Disclaimer

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

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

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

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

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Overview for Request: cder_mpl1r_wp170

Request ID: cder_mpl1r_wp170_nsdp_v01

Request Description: In this report we obtained background incidence of severe uterine bleed (SUB) outcomes for the previous request (cder_mpl1r_wp165_nsdp_v02) from the Sentinel Distributed Database (SDD). These estimates are for populations of women exposed to oral anticoagulants (OACs) or of women with no indication for atrial fibrillation (AF) or deep vein thrombosis (DVT)/pulmonary embolism (PE) and no exposure to OACs. For both populations, we obtained SUB incidence overall, and by calendar year or age group. We also obtained information on types of surgical outcomes.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4

Data Source: We distributed this request to 16 Data Partners on March 11, 2020. The study period included data from October 19, 2010 to September 30, 2015. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We performed a cross-sectional study and calculated the background SUB incidence respectively among individuals in the OAC-exposed and reference populations. We also included a sensitivity OAC-exposed population that relaxed the OAC inclusion criterion to any utilization evidenced by dispensing day supply in the 183 days prior to or on the day of SUB. This is a Type 2 analysis in the Query Request Package (QRP) documentation. These three cohort variations were created for each outcome assessed in the previous request (cder_mpl1r_wp165_nsdp_v02):
- SUB defined using medical management on same day as vaginal bleed (VB) diagnosis
- SUB defined using medical management within 5 days after VB diagnosis
- SUB defined using transfusion management on same day as VB diagnosis
- SUB defined using surgical management within 30 days after VB diagnosis
- SUB defined using surgical management within 60 days after VB diagnosis

We defined these fifteen cohorts to estimate SUB incidence in the overall population and subgroups by the following characteristics upon VB diagnosis:
- age group (17 years of age or less, 18-50 years, 51 or more years of age)
- calendar year

Additionally, we estimated SUB incidence among members with a first VB diagnosis in the overall population and subgroups by the following characteristics upon VB diagnosis:
- age group (less than 17 years, 18-50 years, 51 or more years of age)
- calendar year
- baseline gynecological disorder (uterine myoma, endometrial hyperplasia, endometriosis, ovarian cyst, uterine or cervical polyp, adenomyosis, or uterine cancer/ovarian cancer/cervical cancer)
- baseline intrauterine device (IUD) use
- baseline oral contraceptive use
- cross-stratification of baseline gynecological disorder, IUD use, and oral contraceptive use by age group.

Exposures of Interest: We created exposure episodes of interest indexed on the first qualifying VB diagnosis in non-institutional (non-IS) care settings. We identified VB exposure using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes. We only included the first valid diagnosis per patient. See Appendix B for a list of codes used to define the exposure in this request.

Overview for Request: cder_mpl1r_wp170

Outcomes of Interest: The outcome for this request was SUB, defined as the medical, transfusion, or surgical managements in any care setting following the index VB diagnosis. The definitions for each management were as below.

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

Managements were defined using ICD-9-CM diagnosis and procedure codes, Healthcare Common Procedure Coding System (HCPCS) codes, Current Procedural Terminology, Fourth Edition (CPT-4) Category I and III codes, and Revenue Center codes. Appendix C lists the diagnosis and procedure codes used to define medical, transfusion, and surgical managements. Appendix D lists the generic and brand names used to define medical managements.

Cohort Eligibility Criteria: We required members to be enrolled in health plans with medical and drug coverage in the 183 days prior to their index date in order to be included in the cohort, during which gaps in coverage of up to 45 days were allowed. We also required members to not have the exposure of interest within the 183 days prior to the index date, or hip or knee joint replacement surgery in the 183 days prior to or on the index date. We required members to be female. Only the first valid VB diagnosis of each member was included; cohort reentry was not allowed.

We used inclusion and exclusion criteria to define OAC-exposure and reference cohorts. For the reference population, we excluded members with either OAC indication (AF or DVT/PE) in the 183-day window prior to or on the index date. We also excluded OAC utilization evidenced by dispensing days supply on the index date. For the OAC-exposed population, we included these members instead. For the sensitivity OAC-exposed population, we further relaxed the OAC utilization criterion to the 183 days prior to, or on the index date.

We identified OAC indications with ICD-9-CM diagnosis codes and joint replacement with ICD-9-CM or CPT-4 procedure codes observed in medical claims. We identified OAC exposure with National Drug Codes (NDCs) observed in the outpatient pharmacy dispensings. Diagnosis and procedure inclusion and exclusion codes are listed in Appendix E. Generic and brand names of medical products for OACs are listed in Appendix F.

Follow-Up Time: We operationalized intention-to-treat after the index VB diagnosis and assigned fixed episode lengths to each cohort that equal the maximum allowable gap between VB diagnosis and SUB management per SUB definition: 1 day for the same-day SUB definitions, 5 days for the SUB with medical management, and 30 or 60 days for the SUB with surgical management. Follow-up began on the index date and continued until the first occurrence of: 1) disenrollment; 2) death; 3) the end date of the data provided by each Data Partner; 4) the end of the query period (September 30, 2015); 5) occurrence of the outcome of interest; or 6) end of assigned episode length.

Overview for Request: cder_mpl1r_wp170

Baseline Characteristics: We evaluated the following characteristics during the baseline period: age on the index date (continuous and by age group), calendar year of the index date, race/ethnicity, comorbidity score (Combined Comorbidity Index)[a], health service and drug utilization, gynecological disorders, medical managements, DVT/PE, and AF. The components of gynecological disorders and medical managements were captured separately and as an aggregate characteristic. Gynecological disorders, DVT/PE, and AF were collected from any care setting, while medical managements were collected from non-IS care settings. Occurrence of these characteristics, except for demographics and calendar year, was evaluated in the 183 days prior to and on the index date. Additionally, same-day rivaroxaban, dabigatran, apixaban, and warfarin utilization evidenced by dispensing days supply was evaluated on the index date.

Please see Appendix G for a list of diagnosis and procedure codes used to define baseline characteristics in this request. Generic and brand names of medical products used to define OAC utilization can be found in Appendix F, and those used to define medical managements can be found in Appendix D.

Limitations: 1) As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. 2) Algorithms used to define exposures, outcomes, and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Data should be interpreted with these limitations in mind.

Please see Appendices H.1-H.5 for the specifications of parameters to be used in the analyses and Appendix I for the list of characteristics considered in this request.

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse).

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

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Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) 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). Along with the Principal Diagnosis Indicator, 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.

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

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

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

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

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

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

Event Deduplication - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an 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 days 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

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

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

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

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

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

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

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

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

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

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

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

*all terms may not be used in this report

Table 1a. Baseline Characteristics for Reference Population (Medical Management Outcomes) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Characteristic[1]	Number	Percent
Number of unique patients	4,245,692	100%
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	44.1	14.5
Age	**Number**	**Percent**
17 years or less	210,795	5.0%
18 to 50 years	2,760,939	65.0%
51 years or more	1,273,958	30.0%
Sex		
Female	4,245,692	100.0%
Year		
2010	202,578	4.8%
2011	956,947	22.5%
2012	829,734	19.5%
2013	816,358	19.2%
2014	824,088	19.4%
2015	615,987	14.5%
Recorded history of:	**Mean**	**Standard Deviation**
Charlson/Elixhauser Combined Comorbidity Score	0.4	1.2
	Number	**Percent**
Any gynecological disorders of interest	646,089	15.2%
Uterine myoma	328,205	7.7%
Endometrial hyperplasia	36,618	0.9%
Endometriosis	21,593	0.5%
Ovarian cyst	240,264	5.7%
Uterine or cervical polyp	99,408	2.3%
Adenomyosis	25,644	0.6%
Uterine, ovarian or cervical cancer	43,042	1.0%
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	0	0.0%
Atrial fibrillation or atrial flutter (AF)	0	0.0%
History of use:		
Any medical management	692,161	16.3%
Intrauterine device (IUD)	70,981	1.7%
Oral contraception	620,355	14.6%
Vaginal packing	1,478	0.0%
Antifibrinolytic drug	13,794	0.3%
Ongoing novel oral anticoagulants (NOACs)	0	0.0%
Rivaroxaban	0	0.0%
Dabigatran	0	0.0%
Apixaban	0	0.0%
Ongoing warfarin	0	0.0%

Table 1a. Baseline Characteristics for Reference Population (Medical Management Outcomes) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Health service utilization intensity:	Mean	Standard Deviation
Mean number of ambulatory encounters (AV)	7.8	9.2
Mean number of emergency room encounters (ED)	0.3	1
Mean number of inpatient hospital encounters (IP)	0.1	0.4
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	2	4.7
Mean number of unique drug classes	4.3	3.7
Mean number of generics	4.6	4.2
Mean number of filled prescriptions	10.8	12.9

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 1a.1. Baseline Characteristics for Reference Population (Transfusion and Surgical Management Outcomes) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Characteristic[1]	Number	Percent
Number of unique patients	4,245,694	100%
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	44.1	14.5
Age	**Number**	**Percent**
17 years or less	210,795	5.0%
18 to 50 years	2,760,941	65.0%
51 years or more	1,273,958	30.0%
Sex		
Female	4,245,694	100.0%
Year		
2010	202,578	4.8%
2011	956,948	22.5%
2012	829,735	19.5%
2013	816,358	19.2%
2014	824,088	19.4%
2015	615,987	14.5%
Recorded history of:	**Mean**	**Standard Deviation**
Charlson/Elixhauser Combined Comorbidity Score	0.4	1.2
	Number	**Percent**
Any gynecological disorders of interest	646,089	15.2%
Uterine myoma	328,205	7.7%
Endometrial hyperplasia	36,618	0.9%
Endometriosis	21,593	0.5%
Ovarian cyst	240,264	5.7%
Uterine or cervical polyp	99,408	2.3%
Adenomyosis	25,644	0.6%
Uterine, ovarian or cervical cancer	43,042	1.0%
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	0	0.0%
Atrial fibrillation or atrial flutter (AF)	0	0.0%
History of use:		
Any medical management	692,163	16.3%
Intrauterine device (IUD)	70,981	1.7%
Oral contraception	620,357	14.6%
Vaginal packing	1,478	0.0%
Antifibrinolytic drug	13,794	0.3%
Ongoing novel oral anticoagulants (NOACs)	0	0.0%
Rivaroxaban	0	0.0%
Dabigatran	0	0.0%
Apixaban	0	0.0%
Ongoing warfarin	0	0.0%

Table 1a.1. Baseline Characteristics for Reference Population (Transfusion and Surgical Management Outcomes) in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Health Service Utilization Intensity:	Mean	Standard Deviation
Mean number of ambulatory encounters (AV)	7.8	9.2
Mean number of emergency room encounters (ED)	0.3	1
Mean number of inpatient hospital encounters (IP)	0.1	0.4
Mean number of non-acute institutional encounters (IS)	0	0.2
Mean number of other ambulatory encounters (OA)	2	4.7
Mean number of unique drug classes	4.3	3.7
Mean number of generics	4.6	4.2
Mean number of filled prescriptions	10.8	12.9

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 1b. Baseline Characteristics for Ongoing Oral Anticoagulant (OAC) Exposure Population in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Characteristic[1]	Number	Percent
Number of unique patients	80,967	100%
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	69.3	15.3
Age	**Number**	**Percent**
17 years or less	53	0.1%
18 to 50 years	14,410	17.8%
51 years or more	66,504	82.1%
Sex		
Female	80,967	100.0%
Year		
2010	2,929	3.6%
2011	15,059	18.6%
2012	15,120	18.7%
2013	16,448	20.3%
2014	17,728	21.9%
2015	13,683	16.9%
Recorded history of:	**Mean**	**Standard Deviation**
Charlson/Elixhauser Combined Comorbidity Score	3.3	3
	Number	**Percent**
Any gynecological disorders of interest	11,653	14.4%
Uterine myoma	4,590	5.7%
Endometrial hyperplasia	1,227	1.5%
Endometriosis	120	0.1%
Ovarian cyst	3,009	3.7%
Uterine or cervical polyp	1,682	2.1%
Adenomyosis	231	0.3%
Uterine, ovarian or cervical cancer	3,145	3.9%
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	37,965	46.9%
Atrial fibrillation or atrial flutter (AF)	53,158	65.7%
History of use:		
Any medical management	2,348	2.9%
Intrauterine device (IUD)	529	0.7%
Oral contraception	1,816	2.2%
Vaginal packing	101	0.1%
Antifibrinolytic drug	27	0.0%
Ongoing novel oral anticoagulants (NOACs)	15,686	19.4%
Rivaroxaban	9,406	11.6%
Dabigatran	4,253	5.3%
Apixaban	2,097	2.6%
Ongoing warfarin	66,409	82.0%

