**[680] Female rivaroxaban new users with prior non-valvular atrial fibrillation**

**Initial Event Cohort**

People having any of the following:

* a drug exposure of [631] Rivaroxaban8
  + for the first time in the person's history
  + occurrence start is between 2010-10-19 and 2018-12-31 (inclusive)
  + with age >= 18
  + gender is any of: FEMALE

with continuous observation of at least 183 days prior and 0 days after event index date, and limit initial events to: **earliest event per person.**

**For people matching the Primary Events, include:**

Having all of the following criteria:

* exactly 0 occurrences of a drug exposure of [631] Edoxaban5

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a drug exposure of [631] Apixaban1

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a drug exposure of [631] Dabigatran etexilate4

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a drug exposure of [631] Warfarin14

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a procedure of [631] Hysterectomy procedures6

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a condition occurrence of [631] Vaginal bleed12

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a procedure of [631] Medical managements for severe uterine bleed, procedures and drugs7

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a drug exposure of [631] Medical managements for severe uterine bleed, procedures and drugs7

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a condition occurrence of [631] Surgical management of vaginal bleed, conditions and procedures - OPTIMIZED9

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a procedure of [631] Surgical management of vaginal bleed, conditions and procedures - OPTIMIZED9

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a procedure of [631] Tranfusion management of vaginal bleed, procedures11

Having [object Object] of the following criteria:

* + - at least 1 occurrences of a drug exposure of [631] Conjugated equine estrogen3

where event starts between 0 days Before and 0 days After index start date

where event starts between all days Before and 0 days After index start date

* and exactly 0 occurrences of a device exposure of [631] Tranfusion management of vaginal bleed, procedures11

Having [object Object] of the following criteria:

* + - at least 1 occurrences of a drug exposure of [631] Conjugated equine estrogen3

where event starts between 0 days Before and 0 days After index start date

where event starts between all days Before and 0 days After index start date

Limit cohort of initial events to: **earliest event per person.**

**Inclusion Rules**

Inclusion Criteria #1: With prior non-valvular atrial fibrillation

Having all of the following criteria:

* at least 1 occurrences of a condition occurrence of [631] Atrial fibrillation and flutter2

where event starts between all days Before and 0 days After index start date

Inclusion Criteria #2: With no prior venous thromboembolism in the past 183 days

Having all of the following criteria:

* exactly 0 occurrences of a condition occurrence of [631] Venous thromboembolism (pulmonary embolism and deep vein thrombosis)13

where event starts between 183 days Before and 0 days After index start date

Inclusion Criteria #3: With no prior knee or hip replacement surgery in the past 35 days

Having all of the following criteria:

* exactly 0 occurrences of a procedure of [631] Total Knee and Hip Replacement procedures10

where event starts between 35 days Before and 0 days After index start date

Limit qualifying cohort to: **earliest event per person.**

End Date Strategy

Custom Drug Era Exit Criteria

This strategy creates a drug era from the codes found in the specified concept set. If the index event is found within an era, the cohort end date will use the era's end date. Otherwise, it will use the observation period end date that contains the index event.

Use the era end date of [631] Rivaroxaban8

* allowing 3 days between exposures
* adding 0 days after exposure end
* using days supply and exposure end date for exposure duration.

Cohort Collapse Strategy:

Collapse cohort by era with a gap size of 0 days.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Appendix 1: Concept Set Definitions** | | | | | | |
|  |  |  |  |  |  |  |
| **[631] Apixaban** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 43013024 | apixaban | Drug | RxNorm | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Atrial fibrillation and flutter** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 313217 | Atrial fibrillation | Condition | SNOMED | NO | YES | NO |
| 314665 | Atrial flutter | Condition | SNOMED | NO | YES | NO |
| 37395821 | Familial atrial fibrillation | Condition | SNOMED | YES | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Conjugated equine estrogen** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 1549080 | Estrogens, Conjugated (USP) | Drug | RxNorm | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Dabigatran etexilate** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 40228152 | dabigatran etexilate | Drug | RxNorm | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Edoxaban** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 45892847 | edoxaban | Drug | RxNorm | NO | NO | NO |
|  |  |  |  |  |  |  |
| **[631] Hysterectomy procedures** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 4127886 | Hysterectomy | Procedure | SNOMED | NO | YES | NO |
| 45889633 | Hysterectomy Procedures | Procedure | CPT4 | NO | YES | NO |
| 2890751 | Medical and Surgical @ Female Reproductive System @ Resection @ Cervix | Procedure | ICD10PCS | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Medical managements for severe uterine bleed, procedures and drugs** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 1369939 | 6-Aminocaproic Acid | Drug | RxNorm | NO | YES | NO |
| 19000729 | Aprotinin | Drug | RxNorm | NO | YES | NO |
| 21502572 | Contraceptive Oral - Biphasic | Drug | ETC | NO | YES | NO |
| 21500145 | Contraceptive Oral - Monophasic | Drug | ETC | NO | YES | NO |
| 21500137 | Contraceptive Oral - Progestin | Drug | ETC | NO | YES | NO |
| 40250176 | Contraceptive Oral - Quadraphasic | Drug | ETC | NO | YES | NO |
| 21500146 | Contraceptive Oral - Triphasic | Drug | ETC | NO | YES | NO |
| 21502571 | Contraceptives Oral | Drug | ETC | NO | YES | NO |
| 1517070 | desmopressin | Drug | RxNorm | NO | YES | NO |
| 36234886 | Desogen (contraceptive) Oral Product | Drug | RxNorm | NO | YES | NO |
| 36234887 | Desogen (contraceptive) Pill | Drug | RxNorm | NO | YES | NO |
| 21602472 | HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE | Drug | ATC | NO | YES | NO |
| 4275113 | Insertion of intrauterine contraceptive device | Procedure | SNOMED | NO | YES | NO |
| 1718400 | Levonorgestrel Intrauterine System | Drug | RxNorm | NO | YES | NO |
| 1303425 | Tranexamic Acid | Drug | RxNorm | NO | YES | NO |
| 4197724 | Vaginal pack procedure | Procedure | SNOMED | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Rivaroxaban** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 40241331 | rivaroxaban | Drug | RxNorm | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Surgical management of vaginal bleed, conditions and procedures - OPTIMIZED** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 4300370 | Amputation of cervix | Procedure | SNOMED | YES | NO | NO |
| 2101815 | Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure performed) | Procedure | CPT4 | NO | YES | NO |
| 2101809 | Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care | Procedure | CPT4 | NO | YES | NO |
| 2101015 | Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy | Procedure | CPT4 | NO | YES | NO |
| 2101000 | Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy | Procedure | CPT4 | NO | YES | NO |
| 2101808 | Anesthesia for urgent hysterectomy following delivery | Procedure | CPT4 | NO | YES | NO |
| 2101597 | Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); hysteroscopy and/or hysterosalpingography | Procedure | CPT4 | NO | YES | NO |
| 2101592 | Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy | Procedure | CPT4 | NO | YES | NO |
| 2004524 | Aspiration curettage of uterus | Procedure | ICD9Proc | NO | NO | NO |
| 4181912 | Cone biopsy of cervix | Procedure | SNOMED | YES | NO | NO |
| 42733496 | Dilation and curettage of cervical stump | Procedure | CPT4 | NO | YES | NO |
| 2110163 | Dilation and curettage of cervical stump | Procedure | CPT4 | NO | YES | NO |
| 4015660 | Dilation and curettage of uterus | Procedure | SNOMED | NO | NO | NO |
| 2110171 | Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical) | Procedure | CPT4 | NO | YES | NO |
| 4141940 | Endometrial ablation | Procedure | SNOMED | NO | NO | NO |
