of skull without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
801.52	Open fracture of base of skull without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.53	Open fracture of base of skull without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.54	Open fracture of base of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.55	Open fracture of base of skull without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.56	Open fracture of base of skull without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.59	Open fracture of base of skull without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
801.6	Open fracture of base of skull with cerebral laceration and contusion	ICD-9-CM	Diagnosis
801.60	Open fracture of base of skull with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.61	Open fracture of base of skull with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
801.62	Open fracture of base of skull with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.63	Open fracture of base of skull with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.64	Open fracture of base of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.65	Open fracture of base of skull with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
801.66	Open fracture of base of skull with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.69	Open fracture of base of skull with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
801.7	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis
801.70	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.71	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
801.72	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.73	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.74	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.75	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.76	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.79	Open fracture of base of skull with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
801.8	Open fracture of base of skull with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
801.80	Open fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
801.81	Open fracture of base of skull with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
801.82	Open fracture of base of skull with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.83	Open fracture of base of skull with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.84	Open fracture of base of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.85	Open fracture of base of skull with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.86	Open fracture of base of skull with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.89	Open fracture of base of skull with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
801.9	Open fracture of base of skull with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
801.90	Open fracture of base of skull with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
801.91	Open fracture of base of skull with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis
801.92	Open fracture of base of skull with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
801.93	Open fracture of base of skull with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
801.94	Open fracture of base of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.95	Open fracture of base of skull with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
801.96	Open fracture of base of skull with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
801.99	Open fracture of base of skull with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
802	Fracture of face bones	ICD-9-CM	Diagnosis
802.0	Nasal bones, closed fracture	ICD-9-CM	Diagnosis
802.1	Nasal bones, open fracture	ICD-9-CM	Diagnosis
802.2	Mandible, closed fracture	ICD-9-CM	Diagnosis
802.20	Closed fracture of unspecified site of mandible	ICD-9-CM	Diagnosis
802.21	Closed fracture of condylar process of mandible	ICD-9-CM	Diagnosis
802.22	Closed fracture of subcondylar process of mandible	ICD-9-CM	Diagnosis
802.23	Closed fracture of coronoid process of mandible	ICD-9-CM	Diagnosis
802.24	Closed fracture of unspecified part of ramus of mandible	ICD-9-CM	Diagnosis
802.25	Closed fracture of angle of jaw	ICD-9-CM	Diagnosis
802.26	Closed fracture of symphysis of body of mandible	ICD-9-CM	Diagnosis
802.27	Closed fracture of alveolar border of body of mandible	ICD-9-CM	Diagnosis
802.28	Closed fracture of other and unspecified part of body of mandible	ICD-9-CM	Diagnosis
802.29	Closed fracture of multiple sites of mandible	ICD-9-CM	Diagnosis
802.3	Mandible, open fracture	ICD-9-CM	Diagnosis
802.30	Open fracture of unspecified site of mandible	ICD-9-CM	Diagnosis
802.31	Open fracture of condylar process of mandible	ICD-9-CM	Diagnosis
802.32	Open fracture of subcondylar process of mandible	ICD-9-CM	Diagnosis
802.33	Open fracture of coronoid process of mandible	ICD-9-CM	Diagnosis
802.34	Open fracture of unspecified part of ramus of mandible	ICD-9-CM	Diagnosis
802.35	Open fracture of angle of jaw	ICD-9-CM	Diagnosis
802.36	Open fracture of symphysis of body of mandible	ICD-9-CM	Diagnosis
802.37	Open fracture of alveolar border of body of mandible	ICD-9-CM	Diagnosis
802.38	Open fracture of other and unspecified part of body of mandible	ICD-9-CM	Diagnosis
802.39	Open fracture of multiple sites of mandible	ICD-9-CM	Diagnosis
802.4	Malar and maxillary bones, closed fracture	ICD-9-CM	Diagnosis
802.5	Malar and maxillary bones, open fracture	ICD-9-CM	Diagnosis
802.6	Orbital floor (blow-out), closed fracture	ICD-9-CM	Diagnosis
802.7	Orbital floor (blow-out), open fracture	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
802.8	Other facial bones, closed fracture	ICD-9-CM	Diagnosis
802.9	Other facial bones, open fracture	ICD-9-CM	Diagnosis
803	Other and unqualified skull fractures	ICD-9-CM	Diagnosis
803.0	Other closed skull fracture without mention of intracranial injury	ICD-9-CM	Diagnosis
803.00	Other closed skull fracture without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.01	Other closed skull fracture without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
803.02	Other closed skull fracture without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.03	Other closed skull fracture without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.04	Other closed skull fracture without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.05	Other closed skull fracture without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.06	Other closed skull fracture without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.09	Other closed skull fracture without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
803.1	Other closed skull fracture with cerebral laceration and contusion	ICD-9-CM	Diagnosis
803.10	Other closed skull fracture with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.11	Other closed skull fracture with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
803.12	Other closed skull fracture with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.13	Other closed skull fracture with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.14	Other closed skull fracture with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.15	Other closed skull fracture with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.16	Other closed skull fracture with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.19	Other closed skull fracture with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
803.2	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis
803.20	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.21	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
803.22	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.23	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
803.24	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.25	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.26	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.29	Other closed skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
803.3	Closed skull fracture with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
803.30	Other closed skull fracture with other and unspecified intracranial hemorrhage, unspecified state of unconsciousness	ICD-9-CM	Diagnosis
803.31	Other closed skull fracture with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
803.32	Other closed skull fracture with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.33	Other closed skull fracture with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.34	Other closed skull fracture with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.35	Other closed skull fracture with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.36	Other closed skull fracture with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.39	Other closed skull fracture with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
803.4	Other closed skull fracture with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
803.40	Other closed skull fracture with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.41	Other closed skull fracture with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis
803.42	Other closed skull fracture with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.43	Other closed skull fracture with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.44	Other closed skull fracture with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.45	Other closed skull fracture with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
803.46	Other closed skull fracture with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.49	Other closed skull fracture with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
803.5	Other open skull fracture without mention of intracranial injury	ICD-9-CM	Diagnosis
803.50	Other open skull fracture without mention of injury, state of consciousness unspecified	ICD-9-CM	Diagnosis
803.51	Other open skull fracture without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
803.52	Other open skull fracture without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.53	Other open skull fracture without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.54	Other open skull fracture without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.55	Other open skull fracture without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.56	Other open skull fracture without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.59	Other open skull fracture without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
803.6	Other open skull fracture with cerebral laceration and contusion	ICD-9-CM	Diagnosis
803.60	Other open skull fracture with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.61	Other open skull fracture with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
803.62	Other open skull fracture with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.63	Other open skull fracture with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.64	Other open skull fracture with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.65	Other open skull fracture with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.66	Other open skull fracture with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.69	Other open skull fracture with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
803.7	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis
803.70	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.71	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
803.72	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.73	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
803.74	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.75	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.76	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.79	Other open skull fracture with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
803.8	Other open skull fracture with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
803.80	Other open skull fracture with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.81	Other open skull fracture with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
803.82	Other open skull fracture with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.83	Other open skull fracture with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.84	Other open skull fracture with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.85	Other open skull fracture with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.86	Other open skull fracture with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
803.89	Other open skull fracture with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
803.9	Other open skull fracture with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
803.90	Other open skull fracture with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
803.91	Other open skull fracture with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis
803.92	Other open skull fracture with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
803.93	Other open skull fracture with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
803.94	Other open skull fracture with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.95	Other open skull fracture with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
803.96	Other open skull fracture with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
803.99	Other open skull fracture with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
804	Multiple fractures involving skull or face with other bones	ICD-9-CM	Diagnosis
804.0	Closed fractures involving skull or face with other bones, without mention of intracranial injury	ICD-9-CM	Diagnosis
804.00	Closed fractures involving skull or face with other bones, without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.01	Closed fractures involving skull or face with other bones, without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
804.02	Closed fractures involving skull or face with other bones, without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.03	Closed fractures involving skull or face with other bones, without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.04	Closed fractures involving skull or face with other bones, without mention or intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.05	Closed fractures involving skull of face with other bones, without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.06	Closed fractures involving skull of face with other bones, without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.09	Closed fractures involving skull of face with other bones, without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
804.1	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion	ICD-9-CM	Diagnosis
804.10	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.11	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
804.12	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.13	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.14	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.15	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.16	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.19	Closed fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
804.2	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
804.20	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.21	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
804.22	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.23	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.24	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.25	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.26	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.29	Closed fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
804.3	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
804.30	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.31	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
804.32	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.33	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.34	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to preexisting conscious level	ICD-9-CM	Diagnosis
804.35	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.36	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.39	Closed fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
804.4	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
804.40	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.41	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
804.42	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.43	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.44	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.45	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.46	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.49	Closed fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
804.5	Open fractures involving skull or face with other bones, without mention of intracranial injury	ICD-9-CM	Diagnosis
804.50	Open fractures involving skull or face with other bones, without mention of intracranial injury, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.51	Open fractures involving skull or face with other bones, without mention of intracranial injury, no loss of consciousness	ICD-9-CM	Diagnosis
804.52	Open fractures involving skull or face with other bones, without mention of intracranial injury, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.53	Open fractures involving skull or face with other bones, without mention of intracranial injury, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.54	Open fractures involving skull or face with other bones, without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.55	Open fractures involving skull or face with other bones, without mention of intracranial injury, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.56	Open fractures involving skull or face with other bones, without mention of intracranial injury, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.59	Open fractures involving skull or face with other bones, without mention of intracranial injury, unspecified concussion	ICD-9-CM	Diagnosis
804.6	Open fractures involving skull or face with other bones, with cerebral laceration and contusion	ICD-9-CM	Diagnosis
804.60	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.61	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, no loss of consciousness	ICD-9-CM	Diagnosis
804.62	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.63	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
804.64	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.65	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.66	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.69	Open fractures involving skull or face with other bones, with cerebral laceration and contusion, unspecified concussion	ICD-9-CM	Diagnosis
804.7	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage	ICD-9-CM	Diagnosis
804.70	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.71	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
804.72	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.73	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.74	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.75	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.76	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.79	Open fractures involving skull or face with other bones with subarachnoid, subdural, and extradural hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
804.8	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
804.80	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.81	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, no loss of consciousness	ICD-9-CM	Diagnosis
804.82	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.83	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.84	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
804.85	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.86	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.89	Open fractures involving skull or face with other bones, with other and unspecified intracranial hemorrhage, unspecified concussion	ICD-9-CM	Diagnosis
804.9	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature	ICD-9-CM	Diagnosis
804.90	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified state of consciousness	ICD-9-CM	Diagnosis
804.91	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, no loss of consciousness	ICD-9-CM	Diagnosis
804.92	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
804.93	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
804.94	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
804.95	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing level	ICD-9-CM	Diagnosis
804.96	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
804.99	Open fractures involving skull or face with other bones, with intracranial injury of other and unspecified nature, unspecified concussion	ICD-9-CM	Diagnosis
805	Fracture of vertebral column without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.0	Closed fracture of cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.00	Closed fracture of cervical vertebra, unspecified level without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.01	Closed fracture of first cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.02	Closed fracture of second cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.03	Closed fracture of third cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.04	Closed fracture of fourth cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.05	Closed fracture of fifth cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.06	Closed fracture of sixth cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.07	Closed fracture of seventh cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.08	Closed fracture of multiple cervical vertebrae without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.1	Open fracture of cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.10	Open fracture of cervical vertebra, unspecified level without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.11	Open fracture of first cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.12	Open fracture of second cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.13	Open fracture of third cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.14	Open fracture of fourth cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
805.15	Open fracture of fifth cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.16	Open fracture of sixth cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.17	Open fracture of seventh cervical vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.18	Open fracture of multiple cervical vertebrae without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.2	Closed fracture of dorsal (thoracic) vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.3	Open fracture of dorsal (thoracic) vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.4	Closed fracture of lumbar vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.5	Open fracture of lumbar vertebra without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.6	Closed fracture of sacrum and coccyx without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.7	Open fracture of sacrum and coccyx without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.8	Closed fracture of unspecified part of vertebral column without mention of spinal cord injury	ICD-9-CM	Diagnosis
805.9	Open fracture of unspecified part of vertebral column without mention of spinal cord injury	ICD-9-CM	Diagnosis
806	Fracture of vertebral column with spinal cord injury	ICD-9-CM	Diagnosis
806.0	Closed fracture of cervical vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.0	Closed fracture of cervical vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.0	Closed fracture of cervical vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.00	Closed fracture of C1-C4 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.00	Closed fracture of C1-C4 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.00	Closed fracture of C1-C4 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.01	Closed fracture of C1-C4 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.01	Closed fracture of C1-C4 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.01	Closed fracture of C1-C4 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.02	Closed fracture of C1-C4 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.02	Closed fracture of C1-C4 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.02	Closed fracture of C1-C4 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.03	Closed fracture of C1-C4 level with central cord syndrome	ICD-9-CM	Diagnosis
806.03	Closed fracture of C1-C4 level with central cord syndrome	ICD-9-CM	Diagnosis
806.03	Closed fracture of C1-C4 level with central cord syndrome	ICD-9-CM	Diagnosis
806.04	Closed fracture of C1-C4 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.04	Closed fracture of C1-C4 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.04	Closed fracture of C1-C4 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.05	Closed fracture of C5-C7 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.05	Closed fracture of C5-C7 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.05	Closed fracture of C5-C7 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.06	Closed fracture of C5-C7 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.06	Closed fracture of C5-C7 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.06	Closed fracture of C5-C7 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.07	Closed fracture of C5-C7 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.07	Closed fracture of C5-C7 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.07	Closed fracture of C5-C7 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.08	Closed fracture of C5-C7 level with central cord syndrome	ICD-9-CM	Diagnosis
806.08	Closed fracture of C5-C7 level with central cord syndrome	ICD-9-CM	Diagnosis
806.08	Closed fracture of C5-C7 level with central cord syndrome	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
806.09	Closed fracture of C5-C7 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.09	Closed fracture of C5-C7 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.09	Closed fracture of C5-C7 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.1	Open fracture of cervical vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.1	Open fracture of cervical vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.10	Open fracture of C1-C4 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.10	Open fracture of C1-C4 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.11	Open fracture of C1-C4 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.11	Open fracture of C1-C4 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.12	Open fracture of C1-C4 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.12	Open fracture of C1-C4 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.13	Open fracture of C1-C4 level with central cord syndrome	ICD-9-CM	Diagnosis
806.13	Open fracture of C1-C4 level with central cord syndrome	ICD-9-CM	Diagnosis
806.14	Open fracture of C1-C4 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.14	Open fracture of C1-C4 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.15	Open fracture of C5-C7 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.15	Open fracture of C5-C7 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.16	Open fracture of C5-C7 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.16	Open fracture of C5-C7 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.17	Open fracture of C5-C7 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.17	Open fracture of C5-C7 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.18	Open fracture of C5-C7 level with central cord syndrome	ICD-9-CM	Diagnosis
806.18	Open fracture of C5-C7 level with central cord syndrome	ICD-9-CM	Diagnosis
806.19	Open fracture of C5-C7 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.19	Open fracture of C5-C7 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.2	Closed fracture of dorsal (thoracic) vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.2	Closed fracture of dorsal (thoracic) vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.2	Closed fracture of dorsal (thoracic) vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.20	Closed fracture of T1-T6 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.20	Closed fracture of T1-T6 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.20	Closed fracture of T1-T6 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.21	Closed fracture of T1-T6 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.21	Closed fracture of T1-T6 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.21	Closed fracture of T1-T6 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.22	Closed fracture of T1-T6 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.22	Closed fracture of T1-T6 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.22	Closed fracture of T1-T6 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.23	Closed fracture of T1-T6 level with central cord syndrome	ICD-9-CM	Diagnosis
806.23	Closed fracture of T1-T6 level with central cord syndrome	ICD-9-CM	Diagnosis
806.23	Closed fracture of T1-T6 level with central cord syndrome	ICD-9-CM	Diagnosis
806.24	Closed fracture of T1-T6 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.24	Closed fracture of T1-T6 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.24	Closed fracture of T1-T6 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.25	Closed fracture of T7-T12 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.25	Closed fracture of T7-T12 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
806.25	Closed fracture of T7-T12 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.26	Closed fracture of T7-T12 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.26	Closed fracture of T7-T12 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.26	Closed fracture of T7-T12 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.27	Closed fracture of T7-T12 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.27	Closed fracture of T7-T12 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.27	Closed fracture of T7-T12 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.28	Closed fracture of T7-T12 level with central cord syndrome	ICD-9-CM	Diagnosis
806.28	Closed fracture of T7-T12 level with central cord syndrome	ICD-9-CM	Diagnosis
806.28	Closed fracture of T7-T12 level with central cord syndrome	ICD-9-CM	Diagnosis
806.29	Closed fracture of T7-T12 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.29	Closed fracture of T7-T12 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.29	Closed fracture of T7-T12 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.3	Open fracture of dorsal vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.3	Open fracture of dorsal vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.30	Open fracture of T1-T6 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.30	Open fracture of T1-T6 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.31	Open fracture of T1-T6 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.31	Open fracture of T1-T6 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.32	Open fracture of T1-T6 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.32	Open fracture of T1-T6 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.33	Open fracture of T1-T6 level with central cord syndrome	ICD-9-CM	Diagnosis
806.33	Open fracture of T1-T6 level with central cord syndrome	ICD-9-CM	Diagnosis
806.34	Open fracture of T1-T6 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.34	Open fracture of T1-T6 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.35	Open fracture of T7-T12 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.35	Open fracture of T7-T12 level with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.36	Open fracture of T7-T12 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.36	Open fracture of T7-T12 level with complete lesion of cord	ICD-9-CM	Diagnosis
806.37	Open fracture of T7-T12 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.37	Open fracture of T7-T12 level with anterior cord syndrome	ICD-9-CM	Diagnosis
806.38	Open fracture of T7-T12 level with central cord syndrome	ICD-9-CM	Diagnosis
806.38	Open fracture of T7-T12 level with central cord syndrome	ICD-9-CM	Diagnosis
806.39	Open fracture of T7-T12 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.39	Open fracture of T7-T12 level with other specified spinal cord injury	ICD-9-CM	Diagnosis
806.4	Closed fracture of lumbar spine with spinal cord injury	ICD-9-CM	Diagnosis
806.4	Closed fracture of lumbar spine with spinal cord injury	ICD-9-CM	Diagnosis
806.5	Open fracture of lumbar spine with spinal cord injury	ICD-9-CM	Diagnosis
806.5	Open fracture of lumbar spine with spinal cord injury	ICD-9-CM	Diagnosis
806.6	Closed fracture of sacrum and coccyx with spinal cord injury	ICD-9-CM	Diagnosis
806.6	Closed fracture of sacrum and coccyx with spinal cord injury	ICD-9-CM	Diagnosis
806.60	Closed fracture of sacrum and coccyx with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.60	Closed fracture of sacrum and coccyx with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.61	Closed fracture of sacrum and coccyx with complete cauda equina lesion	ICD-9-CM	Diagnosis
806.61	Closed fracture of sacrum and coccyx with complete cauda equina lesion	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
806.62	Closed fracture of sacrum and coccyx with other cauda equina injury	ICD-9-CM	Diagnosis
806.62	Closed fracture of sacrum and coccyx with other cauda equina injury	ICD-9-CM	Diagnosis
806.69	Closed fracture of sacrum and coccyx with other spinal cord injury	ICD-9-CM	Diagnosis
806.69	Closed fracture of sacrum and coccyx with other spinal cord injury	ICD-9-CM	Diagnosis
806.7	Open fracture of sacrum and coccyx with spinal cord injury	ICD-9-CM	Diagnosis
806.7	Open fracture of sacrum and coccyx with spinal cord injury	ICD-9-CM	Diagnosis
806.70	Open fracture of sacrum and coccyx with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.70	Open fracture of sacrum and coccyx with unspecified spinal cord injury	ICD-9-CM	Diagnosis
806.71	Open fracture of sacrum and coccyx with complete cauda equina lesion	ICD-9-CM	Diagnosis
806.71	Open fracture of sacrum and coccyx with complete cauda equina lesion	ICD-9-CM	Diagnosis
806.72	Open fracture of sacrum and coccyx with other cauda equina injury	ICD-9-CM	Diagnosis
806.72	Open fracture of sacrum and coccyx with other cauda equina injury	ICD-9-CM	Diagnosis
806.79	Open fracture of sacrum and coccyx with other spinal cord injury	ICD-9-CM	Diagnosis
806.79	Open fracture of sacrum and coccyx with other spinal cord injury	ICD-9-CM	Diagnosis
806.8	Closed fracture of unspecified vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.8	Closed fracture of unspecified vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.9	Open fracture of unspecified vertebra with spinal cord injury	ICD-9-CM	Diagnosis
806.9	Open fracture of unspecified vertebra with spinal cord injury	ICD-9-CM	Diagnosis
807	Fracture of rib(s), sternum, larynx, and trachea	ICD-9-CM	Diagnosis
807.0	Closed fracture of rib(s)	ICD-9-CM	Diagnosis
807.00	Closed fracture of rib(s), unspecified	ICD-9-CM	Diagnosis
807.01	Closed fracture of one rib	ICD-9-CM	Diagnosis
807.02	Closed fracture of two ribs	ICD-9-CM	Diagnosis
807.03	Closed fracture of three ribs	ICD-9-CM	Diagnosis
807.04	Closed fracture of four ribs	ICD-9-CM	Diagnosis
807.05	Closed fracture of five ribs	ICD-9-CM	Diagnosis
807.06	Closed fracture of six ribs	ICD-9-CM	Diagnosis
807.07	Closed fracture of seven ribs	ICD-9-CM	Diagnosis
807.08	Closed fracture of eight or more ribs	ICD-9-CM	Diagnosis
807.09	Closed fracture of multiple ribs, unspecified	ICD-9-CM	Diagnosis
807.1	Open fracture of rib(s)	ICD-9-CM	Diagnosis
807.10	Open fracture of rib(s), unspecified	ICD-9-CM	Diagnosis
807.11	Open fracture of one rib	ICD-9-CM	Diagnosis
807.12	Open fracture of two ribs	ICD-9-CM	Diagnosis
807.13	Open fracture of three ribs	ICD-9-CM	Diagnosis
807.14	Open fracture of four ribs	ICD-9-CM	Diagnosis
807.15	Open fracture of five ribs	ICD-9-CM	Diagnosis
807.16	Open fracture of six ribs	ICD-9-CM	Diagnosis
807.17	Open fracture of seven ribs	ICD-9-CM	Diagnosis
807.18	Open fracture of eight or more ribs	ICD-9-CM	Diagnosis
807.19	Open fracture of multiple ribs, unspecified	ICD-9-CM	Diagnosis
807.2	Closed fracture of sternum	ICD-9-CM	Diagnosis
807.3	Open fracture of sternum	ICD-9-CM	Diagnosis
807.4	Flail chest	ICD-9-CM	Diagnosis
807.4	Flail chest	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
807.5	Closed fracture of larynx and trachea	ICD-9-CM	Diagnosis
807.6	Open fracture of larynx and trachea	ICD-9-CM	Diagnosis
808	Fracture of pelvis	ICD-9-CM	Diagnosis
808	Fracture of pelvis	ICD-9-CM	Diagnosis
808.0	Closed fracture of acetabulum	ICD-9-CM	Diagnosis
808.0	Closed fracture of acetabulum	ICD-9-CM	Diagnosis
808.1	Open fracture of acetabulum	ICD-9-CM	Diagnosis
808.1	Open fracture of acetabulum	ICD-9-CM	Diagnosis
808.2	Closed fracture of pubis	ICD-9-CM	Diagnosis
808.2	Closed fracture of pubis	ICD-9-CM	Diagnosis
808.3	Open fracture of pubis	ICD-9-CM	Diagnosis
808.3	Open fracture of pubis	ICD-9-CM	Diagnosis
808.4	Closed fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.4	Closed fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.41	Closed fracture of ilium	ICD-9-CM	Diagnosis
808.41	Closed fracture of ilium	ICD-9-CM	Diagnosis
808.42	Closed fracture of ischium	ICD-9-CM	Diagnosis
808.42	Closed fracture of ischium	ICD-9-CM	Diagnosis
808.43	Multiple closed pelvic fractures with disruption of pelvic circle	ICD-9-CM	Diagnosis
808.43	Multiple closed pelvic fractures with disruption of pelvic circle	ICD-9-CM	Diagnosis
808.44	Multiple closed pelvic fractures without disruption of pelvic circle	ICD-9-CM	Diagnosis
808.44	Multiple closed pelvic fractures without disruption of pelvic circle	ICD-9-CM	Diagnosis
808.49	Closed fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.49	Closed fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.5	Open fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.5	Open fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.51	Open fracture of ilium	ICD-9-CM	Diagnosis
808.51	Open fracture of ilium	ICD-9-CM	Diagnosis
808.52	Open fracture of ischium	ICD-9-CM	Diagnosis
808.52	Open fracture of ischium	ICD-9-CM	Diagnosis
808.53	Multiple open pelvic fractures with disruption of pelvic circle	ICD-9-CM	Diagnosis
808.53	Multiple open pelvic fractures with disruption of pelvic circle	ICD-9-CM	Diagnosis
808.54	Multiple open pelvic fractures without disruption of pelvic circle	ICD-9-CM	Diagnosis
808.54	Multiple open pelvic fractures without disruption of pelvic circle	ICD-9-CM	Diagnosis
808.59	Open fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.59	Open fracture of other specified part of pelvis	ICD-9-CM	Diagnosis
808.8	Unspecified closed fracture of pelvis	ICD-9-CM	Diagnosis
808.8	Unspecified closed fracture of pelvis	ICD-9-CM	Diagnosis