Table 1b. Baseline Characteristics for Ongoing Oral Anticoagulant (OAC) Exposure Population in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Health service utilization intensity:	Mean	Standard Deviation
Mean number of ambulatory encounters (AV)	20.4	16.8
Mean number of emergency room encounters (ED)	0.9	1.9
Mean number of inpatient hospital encounters (IP)	0.6	1.1
Mean number of non-acute institutional encounters (IS)	0.2	0.7
Mean number of other ambulatory encounters (OA)	11.7	17.9
Mean number of unique drug classes	11.2	5.2
Mean number of generics	12	5.9
Mean number of filled prescriptions	37	26.3

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 1c. Baseline Characteristics for Baseline or Ongoing Oral Anticoagulant (OAC) Exposure Population in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Characteristic[1]	Number	Percent
Number of unique patients	101,356	100%
Demographics	**Mean**	**Standard Deviation**
Mean Age (years)	68.8	15.4
Age	**Number**	**Percent**
17 years or less	70	0.1%
18 to 50 years	18,872	18.6%
51 years or more	82,414	81.3%
Sex		
Female	101,356	100.0%
Year		
2010	3,840	3.8%
2011	19,439	19.2%
2012	19,141	18.9%
2013	20,434	20.2%
2014	21,741	21.5%
2015	16,761	16.5%
Recorded history of:	**Mean**	**Standard Deviation**
Charlson/Elixhauser Combined Comorbidity Score	3.4	3.1
	Number	**Percent**
Any gynecological disorders of interest	14,913	14.7%
Uterine myoma	5,796	5.7%
Endometrial hyperplasia	1,512	1.5%
Endometriosis	168	0.2%
Ovarian cyst	3,900	3.8%
Uterine or cervical polyp	2,118	2.1%
Adenomyosis	300	0.3%
Uterine, ovarian or cervical cancer	4,073	4.0%
Deep vein thrombosis (DVT) / pulmonary embolism (PE)	48,519	47.9%
Atrial fibrillation or atrial flutter (AF)	65,510	64.6%
History of use:		
Any medical management	2,929	2.9%
Intrauterine device (IUD)	705	0.7%
Oral contraception	2,228	2.2%
Vaginal packing	119	0.1%
Antifibrinolytic drug	36	0.0%
Ongoing novel oral anticoagulants (NOACs)	15,501	15.3%
Rivaroxaban	9,283	9.2%
Dabigatran	4,211	4.2%
Apixaban	2,077	2.0%
Ongoing warfarin	65,380	64.5%

Table 1c. Baseline Characteristics for Baseline or Ongoing Oral Anticoagulant (OAC) Exposure Population in the Sentinel Distributed Database (SDD) between October 19, 2010 to September 30, 2015

Health service utilization intensity:	Mean	Standard Deviation
Mean number of ambulatory encounters (AV)	20.6	17.2
Mean number of emergency room encounters (ED)	0.9	2
Mean number of inpatient hospital encounters (IP)	0.7	1.2
Mean number of non-acute institutional encounters (IS)	0.2	0.7
Mean number of other ambulatory encounters (OA)	11.9	18.3
Mean number of unique drug classes	11	5.2
Mean number of generics	11.9	5.9
Mean number of filled prescriptions	35.3	25.4

[1]All metrics are based on total number of episodes per group, except for sex which is based on total number of unique patients

Table 2. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, Overall

	Eligible Members[1]	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per 1,000 Eligible Members	SUB per New VB Diagnosis
Same-Day Medical Management					
Reference Population	61,697,747	4,245,692[2]	216,592	3.51	0.05
Ongoing OAC Exposure Population	2,345,188	80,967	443	0.19	0.01
Baseline or Ongoing OAC Exposure Population	2,477,502	101,356	562	0.23	0.01
5-Day Gap Medical Management					
Reference Population	61,697,747	4,245,692[2]	296,956	4.81	0.07
Ongoing OAC Exposure Population	2,345,188	80,967	594	0.25	0.01
Baseline or Ongoing OAC Exposure Population	2,477,502	101,356	761	0.31	0.01
Same-Day Transfusion Management					
Reference Population	61,697,747	4,245,694	16,523	0.27	0.00
Ongoing OAC Exposure Population	2,345,188	80,967	2,078	0.89	0.03
Baseline or Ongoing OAC Exposure Population	2,477,502	101,356	2,711	1.09	0.03
30-Day Gap Surgical Management					
Reference Population	61,697,747	4,245,694	306,488	4.97	0.07
Ongoing OAC Exposure Population	2,345,188	80,967	5,888	2.51	0.07
Baseline or Ongoing OAC Exposure Population	2,477,502	101,356	7,502	3.03	0.07
60-Day Gap Surgical Management					
Reference Population	61,697,747	4,245,694	479,527	7.77	0.11
Ongoing OAC Exposure Population	2,345,188	80,967	9,441	4.03	0.12
Baseline or Ongoing OAC Exposure Population	2,477,502	101,356	11,916	4.81	0.12

[1]Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

[2]When compared to the SUB transfusion or surgical management cohorts, two additional VB patients were excluded for the SUB medical management cohort due to initiation of their SUB-defining oral contraception or antifibrinolytic use before the VB diagnosis.

Table 3. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Year

Year	Eligible Members[1]	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per 1,000 Eligible Members	SUB per New VB Diagnosis
Same-Day Medical Management					
Reference Population					
2010	27,316,000	202,578	7,633	0.28	0.04
2011	31,417,333	956,947	39,784	1.27	0.04
2012	31,340,756	829,734	38,950	1.24	0.05
2013	34,057,806	816,358	43,572	1.28	0.05
2014	35,011,898	824,088	48,047	1.37	0.06
2015	33,551,230	615,987	38,606	1.15	0.06
Ongoing OAC Exposure Population					
2010	689,920	2,929	23	0.03	0.01
2011	976,763	15,059	70	0.07	0.00
2012	1,033,774	15,120	69	0.07	0.00
2013	1,158,045	16,448	86	0.07	0.01
2014	1,231,574	17,728	116	0.09	0.01
2015	1,196,619	13,683	79	0.07	0.01
Baseline or Ongoing OAC Exposure Population					
2010	773,565	3,840	28	0.04	0.01
2011	1,049,407	19,439	94	0.09	0.00
2012	1,107,101	19,141	92	0.08	0.00
2013	1,235,546	20,434	109	0.09	0.01
2014	1,309,714	21,741	143	0.11	0.01
2015	1,275,704	16,761	96	0.08	0.01
5-Day Gap Medical Management					
Reference Population					
2010	27,316,000	202,578	11,153	0.41	0.06
2011	31,417,333	956,947	57,097	1.82	0.06
2012	31,340,756	829,734	54,421	1.74	0.07
2013	34,057,806	816,358	59,238	1.74	0.07
2014	35,011,898	824,088	64,267	1.84	0.08
2015	33,551,230	615,987	50,780	1.51	0.08
Ongoing OAC Exposure Population					
2010	689,920	2,929	24	0.03	0.01
2011	976,763	15,059	93	0.10	0.01
2012	1,033,774	15,120	103	0.10	0.01
2013	1,158,045	16,448	114	0.10	0.01
2014	1,231,574	17,728	151	0.12	0.01
2015	1,196,619	13,683	109	0.09	0.01
Baseline or Ongoing OAC Exposure Population					
2010	773,565	3,840	30	0.04	0.01
2011	1,049,407	19,439	130	0.12	0.01
2012	1,107,101	19,141	138	0.12	0.01
2013	1,235,546	20,434	144	0.12	0.01

Table 3. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Year

Year	Eligible Members[1]	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per 1,000 Eligible Members	SUB per New VB Diagnosis
2014	1,309,714	21,741	183	0.14	0.01
2015	1,275,704	16,761	136	0.11	0.01
Same-Day Transfusion Management					
Reference Population					
2010	27,316,000	202,578	729	0.03	0.00
2011	31,417,333	956,948	3,934	0.13	0.00
2012	31,340,755	829,735	3,413	0.11	0.00
2013	34,057,806	816,358	3,022	0.09	0.00
2014	35,011,898	824,088	3,149	0.09	0.00
2015	33,551,230	615,987	2,276	0.07	0.00
Ongoing OAC Exposure Population					
2010	689,920	2,929	83	0.12	0.03
2011	976,763	15,059	380	0.39	0.03
2012	1,033,774	15,120	457	0.44	0.03
2013	1,158,045	16,448	432	0.37	0.03
2014	1,231,574	17,728	435	0.35	0.02
2015	1,196,619	13,683	291	0.24	0.02
Baseline or Ongoing OAC Exposure Population					
2010	773,565	3,840	106	0.14	0.03
2011	1,049,407	19,439	526	0.50	0.03
2012	1,107,101	19,141	579	0.52	0.03
2013	1,235,546	20,434	547	0.44	0.03
2014	1,309,714	21,741	569	0.43	0.03
2015	1,275,704	16,761	384	0.30	0.02
30-Day Gap Surgical Management					
Reference Population					
2010	27,316,000	202,578	17,285	0.63	0.09
2011	31,417,333	956,948	76,513	2.44	0.08
2012	31,340,755	829,735	61,956	1.98	0.07
2013	34,057,806	816,358	59,211	1.74	0.07
2014	35,011,898	824,088	55,010	1.57	0.07
2015	33,551,230	615,987	36,513	1.09	0.06
Ongoing OAC Exposure Population					
2010	689,920	2,929	211	0.31	0.07
2011	976,763	15,059	1,166	1.19	0.08
2012	1,033,774	15,120	1,127	1.09	0.07
2013	1,158,045	16,448	1,249	1.08	0.08
2014	1,231,574	17,728	1,254	1.02	0.07
2015	1,196,619	13,683	881	0.74	0.06
Baseline or Ongoing OAC Exposure Population					
2010	773,565	3,840	285	0.37	0.07
2011	1,049,407	19,439	1,547	1.47	0.08

Table 3. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Year

Year	Eligible Members[1]	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per 1,000 Eligible Members	SUB per New VB Diagnosis
2012	1,107,101	19,141	1,466	1.32	0.08
2013	1,235,546	20,434	1,549	1.25	0.08
2014	1,309,714	21,741	1,563	1.19	0.07
2015	1,275,704	16,761	1,092	0.86	0.07
60-Day Gap Surgical Management					
Reference Population					
2010	27,316,000	202,578	25,440	0.93	0.13
2011	31,417,333	956,948	117,886	3.75	0.12
2012	31,340,755	829,735	97,223	3.10	0.12
2013	34,057,806	816,358	93,508	2.75	0.11
2014	35,011,898	824,088	88,553	2.53	0.11
2015	33,551,230	615,987	56,917	1.70	0.09
Ongoing OAC Exposure Population					
2010	689,920	2,929	349	0.51	0.12
2011	976,763	15,059	1,800	1.84	0.12
2012	1,033,774	15,120	1,825	1.77	0.12
2013	1,158,045	16,448	1,995	1.72	0.12
2014	1,231,574	17,728	2,068	1.68	0.12
2015	1,196,619	13,683	1,404	1.17	0.10
Baseline or Ongoing OAC Exposure Population					
2010	773,565	3,840	460	0.59	0.12
2011	1,049,407	19,439	2,373	2.26	0.12
2012	1,107,101	19,141	2,331	2.11	0.12
2013	1,235,546	20,434	2,483	2.01	0.12
2014	1,309,714	21,741	2,548	1.95	0.12
2015	1,275,704	16,761	1,721	1.35	0.10

[1]Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Table 4. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Age Group

Age Group	Eligible Members[1]	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per 1,000 Eligible Members	SUB per New VB Diagnosis
Same-Day Medical Management					
Reference Population					
17 years or less	10,025,331	210,795	41,087	4.10	0.19
18 to 50 years	25,589,300	2,760,939	169,856	6.64	0.06
51 years or more	28,950,681	1,273,958	5,649	0.20	0.00
Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	11.98	0.15
18 to 50 years	128,192	14,410	301	2.35	0.02
51 years or more	*****	*****	*****	0.06	0.00
Baseline or Ongoing OAC Exposure Population					
17 years or less	744	70	11	14.78	0.16
18 to 50 years	140,741	18,872	392	2.79	0.02
51 years or more	2,350,955	82,414	159	0.07	0.00
5-Day Gap Medical Management					
Reference Population					
17 years or less	10,025,331	210,795	53,426	5.33	0.25
18 to 50 years	25,589,300	2,760,939	235,744	9.21	0.09
51 years or more	28,950,681	1,273,958	7,786	0.27	0.01
Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	14.97	0.19
18 to 50 years	128,192	14,410	422	3.29	0.03
51 years or more	*****	*****	*****	0.07	0.00
Baseline or Ongoing OAC Exposure Population					
17 years or less	744	70	13	17.47	0.19
18 to 50 years	140,741	18,872	551	3.91	0.03
51 years or more	2,350,955	82,414	197	0.08	0.00
Same-Day Transfusion Management					
Reference Population					
17 years or less	10,025,331	210,795	370	0.04	0.00
18 to 50 years	25,589,300	2,760,941	10,323	0.40	0.00
51 years or more	28,950,681	1,273,958	5,830	0.20	0.00
Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	2.99	0.04
18 to 50 years	128,192	14,410	520	4.06	0.04
51 years or more	*****	*****	*****	0.70	0.02
Baseline or Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	2.69	0.03
18 to 50 years	140,741	18,872	659	4.68	0.03
51 years or more	*****	*****	*****	0.87	0.02