| 2110203 | Endometrial ablation, thermal, without hysteroscopic guidance | Procedure | CPT4 | NO | YES | NO |
| 42739908 | Endometrial cryoablation with ultrasonic guidance | Procedure | CPT4 | NO | YES | NO |
| 2110204 | Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed | Procedure | CPT4 | NO | YES | NO |
| 1314496 | Endometrial sampling or hysteroscopy with biopsy and results documented | Observation | HCPCS | NO | YES | NO |
| 1314497 | Endometrial sampling or hysteroscopy with biopsy and results not documented | Observation | HCPCS | NO | YES | NO |
| 4127886 | Hysterectomy | Procedure | SNOMED | NO | YES | NO |
| 2110228 | Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants | Procedure | CPT4 | NO | YES | NO |
| 2722224 | Hysteroscopy, surgical; with division or resection of intrauterine septum (any method). | Procedure | CPT4 | NO | YES | NO |
| 2722227 | Hysteroscopy, surgical; with endometrial ablation (any method). | Procedure | CPT4 | NO | YES | NO |
| 2110223 | Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method) | Procedure | CPT4 | NO | YES | NO |
| 2722223 | Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method). | Procedure | CPT4 | NO | YES | NO |
| 2110226 | Hysteroscopy, surgical; with removal of impacted foreign body | Procedure | CPT4 | NO | YES | NO |
| 2722226 | Hysteroscopy, surgical; with removal of impacted foreign body. | Procedure | CPT4 | NO | YES | NO |
| 2722225 | Hysteroscopy, surgical; with removal of leiomyomata. | Procedure | CPT4 | NO | YES | NO |
| 2722222 | Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C. | Procedure | CPT4 | NO | YES | NO |
| 2110292 | Hysterotomy, abdominal (eg, for hydatidiform mole, abortion) | Procedure | CPT4 | NO | YES | NO |
| 2722207 | Laparoscopy, surgical; with removal of leiomyomata, subserosal (single or multiple). | Procedure | CPT4 | NO | YES | NO |
| 2868153 | Medical and Surgical @ Central Nervous System and Cranial Nerves @ Drainage @ Subdural Space, Intracranial @ Percutaneous Endoscopic | Procedure | ICD10PCS | NO | YES | NO |
| 2802049 | Medical and Surgical @ Peripheral Nervous System @ Drainage @ Radial Nerve @ Percutaneous | Procedure | ICD10PCS | NO | YES | NO |
| 2004527 | Other aspiration curettage of uterus | Procedure | ICD9Proc | NO | NO | NO |
| 2004444 | Other diagnostic procedures on uterus and supporting structures | Procedure | ICD9Proc | NO | NO | NO |
| 2004491 | Other dilation and curettage | Procedure | ICD9Proc | NO | NO | NO |
| 2004449 | Other excision or destruction of lesion of uterus | Procedure | ICD9Proc | NO | NO | NO |
| 2004503 | Other excision or destruction of uterus and supporting structures | Procedure | ICD9Proc | NO | NO | NO |
| 195599 | Prolapse of vaginal vault after hysterectomy | Condition | SNOMED | NO | NO | NO |
| 2722229 | Unlisted procedure, laparoscopy, hysteroscopy. | Procedure | CPT4 | NO | YES | NO |
| 40756770 | Uterine artery embolization [UAE] with coils | Procedure | ICD9Proc | NO | NO | NO |
| 40756808 | Uterine artery embolization [UAE] without coils | Procedure | ICD9Proc | NO | NO | NO |
| 2721144 | UTERINE ARTERY EMBOLIZATION FOR UTERINE FIBROIDS | Procedure | HCPCS | NO | YES | NO |
| 2108349 | Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intra | Procedure | CPT4 | NO | YES | NO |
| 197236 | Uterine leiomyoma | Condition | SNOMED | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Total Knee and Hip Replacement procedures** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 2101660 | Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty | Procedure | CPT4 | NO | YES | NO |
| 4263062 | Anesthesia for total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 2105103 | Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty) | Procedure | CPT4 | NO | YES | NO |
| 42539735 | Attention to total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 4079258 | Conversion to cemented total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 4079260 | Conversion to uncemented total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 4142076 | Primary cemented total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 4079259 | Primary uncemented total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 2774102 | Replacement of Left Knee Joint with Autologous Tissue Substitute, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774106 | Replacement of Left Knee Joint with Nonautologous Tissue Substitute, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774103 | Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774105 | Replacement of Left Knee Joint with Synthetic Substitute, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774104 | Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774097 | Replacement of Right Knee Joint with Autologous Tissue Substitute, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774101 | Replacement of Right Knee Joint with Nonautologous Tissue Substitute, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774098 | Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774100 | Replacement of Right Knee Joint with Synthetic Substitute, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 2774099 | Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach | Procedure | ICD10PCS | NO | YES | NO |