808.9	Unspecified open fracture of pelvis	ICD-9-CM	Diagnosis
808.9	Unspecified open fracture of pelvis	ICD-9-CM	Diagnosis
809	Ill-defined fractures of bones of trunk	ICD-9-CM	Diagnosis
809.0	Fracture of bones of trunk, closed	ICD-9-CM	Diagnosis
809.1	Fracture of bones of trunk, open	ICD-9-CM	Diagnosis
810	Fracture of clavicle	ICD-9-CM	Diagnosis
810.0	Closed fracture of clavicle	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
810.00	Unspecified part of closed fracture of clavicle	ICD-9-CM	Diagnosis
810.01	Closed fracture of sternal end of clavicle	ICD-9-CM	Diagnosis
810.02	Closed fracture of shaft of clavicle	ICD-9-CM	Diagnosis
810.03	Closed fracture of acromial end of clavicle	ICD-9-CM	Diagnosis
810.1	Open fracture of clavicle	ICD-9-CM	Diagnosis
810.10	Unspecified part of open fracture of clavicle	ICD-9-CM	Diagnosis
810.11	Open fracture of sternal end of clavicle	ICD-9-CM	Diagnosis
810.12	Open fracture of shaft of clavicle	ICD-9-CM	Diagnosis
810.13	Open fracture of acromial end of clavicle	ICD-9-CM	Diagnosis
811	Fracture of scapula	ICD-9-CM	Diagnosis
811.0	Closed fracture of scapula	ICD-9-CM	Diagnosis
811.00	Closed fracture of unspecified part of scapula	ICD-9-CM	Diagnosis
811.01	Closed fracture of acromial process of scapula	ICD-9-CM	Diagnosis
811.02	Closed fracture of coracoid process of scapula	ICD-9-CM	Diagnosis
811.03	Closed fracture of glenoid cavity and neck of scapula	ICD-9-CM	Diagnosis
811.09	Closed fracture of other part of scapula	ICD-9-CM	Diagnosis
811.1	Open fracture of scapula	ICD-9-CM	Diagnosis
811.10	Open fracture of unspecified part of scapula	ICD-9-CM	Diagnosis
811.11	Open fracture of acromial process of scapula	ICD-9-CM	Diagnosis
811.12	Open fracture of coracoid process	ICD-9-CM	Diagnosis
811.13	Open fracture of glenoid cavity and neck of scapula	ICD-9-CM	Diagnosis
811.19	Open fracture of other part of scapula	ICD-9-CM	Diagnosis
812	Fracture of humerus	ICD-9-CM	Diagnosis
812	Fracture of humerus	ICD-9-CM	Diagnosis
812.0	Closed fracture of upper end of humerus	ICD-9-CM	Diagnosis
812.0	Closed fracture of upper end of humerus	ICD-9-CM	Diagnosis
812.00	Closed fracture of unspecified part of upper end of humerus	ICD-9-CM	Diagnosis
812.00	Closed fracture of unspecified part of upper end of humerus	ICD-9-CM	Diagnosis
812.01	Closed fracture of surgical neck of humerus	ICD-9-CM	Diagnosis
812.01	Closed fracture of surgical neck of humerus	ICD-9-CM	Diagnosis
812.02	Closed fracture of anatomical neck of humerus	ICD-9-CM	Diagnosis
812.02	Closed fracture of anatomical neck of humerus	ICD-9-CM	Diagnosis
812.03	Closed fracture of greater tuberosity of humerus	ICD-9-CM	Diagnosis
812.03	Closed fracture of greater tuberosity of humerus	ICD-9-CM	Diagnosis
812.09	Other closed fractures of upper end of humerus	ICD-9-CM	Diagnosis
812.09	Other closed fractures of upper end of humerus	ICD-9-CM	Diagnosis
812.1	Open fracture of upper end of humerus	ICD-9-CM	Diagnosis
812.1	Open fracture of upper end of humerus	ICD-9-CM	Diagnosis
812.10	Open fracture of unspecified part of upper end of humerus	ICD-9-CM	Diagnosis
812.10	Open fracture of unspecified part of upper end of humerus	ICD-9-CM	Diagnosis
812.11	Open fracture of surgical neck of humerus	ICD-9-CM	Diagnosis
812.11	Open fracture of surgical neck of humerus	ICD-9-CM	Diagnosis
812.12	Open fracture of anatomical neck of humerus	ICD-9-CM	Diagnosis
812.12	Open fracture of anatomical neck of humerus	ICD-9-CM	Diagnosis
812.13	Open fracture of greater tuberosity of humerus	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
812.13	Open fracture of greater tuberosity of humerus	ICD-9-CM	Diagnosis
812.19	Other open fracture of upper end of humerus	ICD-9-CM	Diagnosis
812.19	Other open fracture of upper end of humerus	ICD-9-CM	Diagnosis
812.2	Closed fracture of shaft or unspecified part of humerus	ICD-9-CM	Diagnosis
812.2	Closed fracture of shaft or unspecified part of humerus	ICD-9-CM	Diagnosis
812.20	Closed fracture of unspecified part of humerus	ICD-9-CM	Diagnosis
812.20	Closed fracture of unspecified part of humerus	ICD-9-CM	Diagnosis
812.21	Closed fracture of shaft of humerus	ICD-9-CM	Diagnosis
812.21	Closed fracture of shaft of humerus	ICD-9-CM	Diagnosis
812.3	Open fracture of shaft or unspecified part of humerus	ICD-9-CM	Diagnosis
812.3	Open fracture of shaft or unspecified part of humerus	ICD-9-CM	Diagnosis
812.30	Open fracture of unspecified part of humerus	ICD-9-CM	Diagnosis
812.30	Open fracture of unspecified part of humerus	ICD-9-CM	Diagnosis
812.31	Open fracture of shaft of humerus	ICD-9-CM	Diagnosis
812.31	Open fracture of shaft of humerus	ICD-9-CM	Diagnosis
812.4	Closed fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.4	Closed fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.40	Closed fracture of unspecified part of lower end of humerus	ICD-9-CM	Diagnosis
812.40	Closed fracture of unspecified part of lower end of humerus	ICD-9-CM	Diagnosis
812.41	Closed fracture of supracondylar humerus	ICD-9-CM	Diagnosis
812.41	Closed fracture of supracondylar humerus	ICD-9-CM	Diagnosis
812.42	Closed fracture of lateral condyle of humerus	ICD-9-CM	Diagnosis
812.42	Closed fracture of lateral condyle of humerus	ICD-9-CM	Diagnosis
812.43	Closed fracture of medial condyle of humerus	ICD-9-CM	Diagnosis
812.43	Closed fracture of medial condyle of humerus	ICD-9-CM	Diagnosis
812.44	Closed fracture of unspecified condyle(s) of humerus	ICD-9-CM	Diagnosis
812.44	Closed fracture of unspecified condyle(s) of humerus	ICD-9-CM	Diagnosis
812.49	Other closed fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.49	Other closed fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.5	Open fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.5	Open fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.50	Open fracture of unspecified part of lower end of humerus	ICD-9-CM	Diagnosis
812.50	Open fracture of unspecified part of lower end of humerus	ICD-9-CM	Diagnosis
812.51	Open fracture of supracondylar humerus	ICD-9-CM	Diagnosis
812.51	Open fracture of supracondylar humerus	ICD-9-CM	Diagnosis
812.52	Open fracture of lateral condyle of humerus	ICD-9-CM	Diagnosis
812.52	Open fracture of lateral condyle of humerus	ICD-9-CM	Diagnosis
812.53	Open fracture of medial condyle of humerus	ICD-9-CM	Diagnosis
812.53	Open fracture of medial condyle of humerus	ICD-9-CM	Diagnosis
812.54	Open fracture of unspecified condyle(s) of humerus	ICD-9-CM	Diagnosis
812.54	Open fracture of unspecified condyle(s) of humerus	ICD-9-CM	Diagnosis
812.59	Other open fracture of lower end of humerus	ICD-9-CM	Diagnosis
812.59	Other open fracture of lower end of humerus	ICD-9-CM	Diagnosis
813	Fracture of radius and ulna	ICD-9-CM	Diagnosis
813.0	Closed fracture of upper end of radius and ulna	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
813.00	Unspecified fracture of radius and ulna, upper end of forearm, closed	ICD-9-CM	Diagnosis
813.01	Closed fracture of olecranon process of ulna	ICD-9-CM	Diagnosis
813.02	Closed fracture of coronoid process of ulna	ICD-9-CM	Diagnosis
813.03	Closed Monteggia's fracture	ICD-9-CM	Diagnosis
813.04	Other and unspecified closed fractures of proximal end of ulna (alone)	ICD-9-CM	Diagnosis
813.05	Closed fracture of head of radius	ICD-9-CM	Diagnosis
813.06	Closed fracture of neck of radius	ICD-9-CM	Diagnosis
813.07	Other and unspecified closed fractures of proximal end of radius (alone)	ICD-9-CM	Diagnosis
813.08	Closed fracture of radius with ulna, upper end (any part)	ICD-9-CM	Diagnosis
813.1	Open fracture of upper end of radius and ulna	ICD-9-CM	Diagnosis
813.10	Unspecified open fracture of upper end of forearm	ICD-9-CM	Diagnosis
813.11	Open fracture of olecranon process of ulna	ICD-9-CM	Diagnosis
813.12	Open fracture of coronoid process of ulna	ICD-9-CM	Diagnosis
813.13	Open Monteggia's fracture	ICD-9-CM	Diagnosis
813.14	Other and unspecified open fractures of proximal end of ulna (alone)	ICD-9-CM	Diagnosis
813.15	Open fracture of head of radius	ICD-9-CM	Diagnosis
813.16	Open fracture of neck of radius	ICD-9-CM	Diagnosis
813.17	Other and unspecified open fractures of proximal end of radius (alone)	ICD-9-CM	Diagnosis
813.18	Open fracture of radius with ulna, upper end (any part)	ICD-9-CM	Diagnosis
813.2	Closed fracture of shaft of radius and ulna	ICD-9-CM	Diagnosis
813.20	Unspecified closed fracture of shaft of radius or ulna	ICD-9-CM	Diagnosis
813.21	Closed fracture of shaft of radius (alone)	ICD-9-CM	Diagnosis
813.22	Closed fracture of shaft of ulna (alone)	ICD-9-CM	Diagnosis
813.23	Closed fracture of shaft of radius with ulna	ICD-9-CM	Diagnosis
813.3	Open fracture of shaft of radius and ulna	ICD-9-CM	Diagnosis
813.30	Unspecified open fracture of shaft of radius or ulna	ICD-9-CM	Diagnosis
813.31	Open fracture of shaft of radius (alone)	ICD-9-CM	Diagnosis
813.32	Open fracture of shaft of ulna (alone)	ICD-9-CM	Diagnosis
813.33	Open fracture of shaft of radius with ulna	ICD-9-CM	Diagnosis
813.4	Closed fracture of lower end of radius and ulna	ICD-9-CM	Diagnosis
813.40	Unspecified closed fracture of lower end of forearm	ICD-9-CM	Diagnosis
813.41	Closed Colles' fracture	ICD-9-CM	Diagnosis
813.42	Other closed fractures of distal end of radius (alone)	ICD-9-CM	Diagnosis
813.43	Closed fracture of distal end of ulna (alone)	ICD-9-CM	Diagnosis
813.44	Closed fracture of lower end of radius with ulna	ICD-9-CM	Diagnosis
813.45	Torus fracture of radius (alone)	ICD-9-CM	Diagnosis
813.46	Torus fracture of ulna (alone)	ICD-9-CM	Diagnosis
813.47	Torus fracture of radius and ulna	ICD-9-CM	Diagnosis
813.5	Open fracture of lower end of radius and ulna	ICD-9-CM	Diagnosis
813.50	Unspecified open fracture of lower end of forearm	ICD-9-CM	Diagnosis
813.51	Open Colles' fracture	ICD-9-CM	Diagnosis
813.52	Other open fractures of distal end of radius (alone)	ICD-9-CM	Diagnosis
813.53	Open fracture of distal end of ulna (alone)	ICD-9-CM	Diagnosis
813.54	Open fracture of lower end of radius with ulna	ICD-9-CM	Diagnosis
813.8	Closed fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
813.80	Closed fracture of unspecified part of forearm	ICD-9-CM	Diagnosis
813.81	Closed fracture of unspecified part of radius (alone)	ICD-9-CM	Diagnosis
813.82	Closed fracture of unspecified part of ulna (alone)	ICD-9-CM	Diagnosis
813.83	Closed fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
813.9	Open fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
813.90	Open fracture of unspecified part of forearm	ICD-9-CM	Diagnosis
813.91	Open fracture of unspecified part of radius (alone)	ICD-9-CM	Diagnosis
813.92	Open fracture of unspecified part of ulna (alone)	ICD-9-CM	Diagnosis
813.93	Open fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
818	Ill-defined fractures of upper limb	ICD-9-CM	Diagnosis
818.0	Ill-defined closed fractures of upper limb	ICD-9-CM	Diagnosis
818.1	Ill-defined open fractures of upper limb	ICD-9-CM	Diagnosis
819	Multiple fractures involving both upper limbs, and upper limb with rib(s) and sternum	ICD-9-CM	Diagnosis
819.0	Multiple closed fractures involving both upper limbs, and upper limb with rib(s) and sternum	ICD-9-CM	Diagnosis
819.1	Multiple open fractures involving both upper limbs, and upper limb with rib(s) and sternum	ICD-9-CM	Diagnosis
820	Fracture of neck of femur	ICD-9-CM	Diagnosis
820	Fracture of neck of femur	ICD-9-CM	Diagnosis
820.0	Closed transcervical fracture	ICD-9-CM	Diagnosis
820.0	Closed transcervical fracture	ICD-9-CM	Diagnosis
820.00	Closed fracture of unspecified intracapsular section of neck of femur	ICD-9-CM	Diagnosis
820.00	Closed fracture of unspecified intracapsular section of neck of femur	ICD-9-CM	Diagnosis
820.01	Closed fracture of epiphysis (separation) (upper) of neck of femur	ICD-9-CM	Diagnosis
820.01	Closed fracture of epiphysis (separation) (upper) of neck of femur	ICD-9-CM	Diagnosis
820.02	Closed fracture of midcervical section of femur	ICD-9-CM	Diagnosis
820.02	Closed fracture of midcervical section of femur	ICD-9-CM	Diagnosis
820.03	Closed fracture of base of neck of femur	ICD-9-CM	Diagnosis
820.03	Closed fracture of base of neck of femur	ICD-9-CM	Diagnosis
820.09	Other closed transcervical fracture of femur	ICD-9-CM	Diagnosis
820.09	Other closed transcervical fracture of femur	ICD-9-CM	Diagnosis
820.1	Open transcervical fracture	ICD-9-CM	Diagnosis
820.1	Open transcervical fracture	ICD-9-CM	Diagnosis
820.10	Open fracture of unspecified intracapsular section of neck of femur	ICD-9-CM	Diagnosis
820.10	Open fracture of unspecified intracapsular section of neck of femur	ICD-9-CM	Diagnosis
820.11	Open fracture of epiphysis (separation) (upper) of neck of femur	ICD-9-CM	Diagnosis
820.11	Open fracture of epiphysis (separation) (upper) of neck of femur	ICD-9-CM	Diagnosis
820.12	Open fracture of midcervical section of femur	ICD-9-CM	Diagnosis
820.12	Open fracture of midcervical section of femur	ICD-9-CM	Diagnosis
820.13	Open fracture of base of neck of femur	ICD-9-CM	Diagnosis
820.13	Open fracture of base of neck of femur	ICD-9-CM	Diagnosis
820.19	Other open transcervical fracture of femur	ICD-9-CM	Diagnosis
820.19	Other open transcervical fracture of femur	ICD-9-CM	Diagnosis
820.2	Closed pertrochanteric fracture of femur	ICD-9-CM	Diagnosis
820.2	Closed pertrochanteric fracture of femur	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
820.20	Closed fracture of unspecified trochanteric section of femur	ICD-9-CM	Diagnosis
820.20	Closed fracture of unspecified trochanteric section of femur	ICD-9-CM	Diagnosis
820.21	Closed fracture of intertrochanteric section of femur	ICD-9-CM	Diagnosis
820.21	Closed fracture of intertrochanteric section of femur	ICD-9-CM	Diagnosis
820.22	Closed fracture of subtrochanteric section of femur	ICD-9-CM	Diagnosis
820.22	Closed fracture of subtrochanteric section of femur	ICD-9-CM	Diagnosis
820.3	Open pertrochanteric fracture of femur	ICD-9-CM	Diagnosis
820.3	Open pertrochanteric fracture of femur	ICD-9-CM	Diagnosis
820.30	Open fracture of unspecified trochanteric section of femur	ICD-9-CM	Diagnosis
820.30	Open fracture of unspecified trochanteric section of femur	ICD-9-CM	Diagnosis
820.31	Open fracture of intertrochanteric section of femur	ICD-9-CM	Diagnosis
820.31	Open fracture of intertrochanteric section of femur	ICD-9-CM	Diagnosis
820.32	Open fracture of subtrochanteric section of femur	ICD-9-CM	Diagnosis
820.32	Open fracture of subtrochanteric section of femur	ICD-9-CM	Diagnosis
820.8	Closed fracture of unspecified part of neck of femur	ICD-9-CM	Diagnosis
820.8	Closed fracture of unspecified part of neck of femur	ICD-9-CM	Diagnosis
820.9	Open fracture of unspecified part of neck of femur	ICD-9-CM	Diagnosis
820.9	Open fracture of unspecified part of neck of femur	ICD-9-CM	Diagnosis
821	Fracture of other and unspecified parts of femur	ICD-9-CM	Diagnosis
821	Fracture of other and unspecified parts of femur	ICD-9-CM	Diagnosis
821.0	Closed fracture of shaft or unspecified part of femur	ICD-9-CM	Diagnosis
821.0	Closed fracture of shaft or unspecified part of femur	ICD-9-CM	Diagnosis
821.00	Closed fracture of unspecified part of femur	ICD-9-CM	Diagnosis
821.00	Closed fracture of unspecified part of femur	ICD-9-CM	Diagnosis
821.01	Closed fracture of shaft of femur	ICD-9-CM	Diagnosis
821.01	Closed fracture of shaft of femur	ICD-9-CM	Diagnosis
821.1	Open fracture of shaft or unspecified part of femur	ICD-9-CM	Diagnosis
821.1	Open fracture of shaft or unspecified part of femur	ICD-9-CM	Diagnosis
821.10	Open fracture of unspecified part of femur	ICD-9-CM	Diagnosis
821.10	Open fracture of unspecified part of femur	ICD-9-CM	Diagnosis
821.11	Open fracture of shaft of femur	ICD-9-CM	Diagnosis
821.11	Open fracture of shaft of femur	ICD-9-CM	Diagnosis
821.2	Closed fracture of lower end of femur	ICD-9-CM	Diagnosis
821.2	Closed fracture of lower end of femur	ICD-9-CM	Diagnosis
821.20	Closed fracture of unspecified part of lower end of femur	ICD-9-CM	Diagnosis
821.20	Closed fracture of unspecified part of lower end of femur	ICD-9-CM	Diagnosis
821.21	Closed fracture of femoral condyle	ICD-9-CM	Diagnosis
821.21	Closed fracture of femoral condyle	ICD-9-CM	Diagnosis
821.22	Closed fracture of lower epiphysis of femur	ICD-9-CM	Diagnosis
821.22	Closed fracture of lower epiphysis of femur	ICD-9-CM	Diagnosis
821.23	Closed supracondylar fracture of femur	ICD-9-CM	Diagnosis
821.23	Closed supracondylar fracture of femur	ICD-9-CM	Diagnosis
821.29	Other closed fracture of lower end of femur	ICD-9-CM	Diagnosis
821.29	Other closed fracture of lower end of femur	ICD-9-CM	Diagnosis
821.3	Open fracture of lower end of femur	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
821.3	Open fracture of lower end of femur	ICD-9-CM	Diagnosis
821.30	Open fracture of unspecified part of lower end of femur	ICD-9-CM	Diagnosis
821.30	Open fracture of unspecified part of lower end of femur	ICD-9-CM	Diagnosis
821.31	Open fracture of femoral condyle	ICD-9-CM	Diagnosis
821.31	Open fracture of femoral condyle	ICD-9-CM	Diagnosis
821.32	Open fracture of lower epiphysis of femur	ICD-9-CM	Diagnosis
821.32	Open fracture of lower epiphysis of femur	ICD-9-CM	Diagnosis
821.33	Open supracondylar fracture of femur	ICD-9-CM	Diagnosis
821.33	Open supracondylar fracture of femur	ICD-9-CM	Diagnosis
821.39	Other open fracture of lower end of femur	ICD-9-CM	Diagnosis
821.39	Other open fracture of lower end of femur	ICD-9-CM	Diagnosis
822	Fracture of patella	ICD-9-CM	Diagnosis
822.0	Closed fracture of patella	ICD-9-CM	Diagnosis
822.1	Open fracture of patella	ICD-9-CM	Diagnosis
823	Fracture of tibia and fibula	ICD-9-CM	Diagnosis
823.0	Closed fracture of upper end of tibia and fibula	ICD-9-CM	Diagnosis
823.00	Closed fracture of upper end of tibia	ICD-9-CM	Diagnosis
823.01	Closed fracture of upper end of fibula	ICD-9-CM	Diagnosis
823.02	Closed fracture of upper end of fibula with tibia	ICD-9-CM	Diagnosis
823.1	Open fracture of upper end of tibia and fibula	ICD-9-CM	Diagnosis
823.10	Open fracture of upper end of tibia	ICD-9-CM	Diagnosis
823.11	Open fracture of upper end of fibula	ICD-9-CM	Diagnosis
823.12	Open fracture of upper end of fibula with tibia	ICD-9-CM	Diagnosis
823.2	Closed fracture of shaft of tibia and fibula	ICD-9-CM	Diagnosis
823.20	Closed fracture of shaft of tibia	ICD-9-CM	Diagnosis
823.21	Closed fracture of shaft of fibula	ICD-9-CM	Diagnosis
823.22	Closed fracture of shaft of fibula with tibia	ICD-9-CM	Diagnosis
823.3	Open fracture of shaft of tibia and fibula	ICD-9-CM	Diagnosis
823.30	Open fracture of shaft of tibia	ICD-9-CM	Diagnosis
823.31	Open fracture of shaft of fibula	ICD-9-CM	Diagnosis
823.32	Open fracture of shaft of fibula with tibia	ICD-9-CM	Diagnosis
823.4	Torus fracture of tibia and fibula	ICD-9-CM	Diagnosis
823.40	Torus fracture of tibia alone	ICD-9-CM	Diagnosis
823.41	Torus fracture of fibula alone	ICD-9-CM	Diagnosis
823.42	Torus fracture of fibula with tibia	ICD-9-CM	Diagnosis
823.8	Closed fracture of unspecified part of tibia and fibula	ICD-9-CM	Diagnosis
823.80	Closed fracture of unspecified part of tibia	ICD-9-CM	Diagnosis
823.81	Closed fracture of unspecified part of fibula	ICD-9-CM	Diagnosis
823.82	Closed fracture of unspecified part of fibula with tibia	ICD-9-CM	Diagnosis
823.9	Open fracture of unspecified part of tibia and fibula	ICD-9-CM	Diagnosis
823.90	Open fracture of unspecified part of tibia	ICD-9-CM	Diagnosis
823.91	Open fracture of unspecified part of fibula	ICD-9-CM	Diagnosis
823.92	Open fracture of unspecified part of fibula with tibia	ICD-9-CM	Diagnosis
824	Fracture of ankle	ICD-9-CM	Diagnosis
824.0	Closed fracture of medial malleolus	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
824.1	Open fracture of medial malleolus	ICD-9-CM	Diagnosis
824.2	Closed fracture of lateral malleolus	ICD-9-CM	Diagnosis
824.3	Open fracture of lateral malleolus	ICD-9-CM	Diagnosis
824.4	Closed bimalleolar fracture	ICD-9-CM	Diagnosis
824.5	Open bimalleolar fracture	ICD-9-CM	Diagnosis
824.6	Closed trimalleolar fracture	ICD-9-CM	Diagnosis
824.7	Open trimalleolar fracture	ICD-9-CM	Diagnosis
824.8	Unspecified closed fracture of ankle	ICD-9-CM	Diagnosis
824.9	Unspecified open fracture of ankle	ICD-9-CM	Diagnosis
827	Other, multiple, and ill-defined fractures of lower limb	ICD-9-CM	Diagnosis
827.0	Other, multiple and ill-defined closed fractures of lower limb	ICD-9-CM	Diagnosis
827.1	Other, multiple and ill-defined open fractures of lower limb	ICD-9-CM	Diagnosis
828	Multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum	ICD-9-CM	Diagnosis
828	Multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum	ICD-9-CM	Diagnosis
828.0	Multiple closed fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum	ICD-9-CM	Diagnosis
828.0	Multiple closed fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum	ICD-9-CM	Diagnosis
828.1	Multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum, open	ICD-9-CM	Diagnosis
828.1	Multiple fractures involving both lower limbs, lower with upper limb, and lower limb(s) with rib(s) and sternum, open	ICD-9-CM	Diagnosis
829	Fracture of unspecified bones	ICD-9-CM	Diagnosis
829.0	Closed fracture of unspecified bone	ICD-9-CM	Diagnosis
829.1	Open fracture of unspecified bone	ICD-9-CM	Diagnosis
860	Traumatic pneumothorax and hemothorax	ICD-9-CM	Diagnosis
860.0	Traumatic pneumothorax without mention of open wound into thorax	ICD-9-CM	Diagnosis
860.1	Traumatic pneumothorax with open wound into thorax	ICD-9-CM	Diagnosis
860.2	Traumatic hemothorax without mention of open wound into thorax	ICD-9-CM	Diagnosis
860.3	Traumatic hemothorax with open wound into thorax	ICD-9-CM	Diagnosis
860.4	Traumatic pneumohemothorax without mention of open wound into thorax	ICD-9-CM	Diagnosis
860.5	Traumatic pneumohemothorax with open wound into thorax	ICD-9-CM	Diagnosis
862.0	Diaphragm injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
862.1	Diaphragm injury with open wound into cavity	ICD-9-CM	Diagnosis
862.8	Injury to multiple and unspecified intrathoracic organs without mention of open wound into cavity	ICD-9-CM	Diagnosis
862.9	Injury to multiple and unspecified intrathoracic organs with open wound into cavity	ICD-9-CM	Diagnosis
863.0	Stomach injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.1	Stomach injury with open wound into cavity	ICD-9-CM	Diagnosis
863.2	Small intestine injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.20	Small intestine injury, unspecified site, without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.21	Duodenum injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.29	Other injury to small intestine without mention of open wound into cavity	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
863.3	Small intestine injury with open wound into cavity	ICD-9-CM	Diagnosis
863.30	Small intestine injury, unspecified site, with open wound into cavity	ICD-9-CM	Diagnosis
863.31	Duodenum injury with open wound into cavity	ICD-9-CM	Diagnosis
863.39	Other injury to small intestine with open wound into cavity	ICD-9-CM	Diagnosis
863.4	Colon or rectal injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.40	Colon injury unspecified site, without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.41	Ascending (right) colon injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.42	Transverse colon injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.43	Descending (left) colon injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.44	Sigmoid colon injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.45	Rectum injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.46	Injury to multiple sites in colon and rectum without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.49	Other colon and rectum injury, without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.5	Injury to colon or rectum with open wound into cavity	ICD-9-CM	Diagnosis
863.50	Colon injury, unspecified site, with open wound into cavity	ICD-9-CM	Diagnosis
863.51	Ascending (right) colon injury with open wound into cavity	ICD-9-CM	Diagnosis
863.52	Transverse colon injury with open wound into cavity	ICD-9-CM	Diagnosis
863.53	Descending (left) colon injury with open wound into cavity	ICD-9-CM	Diagnosis
863.54	Sigmoid colon injury with open wound into cavity	ICD-9-CM	Diagnosis
863.55	Rectum injury with open wound into cavity	ICD-9-CM	Diagnosis
863.56	Injury to multiple sites in colon and rectum with open wound into cavity	ICD-9-CM	Diagnosis
863.59	Other injury to colon and rectum with open wound into cavity	ICD-9-CM	Diagnosis
863.8	Injury to other and unspecified gastrointestinal sites without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.80	Gastrointestinal tract injury, unspecified site, without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.81	Pancreas head injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.82	Pancreas body injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.83	Pancreas tail injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.84	Pancreas injury, multiple and unspecified sites, without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.85	Appendix injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.89	Injury to other and unspecified gastrointestinal sites without mention of open wound into cavity	ICD-9-CM	Diagnosis
863.9	Injury to other and unspecified gastrointestinal sites, with open wound into cavity	ICD-9-CM	Diagnosis
863.90	Gastrointestinal tract injury, unspecified site, with open wound into cavity	ICD-9-CM	Diagnosis
863.91	Pancreas head injury with open wound into cavity	ICD-9-CM	Diagnosis
863.92	Pancreas body injury with open wound into cavity	ICD-9-CM	Diagnosis
863.93	Pancreas tail injury with open wound into cavity	ICD-9-CM	Diagnosis
863.94	Pancreas injury, multiple and unspecified sites, with open wound into cavity	ICD-9-CM	Diagnosis
863.95	Appendix injury with open wound into cavity	ICD-9-CM	Diagnosis
863.99	Injury to other and unspecified gastrointestinal sites with open wound into cavity	ICD-9-CM	Diagnosis
864.1	Liver injury with open wound into cavity	ICD-9-CM	Diagnosis
864.10	Unspecified liver injury with open wound into cavity	ICD-9-CM	Diagnosis
864.11	Liver hematoma and contusion with open wound into cavity	ICD-9-CM	Diagnosis
864.12	Liver laceration, minor, with open wound into cavity	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
864.13	Liver laceration, moderate, with open wound into cavity	ICD-9-CM	Diagnosis
864.14	Liver laceration, major, with open wound into cavity	ICD-9-CM	Diagnosis
864.15	Liver injury with open wound into cavity, unspecified laceration	ICD-9-CM	Diagnosis
864.19	Other liver injury with open wound into cavity	ICD-9-CM	Diagnosis
865.1	Spleen injury with open wound into cavity	ICD-9-CM	Diagnosis
865.10	Unspecified spleen injury with open wound into cavity	ICD-9-CM	Diagnosis
865.11	Spleen hematoma, without rupture of capsule, with open wound into cavity	ICD-9-CM	Diagnosis
865.12	Capsular tears to spleen, without major disruption of parenchyma, with open wound into cavity	ICD-9-CM	Diagnosis
865.13	Spleen laceration extending into parenchyma, with open wound into cavity	ICD-9-CM	Diagnosis
865.14	Massive parenchyma disruption of spleen with open wound into cavity	ICD-9-CM	Diagnosis
865.19	Other spleen injury with open wound into cavity	ICD-9-CM	Diagnosis
866	Injury to kidney	ICD-9-CM	Diagnosis
866.0	Kidney injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
866.00	Unspecified kidney injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
866.01	Kidney hematoma without rupture of capsule or mention of open wound into cavity	ICD-9-CM	Diagnosis
866.02	Kidney laceration without mention of open wound into cavity	ICD-9-CM	Diagnosis
866.03	Complete disruption of kidney parenchyma, without mention of open wound into cavity	ICD-9-CM	Diagnosis
866.1	Kidney injury with open wound into cavity	ICD-9-CM	Diagnosis
866.10	Unspecified kidney injury with open wound into cavity	ICD-9-CM	Diagnosis
866.11	Kidney hematoma, without rupture of capsule, with open wound into cavity	ICD-9-CM	Diagnosis
866.12	Kidney laceration with open wound into cavity	ICD-9-CM	Diagnosis
866.13	Complete disruption of kidney parenchyma, with open wound into cavity	ICD-9-CM	Diagnosis
867	Injury to pelvic organs	ICD-9-CM	Diagnosis
867.0	Bladder and urethra injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
867.1	Bladder and urethra injury with open wound into cavity	ICD-9-CM	Diagnosis
867.2	Ureter injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
867.3	Ureter injury with open wound into cavity	ICD-9-CM	Diagnosis
867.4	Uterus injury without mention of open wound into cavity	ICD-9-CM	Diagnosis
867.5	Uterus injury with open wound into cavity	ICD-9-CM	Diagnosis
867.6	Injury to other specified pelvic organs without mention of open wound into cavity	ICD-9-CM	Diagnosis
867.7	Injury to other specified pelvic organs with open wound into cavity	ICD-9-CM	Diagnosis
867.8	Injury to unspecified pelvic organ without mention of open wound into cavity	ICD-9-CM	Diagnosis
867.9	Injury to unspecified pelvic organ with open wound into cavity	ICD-9-CM	Diagnosis
873.0	Open wound of scalp, without mention of complication	ICD-9-CM	Diagnosis
873.1	Open wound of scalp, complicated	ICD-9-CM	Diagnosis
875.0	Open wound of chest (wall), without mention of complication	ICD-9-CM	Diagnosis
875.1	Open wound of chest (wall), complicated	ICD-9-CM	Diagnosis
902.4	Renal blood vessel injury	ICD-9-CM	Diagnosis
902.40	Renal vessel(s) injury, unspecified	ICD-9-CM	Diagnosis
902.41	Renal artery injury	ICD-9-CM	Diagnosis
902.42	Renal vein injury	ICD-9-CM	Diagnosis
902.49	Renal blood vessel injury, other	ICD-9-CM	Diagnosis
902.55	Uterine artery injury	ICD-9-CM	Diagnosis
902.56	Uterine vein injury	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
902.81	Ovarian artery injury	ICD-9-CM	Diagnosis
902.82	Ovarian vein injury	ICD-9-CM	Diagnosis
925	Crushing injury of face, scalp, and neck	ICD-9-CM	Diagnosis
925.1	Crushing injury of face and scalp	ICD-9-CM	Diagnosis
925.2	Crushing injury of neck	ICD-9-CM	Diagnosis
926	Crushing injury of trunk	ICD-9-CM	Diagnosis
926.0	Crushing injury of external genitalia	ICD-9-CM	Diagnosis
926.1	Crushing injury of other specified sites of trunk	ICD-9-CM	Diagnosis
926.11	Crushing injury of back	ICD-9-CM	Diagnosis
926.12	Crushing injury of buttock	ICD-9-CM	Diagnosis
926.19	Crushing injury of other specified sites of trunk	ICD-9-CM	Diagnosis
926.8	Crushing injury of multiple sites of trunk	ICD-9-CM	Diagnosis
926.9	Crushing injury of unspecified site of trunk	ICD-9-CM	Diagnosis
927	Crushing injury of upper limb	ICD-9-CM	Diagnosis
927.0	Crushing injury of shoulder and upper arm	ICD-9-CM	Diagnosis
927.00	Crushing injury of shoulder region	ICD-9-CM	Diagnosis
927.01	Crushing injury of scapular region	ICD-9-CM	Diagnosis
927.02	Crushing injury of axillary region	ICD-9-CM	Diagnosis
927.03	Crushing injury of upper arm	ICD-9-CM	Diagnosis
927.09	Crushing injury of multiple sites of upper arm	ICD-9-CM	Diagnosis
927.1	Crushing injury of elbow and forearm	ICD-9-CM	Diagnosis
927.10	Crushing injury of forearm	ICD-9-CM	Diagnosis
927.11	Crushing injury of elbow	ICD-9-CM	Diagnosis
927.2	Crushing injury of wrist and hand(s), except finger(s) alone	ICD-9-CM	Diagnosis
927.20	Crushing injury of hand(s)	ICD-9-CM	Diagnosis
927.21	Crushing injury of wrist	ICD-9-CM	Diagnosis
927.3	Crushing injury of finger(s)	ICD-9-CM	Diagnosis
927.8	Crushing injury of multiple sites of upper limb	ICD-9-CM	Diagnosis
927.9	Crushing injury of unspecified site of upper limb	ICD-9-CM	Diagnosis
928	Crushing injury of lower limb	ICD-9-CM	Diagnosis
928.0	Crushing injury of hip and thigh	ICD-9-CM	Diagnosis
928.00	Crushing injury of thigh	ICD-9-CM	Diagnosis
928.01	Crushing injury of hip	ICD-9-CM	Diagnosis
928.1	Crushing injury of knee and lower leg	ICD-9-CM	Diagnosis
928.10	Crushing injury of lower leg	ICD-9-CM	Diagnosis
928.11	Crushing injury of knee	ICD-9-CM	Diagnosis
928.2	Crushing injury of ankle and foot, excluding toe(s) alone	ICD-9-CM	Diagnosis
928.20	Crushing injury of foot	ICD-9-CM	Diagnosis
928.21	Crushing injury of ankle	ICD-9-CM	Diagnosis
928.3	Crushing injury of toe(s)	ICD-9-CM	Diagnosis
928.8	Crushing injury of multiple sites of lower limb	ICD-9-CM	Diagnosis
928.9	Crushing injury of unspecified site of lower limb	ICD-9-CM	Diagnosis
929	Crushing injury of multiple and unspecified sites	ICD-9-CM	Diagnosis
929.0	Crushing injury of multiple sites, not elsewhere classified	ICD-9-CM	Diagnosis
929.9	Crushing injury of unspecified site	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
958.4	Traumatic shock	ICD-9-CM	Diagnosis
958.5	Traumatic anuria	ICD-9-CM	Diagnosis
958.7	Traumatic subcutaneous emphysema	ICD-9-CM	Diagnosis
996.7	Other complications of internal prosthetic device, implant, and graft	ICD-9-CM	Diagnosis
996.70	Other complications due to unspecified device, implant, and graft	ICD-9-CM	Diagnosis
996.71	Other complications due to heart valve prosthesis	ICD-9-CM	Diagnosis
996.72	Other complications due to other cardiac device, implant, and graft	ICD-9-CM	Diagnosis
996.73	Other complications due to renal dialysis device, implant, and graft	ICD-9-CM	Diagnosis
996.74	Other complications due to other vascular device, implant, and graft	ICD-9-CM	Diagnosis
996.75	Other complications due to nervous system device, implant, and graft	ICD-9-CM	Diagnosis
996.76	Other complications due to genitourinary device, implant, and graft	ICD-9-CM	Diagnosis
996.77	Other complications due to internal joint prosthesis	ICD-9-CM	Diagnosis
996.78	Other complications due to other internal orthopedic device, implant, and graft	ICD-9-CM	Diagnosis
996.79	Other complications due to other internal prosthetic device, implant, and graft	ICD-9-CM	Diagnosis
998.11	Hemorrhage complicating a procedure	ICD-9-CM	Diagnosis
998.12	Hematoma complicating a procedure	ICD-9-CM	Diagnosis
998.2	Accidental puncture or laceration during procedure	ICD-9-CM	Diagnosis
E805	Hit by rolling stock	ICD-9-CM	Diagnosis
E805.0	Railway employee hit by rolling stock	ICD-9-CM	Diagnosis
E805.1	Passenger on railway hit by rolling stock	ICD-9-CM	Diagnosis
E805.2	Pedestrian hit by rolling stock	ICD-9-CM	Diagnosis
E805.3	Pedal cyclist hit by rolling stock	ICD-9-CM	Diagnosis
E805.8	Other specified person hit by rolling stock	ICD-9-CM	Diagnosis
E805.9	Unspecified person hit by rolling stock	ICD-9-CM	Diagnosis
E870	Accidental cut, puncture, perforation, or hemorrhage during medical care	ICD-9-CM	Diagnosis
E870.0	Accidental cut, puncture, perforation, or hemorrhage during surgical operation	ICD-9-CM	Diagnosis
E870.1	Accidental cut, puncture, perforation, or hemorrhage during infusion or transfusion	ICD-9-CM	Diagnosis
E870.2	Accidental cut, puncture, perforation, or hemorrhage during kidney dialysis or other perfusion	ICD-9-CM	Diagnosis
E870.3	Accidental cut, puncture, perforation, or hemorrhage during injection or vaccination	ICD-9-CM	Diagnosis
E870.4	Accidental cut, puncture, perforation, or hemorrhage during endoscopic examination	ICD-9-CM	Diagnosis
E870.5	Accidental cut, puncture, perforation, or hemorrhage during aspiration of fluid or tissue, puncture, and catheterization	ICD-9-CM	Diagnosis
E870.6	Accidental cut, puncture, perforation, or hemorrhage during heart catheterization	ICD-9-CM	Diagnosis
E870.7	Accidental cut, puncture, perforation, or hemorrhage during administration of enema	ICD-9-CM	Diagnosis
E870.8	Accidental cut, puncture, perforation, or hemorrhage during other specified medical care	ICD-9-CM	Diagnosis
E870.9	Accidental cut, puncture, perforation, or hemorrhage during unspecified medical care	ICD-9-CM	Diagnosis
E881	Accidental fall on or from ladders or scaffolding	ICD-9-CM	Diagnosis
E881.0	Accidental fall from ladder	ICD-9-CM	Diagnosis
E881.1	Accidental fall from scaffolding	ICD-9-CM	Diagnosis
E882	Accidental fall from or out of building or other structure	ICD-9-CM	Diagnosis
E883	Accidental fall into hole or other opening in surface	ICD-9-CM	Diagnosis
E883.0	Accident from diving or jumping into water (swimming pool)	ICD-9-CM	Diagnosis
E883.1	Accidental fall into well	ICD-9-CM	Diagnosis
E883.2	Accidental fall into storm drain or manhole	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
E883.9	Accidental fall into other hole or other opening in surface	ICD-9-CM	Diagnosis
E922	Accident caused by firearm, and air gun missiles	ICD-9-CM	Diagnosis
E922.0	Accident caused by handgun	ICD-9-CM	Diagnosis
E922.1	Accident caused by shotgun (automatic)	ICD-9-CM	Diagnosis
E922.2	Accident caused by hunting rifle	ICD-9-CM	Diagnosis
E922.3	Accident caused by military firearms	ICD-9-CM	Diagnosis
E922.4	Accident caused by air gun	ICD-9-CM	Diagnosis
E922.5	Accident caused by paintball gun	ICD-9-CM	Diagnosis
E922.8	Accident caused by other specified firearm missile	ICD-9-CM	Diagnosis
E922.9	Accident caused by unspecified firearm missile	ICD-9-CM	Diagnosis
E923	Accident caused by explosive material	ICD-9-CM	Diagnosis
E923.0	Accident caused by fireworks	ICD-9-CM	Diagnosis
E923.1	Accident caused by blasting materials	ICD-9-CM	Diagnosis
E923.2	Accident caused by explosive gases	ICD-9-CM	Diagnosis
E923.8	Accident caused by other explosive materials	ICD-9-CM	Diagnosis
E923.9	Accident caused by unspecified explosive material	ICD-9-CM	Diagnosis
E955	Suicide and self-inflicted injury by firearms, air guns and explosives	ICD-9-CM	Diagnosis
E955.0	Suicide and self-inflicted injury by handgun	ICD-9-CM	Diagnosis
E955.1	Suicide and self-inflicted injury by shotgun	ICD-9-CM	Diagnosis
E955.2	Suicide and self-inflicted injury by hunting rifle	ICD-9-CM	Diagnosis
E955.3	Suicide and self-inflicted injury by military firearms	ICD-9-CM	Diagnosis
E955.4	Suicide and self-inflicted injury by other and unspecified firearm	ICD-9-CM	Diagnosis
E955.5	Suicide and self-inflicted injury by explosives	ICD-9-CM	Diagnosis
E955.6	Suicide and self-inflicted injury by air gun	ICD-9-CM	Diagnosis
E955.7	Suicide and self-inflicted injury by paintball gun	ICD-9-CM	Diagnosis
E955.9	Suicide and self-inflicted injury by firearms and explosives, unspecified	ICD-9-CM	Diagnosis
E960	Fight, brawl, rape	ICD-9-CM	Diagnosis
E960.0	Unarmed fight or brawl	ICD-9-CM	Diagnosis
E960.1	Rape	ICD-9-CM	Diagnosis
E965	Assault by firearms and explosives	ICD-9-CM	Diagnosis
E965.0	Assault by handgun	ICD-9-CM	Diagnosis
E965.1	Assault by shotgun	ICD-9-CM	Diagnosis
E965.2	Assault by hunting rifle	ICD-9-CM	Diagnosis
E965.3	Assault by military firearms	ICD-9-CM	Diagnosis
E965.4	Assault by other and unspecified firearm	ICD-9-CM	Diagnosis
E965.5	Assault by antipersonnel bomb	ICD-9-CM	Diagnosis
E965.6	Assault by gasoline bomb	ICD-9-CM	Diagnosis
E965.7	Assault by letter bomb	ICD-9-CM	Diagnosis
E965.8	Assault by other specified explosive	ICD-9-CM	Diagnosis
E965.9	Assault by unspecified explosive	ICD-9-CM	Diagnosis
E970	Injury due to legal intervention by firearms	ICD-9-CM	Diagnosis
E985	Injury by firearms, air guns and explosives, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
E985.0	Injury by handgun, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
E985.1	Injury by shotgun, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
E985.2	Injury by hunting rifle, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
E985.3	Injury by military firearms, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
E985.4	Injury by other and unspecified firearm, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
E985.5	Injury by explosives, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
E985.6	Injury by air gun, undetermined whether accidental, or purposefully inflicted	ICD-9-CM	Diagnosis
E985.7	Injury by paintball gun, undetermined whether accidentally or purposefully inflicted	ICD-9-CM	Diagnosis