Table 4. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Age Group

Age Group	Eligible Members[1]	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per 1,000 Eligible Members	SUB per New VB Diagnosis
30-Day Gap Surgical Management					
Reference Population					
17 years or less	10,025,331	210,795	981	0.10	0.00
18 to 50 years	25,589,300	2,760,941	190,841	7.46	0.07
51 years or more	28,950,681	1,273,958	114,666	3.96	0.09
Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	1.50	0.02
18 to 50 years	128,192	14,410	1,208	9.42	0.08
51 years or more	*****	*****	*****	2.10	0.07
Baseline or Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	1.34	0.01
18 to 50 years	140,741	18,872	1,593	11.32	0.08
51 years or more	*****	*****	*****	2.51	0.07
60-Day Gap Surgical Management					
Reference Population					
17 years or less	10,025,331	210,795	1,415	0.14	0.01
18 to 50 years	25,589,300	2,760,941	293,316	11.46	0.11
51 years or more	28,950,681	1,273,958	184,796	6.38	0.15
Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	1.50	0.02
18 to 50 years	128,192	14,410	1,834	14.31	0.13
51 years or more	*****	*****	*****	3.41	0.11
Baseline or Ongoing OAC Exposure Population					
17 years or less	*****	*****	*****	1.34	0.01
18 to 50 years	140,741	18,872	2,452	17.42	0.13
51 years or more	*****	*****	*****	4.03	0.11

[1]Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

*****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 5. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Presence of any Gynecological Disorders of Interest

Gynecological Disorders of Interest	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Same-Day Medical Management			
Reference Population			
No evidence of any gynecological disorders of interest	3,599,603	198,336	0.06
Evidence of any gynecological disorders of interest	646,089	18,256	0.03
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	69,314	347	0.01
Evidence of any gynecological disorders of interest	11,653	96	0.01
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	86,443	435	0.01
Evidence of any gynecological disorders of interest	14,913	127	0.01
5-Day Gap Medical Management			
Reference Population			
No evidence of any gynecological disorders of interest	3,599,603	269,563	0.07
Evidence of any gynecological disorders of interest	646,089	27,393	0.04
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	69,314	473	0.01
Evidence of any gynecological disorders of interest	11,653	121	0.01
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	86,443	598	0.01
Evidence of any gynecological disorders of interest	14,913	163	0.01
Same-Day Transfusion Management			
Reference Population			
No evidence of any gynecological disorders of interest	3,599,605	10,179	0.00
Evidence of any gynecological disorders of interest	646,089	6,344	0.01
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	69,314	1,481	0.02

Table 5. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Presence of any Gynecological Disorders of Interest

Gynecological Disorders of Interest	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Evidence of any gynecological disorders of interest	11,653	597	0.05
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	86,443	1,950	0.02
Evidence of any gynecological disorders of interest	14,913	761	0.05
30-Day Gap Surgical Management			
Reference Population			
No evidence of any gynecological disorders of interest	3,599,605	167,613	0.05
Evidence of any gynecological disorders of interest	646,089	138,875	0.21
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	69,314	3,822	0.06
Evidence of any gynecological disorders of interest	11,653	2,066	0.18
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	86,443	4,809	0.06
Evidence of any gynecological disorders of interest	14,913	2,693	0.18
60-Day Gap Surgical Management			
Reference Population			
No evidence of any gynecological disorders of interest	3,599,605	294,939	0.08
Evidence of any gynecological disorders of interest	646,089	184,588	0.29
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	69,314	6,695	0.10
Evidence of any gynecological disorders of interest	11,653	2,746	0.24
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest	86,443	8,344	0.10
Evidence of any gynecological disorders of interest	14,913	3,572	0.24

Table 6. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Intrauterine Device (IUD) Use

IUD	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Same-Day Medical Management			
Reference Population			
No evidence of IUD	4,174,711	184,041	0.04
Evidence of IUD	70,981	32,551	0.46
Ongoing OAC Exposure Population			
No evidence of IUD	80,438	212	0.00
Evidence of IUD	529	231	0.44
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD	100,651	267	0.00
Evidence of IUD	705	295	0.42
5-Day Gap Medical Management			
Reference Population			
No evidence of IUD	4,174,711	263,326	0.06
Evidence of IUD	70,981	33,630	0.47
Ongoing OAC Exposure Population			
No evidence of IUD	80,438	355	0.00
Evidence of IUD	529	239	0.45
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD	100,651	455	0.00
Evidence of IUD	705	306	0.43
Same-Day Transfusion Management			
Reference Population			
No evidence of IUD	4,174,713	16,426	0.00
Evidence of IUD	70,981	97	0.00
Ongoing OAC Exposure Population			
No evidence of IUD	80,438	2,062	0.03
Evidence of IUD	529	16	0.03
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD	100,651	2,694	0.03
Evidence of IUD	705	17	0.02
30-Day Gap Surgical Management			
Reference Population			
No evidence of IUD	4,174,713	303,496	0.07
Evidence of IUD	70,981	2,992	0.04
Ongoing OAC Exposure Population			
No evidence of IUD	80,438	5,836	0.07
Evidence of IUD	529	52	0.10
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD	100,651	7,439	0.07
Evidence of IUD	705	63	0.09

Table 6. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Intrauterine Device (IUD) Use

IUD	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
60-Day Gap Surgical Management			
Reference Population			
No evidence of IUD	4,174,713	475,706	0.11
Evidence of IUD	70,981	3,821	0.05
Ongoing OAC Exposure Population			
No evidence of IUD	80,438	9,379	0.12
Evidence of IUD	529	62	0.12
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD	100,651	11,836	0.12
Evidence of IUD	705	80	0.11

Table 7. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Oral Contraception Use

Oral Contraception	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Same-Day Medical Management			
Reference Population			
No evidence of oral contraception	3,625,337	34,291	0.01
Evidence of oral contraception	620,355	182,301	0.29
Ongoing OAC Exposure Population			
No evidence of oral contraception	79,151	282	0.00
Evidence of oral contraception	1,816	161	0.09
Baseline or Ongoing OAC Exposure Population			
No evidence of oral contraception	99,128	355	0.00
Evidence of oral contraception	2,228	207	0.09
5-Day Gap Medical Management			
Reference Population			
No evidence of oral contraception	3,625,337	76,407	0.02
Evidence of oral contraception	620,355	220,549	0.36
Ongoing OAC Exposure Population			
No evidence of oral contraception	79,151	380	0.00
Evidence of oral contraception	1,816	214	0.12
Baseline or Ongoing OAC Exposure Population			
No evidence of oral contraception	99,128	488	0.00
Evidence of oral contraception	2,228	273	0.12
Same-Day Transfusion Management			
Reference Population			
No evidence of oral contraception	3,625,337	15,724	0.00
Evidence of oral contraception	620,357	799	0.00
Ongoing OAC Exposure Population			
No evidence of oral contraception	79,151	2,049	0.03
Evidence of oral contraception	1,816	29	0.02
Baseline or Ongoing OAC Exposure Population			
No evidence of oral contraception	99,128	2,674	0.03
Evidence of oral contraception	2,228	37	0.02
30-Day Gap Surgical Management			
Reference Population			
No evidence of oral contraception	3,625,337	279,959	0.08
Evidence of oral contraception	620,357	26,529	0.04
Ongoing OAC Exposure Population			
No evidence of oral contraception	79,151	5,753	0.07
Evidence of oral contraception	1,816	135	0.07
Baseline or Ongoing OAC Exposure Population			
No evidence of oral contraception	99,128	7,327	0.07
Evidence of oral contraception	2,228	175	0.08

Table 7. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Oral Contraception Use

Oral Contraception	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
60-Day Gap Surgical Management			
Reference Population			
No evidence of oral contraception	3,625,337	440,717	0.12
Evidence of oral contraception	620,357	38,810	0.06
Ongoing OAC Exposure Population			
No evidence of oral contraception	79,151	9,232	0.12
Evidence of oral contraception	1,816	209	0.12
Baseline or Ongoing OAC Exposure Population			
No evidence of oral contraception	99,128	11,639	0.12
Evidence of oral contraception	2,228	277	0.12

Table 8. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Presence of any Gynecological Disorders of Interest and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Same-Day Medical Management			
Reference Population			
No evidence of any gynecological disorders of interest			
17 years or less	205,473	40,237	0.20
18 to 50 years	2,323,537	153,609	0.07
51 years or more	1,070,593	4,490	0.00
Evidence of any gynecological disorders of interest			
17 years or less	5,322	850	0.16
18 to 50 years	437,402	16,247	0.04
51 years or more	203,365	1,159	0.01
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.16
18 to 50 years	11,415	245	0.02
51 years or more	*****	*****	0.00
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	2,995	56	0.02
51 years or more	*****	*****	0.00
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.17
18 to 50 years	14,862	314	0.02
51 years or more	*****	*****	0.00
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	4,010	78	0.02
51 years or more	*****	*****	0.00
5-Day Gap Medical Management			
Reference Population			
No evidence of any gynecological disorders of interest			
17 years or less	205,473	52,225	0.25
18 to 50 years	2,323,537	211,189	0.09
51 years or more	1,070,593	6,149	0.01
Evidence of any gynecological disorders of interest			
17 years or less	5,322	1,201	0.23
18 to 50 years	437,402	24,555	0.06
51 years or more	203,365	1,637	0.01

Table 8. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Presence of any Gynecological Disorders of Interest and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.20
18 to 50 years	11,415	346	0.03
51 years or more	*****	*****	0.00
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	2,995	76	0.03
51 years or more	*****	*****	0.01
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.21
18 to 50 years	14,862	445	0.03
51 years or more	*****	*****	0.00
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	4,010	106	0.03
51 years or more	*****	*****	0.01
Same-Day Transfusion Management			
Reference Population			
No evidence of any gynecological disorders of interest			
17 years or less	205,473	332	0.00
18 to 50 years	2,323,539	6,023	0.00
51 years or more	1,070,593	3,824	0.00
Evidence of any gynecological disorders of interest			
17 years or less	5,322	38	0.01
18 to 50 years	437,402	4,300	0.01
51 years or more	203,365	2,006	0.01
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.04
18 to 50 years	11,415	333	0.03
51 years or more	*****	*****	0.02
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	2,995	187	0.06
51 years or more	*****	*****	0.05
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.03
18 to 50 years	14,862	439	0.03
51 years or more	*****	*****	0.02

Table 8. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Presence of any Gynecological Disorders of Interest and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	4,010	220	0.05
51 years or more	*****	*****	0.05
30-Day Gap Surgical Management			
Reference Population			
No evidence of any gynecological disorders of interest			
17 years or less	205,473	864	0.00
18 to 50 years	2,323,539	100,679	0.04
51 years or more	1,070,593	66,070	0.06
Evidence of any gynecological disorders of interest			
17 years or less	5,322	117	0.02
18 to 50 years	437,402	90,162	0.21
51 years or more	203,365	48,596	0.24
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.02
18 to 50 years	11,415	712	0.06
51 years or more	*****	*****	0.05
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	2,995	496	0.17
51 years or more	*****	*****	0.18
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.02
18 to 50 years	14,862	912	0.06
51 years or more	*****	*****	0.05
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	4,010	681	0.17
51 years or more	*****	*****	0.18
60-Day Gap Surgical Management			
Reference Population			
No evidence of any gynecological disorders of interest			
17 years or less	205,473	1,285	0.01
18 to 50 years	2,323,539	173,935	0.07
51 years or more	1,070,593	119,719	0.11
Evidence of any gynecological disorders of interest			
17 years or less	5,322	130	0.02
18 to 50 years	437,402	119,381	0.27
51 years or more	203,365	65,077	0.32

Table 8. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Presence of any Gynecological Disorders of Interest and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.02
18 to 50 years	11,415	1,175	0.10
51 years or more	*****	*****	0.10
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	2,995	659	0.22
51 years or more	*****	*****	0.24
Baseline or Ongoing OAC Exposure Population			
No evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.02
18 to 50 years	14,862	1,535	0.10
51 years or more	*****	*****	0.10
Evidence of any gynecological disorders of interest			
17 years or less	*****	*****	0.00
18 to 50 years	4,010	917	0.23
51 years or more	*****	*****	0.24