| 4076468 | Revision cemented total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 4266062 | Revision of total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 4076070 | Revision uncemented total hip replacement | Procedure | SNOMED | NO | YES | NO |
| 43531648 | Total knee replacement | Procedure | SNOMED | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Tranfusion management of vaginal bleed, procedures** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 38003219 | Blood - Packed Red Cells | Revenue Code | Revenue Code | NO | NO | NO |
| 4125928 | Packed blood cell transfusion | Procedure | SNOMED | NO | YES | NO |
| 2720538 | Red blood cells, deglycerolized, each unit | Device | HCPCS | NO | NO | NO |
| 2720527 | Red blood cells, each unit | Device | HCPCS | NO | NO | NO |
| 2720555 | Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit | Device | HCPCS | NO | NO | NO |
| 2720537 | Red blood cells, irradiated, each unit | Device | HCPCS | NO | NO | NO |
| 2720556 | Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit | Device | HCPCS | NO | NO | NO |
| 2720522 | Red blood cells, leukocytes reduced, each unit | Device | HCPCS | NO | NO | NO |
| 2720539 | Red blood cells, leukocytes reduced, irradiated, each unit | Device | HCPCS | NO | NO | NO |
| 2720528 | Red blood cells, washed, each unit | Device | HCPCS | NO | NO | NO |
| 2720549 | Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit | Device | HCPCS | NO | NO | NO |
| 2720552 | Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit | Device | HCPCS | NO | NO | NO |
|  |  |  |  |  |  |  |
| **[631] Vaginal bleed** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 37119535 | Artificial menopause | Condition | MedDRA | NO | NO | NO |
| 194696 | Dysmenorrhea | Condition | SNOMED | YES | YES | NO |
| 4302555 | Menorrhagia | Condition | SNOMED | NO | YES | NO |
| 37119544 | Menstrual disorder | Condition | MedDRA | NO | YES | NO |
| 37119545 | Metrorrhagia | Condition | MedDRA | NO | YES | NO |
| 195867 | Noninflammatory disorder of the vagina | Condition | SNOMED | NO | NO | NO |
| 440155 | Postartificial menopausal syndrome | Condition | SNOMED | NO | NO | NO |
| 195321 | Postmenopausal bleeding | Condition | SNOMED | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Venous thromboembolism (pulmonary embolism and deep vein thrombosis)** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 435616 | Amniotic fluid embolism | Condition | SNOMED | YES | YES | NO |
| 435887 | Antepartum deep vein thrombosis | Condition | SNOMED | YES | YES | NO |
| 196715 | Budd-Chiari syndrome | Condition | SNOMED | YES | YES | NO |
| 4062269 | Cerebral venous thrombosis in pregnancy | Condition | SNOMED | YES | YES | NO |
| 442055 | Obstetric air pulmonary embolism | Condition | SNOMED | YES | YES | NO |
| 433832 | Obstetric blood-clot pulmonary embolism | Condition | SNOMED | YES | YES | NO |
| 435026 | Obstetric pulmonary embolism | Condition | SNOMED | YES | YES | NO |
| 440477 | Obstetric pyemic and septic pulmonary embolism | Condition | SNOMED | YES | YES | NO |
| 318137 | Phlebitis and thrombophlebitis of intracranial sinuses | Condition | SNOMED | YES | YES | NO |
| 199837 | Portal vein thrombosis | Condition | SNOMED | YES | YES | NO |
| 438820 | Postpartum deep phlebothrombosis | Condition | SNOMED | YES | YES | NO |
| 440417 | Pulmonary embolism | Condition | SNOMED | NO | YES | NO |
| 254662 | Pulmonary infarction | Condition | SNOMED | NO | YES | NO |
| 4235812 | Septic thrombophlebitis | Condition | SNOMED | YES | YES | NO |
| 195294 | Thrombosed hemorrhoids | Condition | SNOMED | YES | YES | NO |
| 4187790 | Thrombosis of retinal vein | Condition | SNOMED | YES | YES | NO |
| 444247 | Venous thrombosis | Condition | SNOMED | NO | YES | NO |
|  |  |  |  |  |  |  |
| **[631] Warfarin** | | | | | | |
| Concept Id | Concept Name | Domain | Vocabulary | Excluded | Descendants | Mapped |
| 1310149 | Warfarin | Drug | RxNorm | NO | YES | NO |