Appendix D. List of Generic and Brand Names of Medical Products Used to Define Exposure Incidence and Censoring Criteria in this Request

Generic Name	Brand Name
	Apixaban
apixaban	Eliquis
	Dabigatran
dabigatran etexilate mesylate	Pradaxa
	Edoxaban
edoxaban tosylate	Savaysa
	Rivaroxaban
rivaroxaban	Xarelto
	Warfarin
warfarin sodium	Warfarin
warfarin sodium	Coumadin
warfarin sodium	Jantoven

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

Code	Description	Code Type	Code Category
Atrial Fibrillation			
427.31	Atrial fibrillation	ICD-9-CM	Diagnosis
427.32	Atrial flutter	ICD-9-CM	Diagnosis
427.3	Atrial fibrillation and flutter	ICD-9-CM	Diagnosis
Deep Vein Thrombosis			
451.1	Phlebitis and thrombophlebitis of deep veins of lower extremities	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
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
Dialysis			
792.5	Cloudy (hemodialysis) (peritoneal) dialysis affluent	ICD-9-CM	Diagnosis
V45.1	Renal dialysis status	ICD-9-CM	Diagnosis
V45.11	Renal dialysis status	ICD-9-CM	Diagnosis
V45.12	Noncompliance with renal dialysis	ICD-9-CM	Diagnosis
V56.0	Encounter for extracorporeal dialysis	ICD-9-CM	Diagnosis
V56.1	Fitting and adjustment of extracorporeal dialysis catheter	ICD-9-CM	Diagnosis
V56.2	Fitting and adjustment of peritoneal dialysis catheter	ICD-9-CM	Diagnosis
V56.3	Encounter for adequacy testing for dialysis	ICD-9-CM	Diagnosis
V56.31	Encounter for adequacy testing for hemodialysis	ICD-9-CM	Diagnosis
V56.32	Encounter for adequacy testing for peritoneal dialysis	ICD-9-CM	Diagnosis
V56.8	Encounter other dialysis	ICD-9-CM	Diagnosis
90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional	CPT-4	Procedure
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription	CPT-4	Procedure
90939	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator dilution method, hook-up; transcutaneous measurement and disconnection	CPT-4	Procedure
90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method	CPT-4	Procedure
90941	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90942	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90943	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90944	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
90945	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional	CPT-4	Procedure
90947	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription	CPT-4	Procedure
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	CPT-4	Procedure
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age	CPT-4	Procedure
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	CPT-4	Procedure
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	CPT-4	Procedure
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	CPT-4	Procedure
90976	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90977	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90978	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90979	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90982	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90983	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90984	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90985	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90988	Supervision Of Hemodialysis In Hospital Or Other Facility (excluding Home Dialysis), On Monthly Basis	CPT-4	Procedure
90989	Dialysis training, patient, including helper where applicable, any mode, completed course	CPT-4	Procedure
90990	Hemodialysis Training And/or Counseling	CPT-4	Procedure
90991	Home Hemodialysis Care, Outpatient, For Those Services Either Provided By The Physician Primarily Responsible	CPT-4	Procedure
90992	Peritoneal Dialysis Training And/or Counseling	CPT-4	Procedure
90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
90994	Supervision Of Chronic Ambulatory Peritoneal Dialysis (capd), Home Or Out-patient (monthly)	CPT-4	Procedure
90995	End Stage Renal Disease (esrd) Related Services, Per Full Month	CPT-4	Procedure
90996	Continuous Arteriovenous Hemofiltration (cavh) (per Day)	CPT-4	Procedure
90997	Hemoperfusion (eg, with activated charcoal or resin)	CPT-4	Procedure
90998	End Stage Renal Disease (esrd) Related Services (less Than Full Month), Per Day	CPT-4	Procedure
90999	Unlisted dialysis procedure, inpatient or outpatient	CPT-4	Procedure
Joint Replacement			
V43.6	Joint replaced by other means	ICD-9-CM	Diagnosis
V43.60	Unspecified joint replacement by other means	ICD-9-CM	Diagnosis
V43.61	Shoulder joint replacement by other means	ICD-9-CM	Diagnosis
V43.62	Elbow joint replacement by other means	ICD-9-CM	Diagnosis
V43.63	Wrist joint replacement by other means	ICD-9-CM	Diagnosis
V43.64	Hip joint replacement by other means	ICD-9-CM	Diagnosis
V43.65	Knee joint replacement by other means	ICD-9-CM	Diagnosis
V43.66	Ankle joint replacement by other means	ICD-9-CM	Diagnosis
V43.69	Other joint replacement by other means	ICD-9-CM	Diagnosis
81.5	Joint replacement of lower extremity	ICD-9-CM	Procedure
81.51	Total hip replacement	ICD-9-CM	Procedure
81.52	Partial hip replacement	ICD-9-CM	Procedure
81.53	Revision of hip replacement, not otherwise specified	ICD-9-CM	Procedure
81.54	Total knee replacement	ICD-9-CM	Procedure
81.55	Revision of knee replacement, not otherwise specified	ICD-9-CM	Procedure
81.56	Total ankle replacement	ICD-9-CM	Procedure
81.57	Replacement of joint of foot and toe	ICD-9-CM	Procedure
81.59	Revision of joint replacement of lower extremity, not elsewhere classified	ICD-9-CM	Procedure
81.8	Arthroplasty and repair of shoulder and elbow	ICD-9-CM	Procedure
81.80	Total shoulder replacement	ICD-9-CM	Procedure
81.81	Partial shoulder replacement	ICD-9-CM	Procedure
81.82	Repair of recurrent dislocation of shoulder	ICD-9-CM	Procedure
81.83	Other repair of shoulder	ICD-9-CM	Procedure
81.84	Total elbow replacement	ICD-9-CM	Procedure
81.85	Other repair of elbow	ICD-9-CM	Procedure
81.88	Reverse total shoulder replacement	ICD-9-CM	Procedure
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	CPT-3	Procedure
0375T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels	CPT-3	Procedure
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement	CPT-4	Procedure
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	CPT-4	Procedure
24361	Arthroplasty, elbow; with distal humeral prosthetic replacement	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
24363	Arthroplasty, elbow; with distal humerus and proximal ulnar prosthetic replacement (eg, total elbow)	CPT-4	Procedure
24666	Open treatment of radial head or neck fracture, includes internal fixation or radial head excision, when performed; with radial head prosthetic replacement	CPT-4	Procedure
25441	Arthroplasty with prosthetic replacement; distal radius	CPT-4	Procedure
25442	Arthroplasty with prosthetic replacement; distal ulna	CPT-4	Procedure
25443	Arthroplasty with prosthetic replacement; scaphoid carpal (navicular)	CPT-4	Procedure
25444	Arthroplasty with prosthetic replacement; lunate	CPT-4	Procedure
25445	Arthroplasty with prosthetic replacement; trapezium	CPT-4	Procedure
25446	Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)	CPT-4	Procedure
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	CPT-4	Procedure
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	CPT-4	Procedure
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	CPT-4	Procedure
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	CPT-4	Procedure
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	CPT-4	Procedure
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	CPT-4	Procedure
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
L8631	Metacarpal phalangeal joint replacement, 2 or more pieces, metal (e.g., stainless steel or cobalt chrome), ceramic-like material (e.g., pyrocarbon), for surgical implantation (all sizes, includes entire system)	HCPCS	Procedure
L8659	Interphalangeal finger joint replacement, 2 or more pieces, metal (e.g., stainless steel or cobalt chrome), ceramic-like material (e.g., pyrocarbon) for surgical implantation, any size	HCPCS	Procedure
Kidney Replacement			
996.81	Complications of transplanted kidney	ICD-9-CM	Diagnosis
V42	Organ or tissue replaced by transplant	ICD-9-CM	Diagnosis
V42.0	Kidney replaced by transplant	ICD-9-CM	Diagnosis
55.6	Transplant of kidney	ICD-9-CM	Procedure
55.61	Renal autotransplantation	ICD-9-CM	Procedure
55.69	Other kidney transplantation	ICD-9-CM	Procedure
Mitral Stenosis			
394	Diseases of mitral valve	ICD-9-CM	Diagnosis
394.0	Mitral stenosis	ICD-9-CM	Diagnosis
394.1	Rheumatic mitral insufficiency	ICD-9-CM	Diagnosis
394.2	Mitral stenosis with insufficiency	ICD-9-CM	Diagnosis
394.9	Other and unspecified mitral valve diseases	ICD-9-CM	Diagnosis
396.0	Mitral valve stenosis and aortic valve stenosis	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
396.1	Mitral valve stenosis and aortic valve insufficiency	ICD-9-CM	Diagnosis
396.8	Multiple involvement of mitral and aortic valves	ICD-9-CM	Diagnosis
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
Valve Repair			
0343T	Transcatheter mitral valve repair percutaneous approach including transeptal puncture when performed; initial prosthesis	CPT-3 (Category 3)	Procedure
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus	CPT-3	Procedure
33400	Valvuloplasty, aortic valve; open, with cardiopulmonary bypass	CPT-4	Procedure
33401	Valvuloplasty, aortic valve; open, with inflow occlusion	CPT-4	Procedure
33403	Valvuloplasty, aortic valve; using transventricular dilation, with cardiopulmonary bypass	CPT-4	Procedure
33420	Valvotomy, mitral valve; closed heart	CPT-4	Procedure
33422	Valvotomy, mitral valve; open heart, with cardiopulmonary bypass	CPT-4	Procedure
33425	Valvuloplasty, mitral valve, with cardiopulmonary bypass;	CPT-4	Procedure
33426	Valvuloplasty, mitral valve, with cardiopulmonary bypass; with prosthetic ring	CPT-4	Procedure
33427	Valvuloplasty, mitral valve, with cardiopulmonary bypass; radical reconstruction, with or without ring	CPT-4	Procedure
33460	Valvectomy, tricuspid valve, with cardiopulmonary bypass	CPT-4	Procedure
33463	Valvuloplasty, tricuspid valve; without ring insertion	CPT-4	Procedure
33464	Valvuloplasty, tricuspid valve; with ring insertion	CPT-4	Procedure
33468	Tricuspid valve repositioning and plication for Ebstein anomaly	CPT-4	Procedure
33470	Valvotomy, pulmonary valve, closed heart; transventricular	CPT-4	Procedure
33471	Valvotomy, pulmonary valve, closed heart; via pulmonary artery	CPT-4	Procedure
33472	Valvotomy, pulmonary valve, open heart; with inflow occlusion	CPT-4	Procedure
33474	Valvotomy, pulmonary valve, open heart, with cardiopulmonary bypass	CPT-4	Procedure
33476	Right ventricular resection for infundibular stenosis, with or without commissurotomy	CPT-4	Procedure
33496	Repair of non-structural prosthetic valve dysfunction with cardiopulmonary bypass (separate procedure)	CPT-4	Procedure
92986	Percutaneous balloon valvuloplasty; aortic valve	CPT-4	Procedure
92987	Percutaneous balloon valvuloplasty; mitral valve	CPT-4	Procedure
92990	Percutaneous balloon valvuloplasty; pulmonary valve	CPT-4	Procedure
Valve Replacement			
V42.2	Heart valve replaced by transplant	ICD-9-CM	Diagnosis
V43.3	Heart valve replaced by other means	ICD-9-CM	Diagnosis
35.2	Replacement of heart valve	ICD-9-CM	Procedure
35.20	Replacement of unspecified heart valve	ICD-9-CM	Procedure
35.21	Replacement of aortic valve with tissue graft	ICD-9-CM	Procedure
35.22	Other replacement of aortic valve	ICD-9-CM	Procedure
35.23	Replacement of mitral valve with tissue graft	ICD-9-CM	Procedure
35.24	Other replacement of mitral valve	ICD-9-CM	Procedure
35.25	Replacement of pulmonary valve with tissue graft	ICD-9-CM	Procedure
35.26	Other replacement of pulmonary valve	ICD-9-CM	Procedure

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Code	Description	Code Type	Code Category
35.27	Replacement of tricuspid valve with tissue graft	ICD-9-CM	Procedure
35.28	Other replacement of tricuspid valve	ICD-9-CM	Procedure
0258T	Transthoracic cardiac exposure (eg, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; without cardiopulmonary bypass	CPT-3	Procedure
0259T	Transthoracic cardiac exposure (eg, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; with cardiopulmonary bypass	CPT-3	Procedure
0318T	Implantation of catheter-delivered prosthetic aortic heart valve, open thoracic approach, (eg, transapical, other than transaortic)	CPT-3	Procedure
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	CPT-4	Procedure
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	CPT-4	Procedure
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	CPT-4	Procedure
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	CPT-4	Procedure
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)	CPT-4	Procedure
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)	CPT-4	Procedure
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)	CPT-4	Procedure
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)	CPT-4	Procedure
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)	CPT-4	Procedure
33405	Replacement, aortic valve, open, with cardiopulmonary bypass; with prosthetic valve other than homograft or stentless valve	CPT-4	Procedure
33406	Replacement, aortic valve, open, with cardiopulmonary bypass; with allograft valve (freehand)	CPT-4	Procedure
33410	Replacement, aortic valve, open, with cardiopulmonary bypass; with stentless tissue valve	CPT-4	Procedure
33411	Replacement, aortic valve; with aortic annulus enlargement, noncoronary sinus	CPT-4	Procedure
33412	Replacement, aortic valve; with transventricular aortic annulus enlargement (Konno procedure)	CPT-4	Procedure
33413	Replacement, aortic valve; by translocation of autologous pulmonary valve with allograft replacement of pulmonary valve (Ross procedure)	CPT-4	Procedure
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	CPT-4	Procedure

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Code	Description	Code Type	Code Category
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)	CPT-4	Procedure
33430	Replacement, mitral valve, with cardiopulmonary bypass	CPT-4	Procedure
33465	Replacement, tricuspid valve, with cardiopulmonary bypass	CPT-4	Procedure
33475	Replacement, pulmonary valve	CPT-4	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Censoring Criteria in this Request

Code	Description	Code Type	Code Category
Dialysis			
792.5	Cloudy (hemodialysis) (peritoneal) dialysis affluent	ICD-9-CM	Diagnosis
V45.1	Renal dialysis status	ICD-9-CM	Diagnosis
V45.11	Renal dialysis status	ICD-9-CM	Diagnosis
V45.12	Noncompliance with renal dialysis	ICD-9-CM	Diagnosis
V56.0	Encounter for extracorporeal dialysis	ICD-9-CM	Diagnosis
V56.1	Fitting and adjustment of extracorporeal dialysis catheter	ICD-9-CM	Diagnosis
V56.2	Fitting and adjustment of peritoneal dialysis catheter	ICD-9-CM	Diagnosis
V56.3	Encounter for adequacy testing for dialysis	ICD-9-CM	Diagnosis
V56.31	Encounter for adequacy testing for hemodialysis	ICD-9-CM	Diagnosis
V56.32	Encounter for adequacy testing for peritoneal dialysis	ICD-9-CM	Diagnosis
V56.8	Encounter other dialysis	ICD-9-CM	Diagnosis
90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional	CPT-4	Procedure
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription	CPT-4	Procedure
90939	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator dilution method, hook-up; transcutaneous measurement and disconnection	CPT-4	Procedure
90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method	CPT-4	Procedure
90941	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90942	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90943	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90944	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90945	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional	CPT-4	Procedure
90947	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription	CPT-4	Procedure
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Censoring Criteria in this Request

Code	Description	Code Type	Code Category
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	CPT-4	Procedure

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Censoring Criteria in this Request