*****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 9. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Intrauterine Device (IUD) Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Same-Day Medical Management			
Reference Population			
No evidence of IUD			
17 years or less	209,590	40,597	0.19
18 to 50 years	2,692,979	139,026	0.05
51 years or more	1,272,142	4,418	0.00
Evidence of IUD			
17 years or less	1,205	490	0.41
18 to 50 years	67,960	30,830	0.45
51 years or more	1,816	1,231	0.68
Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.06
18 to 50 years	13,945	109	0.01
51 years or more	*****	*****	0.00
Evidence of IUD			
17 years or less	*****	*****	1.00
18 to 50 years	465	192	0.41
51 years or more	*****	*****	0.58
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.09
18 to 50 years	18,246	145	0.01
51 years or more	*****	*****	0.00
Evidence of IUD			
17 years or less	*****	*****	0.83
18 to 50 years	626	247	0.39
51 years or more	*****	*****	0.59
5-Day Gap Medical Management			
Reference Population			
No evidence of IUD			
17 years or less	209,590	52,912	0.25
18 to 50 years	2,692,979	203,870	0.08
51 years or more	1,272,142	6,544	0.01
Evidence of IUD			
17 years or less	1,205	514	0.43
18 to 50 years	67,960	31,874	0.47
51 years or more	1,816	1,242	0.68

Table 9. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Intrauterine Device (IUD) Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.10
18 to 50 years	13,945	223	0.02
51 years or more	*****	*****	0.00
Evidence of IUD			
17 years or less	*****	*****	1.00
18 to 50 years	465	199	0.43
51 years or more	*****	*****	0.59
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.13
18 to 50 years	18,246	296	0.02
51 years or more	*****	*****	0.00
Evidence of IUD			
17 years or less	*****	*****	0.83
18 to 50 years	626	255	0.41
51 years or more	*****	*****	0.63
Same-Day Transfusion Management			
Reference Population			
No evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	2,692,981	10,231	0.00
51 years or more	*****	*****	0.00
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	67,960	92	0.00
51 years or more	*****	*****	0.00
Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.04
18 to 50 years	13,945	506	0.04
51 years or more	*****	*****	0.02
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	465	14	0.03
51 years or more	*****	*****	0.03
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.03
18 to 50 years	18,246	644	0.04
51 years or more	*****	*****	0.02

Table 9. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Intrauterine Device (IUD) Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	626	15	0.02
51 years or more	*****	*****	0.03
30-Day Gap Surgical Management			
Reference Population			
No evidence of IUD			
17 years or less	209,590	970	0.00
18 to 50 years	2,692,981	188,091	0.07
51 years or more	1,272,142	114,435	0.09
Evidence of IUD			
17 years or less	1,205	11	0.01
18 to 50 years	67,960	2,750	0.04
51 years or more	1,816	231	0.13
Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.02
18 to 50 years	13,945	1,168	0.08
51 years or more	*****	*****	0.07
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	465	40	0.09
51 years or more	*****	*****	0.20
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.02
18 to 50 years	18,246	1,546	0.08
51 years or more	*****	*****	0.07
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	626	47	0.08
51 years or more	*****	*****	0.22
60-Day Gap Surgical Management			
Reference Population			
No evidence of IUD			
17 years or less	209,590	1,402	0.01
18 to 50 years	2,692,981	289,801	0.11
51 years or more	1,272,142	184,503	0.15
Evidence of IUD			
17 years or less	1,205	13	0.01
18 to 50 years	67,960	3,515	0.05
51 years or more	1,816	293	0.16

Table 9. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Intrauterine Device (IUD) Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.02
18 to 50 years	13,945	1,786	0.13
51 years or more	*****	*****	0.11
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	465	48	0.10
51 years or more	*****	*****	0.24
Baseline or Ongoing OAC Exposure Population			
No evidence of IUD			
17 years or less	*****	*****	0.02
18 to 50 years	18,246	2,390	0.13
51 years or more	*****	*****	0.11
Evidence of IUD			
17 years or less	*****	*****	0.00
18 to 50 years	626	62	0.10
51 years or more	*****	*****	0.25

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

Table 10. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Oral Contraception Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Same-Day Medical Management			
Reference Population			
No evidence of Oral contraception			
17 years or less	141,346	570	0.00
18 to 50 years	2,225,633	31,031	0.01
51 years or more	1,258,358	2,690	0.00
Evidence of Oral contraception			
17 years or less	69,449	40,517	0.58
18 to 50 years	535,306	138,825	0.26
51 years or more	15,600	2,959	0.19
Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.07
18 to 50 years	12,737	158	0.01
51 years or more	*****	*****	0.00
Evidence of Oral contraception			
17 years or less	*****	*****	0.25
18 to 50 years	1,673	143	0.09
51 years or more	*****	*****	0.10
Baseline or Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.05
18 to 50 years	16,815	207	0.01
51 years or more	*****	*****	0.00
Evidence of Oral contraception			
17 years or less	*****	*****	0.27
18 to 50 years	2,057	185	0.09
51 years or more	*****	*****	0.09
5-Day Gap Medical Management			
Reference Population			
No evidence of Oral contraception			
17 years or less	141,346	9,253	0.07
18 to 50 years	2,225,633	63,169	0.03
51 years or more	1,258,358	3,985	0.00
Evidence of Oral contraception			
17 years or less	69,449	44,173	0.64
18 to 50 years	535,306	172,575	0.32
51 years or more	15,600	3,801	0.24

Table 10. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Oral Contraception Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.14
18 to 50 years	12,737	229	0.02
51 years or more	*****	*****	0.00
Evidence of Oral contraception			
17 years or less	*****	*****	0.25
18 to 50 years	1,673	193	0.12
51 years or more	*****	*****	0.13
Baseline or Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.11
18 to 50 years	16,815	305	0.02
51 years or more	*****	*****	0.00
Evidence of Oral contraception			
17 years or less	*****	*****	0.27
18 to 50 years	2,057	246	0.12
51 years or more	*****	*****	0.13
Same-Day Transfusion Management			
Reference Population			
No evidence of Oral contraception			
17 years or less	141,346	323	0.00
18 to 50 years	2,225,633	9,603	0.00
51 years or more	1,258,358	5,798	0.00
Evidence of Oral contraception			
17 years or less	69,449	47	0.00
18 to 50 years	535,308	720	0.00
51 years or more	15,600	32	0.00
Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	12,737	493	0.04
51 years or more	*****	*****	0.02
Evidence of Oral contraception			
17 years or less	*****	*****	0.04
18 to 50 years	1,673	27	0.02
51 years or more	*****	*****	0.01
Baseline or Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	16,815	624	0.04
51 years or more	*****	*****	0.02

Table 10. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Oral Contraception Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	2,057	35	0.02
51 years or more	*****	*****	0.01
30-Day Gap Surgical Management			
Reference Population			
No evidence of Oral contraception			
17 years or less	141,346	695	0.00
18 to 50 years	2,225,633	165,776	0.07
51 years or more	1,258,358	113,488	0.09
Evidence of Oral contraception			
17 years or less	69,449	286	0.00
18 to 50 years	535,308	25,065	0.05
51 years or more	15,600	1,178	0.08
Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	12,737	1,085	0.09
51 years or more	*****	*****	0.07
Evidence of Oral contraception			
17 years or less	*****	*****	0.00
18 to 50 years	1,673	123	0.07
51 years or more	*****	*****	0.10
Baseline or Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	16,815	1,431	0.09
51 years or more	*****	*****	0.07
Evidence of Oral contraception			
17 years or less	*****	*****	0.00
18 to 50 years	2,057	162	0.08
51 years or more	*****	*****	0.09
60-Day Gap Surgical Management			
Reference Population			
No evidence of Oral contraception			
17 years or less	141,346	962	0.01
18 to 50 years	2,225,633	256,831	0.12
51 years or more	1,258,358	182,924	0.15
Evidence of Oral contraception			
17 years or less	69,449	453	0.01
18 to 50 years	535,308	36,485	0.07
51 years or more	15,600	1,872	0.12

Table 10. Summary of Background Severe Uterine Bleed Rates in Reference and Oral Anticoagulant (OAC) Exposure Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015 by Baseline Oral Contraception Use and Age Group

Age Group	Patients with New Vaginal Bleed (VB) Diagnosis	Patients with Severe Uterine Bleed (SUB) Event	SUB per New VB Diagnosis
Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	12,737	1,643	0.13
51 years or more	*****	*****	0.11
Evidence of Oral contraception			
17 years or less	*****	*****	0.00
18 to 50 years	1,673	191	0.11
51 years or more	*****	*****	0.15
Baseline or Ongoing OAC Exposure Population			
No evidence of Oral contraception			
17 years or less	*****	*****	0.03
18 to 50 years	16,815	2,197	0.13
51 years or more	*****	*****	0.11
Evidence of Oral contraception			
17 years or less	*****	*****	0.00
18 to 50 years	2,057	255	0.12
51 years or more	*****	*****	0.16

*****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 11. Distribution of Surgical Managements Used to Identify Severe Uterine Bleed (SUB) as Outcome in Reference and Oral Anticoagulant (OAC) Populations in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015

	30-Day Gap Surgical Management						60-Day Gap Surgical Management					
Description	**Reference Population**		**Ongoing OAC Exposure Population**		**Baseline or Ongoing OAC Exposure Population**		**Reference Population**		**Ongoing OAC Exposure Population**		**Baseline or Ongoing OAC Exposure Population**	
Surgical Management	**Count**	**Percent[1]**	**Count**	**Percent[1]**	**Count**	**Percent[1]**	**Count**	**Percent[1]**	**Count**	**Percent[1]**	**Count**	**Percent[1]**
Dilation and curettage with or without hysteroscopy	32,391	10.57%	1,247	21.18%	1,563	20.83%	42,343	8.83%	1,620	17.16%	2,012	16.88%
Thermal, cryo or section endometrial ablation	128,900	42.06%	1,774	30.13%	2,277	30.35%	200,778	41.87%	2,955	31.30%	3,733	31.33%
Hysterectomy	86,327	28.17%	1,427	24.24%	1,850	24.66%	142,902	29.80%	2,526	26.76%	3,282	27.54%
Hysteroscopy (not listed in other surgical managements)	49,380	16.11%	1,364	23.17%	1,714	22.85%	78,757	16.42%	2,219	23.50%	2,738	22.98%
Hysteroscopic, laparoscopic or abdominal myomectomy	8,291	2.71%	47	0.80%	64	0.85%	12,827	2.67%	81	0.86%	104	0.87%
Hysteroscopic polypectomy	89,387	29.16%	1,400	23.78%	1,796	23.94%	134,372	28.02%	2,378	25.19%	2,982	25.03%
Uterine artery embolization	1,199	0.39%	29	0.49%	34	0.45%	1,920	0.40%	40	0.42%	47	0.39%

[1]Surgical management percentages are the number of respective surgical procedures divided by the total number of SUB events.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (March 11, 2020)

DP ID	Start Date[1]	End Date[1]
DP01	1/1/2000	2/28/2019
DP02	1/1/2000	1/31/2019
DP03	1/1/2004	8/31/2019
DP04	1/1/2008	9/30/2019
DP05	1/1/2006	6/30/2019
DP06	1/1/2000	12/31/2017
DP07	1/1/2010	6/30/2019
DP08	1/1/2000	7/31/2019
DP09	6/1/2007	4/30/2019
DP10	1/1/2000	4/30/2018
DP11	1/1/2005	7/31/2018
DP12	1/1/2000	4/30/2019
DP13	1/1/2000	6/30/2019
DP14	1/1/2008	3/31/2019
DP15	1/1/2000	3/31/2019
DP16	1/1/2012	6/30/2018

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

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

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

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

Code	Description	Code Type	Code Category
	Medical Managements		
	Insertion of Intrauterine System Device (IUD)		
V25.11	Encounter for insertion of intrauterine contraceptive device	ICD-9-CM	Diagnosis
V25.13	Encounter for removal and reinsertion of intrauterine contraceptive device	ICD-9-CM	Diagnosis
V45.51	Presence of intrauterine contraceptive device	ICD-9-CM	Diagnosis
J7297	Levonorgestrel-releasing intrauterine contraceptive system (Liletta), 52 mg	HCPCS	Procedure
J7298	Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52 mg	HCPCS	Procedure
J7301	Levonorgestrel-releasing intrauterine contraceptive system, 13.5 mg	HCPCS	Procedure
J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg	HCPCS	Procedure
Q0090	Levonorgestrel-releasing intrauterine contraceptive system, (Skyla), 13.5 mg	HCPCS	Procedure
S4980	Levonorgestrel - releasing intrauterine system, each	HCPCS	Procedure
S4981	Insertion of levonorgestrel-releasing intrauterine system	HCPCS	Procedure
S4989	Contraceptive intrauterine device (e.g., Progestacert IUD), including implants and supplies	HCPCS	Procedure
69.7	INSERTION OF INTRAUTERINE CONTRACEPTIVE DEVICE	ICD-9-CM	Procedure
58300	Insertion of intrauterine device (IUD)	CPT-4	Procedure
	Vaginal Packing		
57180	Introduction of any hemostatic agent or pack for spontaneous or traumatic nonobstetrical vaginal hemorrhage (separate procedure)	CPT-4	Procedure
96.14	Vaginal packing	ICD-9-CM	Procedure
	Transfusion Managements		
	Red Blood Cell-Only Transfusion		
C1010	Whole blood or red blood cells, leukoreduced, cmv negative, each unit	HCPCS	Procedure
C1016	Whole blood or red blood cells, leukoreduced, frozen, deglycerol, washed, each unit	HCPCS	Procedure
C1020	Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated,	HCPCS	Procedure
C1021	Red blood cells, leukocyte-reduced, cmv negative, irradiated, each unit	HCPCS	Procedure
P9016	Red blood cells, leukocytes reduced, each unit	HCPCS	Procedure
P9021	Red blood cells, each unit	HCPCS	Procedure
P9022	Red blood cells, washed, each unit	HCPCS	Procedure
P9038	Red blood cells, irradiated, each unit	HCPCS	Procedure
P9039	Red blood cells, deglycerolized, each unit	HCPCS	Procedure
P9040	Red blood cells, leukocytes reduced, irradiated, each unit	HCPCS	Procedure
P9051	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit	HCPCS	Procedure
P9054	Each unit whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed,	HCPCS	Procedure
P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	HCPCS	Procedure
P9058	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit	HCPCS	Procedure
9904	transfusion of packed cells	ICD-9-CM	Procedure
0381	Blood and blood products-packed red cells	Revenue Center	Procedure

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

Code	Description	Code Type	Code Category
	Surgical Managements		
	Hysteroscopic Polypectomy		
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C	CPT-4	Procedure
	Hysteroscopic/Laparoscopic/Abdominal Myomectomy		
218.0	Submucous leiomyoma of uterus	ICD-9-CM[A]	Diagnosis
218	Uterine leiomyoma	ICD-9-CM[A]	Diagnosis
218.1	Intramural leiomyoma of uterus	ICD-9-CM[A]	Diagnosis
218.2	Subserous leiomyoma of uterus	ICD-9-CM[A]	Diagnosis
218.9	Leiomyoma of uterus, unspecified	ICD-9-CM[A]	Diagnosis
56309	LAP SURG; W/REMOV LEIOMYOMATA (SINGL/MX)	CPT-4	Procedure
56354	HYSTEROSCOPY SURG; W/REMOV LEIOMYOMATA	CPT-4	Procedure
58140	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; abdominal approach	CPT-4	Procedure
58145	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with total weight of 250 g or less and/or removal of surface myomas; vaginal approach	CPT-4	Procedure
58146	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g, abdominal approach	CPT-4	Procedure
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas	CPT-4	Procedure
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g	CPT-4	Procedure
58561	Hysteroscopy, surgical; with removal of leiomyomata	CPT-4	Procedure
58994	Hysteroscopy; With Removal Of Submucous Leiomyomata (any Method)	CPT-4	Procedure
68.19	Other diagnostic procedures on uterus and supporting structures	ICD-9-CM[B]	Procedure
68.29	Other excision or destruction of lesion of uterus	ICD-9-CM[B]	Procedure
69.19	Other excision or destruction of uterus and supporting structures	ICD-9-CM[B]	Procedure

[A]Myomectomy diagnosis codes and [B]myomectomy procedure codes are used in combination to detect myomectomy.

	Dilation and Curettage (with or without Hysteroscopy)		
57558	Dilation and curettage of cervical stump	CPT-4	Procedure
57820	Dilation and curettage of cervical stump	CPT-4	Procedure
58120	Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical)	CPT-4	Procedure
69.0	Dilation and curettage of uterus	ICD-9-CM	Procedure
69.09	Other dilation and curettage of uterus	ICD-9-CM	Procedure
69.5	Aspiration curettage of uterus	ICD-9-CM	Procedure
69.59	Other aspiration curettage of uterus	ICD-9-CM	Procedure

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

Code	Description	Code Type	Code Category
	Hysteroscopy (Not Listed in Other Surgical Managements)		
00952	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); hysteroscopy and/or hysterosalpingography	CPT-4	Procedure
56352	HYSTEROSCOPY SURG; W/LYSIS INTRAUTERINE ADHESION	CPT-4	Procedure
56353	HYSTEROSCOPY SURG; W/DIVIS/RESECT SEPTUM	CPT-4	Procedure
56355	HYSTEROSCOPY SURG; W/REMOV IMPACTED F B	CPT-4	Procedure
56399	UNLISTED PROC-LAP/HYSTEROSCOPY	CPT-4	Procedure
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)	CPT-4	Procedure
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)	CPT-4	Procedure
58562	Hysteroscopy, surgical; with removal of impacted foreign body	CPT-4	Procedure
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants	CPT-4	Procedure
58992	Hysteroscopy; With Lysis Of Intrauterine Adhesions Or Resection Of Intrauterine Septum (any Method)	CPT-4	Procedure
58995	Hysteroscopy	CPT-4	Procedure
G9823	Endometrial sampling or hysteroscopy with biopsy and results documented	HCPCS	Procedure
G9824	Endometrial sampling or hysteroscopy with biopsy and results not documented	HCPCS	Procedure
S2255	Hysteroscopy, surgical; with occlusion of oviducts bilaterally by micro-inserts for permanent sterilization	HCPCS	Procedure
68.12	Hysteroscopy	ICD-9-CM	Procedure
68.14	Open biopsy of uterine ligaments	ICD-9-CM	Procedure
68.16	Closed biopsy of uterine ligaments	ICD-9-CM	Procedure
	Hysterectomy		
68.3	Subtotal abdominal hysterectomy	ICD-9-CM	Diagnosis
68.31	Laparoscopic supracervical hysterectomy [LSH]	ICD-9-CM	Diagnosis
68.39	Other and unspecified subtotal abdominal hysterectomy	ICD-9-CM	Diagnosis
68.4	Total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.41	Laparoscopic total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.49	Other and unspecified total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.5	Vaginal hysterectomy	ICD-9-CM	Diagnosis
68.51	Laparoscopically assisted vaginal hysterectomy (LAVH)	ICD-9-CM	Diagnosis
68.59	Other and unspecified vaginal hysterectomy	ICD-9-CM	Diagnosis
68.6	Radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.61	Laparoscopic radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.69	Other and unspecified radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.7	Radical vaginal hysterectomy	ICD-9-CM	Diagnosis
68.71	Laparoscopic radical vaginal hysterectomy [LRVH]	ICD-9-CM	Diagnosis
68.79	Other and unspecified radical vaginal hysterectomy	ICD-9-CM	Diagnosis
68.9	Other and unspecified hysterectomy	ICD-9-CM	Diagnosis
618.5	Prolapse of vaginal vault after hysterectomy	ICD-9-CM	Diagnosis
00846	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
00855	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy	CPT-4	Procedure
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	CPT-4	Procedure
01962	Anesthesia for urgent hysterectomy following delivery	CPT-4	Procedure
01963	Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care	CPT-4	Procedure
01969	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure performed)	CPT-4	Procedure
51925	closure of vesicouterine fistula; w/hysterectomy	CPT-4	Procedure
58150	tah w/wo removal of tube w/wo removal of ovary;	CPT-4	Procedure
58152	tah; w/wo remv tube-ovry w/colpo-urethrocystopex	CPT-4	Procedure
58180	supracerv abd hysterectomy w/wo remov tube-ovary	CPT-4	Procedure
58200	tah incl part vaginect w/pelv lymph node sampl	CPT-4	Procedure
58205	Total Hysterectomy, Extended, Corpus Cancer, Including Partial	CPT-4	Procedure
58210	rad abd hyst w/bilat tot pelvic lymphadenect bx	CPT-4	Procedure
58260	vag hyst 250 gm/<	CPT-4	Procedure
58262	vag hyst 250 gm/< w/rmvl tube&/ovary	CPT-4	Procedure
58263	vag hyst 250 gm/< w/rmvl tube ovary w/rpr ntrcl	CPT-4	Procedure
58265	Vaginal Hysterectomy With Plastic Repair Of Vagina, Anterior	CPT-4	Procedure
58267	vag hyst 250 gm/< w/colpo-urtcstopexy	CPT-4	Procedure
58270	vag hyst 250 gm/< w/rpr ntrcl	CPT-4	Procedure
58275	vag hyst with total or partial vaginectomy;	CPT-4	Procedure
58280	vag hyst w/tot/part vaginectomy; w/repr enterocl	CPT-4	Procedure
58285	vaginal hysterectomy radical	CPT-4	Procedure
58290	vag hyst for uterus greater than 250 grams;	CPT-4	Procedure
58291	vag hyst utrus >250 gms; w/remv tube &/ ovary	CPT-4	Procedure
58292	vag hyst utrus>250 gms; remv t&/o rep enterocl	CPT-4	Procedure
58293	vag hyst utrus > 250 gms; w/colpo-urethrocystProcedurey	CPT-4	Procedure
58294	vag hyst uterus > 250 grams; w/repair enterocele	CPT-4	Procedure
58541	laps supracrv hyst 250 g/<	CPT-4	Procedure
58542	laps supracrv hyst 250 g/< rmvl tube/ovary	CPT-4	Procedure
58543	laps supracrv hyst >250 g	CPT-4	Procedure
58544	laps supracrv hyst >250 g rmvl tube/ovary	CPT-4	Procedure
58548	laps w/rad hyst w/bilat lmphadec rmvl tube/ovary	CPT-4	Procedure
58550	laparscpy surg w/vag hyst uterus 250 gms/less;	CPT-4	Procedure
58552	lap vag hyst utrus 250 gms/<; w/remv tube&/ovry	CPT-4	Procedure
58553	laparscpy surgical w/vag hyst uterus > 250 gms;	CPT-4	Procedure
58554	lap w/vag hyst utrus >250 gms; w/remv tube&/ovry	CPT-4	Procedure
58570	laparoscopy w total hysterectomy uterus 250 g/<	CPT-4	Procedure
58571	laps total hysterectomy 250 g/<w tube/ovary	CPT-4	Procedure
58572	laparoscopy total hysterectomy uterus>250 g	CPT-4	Procedure
58573	laparoscopy tot hysterectomy >250 g w tube/ovary	CPT-4	Procedure
58951	rescj prim prtl mal w/bso&omntc tah&lmphadec	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
58953	bilat s-o w/omentect tah&radl dissect debulking;	CPT-4	Procedure
58954	bil s-o w/omentect tah&radl dbulk; pelv lymphect	CPT-4	Procedure
58956	bil salpingooophorect w/tot omentect tah malig	CPT-4	Procedure
59100	hysterotomy abdominal	CPT-4	Procedure
59135	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy	CPT-4	Procedure
59525	subtotal/total hysterectomy after c-sect deliv	CPT-4	Procedure
59560	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59561	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59580	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
59581	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
S2078	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)	HCPCS	Procedure
683	subtotal abdominal hysterectomy	ICD-9-CM	Procedure
684	total abdominal hysterectomy	ICD-9-CM	Procedure
685	vaginal hysterectomy	ICD-9-CM	Procedure
686	radical abdominal hysterectomy	ICD-9-CM	Procedure
687	radical vaginal hysterectomy	ICD-9-CM	Procedure
688	pelvic evisceration	ICD-9-CM	Procedure
689	hysterectomy nos	ICD-9-CM	Procedure
6831	laparoscopic supracervical hysterectomy	ICD-9-CM	Procedure
6839	other and unspecified subtotal abdominal hysterect	ICD-9-CM	Procedure
6841	laparoscopic total abdominal hysterectomy	ICD-9-CM	Procedure
6849	other and unspecified total abdoinal hysterectomy	ICD-9-CM	Procedure
6851	laparoscopically assisted vaginal hysterectomy	ICD-9-CM	Procedure
6859	other and unspecified vaginal hysterectomy	ICD-9-CM	Procedure
6861	laparoscopic radical abdominal hysterectomy	ICD-9-CM	Procedure
6869	other and unspecified radical abdominal hysterecto	ICD-9-CM	Procedure
6871	laparoscopic radical vaginal hysterectomy	ICD-9-CM	Procedure
6879	other and unspecified radical vaginal hysterectomy	ICD-9-CM	Procedure
	Endometrial Ablation (Thermal, Cryo, Section)		
0009T	Endometrial cryoablation with ultrasonic guidance	CPT Category III	Procedure
56351	HYSTEROSCOPY SURG; W/SAMPL ENDOMETRIUM W/WO D&C	CPT-4	Procedure
56356	HYSTEROSCOPY SURG; W/ENDOMETRIAL ABLATION	CPT-4	Procedure
58353	Endometrial ablation, thermal, without hysteroscopic guidance	CPT-4	Procedure
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed	CPT-4	Procedure
58558	HYSTEROSCOPY BX ENDOMETRIUM&/POLYPC W/WO D&C	CPT-4	Procedure
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)	CPT-4	Procedure
58996	Hysteroscopy; With Endometrial Ablation (any Method)	CPT-4	Procedure
68.23	Endometrial ablation	ICD-9-CM	Procedure