Code	Description	Code Type	Code Category
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age	CPT-4	Procedure
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	CPT-4	Procedure
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	CPT-4	Procedure
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	CPT-4	Procedure
90976	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90977	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90978	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90979	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90982	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90983	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90984	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90985	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90988	Supervision Of Hemodialysis In Hospital Or Other Facility (excluding Home Dialysis), On Monthly Basis	CPT-4	Procedure
90989	Dialysis training, patient, including helper where applicable, any mode, completed course	CPT-4	Procedure
90990	Hemodialysis Training And/or Counseling	CPT-4	Procedure
90991	Home Hemodialysis Care, Outpatient, For Those Services Either Provided By The Physician Primarily Responsible	CPT-4	Procedure
90992	Peritoneal Dialysis Training And/or Counseling	CPT-4	Procedure
90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session	CPT-4	Procedure
90994	Supervision Of Chronic Ambulatory Peritoneal Dialysis (capd), Home Or Out-patient (monthly)	CPT-4	Procedure
90995	End Stage Renal Disease (esrd) Related Services, Per Full Month	CPT-4	Procedure
90996	Continuous Arteriovenous Hemofiltration (cavh) (per Day)	CPT-4	Procedure
90997	Hemoperfusion (eg, with activated charcoal or resin)	CPT-4	Procedure
90998	End Stage Renal Disease (esrd) Related Services (less Than Full Month), Per Day	CPT-4	Procedure
90999	Unlisted dialysis procedure, inpatient or outpatient	CPT-4	Procedure
Kidney Replacement			
996.81	Complications of transplanted kidney	ICD-9-CM	Diagnosis
V42	Organ or tissue replaced by transplant	ICD-9-CM	Diagnosis
V42.0	Kidney replaced by transplant	ICD-9-CM	Diagnosis
55.6	Transplant of kidney	ICD-9-CM	Procedure
55.61	Renal autotransplantation	ICD-9-CM	Procedure
55.69	Other kidney transplantation	ICD-9-CM	Procedure

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
Acute Myocardial Infarction			
410	Acute myocardial infarction	ICD-9-CM	Dianosis
410.0	Acute myocardial infarction of anterolateral wall	ICD-9-CM	Dianosis
410.00	Acute myocardial infarction of anterolateral wall, episode of care unspecified	ICD-9-CM	Dianosis
410.01	Acute myocardial infarction of anterolateral wall, initial episode of care	ICD-9-CM	Dianosis
410.02	Acute myocardial infarction of anterolateral wall, subsequent episode of care	ICD-9-CM	Dianosis
410.1	Acute myocardial infarction of other anterior wall	ICD-9-CM	Dianosis
410.10	Acute myocardial infarction of other anterior wall, episode of care unspecified	ICD-9-CM	Dianosis
410.11	Acute myocardial infarction of other anterior wall, initial episode of care	ICD-9-CM	Dianosis
410.12	Acute myocardial infarction of other anterior wall, subsequent episode of care	ICD-9-CM	Dianosis
410.2	Acute myocardial infarction of inferolateral wall	ICD-9-CM	Dianosis
410.20	Acute myocardial infarction of inferolateral wall, episode of care unspecified	ICD-9-CM	Dianosis
410.21	Acute myocardial infarction of inferolateral wall, initial episode of care	ICD-9-CM	Dianosis
410.22	Acute myocardial infarction of inferolateral wall, subsequent episode of care	ICD-9-CM	Dianosis
410.3	Acute myocardial infarction of inferoposterior wall	ICD-9-CM	Dianosis
410.30	Acute myocardial infarction of inferoposterior wall, episode of care unspecified	ICD-9-CM	Dianosis
410.31	Acute myocardial infarction of inferoposterior wall, initial episode of care	ICD-9-CM	Dianosis
410.32	Acute myocardial infarction of inferoposterior wall, subsequent episode of care	ICD-9-CM	Dianosis
410.4	Acute myocardial infarction of other inferior wall	ICD-9-CM	Dianosis
410.40	Acute myocardial infarction of other inferior wall, episode of care unspecified	ICD-9-CM	Dianosis
410.41	Acute myocardial infarction of other inferior wall, initial episode of care	ICD-9-CM	Dianosis
410.42	Acute myocardial infarction of other inferior wall, subsequent episode of care	ICD-9-CM	Dianosis
410.5	Acute myocardial infarction of other lateral wall	ICD-9-CM	Dianosis
410.50	Acute myocardial infarction of other lateral wall, episode of care unspecified	ICD-9-CM	Dianosis
410.51	Acute myocardial infarction of other lateral wall, initial episode of care	ICD-9-CM	Dianosis
410.52	Acute myocardial infarction of other lateral wall, subsequent episode of care	ICD-9-CM	Dianosis
410.6	Acute myocardial infarction, true posterior wall infarction	ICD-9-CM	Dianosis
410.60	Acute myocardial infarction, true posterior wall infarction, episode of care unspecified	ICD-9-CM	Dianosis
410.61	Acute myocardial infarction, true posterior wall infarction, initial episode of care	ICD-9-CM	Dianosis
410.62	Acute myocardial infarction, true posterior wall infarction, subsequent episode of care	ICD-9-CM	Dianosis
410.7	Acute myocardial infarction, subendocardial infarction	ICD-9-CM	Dianosis
410.70	Acute myocardial infarction, subendocardial infarction, episode of care unspecified	ICD-9-CM	Dianosis
410.71	Acute myocardial infarction, subendocardial infarction, initial episode of care	ICD-9-CM	Dianosis
410.72	Acute myocardial infarction, subendocardial infarction, subsequent episode of care	ICD-9-CM	Dianosis
410.8	Acute myocardial infarction of other specified sites	ICD-9-CM	Dianosis
410.80	Acute myocardial infarction of other specified sites, episode of care unspecified	ICD-9-CM	Dianosis
410.81	Acute myocardial infarction of other specified sites, initial episode of care	ICD-9-CM	Dianosis
410.82	Acute myocardial infarction of other specified sites, subsequent episode of care	ICD-9-CM	Dianosis
410.9	Acute myocardial infarction, unspecified site	ICD-9-CM	Dianosis
410.90	Acute myocardial infarction, unspecified site, episode of care unspecified	ICD-9-CM	Dianosis
410.91	Acute myocardial infarction, unspecified site, initial episode of care	ICD-9-CM	Dianosis
410.92	Acute myocardial infarction, unspecified site, subsequent episode of care	ICD-9-CM	Dianosis
Acute Kidney Failure			
584	Acute kidney failure	ICD-9-CM	Diagnosis
584.5	Acute kidney failure with lesion of tubular necrosis	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
Anticoagulants			
C9121	Injection, argatroban, per 5 mg	HCPCS	Procedure
J0583	Injection, bivalirudin, 1 mg	HCPCS	Procedure
J1644	Injection, Heparin sodium, per 1000 units	HCPCS	Procedure
J1645	Injection, dalteparin sodium, per 2500 IU	HCPCS	Procedure
J1650	Injection, enoxaparin sodium, 10 mg	HCPCS	Procedure
J1652	Injection, fondaparinux sodium, 0.5 mg	HCPCS	Procedure
J1655	Injection, tinzaparin sodium, 1000 IU	HCPCS	Procedure
J1945	Injection, lepirudin, 50 mg	HCPCS	Procedure
Cardiac Ablation			
37.33	Excision or destruction of other lesion or tissue of heart, open approach	ICD-9-CM	Procedure
37.34	Excision or destruction of other lesion or tissue of heart, other approach	ICD-9-CM	Procedure
33250	Operative ablation of supraventricular arrhythmogenic focus or pathway (eg, Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); without cardiopulmonary bypass	CPT-4	Procedure
33251	Operative ablation of supraventricular arrhythmogenic focus or pathway (eg, Wolff-Parkinson-White, atrioventricular node re-entry), tract(s) and/or focus (foci); with cardiopulmonary bypass	CPT-4	Procedure
33254	Operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure)	CPT-4	Procedure
33255	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); without cardiopulmonary bypass	CPT-4	Procedure
33256	Operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure); with cardiopulmonary bypass	CPT-4	Procedure
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (eg, modified maze procedure) (List separately in addition to code for primary procedure)	CPT-4	Procedure
33258	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), without cardiopulmonary bypass (List separately in addition to code for primary procedure)	CPT-4	Procedure
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (eg, maze procedure), with cardiopulmonary bypass (List separately in addition to code for primary procedure)	CPT-4	Procedure
33261	Operative ablation of ventricular arrhythmogenic focus with cardiopulmonary bypass	CPT-4	Procedure
33265	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (eg, modified maze procedure), without cardiopulmonary bypass	CPT-4	Procedure
33266	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (eg, maze procedure), without cardiopulmonary bypass	CPT-4	Procedure
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	CPT-4	Procedure

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
93651	Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination	CPT-4	Procedure
93652	Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	CPT-4	Procedure
C1732	Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping	HCPCS	Procedure
C1733	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip	HCPCS	Procedure
C2630	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip	HCPCS	Procedure
Cardioversion			
99.61	Atrial cardioversion	ICD-9-CM	Procedure
99.62	Other electric countershock of heart	ICD-9-CM	Procedure
92960	Cardioversion, elective, electrical conversion of arrhythmia; external	CPT-4	Procedure
92961	Cardioversion, elective, electrical conversion of arrhythmia; internal (separate procedure)	CPT-4	Procedure
Chronic Renal Disease			
585	Chronic kidney disease (CKD)	ICD-9-CM	Dianosis
585.1	Chronic kidney disease, Stage I	ICD-9-CM	Dianosis
585.2	Chronic kidney disease, Stage II (mild)	ICD-9-CM	Dianosis
585.3	Chronic kidney disease, Stage III (moderate)	ICD-9-CM	Dianosis
585.4	Chronic kidney disease, Stage IV (severe)	ICD-9-CM	Dianosis
585.5	Chronic kidney disease, Stage V	ICD-9-CM	Dianosis
585.6	End stage renal disease	ICD-9-CM	Dianosis
585.9	Chronic kidney disease, unspecified	ICD-9-CM	Dianosis
586	Unspecified renal failure	ICD-9-CM	Dianosis
587	Unspecified renal sclerosis	ICD-9-CM	Dianosis
Coronary Revascularization			
V45.81	Postprocedural aortocoronary bypass status	ICD-9-CM	Diagnosis
V45.82	Postprocedural percutaneous transluminal coronary angioplasty status	ICD-9-CM	Diagnosis
V45.88	Status post administration of tPA (rtPA) in a different facility within the last 24 hours prior to admission to current facility	ICD-9-CM	Diagnosis
00.66	Percutaneous transluminal coronary angioplasty [PTCA] or coronary atherectomy	ICD-9-CM	Procedure
36.0	Removal of coronary artery obstruction and insertion of stent(s)	ICD-9-CM	Procedure
36.03	Open chest coronary artery angioplasty	ICD-9-CM	Procedure
36.04	Intracoronary artery thrombolytic infusion	ICD-9-CM	Procedure
36.06	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
36.1	Bypass anastomosis for heart revascularization	ICD-9-CM	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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
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
00566	Anesthesia for direct coronary artery bypass grafting; without 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
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
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
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
35500	Harvest of upper extremity vein, 1 segment, for lower extremity or 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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
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
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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
92995	Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; single vessel	CPT-4	Procedure
92996	Percutaneous transluminal coronary atherectomy, by mechanical or other method, with or without balloon angioplasty; each additional vessel (List separately in addition to code for primary procedure)	CPT-4	Procedure
93540	Injection procedure during cardiac catheterization; for selective opacification of aortocoronary venous bypass grafts, 1 or more coronary arteries	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
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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
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
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

Diabetes

250	Diabetes mellitus	ICD-9-CM	Diagnosis
250.0	Diabetes mellitus without mention of complication	ICD-9-CM	Diagnosis
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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 uncontrolled	ICD-9-CM	Diagnosis
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.8	Diabetes with other specified manifestations	ICD-9-CM	Diagnosis
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.9	Diabetes with unspecified complication	ICD-9-CM	Diagnosis
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multidensity insert(s), per shoe	HCPCS	Procedure
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe	HCPCS	Procedure
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with roller or rigid rocker bottom, per shoe	HCPCS	Procedure
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe	HCPCS	Procedure
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe	HCPCS	Procedure
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe	HCPCS	Procedure
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe	HCPCS	Procedure
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe	HCPCS	Procedure
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe	HCPCS	Procedure
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of Shore A 35 durometer or 3/16 inch material of Shore A 40 durometer (or higher), prefabricated, each	HCPCS	Procedure
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of Shore A 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each	HCPCS	Procedure
G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	HCPCS	Procedure
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes	HCPCS	Procedure

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
G8332	Clinician has not provided care for the diabetic retinopathy patient for the required time for macular edema and retinopathy measurement	HCPCS	Procedure
G8333	Patient documented to have had findings of macular or fundus exam communicated to the physician managing the diabetes care	HCPCS	Procedure
G8334	Documentation of findings of macular or fundus exam not communicated to the physician managing the patient's ongoing diabetes care	HCPCS	Procedure
G8335	Clinician documentation that patient was not an eligible candidate for the findings of their macular or fundus exam being communicated to the physician managing their diabetes care during the reporting year	HCPCS	Procedure
G8336	Clinician has not provided care for the diabetic retinopathy patient for the required time for physician communication measurement	HCPCS	Procedure
G8385	Diabetic patients with no documentation of hemoglobin A1c level (within the last 12 months)	HCPCS	Procedure
G8386	Diabetic patients with no documentation of low-density lipoprotein (within the last 12 months)	HCPCS	Procedure
G8390	Diabetic patients with no documentation of blood pressure measurement (within the last 12 months)	HCPCS	Procedure
Falls			
E880	Accidental fall on or from stairs or steps	ICD-9-CM	
E880.0	Accidental fall on or from escalator	ICD-9-CM	
E880.1	Accidental fall on or from sidewalk curb	ICD-9-CM	
E880.9	Accidental fall on or from other stairs or steps	ICD-9-CM	
E881	Accidental fall on or from ladders or scaffolding	ICD-9-CM	
E881.0	Accidental fall from ladder	ICD-9-CM	
E881.1	Accidental fall from scaffolding	ICD-9-CM	
E882	Accidental fall from or out of building or other structure	ICD-9-CM	
E883	Accidental fall into hole or other opening in surface	ICD-9-CM	
E883.0	Accident from diving or jumping into water (swimming pool)	ICD-9-CM	
E883.1	Accidental fall into well	ICD-9-CM	
E883.2	Accidental fall into storm drain or manhole	ICD-9-CM	
E883.9	Accidental fall into other hole or other opening in surface	ICD-9-CM	
E884	Other accidental fall from one level to another	ICD-9-CM	
E884.0	Accidental fall from playground equipment	ICD-9-CM	
E884.1	Accidental fall from cliff	ICD-9-CM	
E884.2	Accidental fall from chair	ICD-9-CM	
E884.3	Accidental fall from wheelchair	ICD-9-CM	
E884.4	Accidental fall from bed	ICD-9-CM	Diagnosis
E884.5	Accidental fall from other furniture	ICD-9-CM	Diagnosis
E884.6	Accidental fall from commode	ICD-9-CM	Diagnosis
E884.9	Other accidental fall from one level to another	ICD-9-CM	Diagnosis
E885	Accidental fall on same level from slipping, tripping, or stumbling	ICD-9-CM	Diagnosis
E885.0	Fall on same level from (nonmotorized) scooter	ICD-9-CM	Diagnosis
E885.1	Fall from roller skates	ICD-9-CM	Diagnosis
E885.2	Fall from skateboard	ICD-9-CM	Diagnosis
E885.3	Fall from skis	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
E885.4	Fall from snowboard	ICD-9-CM	Diagnosis
E885.9	Fall from other slipping, tripping, or stumbling	ICD-9-CM	Diagnosis
E886	Accidental fall on same level from collision, pushing, or shoving, by or with other person	ICD-9-CM	Diagnosis
E886.0	Accidental fall on same level from collision, pushing, or shoving, by or with other person in sports	ICD-9-CM	Diagnosis
E886.9	Other and unspecified accidental falls on same level from collision, pushing, or shoving, by or with other person	ICD-9-CM	Diagnosis
E887	Fracture in accidental fall, cause unspecified	ICD-9-CM	Diagnosis
E888	Other and unspecified accidental fall	ICD-9-CM	Diagnosis
E888.0	Fall resulting in striking against sharp object	ICD-9-CM	Diagnosis
E888.1	Fall resulting in striking against other object	ICD-9-CM	Diagnosis
E888.8	Other fall	ICD-9-CM	Diagnosis
E888.9	Unspecified fall	ICD-9-CM	Diagnosis
E917.6	Strike against or struck accidentally by crowd, by collective fear or panic with subsequent fall	ICD-9-CM	Diagnosis
E917.7	Strike against or struck accidentally by furniture with subsequent fall	ICD-9-CM	Diagnosis
E917.8	Strike against or struck accidentally by other stationary object with subsequent fall	ICD-9-CM	Diagnosis
E917.9	Other accident caused by striking against or being struck accidentally by objects or persons	ICD-9-CM	Diagnosis
E929.3	Late effects of accidental fall	ICD-9-CM	Diagnosis
Fractures			
807.0	Closed fracture of rib(s)	ICD-9-CM	Diagnosis
807.00	Closed fracture of rib(s), unspecified	ICD-9-CM	Diagnosis
807.01	Closed fracture of one rib	ICD-9-CM	Diagnosis
807.02	Closed fracture of two ribs	ICD-9-CM	Diagnosis
807.03	Closed fracture of three ribs	ICD-9-CM	Diagnosis
807.04	Closed fracture of four ribs	ICD-9-CM	Diagnosis
807.05	Closed fracture of five ribs	ICD-9-CM	Diagnosis
807.06	Closed fracture of six ribs	ICD-9-CM	Diagnosis
807.07	Closed fracture of seven ribs	ICD-9-CM	Diagnosis
807.08	Closed fracture of eight or more ribs	ICD-9-CM	Diagnosis
807.09	Closed fracture of multiple ribs, unspecified	ICD-9-CM	Diagnosis
807.1	Open fracture of rib(s)	ICD-9-CM	Diagnosis
807.10	Open fracture of rib(s), unspecified	ICD-9-CM	Diagnosis
807.11	Open fracture of one rib	ICD-9-CM	Diagnosis
807.12	Open fracture of two ribs	ICD-9-CM	Diagnosis
807.13	Open fracture of three ribs	ICD-9-CM	Diagnosis
807.14	Open fracture of four ribs	ICD-9-CM	Diagnosis
807.15	Open fracture of five ribs	ICD-9-CM	Diagnosis
807.16	Open fracture of six ribs	ICD-9-CM	Diagnosis
807.17	Open fracture of seven ribs	ICD-9-CM	Diagnosis
807.18	Open fracture of eight or more ribs	ICD-9-CM	Diagnosis
807.19	Open fracture of multiple ribs, unspecified	ICD-9-CM	Diagnosis
810	Fracture of clavicle	ICD-9-CM	Diagnosis
810.0	Closed fracture of clavicle	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
810.00	Unspecified part of closed fracture of clavicle	ICD-9-CM	Diagnosis
810.01	Closed fracture of sternal end of clavicle	ICD-9-CM	Diagnosis
810.02	Closed fracture of shaft of clavicle	ICD-9-CM	Diagnosis
810.03	Closed fracture of acromial end of clavicle	ICD-9-CM	Diagnosis
810.1	Open fracture of clavicle	ICD-9-CM	Diagnosis
810.10	Unspecified part of open fracture of clavicle	ICD-9-CM	Diagnosis
810.11	Open fracture of sternal end of clavicle	ICD-9-CM	Diagnosis
810.12	Open fracture of shaft of clavicle	ICD-9-CM	Diagnosis
810.13	Open fracture of acromial end of clavicle	ICD-9-CM	Diagnosis
813	Fracture of radius and ulna	ICD-9-CM	Diagnosis
813.0	Closed fracture of upper end of radius and ulna	ICD-9-CM	Diagnosis
813.00	Unspecified fracture of radius and ulna, upper end of forearm, closed	ICD-9-CM	Diagnosis
813.01	Closed fracture of olecranon process of ulna	ICD-9-CM	Diagnosis
813.02	Closed fracture of coronoid process of ulna	ICD-9-CM	Diagnosis
813.03	Closed Monteggia's fracture	ICD-9-CM	Diagnosis
813.04	Other and unspecified closed fractures of proximal end of ulna (alone)	ICD-9-CM	Diagnosis
813.05	Closed fracture of head of radius	ICD-9-CM	Diagnosis
813.06	Closed fracture of neck of radius	ICD-9-CM	Diagnosis
813.07	Other and unspecified closed fractures of proximal end of radius (alone)	ICD-9-CM	Diagnosis
813.08	Closed fracture of radius with ulna, upper end (any part)	ICD-9-CM	Diagnosis
813.1	Open fracture of upper end of radius and ulna	ICD-9-CM	Diagnosis
813.10	Unspecified open fracture of upper end of forearm	ICD-9-CM	Diagnosis
813.11	Open fracture of olecranon process of ulna	ICD-9-CM	Diagnosis
813.12	Open fracture of coronoid process of ulna	ICD-9-CM	Diagnosis
813.13	Open Monteggia's fracture	ICD-9-CM	Diagnosis
813.14	Other and unspecified open fractures of proximal end of ulna (alone)	ICD-9-CM	Diagnosis
813.15	Open fracture of head of radius	ICD-9-CM	Diagnosis
813.16	Open fracture of neck of radius	ICD-9-CM	Diagnosis
813.17	Other and unspecified open fractures of proximal end of radius (alone)	ICD-9-CM	Diagnosis
813.18	Open fracture of radius with ulna, upper end (any part)	ICD-9-CM	Diagnosis
813.2	Closed fracture of shaft of radius and ulna	ICD-9-CM	Diagnosis
813.20	Unspecified closed fracture of shaft of radius or ulna	ICD-9-CM	Diagnosis
813.21	Closed fracture of shaft of radius (alone)	ICD-9-CM	Diagnosis
813.22	Closed fracture of shaft of ulna (alone)	ICD-9-CM	Diagnosis
813.23	Closed fracture of shaft of radius with ulna	ICD-9-CM	Diagnosis
813.3	Open fracture of shaft of radius and ulna	ICD-9-CM	Diagnosis
813.30	Unspecified open fracture of shaft of radius or ulna	ICD-9-CM	Diagnosis
813.31	Open fracture of shaft of radius (alone)	ICD-9-CM	Diagnosis
813.32	Open fracture of shaft of ulna (alone)	ICD-9-CM	Diagnosis
813.33	Open fracture of shaft of radius with ulna	ICD-9-CM	Diagnosis
813.4	Closed fracture of lower end of radius and ulna	ICD-9-CM	Diagnosis
813.40	Unspecified closed fracture of lower end of forearm	ICD-9-CM	Diagnosis
813.41	Closed Colles' fracture	ICD-9-CM	Diagnosis
813.42	Other closed fractures of distal end of radius (alone)	ICD-9-CM	Diagnosis
813.43	Closed fracture of distal end of ulna (alone)	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
813.44	Closed fracture of lower end of radius with ulna	ICD-9-CM	Diagnosis
813.45	Torus fracture of radius (alone)	ICD-9-CM	Diagnosis
813.46	Torus fracture of ulna (alone)	ICD-9-CM	Diagnosis
813.47	Torus fracture of radius and ulna	ICD-9-CM	Diagnosis
813.5	Open fracture of lower end of radius and ulna	ICD-9-CM	Diagnosis
813.50	Unspecified open fracture of lower end of forearm	ICD-9-CM	Diagnosis
813.51	Open Colles' fracture	ICD-9-CM	Diagnosis
813.52	Other open fractures of distal end of radius (alone)	ICD-9-CM	Diagnosis
813.53	Open fracture of distal end of ulna (alone)	ICD-9-CM	Diagnosis
813.54	Open fracture of lower end of radius with ulna	ICD-9-CM	Diagnosis
813.8	Closed fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
813.80	Closed fracture of unspecified part of forearm	ICD-9-CM	Diagnosis
813.81	Closed fracture of unspecified part of radius (alone)	ICD-9-CM	Diagnosis
813.82	Closed fracture of unspecified part of ulna (alone)	ICD-9-CM	Diagnosis
813.83	Closed fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
813.9	Open fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
813.90	Open fracture of unspecified part of forearm	ICD-9-CM	Diagnosis
813.91	Open fracture of unspecified part of radius (alone)	ICD-9-CM	Diagnosis
813.92	Open fracture of unspecified part of ulna (alone)	ICD-9-CM	Diagnosis
813.93	Open fracture of unspecified part of radius with ulna	ICD-9-CM	Diagnosis
820	Fracture of neck of femur	ICD-9-CM	Diagnosis
820.0	Closed transcervical fracture	ICD-9-CM	Diagnosis
820.00	Closed fracture of unspecified intracapsular section of neck of femur	ICD-9-CM	Diagnosis
820.01	Closed fracture of epiphysis (separation) (upper) of neck of femur	ICD-9-CM	Diagnosis
820.02	Closed fracture of midcervical section of femur	ICD-9-CM	Diagnosis
820.03	Closed fracture of base of neck of femur	ICD-9-CM	Diagnosis
820.09	Other closed transcervical fracture of femur	ICD-9-CM	Diagnosis
820.1	Open transcervical fracture	ICD-9-CM	Diagnosis
820.10	Open fracture of unspecified intracapsular section of neck of femur	ICD-9-CM	Diagnosis
820.11	Open fracture of epiphysis (separation) (upper) of neck of femur	ICD-9-CM	Diagnosis
820.12	Open fracture of midcervical section of femur	ICD-9-CM	Diagnosis
820.13	Open fracture of base of neck of femur	ICD-9-CM	Diagnosis
820.19	Other open transcervical fracture of femur	ICD-9-CM	Diagnosis
820.2	Closed pertrochanteric fracture of femur	ICD-9-CM	Diagnosis
820.20	Closed fracture of unspecified trochanteric section of femur	ICD-9-CM	Diagnosis
820.21	Closed fracture of intertrochanteric section of femur	ICD-9-CM	Diagnosis
820.22	Closed fracture of subtrochanteric section of femur	ICD-9-CM	Diagnosis
820.3	Open pertrochanteric fracture of femur	ICD-9-CM	Diagnosis
820.30	Open fracture of unspecified trochanteric section of femur	ICD-9-CM	Diagnosis
820.31	Open fracture of intertrochanteric section of femur	ICD-9-CM	Diagnosis
820.32	Open fracture of subtrochanteric section of femur	ICD-9-CM	Diagnosis
820.8	Closed fracture of unspecified part of neck of femur	ICD-9-CM	Diagnosis
820.9	Open fracture of unspecified part of neck of femur	ICD-9-CM	Diagnosis
78.11	Application of external fixator device, scapula, clavicle, and thorax [ribs and sternum]	ICD-9-CM	Procedure
78.13	Application of external fixator device, radius and ulna	ICD-9-CM	Procedure

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
78.15	Application of external fixator device, femur	ICD-9-CM	Procedure
78.41	Other repair or plastic operations on scapula, clavicle, and thorax (ribs and sternum)	ICD-9-CM	Procedure
78.43	Other repair or plastic operations on radius and ulna	ICD-9-CM	Procedure
78.45	Other repair or plastic operations on femur	ICD-9-CM	Procedure
78.51	Internal fixation of scapula, clavicle, and thorax (ribs and sternum) without fracture reduction	ICD-9-CM	Procedure
78.53	Internal fixation of radius and ulna without fracture reduction	ICD-9-CM	Procedure
78.55	Internal fixation of femur without fracture reduction	ICD-9-CM	Procedure
78.61	Removal of implanted device from scapula, clavicle, and thorax (ribs and sternum)	ICD-9-CM	Procedure
78.63	Removal of implanted device from radius and ulna	ICD-9-CM	Procedure
78.65	Removal of implanted device from femur	ICD-9-CM	Procedure
79.02	Closed reduction of fracture of radius and ulna without internal fixation	ICD-9-CM	Procedure
79.05	Closed reduction of fracture of femur without internal fixation	ICD-9-CM	Procedure
79.12	Closed reduction of fracture of radius and ulna with internal fixation	ICD-9-CM	Procedure
79.15	Closed reduction of fracture of femur with internal fixation	ICD-9-CM	Procedure
79.22	Open reduction of fracture of radius and ulna without internal fixation	ICD-9-CM	Procedure
79.25	Open reduction of fracture of femur without internal fixation	ICD-9-CM	Procedure
79.32	Open reduction of fracture of radius and ulna with internal fixation	ICD-9-CM	Procedure
79.35	Open reduction of fracture of femur with internal fixation	ICD-9-CM	Procedure
79.62	Debridement of open fracture of radius and ulna	ICD-9-CM	Procedure
79.65	Debridement of open fracture of femur	ICD-9-CM	Procedure
21800	Closed treatment of broken rib	CPT-4	Procedure
21805	Open treatment of broken rib	CPT-4	Procedure
21810	Treatment of broken rib	CPT-4	Procedure
21812	Open treatment of broken ribs with insertion of hardware	CPT-4	Procedure
21813	Open treatment of broken ribs with insertion of hardware	CPT-4	Procedure
23485	Incision to repair collar bone for nonunion of fracture with bone graft	CPT-4	Procedure
23500	Closed treatment of collar bone fracture	CPT-4	Procedure
23505	Closed treatment of collar bone broken with manipulation	CPT-4	Procedure
23515	Open treatment of collar bone broken	CPT-4	Procedure
24586	Open treatment of broken and/or dislocated upper or lower arm bones at elbow	CPT-4	Procedure
24587	Open treatment of broken and/or dislocated upper or lower arm bones at elbow with implant	CPT-4	Procedure
24620	Closed treatment of broken and dislocated forearm bones at elbow with manipulation	CPT-4	Procedure
24635	Open treatment of broken and dislocated forearm bones at elbow	CPT-4	Procedure
24650	Closed treatment of broken forearm bone at elbow	CPT-4	Procedure
24655	Closed treatment of broken forearm bone at elbow with manipulation	CPT-4	Procedure
24665	Open treatment of broken forearm bone at elbow	CPT-4	Procedure
24666	Open treatment of broken forearm bone at elbow with prosthetic replacement	CPT-4	Procedure
24670	Closed treatment of broken forearm bone at elbow	CPT-4	Procedure
24675	Closed treatment of broken forearm bone at elbow with manipulation	CPT-4	Procedure
24685	Open treatment of broken forearm bone at elbow	CPT-4	Procedure
25500	Closed treatment of broken forearm bone	CPT-4	Procedure
25505	Closed treatment of broken forearm bone with manipulation	CPT-4	Procedure
25515	Open treatment of broken forearm bone	CPT-4	Procedure