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

Code	Description	Code Type	Code Category
	Uterine Artery Embolization		
37210	Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure	CPT-4	Procedure
S2250	Uterine artery embolization for uterine fibroids	HCPCS	Procedure
68.24	Uterine artery embolization [UAE] with coils	ICD-9-CM	Procedure
68.25	Uterine artery embolization [UAE] without coils	ICD-9-CM	Procedure

Appendix D. List of Generic and Brand Name Medical Products Used to Define the Outcomes in this Request

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

Generic Name	Brand Name
ethinyl estradiol/drospirenone	Vestura (28)
ethinyl estradiol/drospirenone	Nikki (28)
ethinyl estradiol/drospirenone	Drospirenone-Ethinyl Estradiol
ethinyl estradiol/drospirenone	Ocella
ethinyl estradiol/drospirenone	Syeda
ethinyl estradiol/drospirenone	Yasmin (28)
ethinyl estradiol/drospirenone	Zarah
ethynodiol diacetate-ethinyl estradiol	Kelnor 1/35 (28)
ethynodiol diacetate-ethinyl estradiol	Zovia 1/35E (28)
ethynodiol diacetate-ethinyl estradiol	Ethynodiol Diac-Eth Estradiol
ethynodiol diacetate-ethinyl estradiol	Zovia 1/50E (28)
ethynodiol diacetate-ethinyl estradiol	Demulen 1/50 (28)
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Camrese Lo
levonorgestrel/ethinyl estradiol and ethinyl estradiol	L Norgest/E.Estradiol-E.Estrad
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Loseasonique
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Amethia Lo
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Rivelsa
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Quartette
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Fayosim
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Camrese
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Seasonique
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Amethia
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Ashlyna
levonorgestrel/ethinyl estradiol and ethinyl estradiol	Daysee
levonorgestrel-ethinyl estradiol	Levonogestrel-Ethinyl Estrad
levonorgestrel-ethinyl estradiol	Lessina
levonorgestrel-ethinyl estradiol	Aviane
levonorgestrel-ethinyl estradiol	Orsythia
levonorgestrel-ethinyl estradiol	Vienva
levonorgestrel-ethinyl estradiol	Falmina (28)
levonorgestrel-ethinyl estradiol	Lutera (28)
levonorgestrel-ethinyl estradiol	Aubra
levonorgestrel-ethinyl estradiol	Delyla (28)
levonorgestrel-ethinyl estradiol	Sronyx
levonorgestrel-ethinyl estradiol	Larissa
levonorgestrel-ethinyl estradiol	Jolessa
levonorgestrel-ethinyl estradiol	Introvale
levonorgestrel-ethinyl estradiol	Setlakin
levonorgestrel-ethinyl estradiol	Seasonale Contraceptive
levonorgestrel-ethinyl estradiol	Quasense
levonorgestrel-ethinyl estradiol	Portia
levonorgestrel-ethinyl estradiol	Altavera (28)
levonorgestrel-ethinyl estradiol	Levora-28
levonorgestrel-ethinyl estradiol	Chateal
levonorgestrel-ethinyl estradiol	Nordette (28)
levonorgestrel-ethinyl estradiol	Levora 0.15/30 (28)

Generic Name	Brand Name
levonorgestrel-ethinyl estradiol	Marlissa
levonorgestrel-ethinyl estradiol	Nordette
levonorgestrel-ethinyl estradiol	Kurvelo
levonorgestrel-ethinyl estradiol	Enpresse
levonorgestrel-ethinyl estradiol	Myzilra
levonorgestrel-ethinyl estradiol	Levonest (28)
levonorgestrel-ethinyl estradiol	Trivora (28)
levonorgestrel-ethinyl estradiol	Levonorg-Eth Estrad Triphasic
levonorgestrel-ethinyl estradiol	Lybrel
levonorgestrel-ethinyl estradiol	Amethyst
norethindrone	Ortho Micronor
norethindrone	Norethindrone (Contraceptive)
norethindrone	Errin
norethindrone	Camila
norethindrone	Deblitane
norethindrone	Sharobel
norethindrone	Lyza
norethindrone	Norlyroc
norethindrone	Nor-Qd
norethindrone	Nora-Be
norethindrone	Jolivette
norethindrone	Micronor (28)
norethindrone	Jencycla
norethindrone	Heather
norethindrone acetate-ethinyl estradiol	Norethindrone Ac-Eth Estradiol
norethindrone acetate-ethinyl estradiol	Junel 1/20 (21)
norethindrone acetate-ethinyl estradiol	Gildess 1/20 (21)
norethindrone acetate-ethinyl estradiol	Larin 1/20 (21)
norethindrone acetate-ethinyl estradiol	Loestrin 1/20 (21)
norethindrone acetate-ethinyl estradiol	Microgestin 1/20 (21)
norethindrone acetate-ethinyl estradiol	Junel 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Gildess 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Larin 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Loestrin 1.5/30 (21)
norethindrone acetate-ethinyl estradiol	Microgestin 1.5/30 (21)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Lo Loestrin Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Lo Minastrin Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Taytulla
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Junel Fe 24
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Norethindrone-E.Estradiol-Iron
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Loestrin 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Junel Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Gildess Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Gildess 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Larin Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Larin 24 Fe

Generic Name	Brand Name
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Microgestin Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Loestrin Fe 1/20 (28-Day)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Tarina Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Microgestin 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Lomedia 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Blisovi 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Blisovi Fe 1/20 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Minastrin 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Mibelas 24 Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Junel Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Gildess Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Larin Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Loestrin Fe 1.5/30 (28-Day)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Microgestin Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Blisovi Fe 1.5/30 (28)
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Estrostep Fe-28
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Tri-Legest Fe
norethindrone acetate-ethinyl estradiol/ferrous fumarate	Tilia Fe
norethindrone-ethinyl estradiol	Ortho-Novum 1/35 (28)
norethindrone-ethinyl estradiol	Nortrel 1/35 (21)
norethindrone-ethinyl estradiol	Nortrel 1/35 (28)
norethindrone-ethinyl estradiol	Cyclafem 1/35 (28)
norethindrone-ethinyl estradiol	Dasetta 1/35 (28)
norethindrone-ethinyl estradiol	Necon 1/35 (28)
norethindrone-ethinyl estradiol	Norinyl 1/35 (28)
norethindrone-ethinyl estradiol	Pirmella
norethindrone-ethinyl estradiol	Alyacen 1/35 (28)
norethindrone-ethinyl estradiol	Ovcon-50 (28)
norethindrone-ethinyl estradiol	Zenchent (28)
norethindrone-ethinyl estradiol	Ovcon-35 (28)
norethindrone-ethinyl estradiol	Balziva (28)
norethindrone-ethinyl estradiol	Gildagia
norethindrone-ethinyl estradiol	Philith
norethindrone-ethinyl estradiol	Vyfemla (28)
norethindrone-ethinyl estradiol	Briellyn
norethindrone-ethinyl estradiol	Ortho-Novum 7/7/7 (28)
norethindrone-ethinyl estradiol	Nortrel 7/7/7 (28)
norethindrone-ethinyl estradiol	Cyclafem 7/7/7 (28)
norethindrone-ethinyl estradiol	Dasetta 7/7/7 (28)
norethindrone-ethinyl estradiol	Necon 7/7/7 (28)
norethindrone-ethinyl estradiol	Ortho-Novum 7/7/7 (21)
norethindrone-ethinyl estradiol	Alyacen 7/7/7 (28)
norethindrone-ethinyl estradiol	Aranelle (28)
norethindrone-ethinyl estradiol	Tri-Norinyl (28)
norethindrone-ethinyl estradiol	Leena 28
norethindrone-ethinyl estradiol	Modicon (28)

Generic Name	Brand Name
norethindrone-ethinyl estradiol	Nortrel 0.5/35 (28)
norethindrone-ethinyl estradiol	Wera (28)
norethindrone-ethinyl estradiol	Necon 0.5/35 (28)
norethindrone-ethinyl estradiol	Brevicon (28)
norethindrone-ethinyl estradiol	Necon 10/11 (28)
norethindrone-ethinyl estradiol/ferrous fumarate	Zeosa
norethindrone-ethinyl estradiol/ferrous fumarate	Noreth-Ethinyl Estradiol-Iron
norethindrone-ethinyl estradiol/ferrous fumarate	Femcon Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Zenchent Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Wymzya Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Layolis Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Generess Fe
norethindrone-ethinyl estradiol/ferrous fumarate	Kaitlib Fe
norethindrone-mestranol	Necon 1/50 (28)
norethindrone-mestranol	Norinyl 1+50 (28)
norgestimate-ethinyl estradiol	Ortho Tri-Cyclen Lo (28)
norgestimate-ethinyl estradiol	Ortho Tri-Cyclen (28)
norgestimate-ethinyl estradiol	Tri-Lo-Sprintec
norgestimate-ethinyl estradiol	Norgestimate-Ethinyl Estradiol
norgestimate-ethinyl estradiol	Tri-Sprintec (28)
norgestimate-ethinyl estradiol	Tri-Previfem (28)
norgestimate-ethinyl estradiol	Tri-Estarylla
norgestimate-ethinyl estradiol	Tri-Lo-Estarylla
norgestimate-ethinyl estradiol	Tri-Linyah
norgestimate-ethinyl estradiol	Trinessa (28)
norgestimate-ethinyl estradiol	Trinessa Lo
norgestimate-ethinyl estradiol	Tri-Lo-Marzia
norgestimate-ethinyl estradiol	Ortho-Cyclen (28)
norgestimate-ethinyl estradiol	Sprintec (28)
norgestimate-ethinyl estradiol	Previfem
norgestimate-ethinyl estradiol	Estarylla
norgestimate-ethinyl estradiol	Mono-Linyah
norgestimate-ethinyl estradiol	Mononessa (28)
norgestimate-ethinyl estradiol	Femynor
norgestrel-ethinyl estradiol	Lo-Ovral (28)
norgestrel-ethinyl estradiol	Cryselle (28)
norgestrel-ethinyl estradiol	Elinest
norgestrel-ethinyl estradiol	Norgestrel-Ethinyl Estradiol
norgestrel-ethinyl estradiol	Low-Ogestrel (28)
norgestrel-ethinyl estradiol	Lo-Ovral (8)
norgestrel-ethinyl estradiol	Ogestrel (28)
norgestrel-ethinyl estradiol	Ovral (21)
norgestrel-ethinyl estradiol	Ovral (28)