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Code	Description	Code Type	Code Category
25520	Closed treatment of broken forearm and dislocated wrist bones	CPT-4	Procedure
25525	Open treatment of broken forearm bone and closed treatment of joint dislocation	CPT-4	Procedure
25526	Open treatment of broken forearm bone	CPT-4	Procedure
25530	Closed treatment of broken forearm bone	CPT-4	Procedure
25535	Closed treatment of broken forearm bone with manipulation	CPT-4	Procedure
25545	Open treatment of broken forearm bone	CPT-4	Procedure
25560	Closed treatment of broken forearm bones	CPT-4	Procedure
25565	Closed treatment of broken forearm bones with manipulation	CPT-4	Procedure
25574	Open treatment of broken forearm bones	CPT-4	Procedure
25575	Open treatment of broken forearm bones	CPT-4	Procedure
25600	Closed treatment of broken forearm bones	CPT-4	Procedure
25605	Closed treatment of broken or growth plate separate of forearm bone at wrist with manipulation	CPT-4	Procedure
25606	Insertion of hardware to lower forearm bone broken or growth plate separation, accessed through the skin	CPT-4	Procedure
25607	Open treatment of broken or lower forearm bone or growth plate separation with insertion of hardware	CPT-4	Procedure
25608	Open treatment of broken of lower forearm or growth plate separation with insertion of hardware of 2 fragments	CPT-4	Procedure
25609	Open treatment of broken of lower forearm or growth plate separation with insertion of hardware of 3 or more fragments	CPT-4	Procedure
25611	Percutaneous skeletal fixation of distal radial fracture (eg, colles or smith type) or epiphyseal separation, with or without fracture of ulnar styloid, requiring manipulation, with or without external fixation	CPT-4	Procedure
25620	Open treatment of distal radial fracture (eg, colles or smith type) or epiphyseal separation, with or without fracture of ulnar styloid, with or without internal or external fixation	CPT-4	Procedure
25650	Closed treatment of broken forearm bone at wrist bone	CPT-4	Procedure
25651	Insertion of hardware broken bone of forearm at wrist, accessed through the skin	CPT-4	Procedure
25652	Open treatment of broken wrist	CPT-4	Procedure
27230	Closed treatment of upper thigh bone fracture	CPT-4	Procedure
27232	Closed treatment of thigh bone fracture with manipulation	CPT-4	Procedure
27235	Insertion of hardware to broken thigh bone, accessed through the skin	CPT-4	Procedure
27236	Open treatment of broken thigh bone with insertion of hardware or prosthetic replacement	CPT-4	Procedure
27238	Closed treatment of fracture below neck of upper thigh bone	CPT-4	Procedure
27240	Closed treatment of broken thigh bone with manipulation	CPT-4	Procedure
27244	Surgical treatment of broken thigh bone	CPT-4	Procedure
27245	Surgical treatment of broken thigh bone	CPT-4	Procedure
27246	Closed treatment of broken thigh bone	CPT-4	Procedure
27248	Open treatment of broken thigh bone	CPT-4	Procedure
27254	Open treatment of fracture and traumatic dislocation of hip socket and thigh bone	CPT-4	Procedure
27267	Closed treatment of broken thigh bone	CPT-4	Procedure
27268	Closed treatment of fracture of upper portion and head of thigh bone with manipulation	CPT-4	Procedure
27269	Open treatment of fracture of thigh bone	CPT-4	Procedure

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Code	Description	Code Type	Code Category
27500	Closed treatment of thigh bone fracture	CPT-4	Procedure
27501	Closed treatment of broken thigh bone	CPT-4	Procedure
27502	Closed treatment of broken thigh bone with manipulation	CPT-4	Procedure
27503	Closed treatment of broken thigh bone with manipulation	CPT-4	Procedure
27506	Open treatment of broken thigh bone	CPT-4	Procedure
27507	Open treatment of broken thigh bone	CPT-4	Procedure
27508	Closed treatment of broken thigh bone	CPT-4	Procedure
27509	Insertion of hardware to stabilize broken thigh bone or separated growth plate, accessed through the skin	CPT-4	Procedure
27510	Closed treatment of broken thigh bone with manipulation	CPT-4	Procedure
27511	Open treatment of broken thigh bone	CPT-4	Procedure
27513	Open treatment of broken thigh bone	CPT-4	Procedure
27514	Open treatment of broken thigh bone	CPT-4	Procedure
Heart Failure			
402.01	Malignant hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.11	Benign hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.91	Hypertensive heart disease, unspecified, 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	Unspecified systolic heart failure	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	Unspecified diastolic heart failure	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	Unspecified combined systolic and diastolic heart failure	ICD-9-CM	Diagnosis
428.41	Acute combined systolic and diastolic heart failure	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
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	Unspecified heart failure	ICD-9-CM	Diagnosis
37.66	Insertion of implantable heart assist system	ICD-9-CM	Procedure
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle	CPT-4	Procedure
92970	Cardioassist-method of circulatory assist; internal	CPT-4	Procedure
92971	Cardioassist-method of circulatory assist; external	CPT-4	Procedure
G8027	Heart failure patient with left ventricular systolic dysfunction (LVSD) documented to be on either angiotensin-converting enzyme-inhibitor or angiotensin-receptor blocker (ACE-1 or ARB) therapy	HCPCS	Procedure
G8028	Heart failure patient with left ventricular systolic dysfunction (LVSD) not documented to be on either angiotensin-converting enzyme-inhibitor or angiotensin-receptor blocker (ACE-1 or ARB) therapy	HCPCS	Procedure
G8029	Clinician documented that heart failure patient was not an eligible candidate for either angiotensin-converting enzyme-inhibitor or angiotensin-receptor blocker (ACE-1 or ARB) therapy measure	HCPCS	Procedure
G8030	Heart failure patient with left ventricular systolic dysfunction (LVSD) documented to be on beta-blocker therapy	HCPCS	Procedure
G8031	Heart failure patient with left ventricular systolic dysfunction (LVSD) not documented to be on beta-blocker therapy	HCPCS	Procedure
G8032	Clinician documented that heart failure patient was not eligible candidate for beta-blocker therapy measure	HCPCS	Procedure
G8184	Clinician documented that patient with heart failure and atrial fibrillation was not an eligible candidate for warfarin therapy measure	HCPCS	Procedure
G8184	Clinician documented that patient with heart failure and atrial fibrillation was not an eligible candidate for warfarin therapy measure	HCPCS	Procedure
Hospitalized Bleeding			
280.0	Iron deficiency anemia secondary to blood loss (chronic)	ICD-9-CM	Diagnosis
285.1	Acute posthemorrhagic anemia	ICD-9-CM	Diagnosis
285.9	Unspecified anemia	ICD-9-CM	Diagnosis
423.0	Hemopericardium	ICD-9-CM	Diagnosis
430	Subarachnoid hemorrhage	ICD-9-CM	Diagnosis
431	Intracerebral hemorrhage	ICD-9-CM	Diagnosis
432.0	Nontraumatic extradural hemorrhage	ICD-9-CM	Diagnosis
432.1	Subdural hemorrhage	ICD-9-CM	Diagnosis
432.9	Unspecified intracranial hemorrhage	ICD-9-CM	Diagnosis
455	Hemorrhoids	ICD-9-CM	Diagnosis
455.0	Internal hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.1	Internal thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.2	Internal hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.3	External hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.4	External thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.5	External hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.6	Unspecified hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.7	Unspecified thrombosed hemorrhoids	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.9	Residual hemorrhoidal skin tags	ICD-9-CM	Diagnosis
456.0	Esophageal varices with bleeding	ICD-9-CM	Diagnosis
456.20	Esophageal varices with bleeding in diseases classified elsewhere	ICD-9-CM	Diagnosis
459.0	Unspecified hemorrhage	ICD-9-CM	Diagnosis
530.1	Esophagitis	ICD-9-CM	Diagnosis
530.10	Unspecified esophagitis	ICD-9-CM	Diagnosis
530.11	Reflux esophagitis	ICD-9-CM	Diagnosis
530.12	Acute esophagitis	ICD-9-CM	Diagnosis
530.13	Eosinophilic esophagitis	ICD-9-CM	Diagnosis
530.19	Other esophagitis	ICD-9-CM	Diagnosis
530.7	Gastroesophageal laceration-hemorrhage syndrome	ICD-9-CM	Diagnosis
530.82	Esophageal hemorrhage	ICD-9-CM	Diagnosis
531.0	Acute gastric ulcer with hemorrhage	ICD-9-CM	Diagnosis
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.1	Acute gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.10	Acute gastric ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.11	Acute gastric ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
531.2	Acute gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.3	Acute gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.30	Acute gastric ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
531.31	Acute gastric ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
531.4	Chronic or unspecified gastric ulcer with hemorrhage	ICD-9-CM	Diagnosis
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.5	Chronic or unspecified gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.50	Chronic or unspecified gastric ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.51	Chronic or unspecified gastric ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
531.6	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.7	Chronic gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.70	Chronic gastric ulcer without mention of hemorrhage, perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.71	Chronic gastric ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
531.9	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.90	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
531.91	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
532.0	Acute duodenal ulcer with hemorrhage	ICD-9-CM	Diagnosis
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.1	Acute duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.10	Acute duodenal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.11	Acute duodenal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
532.2	Acute duodenal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.3	Acute duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.30	Acute duodenal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
532.31	Acute duodenal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
532.4	Chronic or unspecified duodenal ulcer with hemorrhage	ICD-9-CM	Diagnosis
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.5	Chronic or unspecified duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.50	Chronic or unspecified duodenal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.51	Chronic or unspecified duodenal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
532.6	Chronic or unspecified duodenal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.7	Chronic duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.70	Chronic duodenal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
532.71	Chronic duodenal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
532.9	Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.90	Duodenal ulcer, unspecified as acute or chronic, without hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
532.91	Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
533.0	Acute peptic ulcer, unspecified site, with hemorrhage	ICD-9-CM	Diagnosis
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.1	Acute peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.10	Acute peptic ulcer, unspecified site, with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.11	Acute peptic ulcer, unspecified site, with perforation and obstruction	ICD-9-CM	Diagnosis
533.2	Acute peptic ulcer, unspecified site, with hemorrhage and perforation	ICD-9-CM	Diagnosis
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.3	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation	ICD-9-CM	Diagnosis
533.30	Acute peptic ulcer, unspecified site, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
533.31	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation, with obstruction	ICD-9-CM	Diagnosis
533.4	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage	ICD-9-CM	Diagnosis
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.5	Chronic or unspecified peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.50	Chronic or unspecified peptic ulcer, unspecified site, with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.51	Chronic or unspecified peptic ulcer, unspecified site, with perforation and obstruction	ICD-9-CM	Diagnosis
533.6	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation	ICD-9-CM	Diagnosis
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.7	Chronic peptic ulcer, unspecified site, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.70	Chronic peptic ulcer, unspecified site, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
533.71	Chronic peptic ulcer of unspecified site without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
533.9	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.90	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
533.91	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
534.0	Acute gastrojejunal ulcer with hemorrhage	ICD-9-CM	Diagnosis
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.1	Acute gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.10	Acute gastrojejunal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.11	Acute gastrojejunal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
534.2	Acute gastrojejunal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.3	Acute gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.30	Acute gastrojejunal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
534.31	Acute gastrojejunal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
534.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage	ICD-9-CM	Diagnosis
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.5	Chronic or unspecified gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis

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Code	Description	Code Type	Code Category
534.50	Chronic or unspecified gastrojejunal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.51	Chronic or unspecified gastrojejunal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
534.6	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.7	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.70	Chronic gastrojejunal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
534.71	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
534.9	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.90	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
534.91	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
535.00	Acute gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.01	Acute gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.10	Atrophic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.11	Atrophic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.20	Gastric mucosal hypertrophy without mention of hemorrhage	ICD-9-CM	Diagnosis
535.21	Gastric mucosal hypertrophy with hemorrhage	ICD-9-CM	Diagnosis
535.30	Alcoholic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.31	Alcoholic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.40	Other specified gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.41	Other specified gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.50	Unspecified gastritis and gastroduodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.51	Unspecified gastritis and gastroduodenitis with hemorrhage	ICD-9-CM	Diagnosis
535.60	Duodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.61	Duodenitis with hemorrhage	ICD-9-CM	Diagnosis
537.83	Angiodysplasia of stomach and duodenum with hemorrhage	ICD-9-CM	Diagnosis
562.00	Diverticulosis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.01	Diverticulitis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.02	Diverticulosis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.03	Diverticulitis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.10	Diverticulosis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.11	Diverticulitis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.12	Diverticulosis of colon with hemorrhage	ICD-9-CM	Diagnosis
562.13	Diverticulitis of colon with hemorrhage	ICD-9-CM	Diagnosis
568.81	Hemoperitoneum (nontraumatic)	ICD-9-CM	Diagnosis
569.3	Hemorrhage of rectum and anus	ICD-9-CM	Diagnosis
569.85	Angiodysplasia of intestine with hemorrhage	ICD-9-CM	Diagnosis
578.0	Hematemesis	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
578.1	Blood in stool	ICD-9-CM	Diagnosis
578.9	Hemorrhage of gastrointestinal tract, unspecified	ICD-9-CM	Diagnosis
593.81	Vascular disorders of kidney	ICD-9-CM	Diagnosis
599.7	Hematuria	ICD-9-CM	Diagnosis
599.70	Hematuria, unspecified	ICD-9-CM	Diagnosis
599.71	Gross hematuria	ICD-9-CM	Diagnosis
599.72	Microscopic hematuria	ICD-9-CM	Diagnosis
623.8	Other specified noninflammatory disorder of vagina	ICD-9-CM	Diagnosis
626.2	Excessive or frequent menstruation	ICD-9-CM	Diagnosis
626.6	Metrorrhagia	ICD-9-CM	Diagnosis
719.1	Hemarthrosis	ICD-9-CM	Diagnosis
719.10	Hemarthrosis, site unspecified	ICD-9-CM	Diagnosis
719.11	Hemarthrosis, shoulder region	ICD-9-CM	Diagnosis
719.12	Hemarthrosis, upper arm	ICD-9-CM	Diagnosis
719.13	Hemarthrosis, forearm	ICD-9-CM	Diagnosis
719.14	Hemarthrosis, hand	ICD-9-CM	Diagnosis
719.15	Hemarthrosis, pelvic region and thigh	ICD-9-CM	Diagnosis
719.16	Hemarthrosis, lower leg	ICD-9-CM	Diagnosis
719.17	Hemarthrosis, ankle and foot	ICD-9-CM	Diagnosis
719.18	Hemarthrosis, other specified site	ICD-9-CM	Diagnosis
719.19	Hemarthrosis, multiple sites	ICD-9-CM	Diagnosis
784.7	Epistaxis	ICD-9-CM	Diagnosis
784.8	Hemorrhage from throat	ICD-9-CM	Diagnosis
786.3	Hemoptysis	ICD-9-CM	Diagnosis
790.92	Abnormal coagulation profile	ICD-9-CM	Diagnosis
852.0	Subarachnoid hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.00	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.01	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.02	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
852.03	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.04	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.05	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.06	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.09	Subarachnoid hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
852.2	Subdural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
852.20	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.21	Subdural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.22	Subdural hemorrhage following injury, without mention of open intracranial wound, brief (less than one hour) loss of consciousness	ICD-9-CM	Diagnosis
852.23	Subdural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.24	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.25	Subdural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.26	Subdural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.29	Subdural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
852.4	Extradural hemorrhage following injury without mention of open intracranial wound	ICD-9-CM	Diagnosis
852.40	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified state of consciousness	ICD-9-CM	Diagnosis
852.41	Extradural hemorrhage following injury, without mention of open intracranial wound, no loss of consciousness	ICD-9-CM	Diagnosis
852.42	Extradural hemorrhage following injury, without mention of open intracranial wound, brief (less than 1 hour) loss of consciousness	ICD-9-CM	Diagnosis
852.43	Extradural hemorrhage following injury, without mention of open intracranial wound, moderate (1-24 hours) loss of consciousness	ICD-9-CM	Diagnosis
852.44	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness and return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.45	Extradural hemorrhage following injury, without mention of open intracranial wound, prolonged (more than 24 hours) loss of consciousness, without return to pre-existing conscious level	ICD-9-CM	Diagnosis
852.46	Extradural hemorrhage following injury, without mention of open intracranial wound, loss of consciousness of unspecified duration	ICD-9-CM	Diagnosis
852.49	Extradural hemorrhage following injury, without mention of open intracranial wound, unspecified concussion	ICD-9-CM	Diagnosis
853.0	Other and unspecified intracranial hemorrhage following injury, without mention of open intracranial wound	ICD-9-CM	Diagnosis
Hypercholesterolemia			
272.0	Pure hypercholesterolemia	ICD-9-CM	Diagnosis
272.2	Mixed hyperlipidemia	ICD-9-CM	Diagnosis
Hypertension			
401	Essential hypertension	ICD-9-CM	Diagnosis
401.0	Essential hypertension, malignant	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
Nicotine Dependency			
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
D1320	tobacco counseling for the control and prevention of oral disease	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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
G8094	Newly diagnosed chronic obstructive pulmonary disease (COPD) patient not documented to have received smoking cessation intervention, within 3 months of diagnosis	HCPCS	Procedure
G8402	Tobacco (smoke) use cessation intervention, counseling	HCPCS	Procedure
G8403	Tobacco (smoke) use cessation intervention not counseled	HCPCS	Procedure
G8453	Tobacco use cessation intervention, counseling	HCPCS	Procedure
G8454	Tobacco use cessation intervention not counseled, reason not specified	HCPCS	Procedure
G8455	Current tobacco smoker	HCPCS	Procedure
G8690	Current tobacco smoker or current 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
G9276	Documentation that patient is a current tobacco user	HCPCS	Procedure
G9458	Patient documented as tobacco user and received tobacco cessation intervention (must include at least one of the following: advice given to quit smoking or tobacco use, counseling on the benefits of quitting smoking or tobacco use, assistance with or referral to external smoking or tobacco cessation support programs, or current enrollment in smoking or tobacco use cessation program) if identified as a tobacco user	HCPCS	Procedure
Obesity			
278.0	Overweight and obesity	ICD-9-CM	Diagnosis
278.00	Obesity, unspecified	ICD-9-CM	Diagnosis
278.01	Morbid obesity	ICD-9-CM	Diagnosis
278.02	Overweight	ICD-9-CM	Diagnosis
278.1	Localized adiposity	ICD-9-CM	Diagnosis
V45.86	Bariatric surgery status	ICD-9-CM	Diagnosis
V85.3	Body Mass Index between 30-39, adult	ICD-9-CM	Diagnosis
V85.30	Body Mass Index 30.0-30.9, adult	ICD-9-CM	Diagnosis
V85.31	Body Mass Index 31.0-31.9, adult	ICD-9-CM	Diagnosis
V85.32	Body Mass Index 32.0-32.9, adult	ICD-9-CM	Diagnosis
V85.33	Body Mass Index 33.0-33.9, adult	ICD-9-CM	Diagnosis
V85.34	Body Mass Index 34.0-34.9, adult	ICD-9-CM	Diagnosis
V85.35	Body Mass Index 35.0-35.9, adult	ICD-9-CM	Diagnosis
V85.36	Body Mass Index 36.0-36.9, adult	ICD-9-CM	Diagnosis
V85.37	Body Mass Index 37.0-37.9, adult	ICD-9-CM	Diagnosis
V85.38	Body Mass Index 38.0-38.9, adult	ICD-9-CM	Diagnosis
V85.39	Body Mass Index 39.0-39.9, adult	ICD-9-CM	Diagnosis
V85.4	Body Mass Index 40 and over, adult	ICD-9-CM	Diagnosis
44.31	High gastric bypass	ICD-9-CM	Procedure
44.68	Laparoscopic gastroplasty	ICD-9-CM	Procedure
44.95	Laparoscopic gastric restrictive procedure	ICD-9-CM	Procedure
Other Ischemic Heart Disease			
411	Other acute and subacute forms of ischemic heart disease	ICD-9-CM	Diagnosis
411.0	Postmyocardial infarction syndrome	ICD-9-CM	Diagnosis
411.1	Intermediate coronary syndrome	ICD-9-CM	Diagnosis
411.8	Other acute and subacute forms of ischemic heart disease	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
411.81	Acute coronary occlusion without myocardial infarction	ICD-9-CM	Diagnosis
411.89	Other acute and subacute form of ischemic heart disease	ICD-9-CM	Diagnosis
413	Angina pectoris	ICD-9-CM	Diagnosis
413.0	Angina decubitus	ICD-9-CM	Diagnosis
413.1	Prinzmetal angina	ICD-9-CM	Diagnosis
413.9	Other and unspecified angina pectoris	ICD-9-CM	Diagnosis
414	Other forms of chronic ischemic heart disease	ICD-9-CM	Diagnosis
414.0	Coronary atherosclerosis	ICD-9-CM	Diagnosis
414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft	ICD-9-CM	Diagnosis
414.01	Coronary atherosclerosis of native coronary artery	ICD-9-CM	Diagnosis
414.02	Coronary atherosclerosis of autologous vein bypass graft	ICD-9-CM	Diagnosis
414.03	Coronary atherosclerosis of nonautologous biological bypass graft	ICD-9-CM	Diagnosis
414.04	Coronary atherosclerosis of artery bypass graft	ICD-9-CM	Diagnosis
414.05	Coronary atherosclerosis of unspecified type of bypass graft	ICD-9-CM	Diagnosis
414.06	Coronary atherosclerosis, of native coronary artery of transplanted heart	ICD-9-CM	Diagnosis
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart	ICD-9-CM	Diagnosis
414.1	Aneurysm and dissection of heart	ICD-9-CM	Diagnosis
414.10	Aneurysm of heart	ICD-9-CM	Diagnosis
414.11	Aneurysm of coronary vessels	ICD-9-CM	Diagnosis
414.12	Dissection of coronary artery	ICD-9-CM	Diagnosis
414.19	Other aneurysm of heart	ICD-9-CM	Diagnosis
414.2	Chronic total occlusion of coronary artery	ICD-9-CM	Diagnosis
414.3	Coronary atherosclerosis due to lipid rich plaque	ICD-9-CM	Diagnosis
414.4	Coronary atherosclerosis due to calcified coronary lesion	ICD-9-CM	Diagnosis
414.8	Other specified forms of chronic ischemic heart disease	ICD-9-CM	Diagnosis
414.9	Unspecified chronic ischemic heart disease	ICD-9-CM	Diagnosis
429.2	Unspecified cardiovascular disease	ICD-9-CM	Diagnosis
429.5	Rupture of chordae tendineae	ICD-9-CM	Diagnosis
429.6	Rupture of papillary muscle	ICD-9-CM	Diagnosis
429.7	Certain sequelae of myocardial infarction, not elsewhere classified	ICD-9-CM	Diagnosis
429.71	Acquired cardiac septal defect	ICD-9-CM	Diagnosis
429.79	Other certain sequelae of myocardial infarction, not elsewhere classified	ICD-9-CM	Diagnosis
429.9	Unspecified heart disease	ICD-9-CM	Diagnosis
G8033	Prior myocardial infarction, coronary artery disease patient documented to be on beta-blocker therapy	HCPCS	Procedure
G8034	Prior myocardial infarction, coronary artery disease patient not documented to be on beta-blocker therapy	HCPCS	Procedure
G8035	Clinician documented that prior myocardial infarction, coronary artery disease patient was not eligible candidate for beta-blocker therapy measure	HCPCS	Procedure
G8036	Coronary artery disease patient documented to be on antiplatelet therapy	HCPCS	Procedure
G8037	Coronary artery disease patient not documented to be on antiplatelet therapy	HCPCS	Procedure
G8038	Clinician documented that coronary artery disease patient was not eligible candidate for antiplatelet therapy measure	HCPCS	Procedure
G8039	Coronary artery disease patient with low-density lipoprotein documented to be greater than 100 mg/dl	HCPCS	Procedure

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
G8040	Coronary artery disease patient with low-density lipoprotein documented to be less than or equal to 100 mg/dl	HCPCS	Procedure
G8041	Clinician documented that coronary artery disease patient was not eligible candidate for low-density lipoprotein measure	HCPCS	Procedure
Peptic Ulcer Disease			
531.0	Acute gastric ulcer with hemorrhage	ICD-9-CM	Diagnosis
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.1	Acute gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.10	Acute gastric ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.11	Acute gastric ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
531.2	Acute gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.3	Acute gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.30	Acute gastric ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
531.31	Acute gastric ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
531.4	Chronic or unspecified gastric ulcer with hemorrhage	ICD-9-CM	Diagnosis
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.5	Chronic or unspecified gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.50	Chronic or unspecified gastric ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.51	Chronic or unspecified gastric ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
531.6	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.7	Chronic gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.70	Chronic gastric ulcer without mention of hemorrhage, perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.71	Chronic gastric ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
532.0	Acute duodenal ulcer with hemorrhage	ICD-9-CM	Diagnosis
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.1	Acute duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.10	Acute duodenal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.11	Acute duodenal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
532.2	Acute duodenal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.3	Acute duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.30	Acute duodenal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
532.31	Acute duodenal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
532.4	Chronic or unspecified duodenal ulcer with hemorrhage	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.5	Chronic or unspecified duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.50	Chronic or unspecified duodenal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.51	Chronic or unspecified duodenal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
532.6	Chronic or unspecified duodenal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.7	Chronic duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.70	Chronic duodenal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
532.71	Chronic duodenal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
533.0	Acute peptic ulcer, unspecified site, with hemorrhage	ICD-9-CM	Diagnosis
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.1	Acute peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.10	Acute peptic ulcer, unspecified site, with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.11	Acute peptic ulcer, unspecified site, with perforation and obstruction	ICD-9-CM	Diagnosis
533.2	Acute peptic ulcer, unspecified site, with hemorrhage and perforation	ICD-9-CM	Diagnosis
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.3	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation	ICD-9-CM	Diagnosis
533.30	Acute peptic ulcer, unspecified site, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
533.31	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation, with obstruction	ICD-9-CM	Diagnosis
533.4	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage	ICD-9-CM	Diagnosis
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.5	Chronic or unspecified peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.50	Chronic or unspecified peptic ulcer, unspecified site, with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.51	Chronic or unspecified peptic ulcer, unspecified site, with perforation and obstruction	ICD-9-CM	Diagnosis
533.6	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation	ICD-9-CM	Diagnosis
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.7	Chronic peptic ulcer, unspecified site, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.70	Chronic peptic ulcer, unspecified site, without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
533.71	Chronic peptic ulcer of unspecified site without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
534.0	Acute gastrojejunal ulcer with hemorrhage	ICD-9-CM	Diagnosis
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.1	Acute gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.10	Acute gastrojejunal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.11	Acute gastrojejunal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
534.2	Acute gastrojejunal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.3	Acute gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.30	Acute gastrojejunal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
534.31	Acute gastrojejunal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
534.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage	ICD-9-CM	Diagnosis
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.5	Chronic or unspecified gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.50	Chronic or unspecified gastrojejunal ulcer with perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.51	Chronic or unspecified gastrojejunal ulcer with perforation and obstruction	ICD-9-CM	Diagnosis
534.6	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534.7	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.70	Chronic gastrojejunal ulcer without mention of hemorrhage, perforation, or obstruction	ICD-9-CM	Diagnosis
534.71	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation, with obstruction	ICD-9-CM	Diagnosis
44.4	Control of hemorrhage and suture of ulcer of stomach or duodenum	ICD-9-CM	Diagnosis
44.40	Suture of peptic ulcer, not otherwise specified	ICD-9-CM	Diagnosis
44.41	Suture of gastric ulcer site	ICD-9-CM	Diagnosis
44.42	Suture of duodenal ulcer site	ICD-9-CM	Diagnosis
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

Appendix G. 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 Covariates in this Request

Code	Description	Code Type	Code Category
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
Syncope			
780.2	Syncope and collapse	ICD-9-CM	Diagnosis
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
Walker Use			
E0130	Walker, rigid (pickup), adjustable or fixed height	HCPCS	Procedure
E0135	Walker, folding (pickup), adjustable or fixed height	HCPCS	Procedure
E0140	Walker, with trunk support, adjustable or fixed height, any type	HCPCS	Procedure
E0141	Walker, rigid, wheeled, adjustable or fixed height	HCPCS	Procedure
E0142	Rigid walker, wheeled, with seat	HCPCS	Procedure
E0143	Walker, folding, wheeled, adjustable or fixed height	HCPCS	Procedure
E0144	Walker, enclosed, 4 sided framed, rigid or folding, wheeled with posterior seat	HCPCS	Procedure
E0145	Walker, wheeled, with seat and crutch attachments	HCPCS	Procedure
E0146	Folding walker, wheeled, with seat	HCPCS	Procedure
E0147	Walker, heavy-duty, multiple braking system, variable wheel resistance	HCPCS	Procedure
E0148	Walker, heavy-duty, without wheels, rigid or folding, any type, each	HCPCS	Procedure
E0149	Walker, heavy-duty, wheeled, rigid or folding, any type	HCPCS	Procedure
E0154	Platform attachment, walker, each	HCPCS	Procedure
E0155	Wheel attachment, rigid pick-up walker, per pair	HCPCS	Procedure
E0156	Seat attachment, walker	HCPCS	Procedure
E0157	Crutch attachment, walker, each	HCPCS	Procedure
E0158	Leg extensions for walker, per set of 4	HCPCS	Procedure
E0159	Brake attachment for wheeled walker, replacement, each	HCPCS	Procedure
K0458	Heavy duty walker, without wheels, each	HCPCS	Procedure
K0459	Heavy duty wheeled walker, each	HCPCS	Procedure
L1520	Thoracic-hip-knee-ankle orthotic (THKAO), swivel walker	HCPCS	Procedure

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Angiotensin-Converting Enzyme Inhibitors and Angiotensin Receptor Blockers

Amlodipine Besylate Benazepril Hcl Cap 2.5 10 Mg
Amlodipine Besylate Benazepril Hcl Cap 5 10 Mg
Amlodipine Besylate Benazepril Hcl Cap 5 20 Mg
Amlodipine Besylate Benazepril Hcl Cap 10 20 Mg
Enalapril Maleate Tab 10 Mg
Enalapril Maleate Tab 5 Mg
Benazepril Hcl Tab 10 Mg
Enalapril Maleate Tab 20 Mg
Telmisartan Hydrochlorothiazide Tab 40 12.5 Mg
Telmisartan Hydrochlorothiazide Tab 80 12.5 Mg
Telmisartan Hydrochlorothiazide Tab 80 25 Mg
Captopril Tab 100 Mg
Lisinopril Tab 30 Mg
Ramipril Cap 10 Mg
Losartan Potassium Tab 25 Mg
Quinapril Hcl Tab 5 Mg
Quinapril Hcl Tab 10 Mg
Quinapril Hcl Tab 20 Mg
Quinapril Hcl Tab 40 Mg
Benazepril Hcl Tab 5 Mg
Amlodipine Besylate Benazepril Hcl Cap 5 40 Mg
Amlodipine Besylate Benazepril Hcl Cap 10 40 Mg
Irbesartan Tab 300 Mg
Benazepril Hcl Tab 40 Mg
Lisinopril Tab 5 Mg
Lisinopril Tab 40 Mg
Losartan Potassium Tab 50 Mg
Captopril Tab 25 Mg
Fosinopril Sodium Tab 40 Mg
Losartan Potassium Hydrochlorothiazide Tab 100 25 Mg
Lisinopril Tab 20 Mg
Lisinopril Hydrochlorothiazide Tab 20 25 Mg
Losartan Potassium Hydrochlorothiazide Tab 100 12.5 Mg
Lisinopril Tab 2.5 Mg
Lisinopril Hydrochlorothiazide Tab 20 12.5 Mg
Lisinopril Tab 10 Mg
Lisinopril Hydrochlorothiazide Tab 10 12.5 Mg
Captopril Tab 12.5 Mg
Captopril Tab 50 Mg
Enalapril Maleate Tab 2.5 Mg
Enalapril Maleate Hydrochlorothiazide Tab 5 12.5 Mg
Enalapril Maleate Hydrochlorothiazide Tab 10 25 Mg
Trandolapril Tab 1 Mg
Trandolapril Tab 2 Mg
Trandolapril Tab 4 Mg
Trandolapril Verapamil Hcl Tab Cr 2 180 Mg
Trandolapril Verapamil Hcl Tab Cr 2 240 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Eprosartan Mesylate Tab 400 Mg
Eprosartan Mesylate Tab 600 Mg
Quinapril Hydrochlorothiazide Tab 20 12.5 Mg
Quinapril Hydrochlorothiazide Tab 10 12.5 Mg
Quinapril Hydrochlorothiazide Tab 20 25 Mg
Captopril Hydrochlorothiazide Tab 25 15 Mg
Captopril Hydrochlorothiazide Tab 50 25 Mg
Irbesartan Tab 150 Mg
Valsartan Tab 80 Mg
Valsartan Tab 160 Mg
Valsartan Hydrochlorothiazide Tab 80 12.5 Mg
Valsartan Hydrochlorothiazide Tab 160 12.5 Mg
Valsartan Hydrochlorothiazide Tab 160 25 Mg
Benazepril Hcl Tab 20 Mg
Irbesartan Tab 75 Mg
Olmesartan Medoxomil Tab 20 Mg
Olmesartan Medoxomil Tab 40 Mg
Valsartan Tab 40 Mg
Losartan Potassium Tab 100 Mg
Ramipril Cap 2.5 Mg
Ramipril Cap 5 Mg
Benazepril Hydrochlorothiazide Tab 10 12.5 Mg
Losartan Potassium Hydrochlorothiazide Tab 50 12.5 Mg
Irbesartan Hydrochlorothiazide Tab 150 12.5 Mg
Amlodipine Besylate Valsartan Tab 10 320 Mg
Amlodipine Besylate Valsartan Tab 5 160 Mg
Valsartan Tab 320 Mg
Valsartan Hydrochlorothiazide Tab 320 25 Mg
Telmisartan Tab 20 Mg
Telmisartan Tab 40 Mg
Telmisartan Tab 80 Mg
Candesartan Cilexetil Tab 8 Mg
Moexipril Hcl Tab 7.5 Mg
Benazepril Hydrochlorothiazide Tab 5 6.25 Mg
Benazepril Hydrochlorothiazide Tab 20 12.5 Mg
Benazepril Hydrochlorothiazide Tab 20 25 Mg
Fosinopril Sodium Hydrochlorothiazide Tab 20 12.5 Mg
Ramipril Cap 1.25 Mg
Fosinopril Sodium Tab 20 Mg
Fosinopril Sodium Tab 10 Mg
Candesartan Cilexetil Hydrochlorothiazide Tab 32 12.5 Mg
Valsartan Hydrochlorothiazide Tab 320 12.5 Mg
Amlodipine Besylate Olmesartan Medoxomil Tab 10 20 Mg
Olmesartan Medoxomil Hydrochlorothiazide Tab 40 12.5 Mg
Olmesartan Medoxomil Hydrochlorothiazide Tab 20 12.5 Mg
Lisinopril Tab 20 Mg Dietary Management Cap Pack
Valsartan Hydrochlorothiazide
Amlodipine Besylate Valsartan Hydrochlorothiazide
Sacubitril Valsartan

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Valsartan
Amlodipine Besylate Valsartan
Lisinopril
Benazepril Hcl Hydrochlorothiazide
Telmisartan Amlodipine Besylate
Telmisartan
Fosinopril Sodium
Perindopril Erbumine
Enalapril Maleate Hydrochlorothiazide
Benazepril Hcl
Ramipril
Enalapril Maleate
Telmisartan Hydrochlorothiazide
Losartan Potassium
Losartan Potassium Hydrochlorothiazide
Quinapril Hcl Hydrochlorothiazide
Trandolapril
Lisinopril Hydrochlorothiazide
Amlodipine Besylate Benazepril Hcl
Irbesartan
Quinapril Hcl
Irbesartan Hydrochlorothiazide
Trandolapril Verapamil Hcl
Azilsartan Medoxomil
Azilsartan Medoxomil Chlorthalidone
Candesartan Cilexetil
Perindopril Arginine Amlodipine Besylate
Captopril Hydrochlorothiazide
Captopril
Eprosartan Mesylate Hydrochlorothiazide
Eprosartan Mesylate
Aliskiren Valsartan
Fosinopril Sodium Hydrochlorothiazide
Moexipril Hcl
Moexipril Hcl Hydrochlorothiazide
Enalapril Maleate Felodipine
Candesartan Cilexetil Hydrochlorothiazide
Olmesartan Medoxomil
Olmesartan Medoxomil Hydrochlorothiazide
Amlodipine Besylate Olmesartan Medoxomil
Olmesartan Medoxomil Amlodipine Besylate Hydrochlorothiazide
Lisinopril Dietary Supplement Comb.10

Amiodarone

Amiodarone Hcl
Amiodarone Hcl Tab 200 Mg
Amiodarone Hcl Tab 400 Mg

Antiarrhythmics

Disopyramide Phosphate Cap 150 Mg
Quinidine Sulfate Tab Cr 300 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Propafenone Hcl Tab 150 Mg
 Propafenone Hcl Tab 300 Mg
 Propafenone Hcl Tab 225 Mg
 Quinidine Gluconate Tab Cr 324 Mg
 Quinidine Sulfate Tab 300 Mg
 Quinidine Sulfate Tab 200 Mg
 Flecainide Acetate Tab 100 Mg
 Sotalol Hcl Tab 80 Mg
 Sotalol Hcl (Afib Afl) Tab 120 Mg
 Sotalol Hcl (Afib Afl) Tab 80 Mg
 Mexiletine Hcl Cap 150 Mg
 Mexiletine Hcl Cap 200 Mg
 Mexiletine Hcl Cap 250 Mg
 Sotalol Hcl Tab 160 Mg
 Sotalol Hcl Tab 240 Mg
 Sotalol Hcl Tab 120 Mg
 Moricizine Hcl Tab 200 Mg
 Moricizine Hcl Tab 300 Mg
 Flecainide Acetate Tab 50 Mg
 Procainamide Hcl Tab Cr 750 Mg
 Procainamide Hcl Cap 375 Mg
 Sotalol Hcl (Afib Afl) Tab 160 Mg
 Procainamide Hcl Tab Sr 12Hr 500 Mg
 Procainamide Hcl Tab Sr 12Hr 1000 Mg
 Propafenone Hcl
 Sotalol Hcl
 Flecainide Acetate
 Adenosine Triphosphate
 Procainamide Hcl
 Disopyramide Phosphate
 Mexiletine Hcl
 Dofetilide
 Quinidine Sulfate
 Tocainide Hcl
 Quinidine Gluconate
 Moricizine Hcl

Anticoagulants

Heparin Sodium (Porcine) 100 Unit MI In D5W
 Heparin Sodium (Bovine) Inj 1000 Unit MI
 Heparin Sodium (Bovine) Inj 5000 Unit MI
 Heparin Sodium (Bovine) Inj 10000 Unit MI
 Heparin Sodium (Porcine) Inj 10000 Unit MI
 Heparin Sodium (Porcine) Inj 2500 Unit MI
 Heparin Sodium (Porcine) Inj 7500 Unit MI
 Heparin Sodium (Porcine) Inj 5000 Unit MI
 Enoxaparin Sodium Inj 10 Mg 0.1MI (100 Mg MI)
 Heparin Sodium (Porcine) Inj 1000 Unit MI
 Enoxaparin Sodium Inj 30 Mg 0.3MI
 Enoxaparin Sodium Inj 40 Mg 0.4MI

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Enoxaparin Sodium Inj 60 Mg 0.6MI
Enoxaparin Sodium Inj 80 Mg 0.8MI
Enoxaparin Sodium Inj 100 Mg MI
Enoxaparin Sodium Inj 120 Mg 0.8MI
Enoxaparin Sodium Inj 150 Mg MI
Tinzaparin Sodium Inj 20000 Anti Xa Unit MI
Dalteparin Sodium Porcine
Heparin Sodium Porcine
Heparin Sodium Porcine In 0.9 % Sodium Chloride Pf
Heparin Sodium Porcine In 0.45 % Sodium Chloride
Heparin Sodium Porcine Dextrose 5 % In Water
Enoxaparin Sodium
Heparin Sodium Porcine In 0.9 % Sodium Chloride
Fondaparinux Sodium
Heparin Sodium Beef
Heparin Sodium Porcine Pf
Heparin Sodium Porcine Normal Saline Pf
Heparin Sodium Porcine 0.5 Normal Saline
Heparin Sodium Porcine Dextrose 5% Water
Heparin Sodium Porcine Normal Saline
Heparin Sodium Porcine Dextrose 5 % In Water Pf
Tinzaparin Sodium Porcine
Heparin Sodium Porcine In 1 2 Normal Saline
Heparin Sodium Porcine Dextrose 5 % Water

Antiplatelet Agents (non-aspirin)

Dipyridamole Tab 75 Mg
Cilostazol Tab 50 Mg
Cilostazol Tab 100 Mg
Clopidogrel Bisulfate Tab 75 Mg (Base Equiv)
Dipyridamole Tab 50 Mg
Clopidogrel Bisulfate Tab 300 Mg (Base Equiv)
Ticlopidine Hcl Tab 250 Mg
Dipyridamole Tab 25 Mg
Aspirin Dipyridamole Cap Sr 12Hr 25 200 Mg
Aspirin Dipyridamole
Ticagrelor
Clopidogrel Bisulfate
Dipyridamole
Cilostazol
Prasugrel Hydrochloride
Prasugrel Hcl
Ticlopidine Hcl

Beta Blockers

Propranolol Hcl Tab 10 Mg
Metoprolol Succinate Tab Sr 24Hr 100 Mg
Bisoprolol Hydrochlorothiazide Tab 5 6.25 Mg
Carvedilol Tab 12.5 Mg
Carvedilol Tab 3.125 Mg
Propranolol Hcl Tab 40 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Acebutolol Hcl Powder
Propranolol Hcl Cap Sr 24Hr 120 Mg
Atenolol Tab 25 Mg
Atenolol Tab 50 Mg
Atenolol Tab 100 Mg
Propranolol Hcl Tab 20 Mg
Metoprolol Succinate Tab Sr 24Hr 50 Mg
Metoprolol Tartrate Tab 100 Mg
Metoprolol Tartrate Tab 25 Mg
Carvedilol Tab 25 Mg
Metoprolol Tartrate Tab 50 Mg
Carvedilol Tab 6.25 Mg
Nadolol Tab 40 Mg
Nadolol Tab 120 Mg
Nadolol Tab 20 Mg
Nadolol Tab 80 Mg
Bisoprolol Hydrochlorothiazide Tab 10 6.25 Mg
Bisoprolol Hydrochlorothiazide Tab 2.5 6.25 Mg
Bisoprolol Fumarate Tab 5 Mg
Bisoprolol Fumarate Tab 10 Mg
Acebutolol Hcl Cap 200 Mg
Betaxolol Hcl Tab 10 Mg
Labetalol Hcl Tab 100 Mg
Labetalol Hcl Tab 200 Mg
Labetalol Hcl Tab 300 Mg
Propranolol Hydrochlorothiazide Tab 40 25 Mg
Atenolol Chlorthalidone Tab 50 25 Mg
Atenolol Chlorthalidone Tab 100 25 Mg
Pindolol Tab 10 Mg
Propranolol Hcl Tab 80 Mg
Propranolol Hcl Cap Sr 24Hr 60 Mg
Metoprolol Succinate Tab Sr 24Hr 25 Mg
Propranolol Hcl Cap Sr 24Hr 160 Mg
Sotalol Hcl Tab 80 Mg
Sotalol Hcl (Afib Afl) Tab 120 Mg
Sotalol Hcl (Afib Afl) Tab 80 Mg
Sotalol Hcl Tab 160 Mg
Sotalol Hcl Tab 240 Mg
Sotalol Hcl Tab 120 Mg
Pindolol Tab 5 Mg
Propranolol Hcl Tab 60 Mg
Metoprolol Succinate Tab Sr 24Hr 200 Mg
Carvedilol Phosphate Cap Sr 24Hr 20 Mg
Timolol Maleate Tab 10 Mg
Propranolol Hcl Cap Sr 24Hr 80 Mg
Sotalol Hcl (Afib Afl) Tab 160 Mg
Metoprolol Hydrochlorothiazide Tab 50 25 Mg
Nebivolol Hcl Tab 2.5 Mg (Base Equivalent)
Nebivolol Hcl Tab 20 Mg (Base Equivalent)

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Nebivolol Hcl Tab 10 Mg (Base Equivalent)
Nebivolol Hcl Tab 5 Mg (Base Equivalent)
Metoprolol Tab 50 Mg Dietary Management Cap Pack
Carvedilol Tab 12.5 Mg Dietary Management Cap Pack
Metoprolol Tartrate
Nebivolol Hcl
Atenolol
Bisoprolol Fumarate Hydrochlorothiazide
Carvedilol
Propranolol Hcl
Metoprolol Tartrate Hydrochlorothiazide
Sotalol Hcl
Nadolol
Pindolol
Metoprolol Succinate
Labetalol Hcl
Atenolol Chlorthalidone
Acebutolol Hcl
Metoprolol Succinate Hydrochlorothiazide
Timolol Maleate
Timolol Maleate Hydrochlorothiazide
Carvedilol Phosphate
Betaxolol Hcl
Propranolol Hcl Hydrochlorothiazide
Carteolol Hcl
Penbutolol Sulfate
Bisoprolol Fumarate
Nadolol Bendroflumethiazide
Levetiracetam
Metoprolol Tartrate Dietary Supplement Comb.10

Calcium Channel Blockers

Amlodipine Besylate Tab 2.5 Mg
Amlodipine Besylate Tab 5 Mg
Amlodipine Besylate Tab 10 Mg
Amlodipine Besylate Benazepril Hcl Cap 2.5 10 Mg
Amlodipine Besylate Benazepril Hcl Cap 5 10 Mg
Amlodipine Besylate Benazepril Hcl Cap 5 20 Mg
Amlodipine Besylate Benazepril Hcl Cap 10 20 Mg
Diltiazem Hcl Tab 60 Mg
Diltiazem Hcl Tab 30 Mg
Diltiazem Hcl Coated Beads Cap Sr 24Hr 240 Mg
Diltiazem Hcl Extended Release Beads Cap Sr 24Hr 180 Mg
Diltiazem Hcl Coated Beads Cap Sr 24Hr 120 Mg
Verapamil Hcl Tab Cr 240 Mg
Amlodipine Besylate Benazepril Hcl Cap 5 40 Mg
Amlodipine Besylate Benazepril Hcl Cap 10 40 Mg
Nifedipine Tab Sr 24Hr Osmotic Release 60 Mg
Nifedipine Tab Sr 24Hr Osmotic Release 30 Mg
Nifedipine Tab Sr 24Hr 30 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Nifedipine Tab Sr 24Hr 60 Mg
Verapamil Hcl Tab Cr 180 Mg
Verapamil Hcl Tab Cr 120 Mg
Trandolapril Verapamil Hcl Tab Cr 2 180 Mg
Trandolapril Verapamil Hcl Tab Cr 2 240 Mg
Nifedipine Cap 10 Mg
Diltiazem Hcl Cap Sr 12Hr 90 Mg
Diltiazem Hcl Cap Sr 12Hr 120 Mg
Nicardipine Hcl Cap 20 Mg
Verapamil Hcl Cap Sr 24Hr 180 Mg
Diltiazem Hcl Tab 90 Mg
Diltiazem Hcl Coated Beads Cap Sr 24Hr 180 Mg
Felodipine Tab Sr 24Hr 2.5 Mg
Felodipine Tab Sr 24Hr 5 Mg
Felodipine Tab Sr 24Hr 10 Mg
Verapamil Hcl Cap Sr 24Hr 120 Mg
Verapamil Hcl Cap Sr 24Hr 240 Mg
Verapamil Hcl Cap Sr 24Hr 360 Mg
Nifedipine Tab Sr 24Hr 90 Mg
Nifedipine Tab Sr 24Hr Osmotic 90 Mg
Verapamil Hcl Tab 80 Mg
Verapamil Hcl Tab 120 Mg
Nifedipine Tab Sr 24Hr Osmotic 60 Mg
Nifedipine Tab Sr 24Hr Osmotic 30 Mg
Diltiazem Hcl Tab 120 Mg
Amlodipine Besylate Valsartan Tab 10 320 Mg
Amlodipine Besylate Valsartan Tab 5 160 Mg
Diltiazem Hcl Coated Beads Cap Sr 24Hr 300 Mg
Nimodipine Cap 30 Mg
Nifedipine Cap 20 Mg
Diltiazem Hcl Cap Sr 12Hr 60 Mg
Verapamil Hcl Tab Sr 24Hr (Controlled Onset) 180 Mg
Verapamil Hcl Tab Sr 24Hr (Controlled Onset) 240 Mg
Nisoldipine Tab Sr 24Hr 30 Mg
Diltiazem Hcl Extended Release Beads Cap Sr 24Hr 120 Mg
Diltiazem Hcl Extended Release Beads Cap Sr 24Hr 240 Mg
Verapamil Hcl Cap Sr 24Hr 100 Mg
Diltiazem Hcl Cap Sr 24Hr 180 Mg
Isradipine Cap 2.5 Mg
Diltiazem Hcl Cap Sr 24Hr 240 Mg
Verapamil Hcl Cap Sr 24Hr 300 Mg
Diltiazem Hcl Cap Sr 24Hr 120 Mg
Amlodipine Besylate Olmesartan Medoxomil Tab 10 20 Mg
Amlodipine Tab 2.5 Mg Dietary Management Cap Pack
Amlodipine Besylate
Amlodipine Besylate Valsartan Hydrochlorothiazide
Amlodipine Besylate Valsartan
Diltiazem Hcl
Telmisartan Amlodipine Besylate

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Amlodipine Besylate Atorvastatin Calcium
 Nimodipine
 Verapamil Hcl
 Felodipine
 Nifedipine
 Isradipine
 Amlodipine Besylate Benazepril Hcl
 Trandolapril Verapamil Hcl
 Perindopril Arginine Amlodipine Besylate
 Nicardipine Hcl
 Bepridil Hcl
 Aliskiren Hemifumarate Amlodipine Besylate
 Aliskiren Hemifumarate Amlodipine Hydrochlorothiazide
 Enalapril Maleate Felodipine
 Nisoldipine
 Amlodipine Besylate Olmesartan Medoxomil
 Fosinopril Sodium
 Olmesartan Medoxomil Amlodipine Besylate Hydrochlorothiazide

Digoxin

Digoxin Tab 125 Mcg (0.125 Mg)
 Digoxin Tab 250 Mcg (0.25 Mg)
 Digoxin Tab 0.125 Mg
 Digoxin Oral Soln 0.05 Mg Ml
 Digoxin Tab 0.25 Mg
 Digoxin

Dronedarone

Dronedarone Hcl

Estrogen Replacement

Levonorgestrel Ethinyl Estradiol Tab 0.1 Mg 20 Mcg
 Levonorgestrel Ethinyl Estradiol (91 Day) Tab 0.15 0.03 Mg
 Estradiol Tab 1 Mg
 Estradiol Tab 2 Mg
 Estradiol Td Patch Weekly 0.025 Mg 24Hr
 Estradiol Tab 0.5 Mg
 Estradiol Estriol Progesterone Micronized Cream (Cmpd Kit)
 Norgestimate Ethinyl Estradiol Tab 0.25 Mg 35 Mcg
 Desogestrel Ethinyl Estradiol Tab 0.15 Mg 30 Mcg
 Norelgestromin Ethinyl Estradiol Td Ptwk 150 35 Mcg 24Hr
 Norethindrone Ethinyl Estradiol Tab 1 Mg 35 Mcg
 Norethindrone Eth Estradiol Tab 0.5 35 0.75 35 1 35 Mg Mcg
 Drospirenone Ethinyl Estradiol Tab 3 0.02 Mg
 Estradiol Implant Pellet 6 Mg
 Estradiol Implant Pellet 10 Mg
 Estradiol Implant Pellet 12.5 Mg
 Estradiol Implant Pellet 18 Mg
 Estradiol Implant Pellet 20 Mg
 Estradiol Implant Pellet 25 Mg
 Estradiol Implant Pellet 31 Mg
 Estradiol Implant Pellet 37.5 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Estradiol Implant Pellet 50 Mg
Estradiol Valerate Im In Oil 40 Mg MI
Estradiol Valerate Im In Oil 10 Mg MI
Estradiol Valerate Im In Oil 20 Mg MI
Estradiol Testosterone Cypionates Im In Oil 2 50 Mg MI
Medroxyprogesterone Ace Estradiol Cyp Im Susp 25 5 Mg 0.5MI
Ethinodiol Diacetate Ethinyl Estradiol Tab 1 Mg 50 Mcg
Ethinodiol Diacetate Ethinyl Estradiol Tab 1 Mg 35 Mcg
Estrogens Conjugated Tab 1.25 Mg
Estrogens Conjugated Tab 0.625 Mg
Estradiol Td Patch Biweekly 0.025 Mg 24Hr
Estradiol Td Patch Biweekly 0.05 Mg 24Hr
Estradiol Td Patch Biweekly 0.1 Mg 24Hr
Estradiol Td Patch Biweekly 0.0375 Mg 24Hr
Estradiol Td Patch Biweekly 0.075 Mg 24Hr
Estropipate Tab 3 Mg
Estradiol Tab 1.5 Mg
Norethindrone Ethinyl Estradiol Fe Chew Tab 0.4 Mg 35 Mcg
Esterified Estrogens Methyltestosterone Tab 0.625 1.25 Mg
Esterified Estrogens Methyltestosterone Tab 1.25 2.5 Mg
Estrogens Conjugated Tab 0.45 Mg
Estradiol Td Patch Weekly 0.05 Mg 24Hr
Estradiol Td Patch Weekly 0.1 Mg 24Hr
Drospirenone Ethinyl Estradiol Tab 3 0.03 Mg
Levonorgestrel Ethinyl Estradiol Tab 0.10 Mg 20 Mcg
Norgestrel Ethinyl Estradiol Tab 0.3 Mg 30 Mcg
Levonorgestrel Ethinyl Estradiol Tab 0.15 Mg 30 Mcg
Estropipate Tab 0.75 Mg
Estropipate Tab 1.5 Mg
Norethindrone Ethinyl Estradiol Tab 0.5 Mg 35 Mcg
Norethindrone Eth Estradiol Tab 0.5 35 1 35 Mg Mcg (10 11)
Norethindrone Ace Ethinyl Estradiol Tab 1 Mg 20 Mcg
Norethindrone Ace Ethinyl Estradiol Fe Tab 1.5 Mg 30 Mcg
Ethinyl Estradiol Tab 0.02 Mg
Esterified Estrogens Tab 0.625 Mg
Esterified Estrogens Tab 0.3 Mg
Estrogens Conjugated Tab 0.9 Mg
Estrogens Conjugated Tab 0.3 Mg
Norgestrel Ethinyl Estradiol Tab 0.5 Mg 50 Mcg
Norethindrone Ethinyl Estradiol Tab 0.4 Mg 35 Mcg
Estradiol Cypionate Im In Oil 5 Mg MI
Conj Est 0.625(14) Conj Est Medroxypro Ac Tab 0.625 5Mg(14)
Norethindrone Acetate Ethinyl Estradiol Tab 1 Mg 5 Mcg
Norethindrone Ace Ethinyl Estradiol Fe Tab 1 Mg 20 Mcg
Norethindrone Ethinyl Estradiol Fe Chew Tab 0.8 Mg 25 Mcg
Norethin Eth Estradiol Fe Tab 1 Mg 10 Mcg (24) 10 Mcg (2)
Esterified Estrogens Tab 1.25 Mg
Estrogens Conjugated Synthetic A Tab 1.25 Mg
Estrogens Conjugated Synthetic A Tab 0.625 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Estrogens Conjugated Synthetic A Tab 0.9 Mg
Esterified Estrogens Tab 2.5 Mg
Estrogens Conjugated Tab 2.5 Mg
Norgestimate Eth Estrad Tab 0.18 35 0.215 35 0.25 35 Mg Mcg
Conjugated Estrogen Medroxyprogest Acetate Tab 0.3 1.5 Mg
Conjugated Estrogen Medroxyprogest Acetate Tab 0.45 1.5 Mg
Conjugated Estrogen Medroxyprogest Acetate Tab 0.625 2.5 Mg
Conjugated Estrogen Medroxyprogest Acetate Tab 0.625 5 Mg
Norelgestromin Ethinyl Estradiol Td Ptwk 150 20 Mcg 24Hr
Estradiol
Desogestrel Ethinyl Estradiol
Norgestimate Ethinyl Estradiol
Norethindrone Acetate Ethinyl Estradiol
Norethindrone Acetate Ethinyl Estradiol Ferrous Fumarate
Norelgestromin Ethinyl Estradiol
Levonorgestrel Ethinyl Estradiol
Levonorgestrel Eth Estra Ethinyl Estradiol
Desogestrel Ethinyl Estradiol Ethinyl Estradiol
Ethinyl Estradiol Drospirenone
Norethindrone Ethinyl Estradiol Ferrous Fumarate
Drospirenone Ethinyl Estradiol Levomefolate Calcium
Norethindrone Ethinyl Estradiol
Levonorgestrel Ethinyl Estradiol And Ethinyl Estradiol
Norgestrel Ethinyl Estradiol
Ethinodiol Diacetate Ethinyl Estradiol
Estradiol Norethindrone Acetate
Levonorgestrel Eth Estra
Estrogens Conjugated Bazedoxifene Acetate
Estradiol Cypionate
Estradiol Cypionate Medroxyprogesterone Acet
Estropipate
Ethinodiol D Ethinyl Estradiol
Methyltestosterone Estrogens Esterified
Estrogens Conjugated
Estrogens Conjugated Medroxyprogesterone Acet
Estrogens Conjugated Medroxyprogesterone Acetate
Etonogestrel Ethinyl Estradiol
Norethindrone Ethinyl Estrad
Estradiol Norgestimate
Ethinyl Estradiol Norelgestromin
Ethinyl Estradiol Norethindrone Acetate
Norethindrone A E Estradiol Ferrous Fumarate
Norethindrone A E Estradiol
Estrone
Estradiol Valerate
Testosterone Enanthate Estradiol Valerate
Estradiol Acetate
Estrogens Esterified Methyltestosterone
Estradiol Valerate Dienogest

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Estradiol Hemihydrate Drospirenone
 Estradiol Levonorgestrel
 Estrogens Conj. Synthetic B
 Estrogens Conj. Synthetic A
 Estrogens Esterified
 Ethinyl Estradiol

Fibrates

Fenofibrate Tab 54 Mg
 Fenofibrate Tab 160 Mg
 Gemfibrozil Tab 600 Mg
 Fenofibrate Micronized Cap 67 Mg
 Fenofibrate Micronized Cap 134 Mg
 Fenofibrate Micronized Cap 200 Mg
 Choline Fenofibrate Cap Dr 135 Mg (Fenofibric Acid Equiv)
 Fenofibrate Tab 48 Mg
 Fenofibrate Tab 145 Mg
 Fenofibrate
 Fenofibric Acid (Choline)
 Gemfibrozil
 Fenofibrate Micronized
 Fenofibrate Nanocrystallized
 Fenofibric Acid

H₂ Antagonists

Ranitidine Hcl Tab 150 Mg
 Ranitidine Hcl Tab 75 Mg
 Ranitidine Hcl Syrup 15 Mg Ml (75 Mg 5Ml)
 Ranitidine Hcl For Oral Susp 22.4 Mg Ml (Compound Kit)
 Famotidine Tab 10 Mg
 Famotidine Tab 20 Mg
 Diclofen Dr Tab 75Mg Ranitidine Tab 150Mg Capsaicin Cr Thpk
 Ranitidine Hcl Tab 300 Mg
 Nizatidine Cap 150 Mg
 Cimetidine Tab 400 Mg
 Diclofen Dr Tab 75Mg Ranitidine Tab 150Mg Lido Cr 3.75% Thpk
 Famotidine Tab 40 Mg
 Cimetidine Tab 300 Mg
 Famotidine Ca Carbonate Mag Hydroxide Chew Tab 10 800 165 Mg
 Cimetidine Tab 800 Mg
 Cimetidine Tab 200 Mg
 Cimetidine Hcl Soln 300 Mg 5Ml
 Famotidine Chew Tab 20 Mg
 Famotidine Ca Carbonate Mag Hydroxide Chew Tab 10 800 185 Mg
 Nizatidine Cap 300 Mg
 Ranitidine Hcl Tab 150 Mg Dietary Management Cap Pack
 Famotidine
 Ranitidine Hcl
 Famotidine Calcium Carbonate Magnesium Hydroxide
 Famotidine Calcium Carbonate Magnesium
 Cimetidine

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Nizatidine
 Cimetidine Hcl
 Ranitidine Hcl Dietary Supplement Misc Comb17
 Ranitidine Hcl Dietary Supplement Misc.Combo8
 Ibuprofen Famotidine

Insulin

Insulin Detemir Soln Pen Injector 100 Unit MI
 Insulin Aspart Inj 100 Unit MI
 Insulin Lispro (Human) Soln Pen Injector 100 Unit MI
 Insulin Aspart Soln Cartridge 100 Unit MI
 Insulin Aspart Soln Pen Injector 100 Unit MI
 Insulin Aspart Prot Aspart (Human) Inj 100 Unit MI (70 30)
 Insulin Aspart Prot Aspart Sus Pen Inj 100 Unit MI (70 30)
 Insulin (Regular) Inj 100 Unit MI
 Insulin Isophane Inj 100 Unit MI
 Insulin Zinc Inj 100 Unit MI
 Insulin Lispro (Human) Inj 100 Unit MI
 Insulin Isophane (Human) Inj 100 Unit MI
 Insulin Regular (Human) Inj 100 Unit MI
 Insulin Detemir Inj 100 Unit MI
 Insulin Glargine Inj 100 Unit MI
 Insulin Isophane Regular (Human) Inj 100 Unit MI (70 30)
 Insulin Zinc (Human) Inj 100 Unit MI
 Insulin Glargine Soln Pen Injector 100 Unit MI
 Insulin Lispro Prot Lispro (Human) Inj 100 Unit MI (75 25)
 Insulin Lispro
 Insulin Lispro Protamine Insulin Lispro
 Insulin Regular Human
 Insulin Glargine Human Recombinant Analog
 Insulin Degludec
 Insulin Detemir
 Diluent Insulin Aspart Combination #1
 Insulin Nph Human Recom
 Insulin Lispro Human Rec.Anlog
 Insulin Lispro (Npl) Insulin Lispro Human Rec.Anlog
 Insulin Pork Purified
 Insulin Regular Human Rec
 Insulin Isophane Pork Pure
 Nph Human Insulin Isophane
 Insulin Zinc Pork Purified
 Insulin Zinc Human Rec
 Insulin Zinc Extend Human Rec
 Insulin Nph Human Recom Insulin Regular Human Rec
 Nph Human Insulin Isophane Insulin Regular Human
 Insulin Regular Human Rec Insulin Release Unit
 Insulin Regular Human Rec Insulin Release Unit Chbr Ihlr
 Insulin Glargine Human Recombinant Analog
 Insulin Glargine Hum.Rec.Anlog
 Insulin Glulisine

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Insulin Reg Hum Rec Buff
Insulin Aspart
Insulin Aspart Protamine Human Insulin Aspart

Loop Diuretics

Bumetanide Tab 0.5 Mg
Bumetanide Tab 1 Mg
Bumetanide Tab 2 Mg
Furosemide Tab 40 Mg
Furosemide Tab 20 Mg
Furosemide Tab 80 Mg
Furosemide Oral Soln 10 Mg Ml
Torsemide Tab 10 Mg
Torsemide Tab 5 Mg
Torsemide Tab 20 Mg
Torsemide
Furosemide
Bumetanide
Ethacrynic Acid

Metformin

Glyburide Metformin Tab 2.5 500 Mg
Metformin Hcl Tab Sr 24Hr 500 Mg
Metformin Hcl Tab 500 Mg
Metformin Hcl Tab 850 Mg
Metformin Hcl Tab 1000 Mg
Metformin Hcl Tab Sr 24Hr 750 Mg
Sitagliptin Metformin Hcl Tab Sr 24Hr 50 1000 Mg
Glyburide Metformin Tab 5 500 Mg
Glipizide Metformin Hcl Tab 2.5 500 Mg
Glipizide Metformin Hcl Tab 5 500 Mg
Sitagliptin Metformin Hcl Tab 50 1000 Mg
Sitagliptin Metformin Hcl Tab 50 500 Mg
Rosiglitazone Maleate Metformin Hcl Tab 4 500 Mg
Pioglitazone Hcl Metformin Hcl Tab 15 850 Mg
Metformin Hcl Tab 500 Mg Dietary Management Cap Pack
Pioglitazone Hcl Metformin Hcl
Saxagliptin Hcl Metformin Hcl
Dapagliflozin Propanediol Metformin Hcl
Empagliflozin Metformin Hcl
Metformin Hcl
Glyburide Metformin Hcl
Alogliptin Benzoate Metformin Hcl
Canagliflozin Metformin Hcl
Repaglinide Metformin Hcl
Sitagliptin Phosphate Metformin Hcl
Rosiglitazone Maleate Metformin Hcl
Glipizide Metformin Hcl
Glyburide Micronized Metformin Hcl
Linagliptin Metformin Hcl
Butalbital Aspirin Caffeine

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Propranolol Hcl
Metformin Caffeine Amino Acids#7 Herbal Comb#125 Choline Bit
Metformin Amino Acids Comb. #7 Herbal Comb.#125 Choline

Nicotine Dependency

Nicotine Polacrilex Lozenge 2 Mg
Nicotine Polacrilex Lozenge 4 Mg
Nicotine Polacrilex Gum 4 Mg
Nicotine Polacrilex Gum 2 Mg
Nicotine Td Patch 24Hr 7 Mg 24Hr
Homeopathic Products Kit
Nicotine Inhaler System 10 Mg (4 Mg Delivered)
Nicotine Td Patch 24Hr 14 Mg 24Hr
Varenicline Tartrate Tab 0.5 Mg (Base Equiv)
Varenicline Tartrate Tab 1 Mg (Base Equiv)
Nicotine Td Patch 24Hr 21 Mg 24Hr
Nicotine Td Patch 24Hr 11 Mg 24Hr
Nicotine Td Patch 24Hr 22 Mg 24Hr
Varenicline Tartrate Tab 0.5 Mg X 11 Tab 1 Mg X 42 Pack
Nicotine
Varenicline Tartrate
Nicotine Polacrilex
Smoking Deterrent Filter
Calcium Carbonate
Bupropion Hcl

Nitrates

Isosorbide Mononitrate Tab Sr 24Hr 120 Mg
Nitroglycerin SI Tab 0.4 Mg
Isosorbide Dinitrate Tab 20 Mg
Isosorbide Mononitrate Tab Sr 24Hr 30 Mg
Isosorbide Dinitrate Tab 10 Mg
Isosorbide Dinitrate Tab 30 Mg
Isosorbide Dinitrate SI Tab 10 Mg
Nitroglycerin Td Patch 24Hr 0.8 Mg Hr
Nitroglycerin Td Patch 24Hr 0.1 Mg Hr
Nitroglycerin Td Patch 24Hr 0.2 Mg Hr
Nitroglycerin Td Patch 24Hr 0.3 Mg Hr
Nitroglycerin Td Patch 24Hr 0.4 Mg Hr
Nitroglycerin Td Patch 24Hr 0.6 Mg Hr
Nitroglycerin Cap Cr 2.5 Mg
Isosorbide Mononitrate Tab Sr 24Hr 60 Mg
Nitroglycerin Oint 2%
Isosorbide Dinitrate SI Tab 2.5 Mg
Isosorbide Mononitrate Tab 20 Mg
Nitroglycerin TI Soln 0.4 Mg Spray (400 Mcg Spray)
Isosorbide Dinitrate Tab 5 Mg
Isosorbide Dinitrate Tab Cr 40 Mg
Nitroglycerin Cap Cr 6.5 Mg
Nitroglycerin SI Tab 0.3 Mg
Nitroglycerin SI Tab 0.6 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Nitroglycerin
Isosorbide Mononitrate
Isosorbide Dinitrate
Amyl Nitrite
Isosorbide Dinitrate Hydralazine Hcl

Other Antidiabetic Drugs

Sitagliptin Metformin Hcl Tab 50 1000 Mg
Sitagliptin Metformin Hcl Tab 50 500 Mg
Acarbose Tab 50 Mg
Sitagliptin Metformin Hcl Tab Sr 24Hr 50 1000 Mg
Pioglitazone Hcl Tab 15 Mg (Base Equiv)
Fructose Dextrose Phosphoric Acid Oral Soln
Rosiglitazone Maleate Glimepiride Tab 4 1 Mg
Rosiglitazone Maleate Glimepiride Tab 4 2 Mg
Rosiglitazone Maleate Glimepiride Tab 4 4 Mg
Miglitol Tab 25 Mg
Pioglitazone Hcl Tab 30 Mg (Base Equiv)
Pioglitazone Hcl Tab 45 Mg (Base Equiv)
Sitagliptin Phosphate Tab 100 Mg (Base Equiv)
Rosiglitazone Maleate Tab 2 Mg (Base Equiv)
Rosiglitazone Maleate Tab 4 Mg (Base Equiv)
Rosiglitazone Maleate Tab 8 Mg (Base Equiv)
Acarbose Tab 25 Mg
Nateglinide Tab 120 Mg
Repaglinide Tab 2 Mg
Liraglutide Soln Pen Injector 18 Mg 3Ml (6 Mg Ml)
Rosiglitazone Maleate Metformin Hcl Tab 4 500 Mg
Pioglitazone Hcl Metformin Hcl Tab 15 850 Mg
Nateglinide Tab 60 Mg
Exenatide Inj 5 Mcg 0.02Ml
Exenatide Inj 10 Mcg 0.04Ml
Sitagliptin Phosphate
Pioglitazone Hcl
Pioglitazone Hcl Metformin Hcl
Liraglutide
Saxagliptin Hcl
Saxagliptin Hcl Metformin Hcl
Exenatide
Exenatide Microspheres
Pramlintide Acetate
Empagliflozin Linagliptin
Nateglinide
Acarbose
Alogliptin Benzoate
Alogliptin Benzoate Pioglitazone Hcl
Repaglinide
Pioglitazone Hcl Glimepiride
Repaglinide Metformin Hcl
Saxagliptin Hydrochloride

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Sitagliptin Phosphate Metformin Hcl
Sitagliptin Phosphate Simvastatin
Rosiglitazone Maleate Glimepiride
Rosiglitazone Maleate Metformin Hcl
Miglitol
Rosiglitazone Maleate
Linagliptin
Linagliptin Metformin Hcl
Pioglitazone Glimepiride
Canagliflozin
Mifepristone

Potassium Sparing Diuretics

Amiloride Hydrochlorothiazide Tab 5 50 Mg
Triamterene Hydrochlorothiazide Tab 75 50 Mg
Triamterene Hydrochlorothiazide Tab 37.5 25 Mg
Triamterene Hydrochlorothiazide Cap 37.5 25 Mg
Spironolactone Tab 25 Mg
Triamterene Hydrochlorothiazide Cap 50 25 Mg
Spironolactone Hydrochlorothiazide Tab 25 25 Mg
Spironolactone Tab 100 Mg
Spironolactone Tab 50 Mg
Amiloride Hcl Tab 5 Mg
Triamterene Hydrochlorothiazide
Spironolactone
Amiloride Hcl
Triamterene
Spironolactone Hydrochlorothiazide
Amiloride Hcl Hydrochlorothiazide

Prescription Nonsteroidal Anti-Inflammatory Drugs

Naproxen Sodium Tab 220 Mg
Ibuprofen Tab 200 Mg
Ibuprofen Cap 200 Mg
Diclofenac Sodium Gel 1%
Naproxen Cream 10% (Compound Kit)
Diclofenac Gabapentin Lidocaine Hcl Cream 5 5 2% (Cmpd Kit)
Naproxen Tab 250 Mg
Naproxen Tab 375 Mg
Naproxen Tab 500 Mg
Naproxen Tab 500 Mg Liniment Topical Gel Kit
Naproxen Tab Ec 500 Mg
Ibuprofen Tab 400 Mg
Naproxen Sodium Tab 550 Mg
Diclofenac Sodium Tab Sr 24Hr 100 Mg
Celecoxib Cap 200 Mg
Meloxicam Tab 15 Mg
Indomethacin Cap 25 Mg
Flurbiprofen Cyclobenzaprine Cream (Cmpd Kit)
Ketoprofen Baclofen Gabapentin Cream (Cmpd Kit)
Ketoprofen Lidocaine Gabapentin Cream (Cmpd Kit)

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Celecoxib Cap 100 Mg
Ketoprofen Baclofen Gabapent Lido Crm 15 4 10 2% (Cmp Kit)
Ibuprofen Tab 600 Mg
Ibuprofen Tab 800 Mg
Metaxalone Tab 800 Mg Diclofenac Sodium Soln 1.5% Kit
Fenoprofen Calcium Cap 400 Mg
Ketorolac Tromethamine Gel 2% (Cmpd Kit) (Base Equiv)
Ketoprofen (Bulk) Cream 10%
Diclofenac Sodium Tab Delayed Release 50 Mg
Nabumetone Tab 500 Mg
Ketorolac Tromethamine Tab 10 Mg
Prasterone Cap 200 Mg Ibuprofen Tab 400 Mg Kit
Diclofenac Sod Tab Dr 75 Mg Lido Men Methyl Sal Ptch Kit
Etodolac Tab 400 Mg
Indomethacin Cap 50 Mg
Oxaprozin Tab 600 Mg
Sulindac Tab 200 Mg
Etodolac Tab 500 Mg
Naproxen Sodium Tab 550 Mg Menthol Gel 2% Therapy Pack
Flurbiprofen Baclofen Cycloben Lido Cream (Cmp Kit)
Naproxen Tab 250 Mg Dietary Management Cap Pack
Meloxicam Tab 7.5 Mg Dietary Management Cap Pack
Piroxicam Cap 20 Mg Dietary Management Cap Pack
Ibuprofen Tab 600 Mg Dietary Management Cap Pack
Naproxen Tab 500 Mg Dietary Management Cap Pack
Ibuprofen Tab 800 Mg Dietary Management Cap Pack
Diclofenac Tab Dr 25 Mg Dietary Management Cap Pack
Meloxicam Tab 7.5 Mg
Ketoprofen Cap 75 Mg
Ibuprofen Susp 100 Mg 5MI
Diclofenac Sodium Tab Delayed Release 75 Mg
Nabumetone Tab 750 Mg
Fluorouracil Diclofenac Sodium Cream 5 1%
Tamoxifen Adapalene Diclofenac Cream 0.2 0.3 2% (Cmpd Kit)
Amantadine Gabapent Diclofenac Baclofen Lido Cr (Cmpd Kit)
Diclofenac Amitriptyline Prilo Lido Cream (Cmpd Kit)
Diclofenac Tab 75Mg Ranitid Tab 150Mg Lido Prilo Cr Thpk
Ketorolac Tromethamine Nasal Spray 15.75 Mg Spray
Ibuprofen Tab 800 Mg Multiple Minerals Cap Therapy Pack
Diclofenac Td Soln 1.5% Camph Men Methyl Sal Patch Kit
Etodolac Tab Sr 24Hr 600 Mg
Piroxicam Cap 20 Mg
Naproxen Sodium Tab 275 Mg
Flurbiprofen Tab 100 Mg
Fenoprofen Calcium Tab 600 Mg
Tolmetin Sodium Tab 600 Mg
Tolmetin Sodium Cap 400 Mg
Indomethacin Cap Cr 75 Mg
Naproxen Sodium Cap 220 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Meclofenamate Sodium Cap 50 Mg
Meclofenamate Sodium Cap 100 Mg
Sulindac Tab 150 Mg
Diclofenac W Misoprostol Tab 75 0.2 Mg
Diclofenac Sodium Tab Delayed Release 25 Mg
Diclofenac Potassium Tab 50 Mg
Etodolac Tab Sr 24Hr 500 Mg
Piroxicam Cap 10 Mg
Etodolac Cap 300 Mg
Diclofenac W Misoprostol Tab 50 0.2 Mg
Naproxen Esomeprazole Magnesium Tab Dr 375 20 Mg
Naproxen Sodium Tab Sr 24Hr 375 Mg (Base Equiv)
Naproxen Susp 125 Mg 5ML
Ketoprofen Cream 5% (Compound Kit)
Diclofenac Potassium Cap 25 Mg
Flurbiprofen Baclofen Lidocaine Cream 15 4 5% (Cmpd Kit)
Ketoprofen Lidocaine Hcl Cream 10 2% (Compound Kit)
Ketoprofen Lidocaine Gabapentin Cream 5 2 5% (Cmpd Kit)
Ketoprofen Ketamine Lidocaine Cream 5 5 2% (Compounding Kit)
Ketoprofen Ketamine Lidocaine Cream 5 5 2% (Compound Kit)
Rofecoxib Tab 50 Mg
Valdecoxib Tab 10 Mg
Valdecoxib Tab 20 Mg
Etodolac Tab Sr 24Hr 400 Mg
Ibuprofen Cream 10% (Compounding Kit)
Ketoprofen Cap Sr 24Hr 200 Mg
Ketoprofen Tab 12.5 Mg
Phenylbutazone Tab 100 Mg
Rofecoxib Tab 25 Mg
Fenoprofen Calcium Cap 200 Mg
Indomethacin Suppos 50 Mg
Naproxen Sodium Tab Sr 24Hr 500 Mg (Base Equiv)
Rofecoxib Tab 12.5 Mg
Etodolac Cap 200 Mg
Flurbiprofen Tab 50 Mg
Mefenamic Acid Cap 250 Mg
Ketoprofen Cap 50 Mg
Flurbiprofen Gabapent Cycloben Lido Dexameth Cr (Cmp Kit)
Ibuprofen
Celecoxib
Etodolac
Naproxen Sodium
Ibuprofen Diphenhydramine Citrate
Ibuprofen Diphenhydramine Hcl
Meloxicam
Nabumetone
Diclofenac Sodium
Diclofenac Sodium Misoprostol
Mefenamic Acid

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Indomethacin
Diclofenac Potassium
Naproxen
Fenoprofen Calcium
Indomethacin Submicronized
Meloxicam Submicronized
Diclofenac Sodium Capsicum Oleoresin
Ketorolac Tromethamine
Phenylephrine Hcl Ketorolac Tromethamine
Naproxen Sodium Menthol
Sumatriptan Succinate Naproxen Sodium
Oxaprozin
Naproxen Capsaicin Menthol Methyl Salicylate
Naproxen Capsaicin Menthol
Celecoxib Capsaicin Menthol
Celecoxib Lidocaine Menthol
Rofecoxib
Sulindac
Ketoprofen
Flurbiprofen
Valdecoxib
Tolmetin Sodium
Piroxicam
Naproxen Esomeprazole Magnesium
Lansoprazole Naproxen
Meclofenamate Sodium
Magnesium Carbonate Aluminum Hydroxide Alginate Acid
Diclofenac Submicronized
Ibuprofen Irritants Counter Irritants Combination #2
Meloxicam Irritants Counter Irritants Combination No.2
Naproxen Irritants Counter Irritants Combination #2
Ibuprofen Caffeine Vitamins B1 B2 B6 B12
Gold Sodium Thiomalate
Naproxen Dietary Supplement Misc. Cb.11
Piroxicam Dietary Supplement Misc. Cb.11
Ibuprofen Dietary Supplement Misc. Cb.11

Proton Pump Inhibitors

Esomeprazole Magnesium Cap Delayed Release 20 Mg (Base Eq)
Omeprazole Cap Delayed Release 40 Mg
Lansoprazole
Pantoprazole Sodium Ec Tab 20 Mg (Base Equiv)
Lansoprazole Cap Delayed Release 15 Mg
Esomeprazole Magnesium Cap Delayed Release 40 Mg (Base Eq)
Omeprazole Susp 2 Mg Ml (Compound Kit)
Rabeprazole Sodium Ec Tab 20 Mg
Lansoprazole Cap Delayed Release 30 Mg
Pantoprazole Sodium Ec Tab 40 Mg (Base Equiv)
Omeprazole Cap Delayed Release 20 Mg
Lansoprazole Tab Delayed Release Orally Disintegrating 15 Mg

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Lansoprazole Tab Delayed Release Orally Disintegrating 30 Mg
 Omeprazole Sodium Bicarbonate Cap 20 1100 Mg
 Esomeprazole Magnesium Cap Delayed Release 40 Mg
 Esomeprazole Magnesium Cap Delayed Release 20 Mg
 Omeprazole Delayed Release Tab 20 Mg
 Omeprazole Sodium Bicarbonate Cap 40 1100 Mg
 Omeprazole Cap Delayed Release 10 Mg
 Naproxen Esomeprazole Magnesium Tab Dr 375 20 Mg
 Dexlansoprazole Cap Delayed Release 60 Mg
 Dexlansoprazole Cap Delayed Release 30 Mg
 Omeprazole Magnesium Delayed Release Tab 20 Mg (Base Equiv)
 Esomeprazole Magnesium
 Lansoprazole Amoxicillin Trihydrate Clarithromycin
 Omeprazole
 Rabeprazole Sodium
 Pantoprazole Sodium
 Omeprazole Magnesium
 Omeprazole Sodium Bicarbonate
 Esomeprazole Strontium
 Omeprazole Clarithromycin Amoxicillin Trihydrate
 Naproxen Esomeprazole Magnesium
 Esomeprazole Mag Trihydrate
 Lansoprazole Naproxen
 Dexlansoprazole
 Colchicine

SSRI Depressants

Citalopram Hydrobromide Tab 20 Mg (Base Equiv)
 Escitalopram Oxalate Tab 10 Mg (Base Equiv)
 Escitalopram Tab 10 Mg Methylfolate B12 B6 D Cap Thpk
 Fluoxetine Hcl Cap 20 Mg
 Paroxetine Hcl Tab 30 Mg
 Fluoxetine Hcl Cap 10 Mg
 Citalopram Hydrobromide Tab 40 Mg (Base Equiv)
 Paroxetine Hcl Tab 10 Mg
 Paroxetine Hcl Tab 20 Mg
 Paroxetine Hcl Tab 40 Mg
 Escitalopram Oxalate Tab 20 Mg (Base Equiv)
 Paroxetine Hcl Tab Sr 24Hr 25 Mg
 Sertraline Hcl Tab 50 Mg
 Fluoxetine Hcl Cap 40 Mg
 Sertraline Hcl Tab 25 Mg
 Sertraline Hcl Tab 100 Mg
 Fluvoxamine Maleate Tab 50 Mg
 Fluvoxamine Maleate Tab 100 Mg
 Fluvoxamine Maleate Tab 25 Mg
 Fluoxetine Hcl Solution 20 Mg 5MI
 Citalopram Hydrobromide Tab 10 Mg (Base Equiv)
 Escitalopram Oxalate Tab 5 Mg (Base Equiv)
 Paroxetine Hcl Tab Sr 24Hr 37.5 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Fluvoxamine Maleate Cap Sr 24Hr 150 Mg
Fluoxetine Hcl Tab 20 Mg
Paroxetine Hcl Tab Sr 24Hr 12.5 Mg
Fluoxetine Hcl Tab 10 Mg
Fluoxetine Hcl Tab 60 Mg
Citalopram Tab 10 Mg Dietary Management Cap Pack
Fluoxetine Hcl Cap 10 Mg Dietary Management Cap Pack
Fluvoxamine Maleate
Escitalopram Oxalate
Citalopram Hydrobromide
Fluoxetine Hcl
Paroxetine Hcl
Sertraline Hcl
Olanzapine Fluoxetine Hcl
Zaleplon
Paroxetine Mesylate
Fluoxetine Hcl Dietary Supplement Misc Comb17
Fluoxetine Hcl Dietary Supplement Misc.Combo8

Statins

Atorvastatin Calcium Tab 10 Mg (Base Equivalent)
Atorvastatin Calcium Tab 20 Mg (Base Equivalent)
Atorvastatin Calcium Tab 40 Mg (Base Equivalent)
Atorvastatin Calcium Tab 80 Mg (Base Equivalent)
Simvastatin Tab 40 Mg
Pravastatin Sodium Tab 20 Mg
Pravastatin Sodium Tab 40 Mg
Lovastatin Tab 10 Mg
Simvastatin Tab 20 Mg
Rosuvastatin Calcium Tab 20 Mg
Pravastatin Sodium Tab 10 Mg
Lovastatin Tab 20 Mg
Lovastatin Tab 40 Mg
Simvastatin Tab 10 Mg
Atorvastatin Tab 20 Mg Coenzyme Q10 Cap 100 Mg Ther Pack
Simvastatin Tab 80 Mg
Fluvastatin Sodium Cap 20 Mg
Simvastatin Tab 5 Mg
Rosuvastatin Calcium Tab 10 Mg
Ezetimibe Simvastatin Tab 10 20 Mg
Pravastatin Sodium Tab 80 Mg
Rosuvastatin Calcium Tab 5 Mg
Ezetimibe Simvastatin Tab 10 40 Mg
Ezetimibe Simvastatin Tab 10 80 Mg
Fluvastatin Sodium Cap 40 Mg
Rosuvastatin Calcium Tab 40 Mg
Atorvastatin Calcium
Amlodipine Besylate Atorvastatin Calcium
Fluvastatin Sodium
Lovastatin

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Pravastatin Sodium
Simvastatin
Rosuvastatin Calcium
Ezetimibe Atorvastatin Calcium
Pitavastatin Calcium
Aspirin Calcium Carbonate Magnesium Pravastatin
Sitagliptin Phosphate Simvastatin
Niacin Lovastatin
Niacin Simvastatin
Ezetimibe Simvastatin

Sulfonyureas

Glyburide Tab 2.5 Mg
Glipizide Tab Sr 24Hr 5 Mg
Glipizide Tab Sr 24Hr 10 Mg
Glimepiride Tab 1 Mg
Glyburide Metformin Tab 2.5 500 Mg
Glipizide Tab 10 Mg
Glipizide Tab 5 Mg
Glyburide Metformin Tab 5 500 Mg
Glyburide Tab 5 Mg
Bulk Chemicals Powder
Rosiglitazone Maleate Glimepiride Tab 4 1 Mg
Rosiglitazone Maleate Glimepiride Tab 4 2 Mg
Rosiglitazone Maleate Glimepiride Tab 4 4 Mg
Chlorpropamide Tab 100 Mg
Chlorpropamide Tab 250 Mg
Glyburide Micronized Tab 1.5 Mg
Glipizide Tab Sr 24Hr 2.5 Mg
Glimepiride Tab 4 Mg
Glimepiride Tab 2 Mg
Glipizide Metformin Hcl Tab 2.5 500 Mg
Glipizide Metformin Hcl Tab 5 500 Mg
Tolazamide Tab 250 Mg
Tolazamide Tab 500 Mg
Glyburide Micronized Tab 3 Mg
Glyburide Tab 1.25 Mg
Glyburide Micronized Tab 6 Mg
Tolazamide Tab 100 Mg
Glipizide
Glimepiride
Triamterene Hydrochlorothiazide
Glyburide Metformin Hcl
Glyburide
Pioglitazone Hcl Glimepiride
Rosiglitazone Maleate Glimepiride
Tolazamide
Glyburide Micronized
Chlorpropamide
Glipizide Metformin Hcl

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Glyburide Micronized Metformin Hcl

Tolbutamide

Acetohexamide

Pioglitazone Glimepiride

Buspironone Hcl

Thiazide Diuretics

Telmisartan Hydrochlorothiazide Tab 40 12.5 Mg

Telmisartan Hydrochlorothiazide Tab 80 12.5 Mg

Telmisartan Hydrochlorothiazide Tab 80 25 Mg

Triamterene Hydrochlorothiazide Tab 75 50 Mg

Bisoprolol Hydrochlorothiazide Tab 5 6.25 Mg

Hydrochlorothiazide Tab 25 Mg

Chlorthalidone Tab 25 Mg

Amiloride Hydrochlorothiazide Tab 5 50 Mg

Triamterene Hydrochlorothiazide Tab 37.5 25 Mg

Hydrochlorothiazide Tab 50 Mg

Triamterene Hydrochlorothiazide Cap 37.5 25 Mg

Losartan Potassium Hydrochlorothiazide Tab 100 25 Mg

Lisinopril Hydrochlorothiazide Tab 20 25 Mg

Losartan Potassium Hydrochlorothiazide Tab 100 12.5 Mg

Hydrochlorothiazide Cap 12.5 Mg

Lisinopril Hydrochlorothiazide Tab 20 12.5 Mg

Lisinopril Hydrochlorothiazide Tab 10 12.5 Mg

Bisoprolol Hydrochlorothiazide Tab 10 6.25 Mg

Bisoprolol Hydrochlorothiazide Tab 2.5 6.25 Mg

Enalapril Maleate Hydrochlorothiazide Tab 5 12.5 Mg

Enalapril Maleate Hydrochlorothiazide Tab 10 25 Mg

Polythiazide Tab 1 Mg

Polythiazide Tab 2 Mg

Quinapril Hydrochlorothiazide Tab 20 12.5 Mg

Quinapril Hydrochlorothiazide Tab 10 12.5 Mg

Quinapril Hydrochlorothiazide Tab 20 25 Mg

Methyclothiazide Tab 5 Mg

Indapamide Tab 2.5 Mg

Indapamide Tab 1.25 Mg

Hydrochlorothiazide Tab 100 Mg

Captopril Hydrochlorothiazide Tab 25 15 Mg

Captopril Hydrochlorothiazide Tab 50 25 Mg

Propranolol Hydrochlorothiazide Tab 40 25 Mg

Atenolol Chlorthalidone Tab 50 25 Mg

Atenolol Chlorthalidone Tab 100 25 Mg

Chlorothiazide Tab 500 Mg

Hydralazine Reserpine Hydrochlorothiazide Tab 25 0.1 15 Mg

Triamterene Hydrochlorothiazide Cap 50 25 Mg

Spironolactone Hydrochlorothiazide Tab 25 25 Mg

Valsartan Hydrochlorothiazide Tab 80 12.5 Mg

Valsartan Hydrochlorothiazide Tab 160 12.5 Mg

Valsartan Hydrochlorothiazide Tab 160 25 Mg

Benazepril Hydrochlorothiazide Tab 10 12.5 Mg

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Losartan Potassium Hydrochlorothiazide Tab 50 12.5 Mg
Irbesartan Hydrochlorothiazide Tab 150 12.5 Mg
Valsartan Hydrochlorothiazide Tab 320 25 Mg
Hydrochlorothiazide Tab 12.5 Mg
Metolazone Tab 2.5 Mg
Metolazone Tab 5 Mg
Reserpine Hydrochlorothiazide Tab 0.125 25 Mg
Methyldopa Hydrochlorothiazide Tab 250 25 Mg
Benazepril Hydrochlorothiazide Tab 5 6.25 Mg
Benazepril Hydrochlorothiazide Tab 20 12.5 Mg
Benazepril Hydrochlorothiazide Tab 20 25 Mg
Reserpine Hydrochlorothiazide Tab 0.125 50 Mg
Fosinopril Sodium Hydrochlorothiazide Tab 20 12.5 Mg
Bendroflumethiazide Rauwolfia Tab 4 50 Mg
Methyldopa Hydrochlorothiazide Tab 250 15 Mg
Trichlormethiazide Tab 4 Mg
Candesartan Cilexetil Hydrochlorothiazide Tab 32 12.5 Mg
Valsartan Hydrochlorothiazide Tab 320 12.5 Mg
Metoprolol Hydrochlorothiazide Tab 50 25 Mg
Losartan Potassium Hydrochlorothiazide
Valsartan Hydrochlorothiazide
Amlodipine Besylate Valsartan Hydrochlorothiazide
Triamterene Hydrochlorothiazide
Benazepril Hcl Hydrochlorothiazide
Enalapril Maleate Hydrochlorothiazide
Hydrochlorothiazide
Bisoprolol Fumarate Hydrochlorothiazide
Telmisartan Hydrochlorothiazide
Metoprolol Tartrate Hydrochlorothiazide
Quinapril Hcl Hydrochlorothiazide
Indapamide
Lisinopril Hydrochlorothiazide
Atenolol Chlorthalidone
Metolazone
Chlorthalidone
Irbesartan Hydrochlorothiazide
Metoprolol Succinate Hydrochlorothiazide
Azilsartan Medoxomil Chlorthalidone
Spironolactone Hydrochlorothiazide
Isosorbide Dinitrate Hydralazine Hcl
Captopril Hydrochlorothiazide
Bendroflumethiazide
Timolol Maleate Hydrochlorothiazide
Chlorothiazide
Methyldopa Hydrochlorothiazide
Methyldopa Chlorothiazide
Amiloride Hcl Hydrochlorothiazide
Methyclothiazide
Propranolol Hcl Hydrochlorothiazide

Appendix H. List of Names of Medical Products Used to Define Covariates in this Request

Prazosin Hcl Polythiazide
Eprosartan Mesylate Hydrochlorothiazide
Deserpidine Methyclothiazide
Aliskiren Hemifumarate Hydrochlorothiazide
Aliskiren Hemifumarate Amlodipine Hydrochlorothiazide
Fosinopril Sodium Hydrochlorothiazide
Moexipril Hcl Hydrochlorothiazide
Nadolol Bendroflumethiazide
Candesartan Cilexetil Hydrochlorothiazide
Clonidine Hcl Chlorthalidone
Hydralazine Hcl Hydrochlorothiazide
Hydroflumethiazide
Hydralazine Hcl Reserpine Hydrochlorothiazide
Spironolactone

Appendix I. Specifications Defining Parameters Used in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.3, with additional programming to compare risk of stroke and bleeding associated with use of dabigatran, rivaroxaban, and apixaban in those aged 65 years or older in the Sentinel Distributed Database (SDD).

Query Period: October 19, 2010 - September 30, 2015
Coverage Requirement: Medical and drug coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 days
Age Groups: 65-74, 75-84, 85+ years
Additional Programming Needed: Risk scores, daily dose requirement

	Thromboembolic stroke					
	Comparison 1		Comparison 2		Comparison 3	
Drug/Exposure	Rivaroxaban	Dabigatran	Rivaroxaban	Apixaban	Dabigatran	Apixaban
Exposure/Comparator	Once daily	Twice daily	Once daily	Twice daily	Twice daily	Twice daily
Daily Dose Requirement	Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)	
Incident with Respect to:	Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)	
Incidence Assessment	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Washout (days)	183		183		183	
Cohort Definition	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Stockpiling Overlapping Claims	33%		33%		33%	
Episode Gap (Days)	3		3		3	
Episode Extension Period (Days)	3		3		3	
Minimum Episode Duration (Days)	1		1		1	
Maximum Episode Duration (Days)	None		None		None	
Minimum Days Supplied (Days)	1		1		1	
Censor Criteria	Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, Non-acute Institutional Stay (IS) encounter, Major extracranial bleeding, Gastrointestinal hemorrhage, Intracranial hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Major extracranial bleeding, Gastrointestinal hemorrhage, Intracranial hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Major extracranial bleeding, Gastrointestinal hemorrhage, Intracranial hemorrhage	

Appendix I. Specifications Defining Parameters Used in this Request						
Inclusion/Exclusion	Atrial fibrillation or flutter		Atrial fibrillation or flutter		Atrial fibrillation or flutter	
Pre-Existing Condition	Include		Include		Include	
Include/Exclude	Any		Any		Any	
Care Setting/Primary Diagnosis	-183, 0		-183, 0		-183, 0	
Lookback Period						
Pre-Existing Condition	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	Low-dose dabigatran, rivaroxaban, apixaban, edoxaban, warfarin	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	Low-dose apixaban, rivaroxaban, dabigatran, edoxaban, warfarin	Low-dose dabigatran, rivaroxaban, apixaban, edoxaban, warfarin	Low-dose apixaban, rivaroxaban, dabigatran, edoxaban, warfarin
Include/Exclude	Exclude		Exclude		Exclude	
Lookback Period	0, 0		0, 0		0, 0	
Pre-Existing Condition	Institutional stay encounter		Institutional stay encounter		Institutional stay encounter	
Include/Exclude	Exclude		Exclude		Exclude	
Lookback Period	0, 0		0, 0		0, 0	
Pre-Existing Condition	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair		Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair		Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair	
Include/Exclude	Exclude		Exclude		Exclude	
Care Setting/Primary Diagnosis	Any, except AV/OA for dialysis		Any, except AV/OA for dialysis		Any, except AV/OA for dialysis	
Lookback Period	-183, 0		-183, 0		-183, 0	
Event/Outcome	Thromboembolic stroke		Thromboembolic stroke		Thromboembolic stroke	
Event/Outcome	IPP		IPP		IPP	
Care Setting/Primary Diagnosis	0		0		0	
Washout (days)	1		1		1	
Blackout Period						
Propensity Score Matching	See Appendix J		See Appendix J		See Appendix J	
Covariates	1:1		1:1		1:1	
Matching Ratio	0.05		0.05		0.05	
Matching Caliper Settings	Conditional and unconditional		Conditional and unconditional		Conditional and unconditional	
Analysis Type						

Appendix I. Specifications Defining Parameters Used in this Request

Subgroup Analyses			
Stratifying variable Re-matching	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort
Stratifying variable Re-matching	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort
Stratifying variable Re-matching	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort

¹The major extracranial bleed outcome is defined as **a)** one code from "MEB_1" tab in the primary inpatient position **AND** no code from "MEB_trauma_exclusion" on the same day **OR b)** one code from "MEB_2" in the primary inpatient position **AND** one code from "MEB_1" in secondary or unspecified inpatient position on the same day **AND** no code from "MEB_trauma_exclusion" on the same day

²The gastrointestinal hemorrhage outcome is defined as **a)** one code from "GI_1" tab in the primary inpatient position **OR b)** one code from "GI_2" in the primary inpatient position **AND** one code from "GI_1" in secondary or unspecified inpatient position on the same day

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix I. Specifications Defining Parameters Used in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.3, with additional programming to compare risk of stroke and bleeding associated with use of dabigatran, rivaroxaban, and apixaban in those aged 65 years or older in the Sentinel Distributed Database (SDD).

Query Period: October 19, 2010 - September 30, 2015
Coverage Requirement: Medical and drug coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 days
Age Groups: 65-74, 75-84, 85+ years
Additional Programming Needed: Risk scores, daily dose requirement

	Major Extracranial Bleeding					
	Comparison 4		Comparison 5		Comparison 6	
Drug/Exposure	Rivaroxaban	Dabigatran	Rivaroxaban	Apixaban	Dabigatran	Apixaban
Exposure/Comparator	Once daily	Twice daily	Once daily	Twice daily	Twice daily	Twice daily
Daily Dose Requirement	Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)	
Incident with Respect to:	Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)	
Incidence Assessment	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Washout (days)	183		183		183	
Cohort Definition	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Stockpiling Overlapping Claims	33%		33%		33%	
Episode Gap (Days)	3		3		3	
Episode Extension Period (Days)	3		3		3	
Minimum Episode Duration (Days)	1		1		1	
Maximum Episode Duration (Days)	None		None		None	
Minimum Days Supplied (Days)	1		1		1	
Censor Criteria	Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Gastrointestinal hemorrhage, Intracranial hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Gastrointestinal hemorrhage, Intracranial hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Gastrointestinal hemorrhage, Intracranial hemorrhage	

Appendix I. Specifications Defining Parameters Used in this Request						
Inclusion/Exclusion	Atrial fibrillation or flutter		Atrial fibrillation or flutter		Atrial fibrillation or flutter	
Pre-Existing Condition	Include		Include		Include	
Include/Exclude	Any		Any		Any	
Care Setting/Primary Diagnosis	-183, 0		-183, 0		-183, 0	
Lookback Period						
Pre-Existing Condition	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	Low-dose dabigatran, rivaroxaban, apixaban, edoxaban, warfarin	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	Low-dose apixaban, rivaroxaban, dabigatran, edoxaban, warfarin	Low-dose dabigatran, rivaroxaban, apixaban, edoxaban, warfarin	Low-dose apixaban, rivaroxaban, dabigatran, edoxaban, warfarin
Include/Exclude	Exclude		Exclude		Exclude	
Lookback Period	0, 0		0, 0		0, 0	
Pre-Existing Condition	Institutional stay encounter		Institutional stay encounter		Institutional stay encounter	
Include/Exclude	Exclude		Exclude		Exclude	
Lookback Period	0, 0		0, 0		0, 0	
Pre-Existing Condition	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair		Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair		Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair	
Include/Exclude	Exclude		Exclude		Exclude	
Care Setting/Primary Diagnosis	Any, except AV/OA for dialysis		Any, except AV/OA for dialysis		Any, except AV/OA for dialysis	
Lookback Period	-183, 0		-183, 0		-183, 0	
Event/Outcome	Major Extracranial Bleeding ¹		Major Extracranial Bleeding ¹		Major Extracranial Bleeding ¹	
Event/Outcome	IPP		IPP		IPP	
Care Setting/Primary Diagnosis	0		0		0	
Washout (days)	1		1		1	
Blackout Period						
Propensity Score Matching	See Appendix J		See Appendix J		See Appendix J	
Covariates	1:1		1:1		1:1	
Matching Ratio	0.05		0.05		0.05	
Matching Caliper Settings	Conditional and unconditional		Conditional and unconditional		Conditional and unconditional	
Analysis Type						

Appendix I. Specifications Defining Parameters Used in this Request

Subgroup Analyses			
Stratifying variable Re-matching	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort
Stratifying variable Re-matching	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort
Stratifying variable Re-matching	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort

¹The major extracranial bleed outcome is defined as **a)** one code from "MEB_1" tab in the primary inpatient position **AND** no code from "MEB_trauma_exclusion" on the same day **OR b)** one code from "MEB_2" in the primary inpatient position **AND** one code from "MEB_1" in secondary or unspecified inpatient position on the same day **AND** no code from "MEB_trauma_exclusion" on the same day

²The gastrointestinal hemorrhage outcome is defined as **a)** one code from "GI_1" tab in the primary inpatient position **OR b)** one code from "GI_2" in the primary inpatient position **AND** one code from "GI_1" in secondary or unspecified inpatient position on the same day

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix I. Specifications Defining Parameters Used in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.3, with additional programming to compare risk of stroke and bleeding associated with use of dabigatran, rivaroxaban, and apixaban in those aged 65 years or older in the Sentinel Distributed Database (SDD).

Query Period: October 19, 2010 - September 30, 2015
Coverage Requirement: Medical and drug coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 days
Age Groups: 65-74, 75-84, 85+ years
Additional Programming Needed: Risk scores, daily dose requirement

	Gastrointestinal Hemorrhage					
	Comparison 7		Comparison 8		Comparison 9	
Drug/Exposure	Rivaroxaban	Dabigatran	Rivaroxaban	Apixaban	Dabigatran	Apixaban
Exposure/Comparator	Once daily	Twice daily	Once daily	Twice daily	Twice daily	Twice daily
Daily Dose Requirement	Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)	
Incident with Respect to:	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Incidence Assessment	183		183		183	
Washout (days)	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Cohort Definition	33%		33%		33%	
Stockpiling Overlapping Claims	3		3		3	
Episode Gap (Days)	3		3		3	
Episode Extension Period (Days)	1		1		1	
Minimum Episode Duration (Days)	None		None		None	
Maximum Episode Duration (Days)	1		1		1	
Minimum Days Supplied (Days)	Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Major extracranial bleeding, Intracranial hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Major extracranial bleeding, Intracranial hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Major extracranial bleeding, Intracranial hemorrhage	

Appendix I. Specifications Defining Parameters Used in this Request			
Inclusion/Exclusion	Atrial fibrillation or flutter		Atrial fibrillation or flutter
Pre-Existing Condition	Include		Include
Include/Exclude	Any		Any
Care Setting/Primary Diagnosis	-183, 0		-183, 0
Lookback Period	Atrial fibrillation or flutter		Atrial fibrillation or flutter
Pre-Existing Condition	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	Low-dose dabigatran, rivaroxaban, apixaban, edoxaban, warfarin	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin
Include/Exclude	Exclude	Exclude	Exclude
Lookback Period	0, 0	0, 0	0, 0
Pre-Existing Condition	Institutional stay encounter		Institutional stay encounter
Include/Exclude	Exclude		Exclude
Lookback Period	0, 0		0, 0
Pre-Existing Condition	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair
Include/Exclude	Exclude		Exclude
Care Setting/Primary Diagnosis	Any, except AV/OA for dialysis		Any, except AV/OA for dialysis
Lookback Period	-183, 0		-183, 0
Event/Outcome	Gastrointestinal hemorrhage ²		Gastrointestinal hemorrhage ²
Event/Outcome	IPP		IPP
Care Setting/Primary Diagnosis	0		0
Washout (days)	1		1
Blackout Period	See Appendix J		See Appendix J
Propensity Score Matching	1:1		1:1
Covariates	0.05		0.05
Matching Ratio	Conditional and unconditional		Conditional and unconditional
Matching Caliper Settings	Conditional and unconditional		Conditional and unconditional
Analysis Type	Conditional and unconditional		Conditional and unconditional

Appendix I. Specifications Defining Parameters Used in this Request

Subgroup Analyses			
Stratifying variable Re-matching	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort
Stratifying variable Re-matching	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort
Stratifying variable Re-matching	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort

¹The major extracranial bleed outcome is defined as **a)** one code from "MEB_1" tab in the primary inpatient position **AND** no code from "MEB_trauma_exclusion" on the same day **OR b)** one code from "MEB_2" in the primary inpatient position **AND** one code from "MEB_1" in secondary or unspecified inpatient position on the same day **AND** no code from "MEB_trauma_exclusion" on the same day

²The gastrointestinal hemorrhage outcome is defined as **a)** one code from "GI_1" tab in the primary inpatient position **OR b)** one code from "GI_2" in the primary inpatient position **AND** one code from "GI_1" in secondary or unspecified inpatient position on the same day

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix I. Specifications Defining Parameters Used in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.3, with additional programming to compare risk of stroke and bleeding associated with use of dabigatran, rivaroxaban, and apixaban in those aged 65 years or older in the Sentinel Distributed Database (SDD).

Query Period: October 19, 2010 - September 30, 2015
Coverage Requirement: Medical and drug coverage
Enrollment Requirement: 183 days
Enrollment Gap: 45 days
Age Groups: 65-74, 75-84, 85+ years
Additional Programming Needed: Risk scores, daily dose requirement

	Intracranial Hemorrhage					
	Comparison 10		Comparison 11		Comparison 12	
Drug/Exposure	Rivaroxaban	Dabigatran	Rivaroxaban	Apixaban	Dabigatran	Apixaban
Exposure/Comparator	Once daily	Twice daily	Once daily	Twice daily	Twice daily	Twice daily
Daily Dose Requirement	Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)		Apixaban, dabigatran, rivaroxaban, edoxaban, warfarin (all doses)	
Incident with Respect to:	Dispensing date or days supply		Dispensing date or days supply		Dispensing date or days supply	
Incidence Assessment	183		183		183	
Washout (days)	First valid incident exposure episode		First valid incident exposure episode		First valid incident exposure episode	
Cohort Definition	33%		33%		33%	
Stockpiling Overlapping Claims	3		3		3	
Episode Gap (Days)	3		3		3	
Episode Extension Period (Days)	1		1		1	
Minimum Episode Duration (Days)	None		None		None	
Maximum Episode Duration (Days)	1		1		1	
Minimum Days Supplied (Days)	Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Major extracranial bleeding, Gastrointestinal hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Major extracranial bleeding, Gastrointestinal hemorrhage		Death, Query end date, Disenrollment, Event, End of exposure episode, Comparator drug dispensing, Low-dose of current exposure, Warfarin dispensing, Edoxaban dispensing, Apixaban dispensing, Kidney transplant, Dialysis, IS encounter, Thromboembolic stroke, Major extracranial bleeding, Gastrointestinal hemorrhage	

Appendix I. Specifications Defining Parameters Used in this Request			
Inclusion/Exclusion	Atrial fibrillation or flutter		Atrial fibrillation or flutter
Pre-Existing Condition	Include		Include
Include/Exclude	Any		Any
Care Setting/Primary Diagnosis	-183, 0		-183, 0
Lookback Period	Atrial fibrillation or flutter		Atrial fibrillation or flutter
Pre-Existing Condition	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin	Low-dose dabigatran, rivaroxaban, apixaban, edoxaban, warfarin	Low-dose rivaroxaban, dabigatran, apixaban, edoxaban, warfarin
Include/Exclude	Exclude	Exclude	Exclude
Lookback Period	0, 0	0, 0	0, 0
Pre-Existing Condition	Institutional stay encounter		Institutional stay encounter
Include/Exclude	Exclude		Exclude
Lookback Period	0, 0		0, 0
Pre-Existing Condition	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair	Dialysis, Kidney replacement, Deep vein thrombosis, Pulmonary embolism, Joint replacement, Mitral stenosis, Valve replacement, Valve repair
Include/Exclude	Exclude		Exclude
Care Setting/Primary Diagnosis	Any, except AV/OA for dialysis		Any, except AV/OA for dialysis
Lookback Period	-183, 0		-183, 0
Event/Outcome	Intracranial Hemorrhage		Intracranial Hemorrhage
Event/Outcome	IPP		IPP
Care Setting/Primary Diagnosis	0		0
Washout (days)	1		1
Blackout Period	See Appendix J		See Appendix J
Propensity Score Matching	1:1		1:1
Covariates	0.05		0.05
Matching Ratio	Conditional and unconditional		Conditional and unconditional
Matching Caliper Settings	Conditional and unconditional		Conditional and unconditional
Analysis Type	Conditional and unconditional		Conditional and unconditional

Appendix I. Specifications Defining Parameters Used in this Request

Subgroup Analyses			
Stratifying variable Re-matching	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort	Age group Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort	Sex Re-matching should be done with the matched cohort
Stratifying variable Re-matching	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort	Antiplatelet drug use Re-matching should be done with the matched cohort
Stratifying variable Re-matching	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort	CHA ₂ DS ₂ -VASc score Re-matching should be done with the matched cohort
Stratifying variable Re-matching	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort	HAS-BLED score Re-matching should be done with the matched cohort

¹The major extracranial bleed outcome is defined as **a)** one code from "MEB_1" tab in the primary inpatient position **AND** no code from "MEB_trauma_exclusion" on the same day **OR b)** one code from "MEB_2" in the primary inpatient position **AND** one code from "MEB_1" in secondary or unspecified inpatient position on the same day **AND** no code from "MEB_trauma_exclusion" on the same day

²The gastrointestinal hemorrhage outcome is defined as **a)** one code from "GI_1" tab in the primary inpatient position **OR b)** one code from "GI_2" in the primary inpatient position **AND** one code from "GI_1" in secondary or unspecified inpatient position on the same day

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix J. Baseline Covariate Groups Evaluated in this Request

Covariate	Evaluation Window	Care Settings¹
Age (continuous)	Index date	-
Age-group		
65-74	Index date	-
75-84	Index date	-
85+	Index date	-
Female	Index date	-
Race/ethnicity		
American Indian or Alaska Native	Index date	-
Asian	Index date	-
Black or African American	Index date	-
Native Hawaiian or Other Pacific Islander	Index date	-
White	Index date	-
Unknown	Index date	-
Year		
2010	Index date	-
2011	Index date	-
2012	Index date	-
2013	Index date	-
2014	Index date	-
2015	Index date	-
Medical comorbidities		
Diabetes	-183 to 0	Any
Hypercholesterolemia	-183 to 0	Any
Hypertension	-183 to 0	Any
Kidney failure		
Acute	-183 to 0	Any
Chronic	-183 to 0	Any
Obesity	-183 to 0	Any
Peptic ulcer disease	-183 to 0	Any
Prior hospitalized bleeding	-183 to 0	IPP
Nicotine dependency	-183 to 0	Any
Cardiovascular disease		
Acute myocardial infarction		
Past 1-30 days	-30 to 0	IPP or IPS
Past 31-183 days	-183 to -31	IPP or IPS
Coronary revascularization	-183 to 0	Any
Heart failure		
Hospitalized	-183 to 0	IP or ED
Outpatient	-183 to 0	AV or OA
Other ischemic heart disease	-183 to 0	Any
Stroke		
Past 1-30 days	-30 to 0	IPP
Past 31-183 days	-183 to -31	IPP
Other		
Transient ischemic attack	-183 to 0	Any
Cardioablation	-183 to 0	Any
Cardioversion	-183 to 0	Any

Appendix J. Baseline Covariate Groups Evaluated in this Request

Covariate	Evaluation Window	Care Settings¹
Other medical conditions		
Falls	-183 to 0	Any
Fractures	-183 to 0	Any
Syncope	-183 to 0	Any
Walker use	-183 to 0	Any
CHA₂DS₂-VAsc score²		
0-1	-183 to 0	-
2	-183 to 0	-
3	-183 to 0	-
4	-183 to 0	-
5	-183 to 0	-
≥6	-183 to 0	-
HAS-BLED score³		
0-1	-183 to 0	-
2	-183 to 0	-
3	-183 to 0	-
≥4	-183 to 0	-
Medication use		
<i>General</i>		
Estrogen replacement	-183 to 0	-
H2-antagonists	-183 to 0	-
Nonsteroidal anti-inflammatory drugs (NSAIDs)	-183 to 0	-
Proton pump inhibitors	-183 to 0	-
Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants	-183 to 0	-
<i>Cardiovascular</i>		
Angiotensin-converting-enzyme inhibitors (ACEI)/Angiotensin II Receptor Blockers (ARB)	-183 to 0	-
Antiarrhythmics	-183 to 0	-
Anticoagulants (injectable)	-183 to 0	-
Anti-platelets	-183 to 0	-
Beta-blockers	-183 to 0	-
Calcium channel blockers	-183 to 0	-
Digoxin	-183 to 0	-
Diuretics		
Loop	-183 to 0	-
Potassium sparing	-183 to 0	-
Thiazide	-183 to 0	-
Nitrates	-183 to 0	-
Statins	-183 to 0	-
Fibrates	-183 to 0	-
<i>Diabetes-related</i>		
Insulin	-183 to 0	-
Metformin	-183 to 0	-
Sulfonylureas	-183 to 0	-
Other	-183 to 0	-

Appendix J. Baseline Covariate Groups Evaluated in this Request

Covariate	Evaluation Window	Care Settings ¹
<i>Metabolic inhibitors</i>		
Amiodarone	-183 to 0	-
Dronedarone	-183 to 0	-
Health care utilization		
Number of inpatient hospital stays	-183 to 0	IP
Number of emergency department visit	-183 to 0	ED
Number of ambulatory visits	-183 to 0	AV
Drug utilization		
Number of unique generics dispensed	-183 to 0	-

Highlighted cells mean that they were not included in the Propensity Score Model, but were included in Table 1

¹Caresetting/Principal Diagnosis

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

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.

Principal Diagnosis - 'IPP' = inpatient principal diagnosis, 'IPS' = inpatient secondary diagnosis