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

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

Code	Description	Code Type	Code Category
453.51	Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity	ICD-9-CM	Diagnosis
453.52	Chronic venous embolism and thrombosis of deep vessels of distal lower extremity	ICD-9-CM	Diagnosis
453.6	Venous embolism and thrombosis of superficial vessels of lower extremity	ICD-9-CM	Diagnosis
453.7	Chronic venous embolism and thrombosis of other specified vessels	ICD-9-CM	Diagnosis
453.71	Chronic venous embolism and thrombosis of superficial veins of upper extremity	ICD-9-CM	Diagnosis
453.72	Chronic venous embolism and thrombosis of deep veins of upper extremity	ICD-9-CM	Diagnosis
453.73	Chronic venous embolism and thrombosis of upper extremity, unspecified	ICD-9-CM	Diagnosis
453.74	Chronic venous embolism and thrombosis of axillary veins	ICD-9-CM	Diagnosis
453.75	Chronic venous embolism and thrombosis of subclavian veins	ICD-9-CM	Diagnosis
453.76	Chronic venous embolism and thrombosis of internal jugular veins	ICD-9-CM	Diagnosis
453.77	Chronic venous embolism and thrombosis of other thoracic veins	ICD-9-CM	Diagnosis
453.79	Chronic venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.8	Acute venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.81	Acute venous embolism and thrombosis of superficial veins of upper extremity	ICD-9-CM	Diagnosis
453.82	Acute venous embolism and thrombosis of deep veins of upper extremity	ICD-9-CM	Diagnosis
453.83	Acute venous embolism and thrombosis of upper extremity, unspecified	ICD-9-CM	Diagnosis
453.84	Acute venous embolism and thrombosis of axillary veins	ICD-9-CM	Diagnosis
453.85	Acute venous embolism and thrombosis of subclavian veins	ICD-9-CM	Diagnosis
453.86	Acute venous embolism and thrombosis of internal jugular veins	ICD-9-CM	Diagnosis
453.87	Acute venous embolism and thrombosis of other thoracic veins	ICD-9-CM	Diagnosis
453.89	Acute venous embolism and thrombosis of other specified veins	ICD-9-CM	Diagnosis
453.9	Embolism and thrombosis of unspecified site	ICD-9-CM	Diagnosis
671.3	Deep phlebothrombosis, antepartum	ICD-9-CM	Diagnosis
671.30	Deep phlebothrombosis, antepartum, unspecified as to episode of care	ICD-9-CM	Diagnosis
671.31	Deep phlebothrombosis, antepartum, with delivery	ICD-9-CM	Diagnosis
671.33	Deep phlebothrombosis, antepartum	ICD-9-CM	Diagnosis
671.4	Deep phlebothrombosis, postpartum	ICD-9-CM	Diagnosis
671.40	Deep phlebothrombosis, postpartum, unspecified as to episode of care	ICD-9-CM	Diagnosis
671.42	Deep phlebothrombosis, postpartum, with delivery	ICD-9-CM	Diagnosis
671.44	Deep phlebothrombosis, postpartum condition or complication	ICD-9-CM	Diagnosis
671.5	Other phlebitis and thrombosis in pregnancy and the puerperium	ICD-9-CM	Diagnosis
671.50	Other phlebitis and thrombosis complicating pregnancy and the puerperium, unspecified as to episode of care	ICD-9-CM	Diagnosis
671.51	Other phlebitis and thrombosis with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.52	Other phlebitis and thrombosis with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.53	Other antepartum phlebitis and thrombosis	ICD-9-CM	Diagnosis
671.54	Other phlebitis and thrombosis, postpartum condition or complication	ICD-9-CM	Diagnosis
673	Obstetrical pulmonary embolism	ICD-9-CM	Diagnosis
673.8	Other obstetrical pulmonary embolism	ICD-9-CM	Diagnosis
673.80	Other obstetrical pulmonary embolism, unspecified as to episode of care	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
673.81	Other obstetrical pulmonary embolism, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
673.82	Other obstetrical pulmonary embolism, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
673.83	Other obstetrical pulmonary embolism, antepartum	ICD-9-CM	Diagnosis
673.84	Other obstetrical pulmonary embolism, postpartum condition or complication	ICD-9-CM	Diagnosis
V12.51	Personal history of venous thrombosis and embolism	ICD-9-CM	Diagnosis
	Knee or Hip Joint Replacement Surgery		
01214	Anesthesia for open procedures involving hip joint; total hip arthroplasty	CPT-4	Procedure
01215	Anesthesia for open procedures involving hip joint; revision of total hip arthroplasty	CPT-4	Procedure
01402	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty	CPT-4	Procedure
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	CPT-4	Procedure
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	CPT-4	Procedure
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	CPT-4	Procedure
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	CPT-4	Procedure
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	CPT-4	Procedure
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	CPT-4	Procedure
27265	Closed treatment of post hip arthroplasty dislocation; without anesthesia	CPT-4	Procedure
27266	Closed treatment of post hip arthroplasty dislocation; requiring regional or general anesthesia	CPT-4	Procedure
27437	Arthroplasty, patella; without prosthesis	CPT-4	Procedure
27438	Arthroplasty, patella; with prosthesis	CPT-4	Procedure
27440	Arthroplasty, knee, tibial plateau;	CPT-4	Procedure
27441	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy	CPT-4	Procedure
27442	Arthroplasty, femoral condyles or tibial plateau(s), knee;	CPT-4	Procedure
27443	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy	CPT-4	Procedure
27445	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)	CPT-4	Procedure
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment	CPT-4	Procedure
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	CPT-4	Procedure
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	CPT-4	Procedure
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	CPT-4	Procedure
29862	Arthroscopy, hip, surgical; with debridement/shaving of articular cartilage (chondroplasty), abrasion arthroplasty, and/or resection of labrum	CPT-4	Procedure

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

Code	Description	Code Type	Code Category
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture	CPT-4	Procedure
81.5	Joint replacement of lower extremity	ICD-9-CM	Procedure

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

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

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

Code	Description	Code Type	Code Category
	Gynecological Disorders		
	Adenomyosis		
617.0	Endometriosis of uterus	ICD-9-CM	Diagnosis
	Endometrial Hyperplasia		
621.30	Endometrial hyperplasia, unspecified	ICD-9-CM	Diagnosis
621.3	Endometrial hyperplasia	ICD-9-CM	Diagnosis
621.31	Simple endometrial hyperplasia without atypia	ICD-9-CM	Diagnosis
621.32	Complex endometrial hyperplasia without atypia	ICD-9-CM	Diagnosis
621.33	Endometrial hyperplasia with atypia	ICD-9-CM	Diagnosis
621.34	Benign endometrial hyperplasia	ICD-9-CM	Diagnosis
	Endometriosis		
617.0	Endometriosis of uterus	ICD-9-CM	Diagnosis
617.1	Endometriosis of ovary	ICD-9-CM	Diagnosis
617.2	Endometriosis of fallopian tube	ICD-9-CM	Diagnosis
617.3	Endometriosis of pelvic peritoneum	ICD-9-CM	Diagnosis
617.4	Endometriosis of rectovaginal septum and vagina	ICD-9-CM	Diagnosis
	Gynecological Cancer		
179	Malignant neoplasm of uterus, part unspecified	ICD-9-CM	Diagnosis
180	Malignant neoplasm of cervix uteri	ICD-9-CM	Diagnosis
180.0	Malignant neoplasm of endocervix	ICD-9-CM	Diagnosis
180.1	Malignant neoplasm of exocervix	ICD-9-CM	Diagnosis
180.8	Malignant neoplasm of other specified sites of cervix	ICD-9-CM	Diagnosis
180.9	Malignant neoplasm of cervix uteri, unspecified site	ICD-9-CM	Diagnosis
181	Malignant neoplasm of placenta	ICD-9-CM	Diagnosis
182	Malignant neoplasm of body of uterus	ICD-9-CM	Diagnosis
182.0	Malignant neoplasm of corpus uteri, except isthmus	ICD-9-CM	Diagnosis
182.1	Malignant neoplasm of isthmus	ICD-9-CM	Diagnosis
182.8	Malignant neoplasm of other specified sites of body of uterus	ICD-9-CM	Diagnosis
183	Malignant neoplasm of ovary and other uterine adnexa	ICD-9-CM	Diagnosis
183.0	Malignant neoplasm of ovary	ICD-9-CM	Diagnosis
183.2	Malignant neoplasm of fallopian tube	ICD-9-CM	Diagnosis
183.3	Malignant neoplasm of broad ligament of uterus	ICD-9-CM	Diagnosis
183.4	Malignant neoplasm of parametrium of uterus	ICD-9-CM	Diagnosis
183.5	Malignant neoplasm of round ligament of uterus	ICD-9-CM	Diagnosis
183.8	Malignant neoplasm of other specified sites of uterine adnexa	ICD-9-CM	Diagnosis
183.9	Malignant neoplasm of uterine adnexa, unspecified site	ICD-9-CM	Diagnosis
184	Malignant neoplasm of other and unspecified female genital organs	ICD-9-CM	Diagnosis
184.0	Malignant neoplasm of vagina	ICD-9-CM	Diagnosis
184.1	Malignant neoplasm of labia majora	ICD-9-CM	Diagnosis
184.3	Malignant neoplasm of clitoris	ICD-9-CM	Diagnosis
184.4	Malignant neoplasm of vulva, unspecified site	ICD-9-CM	Diagnosis
184.8	Malignant neoplasm of other specified sites of female genital organs	ICD-9-CM	Diagnosis
184.9	Malignant neoplasm of female genital organ, site unspecified	ICD-9-CM	Diagnosis

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

Code	Description	Code Type	Code Category
198.6	Secondary malignant neoplasm of ovary	ICD-9-CM	Diagnosis
198.82	Secondary malignant neoplasm of genital organs	ICD-9-CM	Diagnosis
236.0	Neoplasm of uncertain behavior of uterus	ICD-9-CM	Diagnosis
236.2	Neoplasm of uncertain behavior of ovary	ICD-9-CM	Diagnosis
236.3	Neoplasm of uncertain behavior of other and unspecified female genital	ICD-9-CM	Diagnosis
	Ovarian Cyst		
620.0	Follicular cyst of ovary	ICD-9-CM	Diagnosis
620.1	Corpus luteum cyst or hematoma	ICD-9-CM	Diagnosis
620.2	Other and unspecified ovarian cyst	ICD-9-CM	Diagnosis
	Uterine Fibroids/Leiomyoma		
218	UTERINE LEIOMYOMA	ICD-9-CM	Diagnosis
218.0	SUBMUCOUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218	UTERINE LEIOMYOMA	ICD-9-CM	Diagnosis
218.0	SUBMUCOUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.1	INTRAMURAL LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.1	INTRAMURAL LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.2	SUBSEROUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.2	SUBSEROUS LEIOMYOMA OF UTERUS	ICD-9-CM	Diagnosis
218.9	LEIOMYOMA OF UTERUS UNSPECIFIED	ICD-9-CM	Diagnosis
218.9	LEIOMYOMA OF UTERUS UNSPECIFIED	ICD-9-CM	Diagnosis
	Uterine or Cervical Polyp		
621.0	Polyp of corpus uteri	ICD-9-CM	Diagnosis
622.7	Mucous polyp of cervix	ICD-9-CM	Diagnosis

Appendix H.1. Specifications Defining Parameters in this Request: Scenarios 1-3

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to provide background incidence of severe uterine bleed outcomes for a previous request (cder_mpl1r_wp165_nsdp_v02). These estimates are for populations of women exposed to oral anticoagulants (OACs) or of women with no indication for atrial fibrillation (AF) or deep vein thrombosis (DVT)/pulmonary embolism (PE) and no exposure to OACs. Information on types of surgical outcomes was also obtained.

Query Period: October 19, 2010 - Spetember 30, 2015
Coverage Requirement: Medical and Drug Coverage
Pre-exposure Enrollment (days): 6 months (183 days)
Enrollment Gap: 45 days
Sex: Female only
Age Groups: 00-17, 18-50, 51+ years
Patient-level Return: No
Envelope Macro Use: Yes
Create/Run on Frozen Data: No
Subgroups: Age group (00-17 18-50 51+)
Presence of gynecological disorder (Y/N)
Evidence of IUD use (Y/N)
Evidence of oral contraceptive use (Y/N)
Age group * gynecological disorder
Age group * IUD
Age group * oral contraceptive
Calendar year
Additional Output: Code index distribution tool, censoring table

	Scenario 01 Reference Population, Same-Day Medical Management	Scenario 02 OAC-exposure Population, Same-Day Medical Management	Scenario 03 OAC-exposure Population, Same-Day Medical Management, Washout
Exposure	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	Inpatient Hospital Stay (IP*), Emergency Stay (ED*), Ambulatory Visit (AV*), or Other Ambulatory Visit (OA*)	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Fixed Episode Duration (ITT Days)	1 day	1 day	1 day
Incidence with Respect	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Washout (days)	183 days	183 days	183 days

Appendix H.1. Specifications Defining Parameters in this Request: Scenarios 1-3

		Scenario 01 Reference Population, Same-Day Medical Management	Scenario 02 OAC-exposure Population, Same-Day Medical Management	Scenario 03 OAC-exposure Population, Same-Day Medical Management, Washout
Drug/Exposure Definition	**Exposure Episode Truncation Criteria**	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (1 day) *Occurrence of first medical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (1 day) *Occurrence of first medical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (1 day) *Occurrence of first medical management
	Cohort Definition	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)
	Exposure Episode Gap	0 days	0 days	0 days
	Exposure Extension Period	0 days	0 days	0 days
Outcome Definition	**Event/Outcome**	Medical management (Intrauterine device (IUD), oral contraceptives, antifibrinolytics, vaginal packing) (Dispensing date only)	Medical management (Intrauterine device (IUD), oral contraceptives, antifibrinolytics, vaginal packing) (Dispensing date only)	Medical management (Intrauterine device (IUD), oral contraceptives, antifibrinolytics, vaginal packing) (Dispensing date only)
	Care Setting/PDX	Any	Any	Any
	Event Incidence with Respect to	N/A	N/A	N/A
	Event Incidence Criteria Care Setting / PDX	N/A	N/A	N/A
	Event Washout (days)	0 days	0 days	0 days
	Blackout Period	0 days	0 days	0 days
Inclusion/Exclusion Criteria	**Conditions**	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance

Appendix H.1. Specifications Defining Parameters in this Request: Scenarios 1-3

		Scenario 01 Reference Population, Same-Day Medical Management	Scenario 02 OAC-exposure Population, Same-Day Medical Management	Scenario 03 OAC-exposure Population, Same-Day Medical Management, Washout
Inclusion/Exclusion Criteria	**Conditions**	Joint replacement (knee or hip)	Joint replacement (knee or hip)	Joint replacement (knee or hip)
	Include or Exclude	Exclusion	Exclusion	Exclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	N/A	N/A	N/A
	Lookback Period	(0, 0)	(0, 0)	(-183, 0)
	Number of Code Occurrences	1	1	1
Baseline Covariates / Health Services Utilization / Comorbidity Score	**Covariates**	See Appendix I	See Appendix I	See Appendix I
	Care Setting/PDX	See Appendix I	See Appendix I	See Appendix I
	Covariate Evaluation Window (days)	See Appendix I	See Appendix I	See Appendix I
	Comorbidity Score Evaluation window (days)	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Care setting	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED
	Drug Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)

Appendix H.2. Specifications Defining Parameters in this Request: Scenarios 4-6

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to provide background incidence of severe uterine bleed outcomes for a previous request (cder_mpl1r_wp165_nsdp_v02). These estimates are for populations of women exposed to oral anticoagulants (OACs) or of women with no indication for atrial fibrillation (AF) or deep vein thrombosis (DVT)/pulmonary embolism (PE) and no exposure to OACs. Information on types of surgical outcomes was also obtained.

Query Period: October 19, 2010 - Spetember 30, 2015
Coverage Requirement: Medical and Drug Coverage
Pre-exposure Enrollment (days): 6 months (183 days)
Enrollment Gap: 45 days
Sex: Female only
Age Groups: 00-17, 18-50, 51+ years
Patient-level Return: No
Envelope Macro Use: Yes
Create/Run on Frozen Data: No
Subgroups: Age group (00-17 18-50 51+)
Presence of gynecological disorder (Y/N)
Evidence of IUD use (Y/N)
Evidence of oral contraceptive use (Y/N)
Age group * gynecological disorder
Age group * IUD
Age group * oral contraceptive
Calendar year
Additional Output: Code index distribution tool, censoring table

	Scenario 04 Reference Population, 5-Day Gap Medical Management	Scenario 05 OAC-exposure Population, 5-Day Gap Medical Management	Scenario 06 OAC-exposure Population, 5-Day Gap Medical Management, Washout
Exposure	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	Inpatient Hospital Stay (IP*), Emergency Stay (ED*), Ambulatory Visit (AV*), or Other Ambulatory Visit (OA*)	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Fixed Episode Duration (ITT Days)	5 days	5 days	5 days
Incidence with Respect	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Washout (days)	183 days	183 days	183 days

Appendix H.2. Specifications Defining Parameters in this Request: Scenarios 4-6

		Scenario 04 Reference Population, 5-Day Gap Medical Management	Scenario 05 OAC-exposure Population, 5-Day Gap Medical Management	Scenario 06 OAC-exposure Population, 5-Day Gap Medical Management, Washout
Drug/Exposure Definition	**Exposure Episode Truncation Criteria**	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (5 days) *Occurrence of first medical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (5 days) *Occurrence of first medical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (5 days) *Occurrence of first medical management
	Cohort Definition	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)
	Exposure Episode Gap	0 days	0 days	0 days
	Exposure Extension Period	0 days	0 days	0 days
Outcome Definition	**Event/Outcome**	Medical management (Intrauterine device (IUD), oral contraceptives, antifibrinolytics, vaginal packing) (Dispensing date only)	Medical management (Intrauterine device (IUD), oral contraceptives, antifibrinolytics, vaginal packing) (Dispensing date only)	Medical management (Intrauterine device (IUD), oral contraceptives, antifibrinolytics, vaginal packing) (Dispensing date only)
	Care Setting/PDX	Any	Any	Any
	Event Incidence with Respect to	N/A	N/A	N/A
	Event Incidence Criteria Care Setting / PDX	N/A	N/A	N/A
	Event Washout (days)	0 days	0 days	0 days
	Blackout Period	0 days	0 days	0 days
Inclusion/Exclusion Criteria	**Conditions**	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance

Appendix H.2. Specifications Defining Parameters in this Request: Scenarios 4-6

		Scenario 04 Reference Population, 5-Day Gap Medical Management	Scenario 05 OAC-exposure Population, 5-Day Gap Medical Management	Scenario 06 OAC-exposure Population, 5-Day Gap Medical Management, Washout
Inclusion/Exclusion Criteria	**Conditions**	Joint replacement (knee or hip)	Joint replacement (knee or hip)	Joint replacement (knee or hip)
	Include or Exclude	Exclusion	Exclusion	Exclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	N/A	N/A	N/A
	Lookback Period	(0, 0)	(0, 0)	(-183, 0)
	Number of Code Occurrences	1	1	1
Baseline Covariates / Health Services Utilization / Comorbidity Score	**Covariates**	See Appendix I	See Appendix I	See Appendix I
	Care Setting/PDX	See Appendix I	See Appendix I	See Appendix I
	Covariate Evaluation Window (days)	See Appendix I	See Appendix I	See Appendix I
	Comorbidity Score Evaluation window (days)	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Care setting	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED
	Drug Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)

Appendix H.3. Specifications Defining Parameters in this Request: Scenarios 7-9

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to provide background incidence of severe uterine bleed outcomes for a previous request (cder_mpl1r_wp165_nsdp_v02). These estimates are for populations of women exposed to oral anticoagulants (OACs) or of women with no indication for atrial fibrillation (AF) or deep vein thrombosis (DVT)/pulmonary embolism (PE) and no exposure to OACs. Information on types of surgical outcomes was also obtained.

Query Period: October 19, 2010 - Spetember 30, 2015
Coverage Requirement: Medical and Drug Coverage
Pre-exposure Enrollment (days): 6 months (183 days)
Enrollment Gap: 45 days
Sex: Female only
Age Groups: 00-17, 18-50, 51+ years
Patient-level Return: No
Envelope Macro Use: Yes
Create/Run on Frozen Data: No
Subgroups: Age group (00-17 18-50 51+)
Presence of gynecological disorder (Y/N)
Evidence of IUD use (Y/N)
Evidence of oral contraceptive use (Y/N)
Age group * gynecological disorder
Age group * IUD
Age group * oral contraceptive
Calendar year
Additional Output: Code index distribution tool, censoring table

	Scenario 07 Reference Population, Same-Day Transfusion Management	Scenario 08 OAC-exposure Population, Same-Day Transfusion Management	Scenario 09 OAC-exposure Population, Same-Day Transfusion Management, Washout
Exposure	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	Inpatient Hospital Stay (IP*), Emergency Stay (ED*), Ambulatory Visit (AV*), or Other Ambulatory Visit (OA*)	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Fixed Episode Duration (ITT Days)	1 day	1 day	1 day
Incidence with Respect	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Washout (days)	183 days	183 days	183 days

Appendix H.3. Specifications Defining Parameters in this Request: Scenarios 7-9

		Scenario 07 Reference Population, Same-Day Transfusion Management	Scenario 08 OAC-exposure Population, Same-Day Transfusion Management	Scenario 09 OAC-exposure Population, Same-Day Transfusion Management, Washout
Drug/Exposure Definition	**Exposure Episode Truncation Criteria**	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (1 day) *Occurrence of first transfusion management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (1 day) *Occurrence of first transfusion management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (1 day) *Occurrence of first transfusion management
	Cohort Definition	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)
	Exposure Episode Gap	0 days	0 days	0 days
	Exposure Extension Period	0 days	0 days	0 days
Outcome Definition	**Event/Outcome**	Transfusion management (Red blood cell (RBC)-only transfusion)	Transfusion management (Red blood cell (RBC)-only transfusion)	Transfusion management (Red blood cell (RBC)-only transfusion)
	Care Setting/PDX	Any	Any	Any
	Event Incidence with Respect to	N/A	N/A	N/A
	Event Incidence Criteria Care Setting / PDX	N/A	N/A	N/A
	Event Washout (days)	0 days	0 days	0 days
	Blackout Period	0 days	0 days	0 days
Inclusion/Exclusion Criteria	**Conditions**	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance

Appendix H.3. Specifications Defining Parameters in this Request: Scenarios 7-9

		Scenario 07 Reference Population, Same-Day Transfusion Management	Scenario 08 OAC-exposure Population, Same-Day Transfusion Management	Scenario 09 OAC-exposure Population, Same-Day Transfusion Management, Washout
Inclusion/Exclusion Criteria	**Conditions**	Joint replacement (knee or hip)	Joint replacement (knee or hip)	Joint replacement (knee or hip)
	Include or Exclude	Exclusion	Exclusion	Exclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	N/A	N/A	N/A
	Lookback Period	(0, 0)	(0, 0)	(-183, 0)
	Number of Code Occurrences	1	1	1
Baseline Covariates / Health Services Utilization / Comorbidity Score	**Covariates**	See Appendix I	See Appendix I	See Appendix I
	Care Setting/PDX	See Appendix I	See Appendix I	See Appendix I
	Covariate Evaluation Window (days)	See Appendix I	See Appendix I	See Appendix I
	Comorbidity Score Evaluation window (days)	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Care setting	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED
	Drug Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)

Appendix H.4. Specifications Defining Parameters in this Request: Scenarios 10-12

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to provide background incidence of severe uterine bleed outcomes for a previous request (cder_mpl1r_wp165_nsdp_v02). These estimates are for populations of women exposed to oral anticoagulants (OACs) or of women with no indication for atrial fibrillation (AF) or deep vein thrombosis (DVT)/pulmonary embolism (PE) and no exposure to OACs. Information on types of surgical outcomes was also obtained.

Query Period: October 19, 2010 - Spetember 30, 2015
Coverage Requirement: Medical and Drug Coverage
Pre-exposure Enrollment (days): 6 months (183 days)
Enrollment Gap: 45 days
Sex: Female only
Age Groups: 00-17, 18-50, 51+ years
Patient-level Return: No
Envelope Macro Use: Yes
Create/Run on Frozen Data: No
Subgroups: Age group (00-17 18-50 51+)
Presence of gynecological disorder (Y/N)
Evidence of IUD use (Y/N)
Evidence of oral contraceptive use (Y/N)
Age group * gynecological disorder
Age group * IUD
Age group * oral contraceptive
Calendar year
Additional Output: Code index distribution tool, censoring table

	Scenario 10 Reference Population, 30-Day Gap Surgical Management	Scenario 11 OAC-exposure Population, 30-Day Gap Surgical Management	Scenario 12 OAC-exposure Population, 30-Day Gap Surgical Management, Washout
Exposure	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	Inpatient Hospital Stay (IP*), Emergency Stay (ED*), Ambulatory Visit (AV*), or Other Ambulatory Visit (OA*)	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Fixed Episode Duration (ITT Days)	30 days	30 days	30 days
Incidence with Respect to	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Washout (days)	183 days	183 days	183 days

Appendix H.4. Specifications Defining Parameters in this Request: Scenarios 10-12

		Scenario 10	Scenario 11	Scenario 12
		Reference Population, 30-Day Gap Surgical Management	OAC-exposure Population, 30-Day Gap Surgical Management	OAC-exposure Population, 30-Day Gap Surgical Management, Washout
Drug/Exposure Definition	**Exposure Episode Truncation Criteria**	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (30 days) *Occurrence of first surgical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (30 days) *Occurrence of first surgical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (30 days) *Occurrence of first surgical management
	Cohort Definition	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)
	Exposure Episode Gap	0 days	0 days	0 days
	Exposure Extension Period	0 days	0 days	0 days
Outcome Definition	**Event/Outcome**	Surgical management (Dilation and curettage, Thermal/cryo/section endometrial ablation, hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, hysterectomy, hysteroscopy (not otherwise listed), uterine artery embolization)	Surgical management (Dilation and curettage, Thermal/cryo/section endometrial ablation, hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, hysterectomy, hysteroscopy (not otherwise listed), uterine artery embolization)	Surgical management (Dilation and curettage, Thermal/cryo/section endometrial ablation, hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, hysterectomy, hysteroscopy (not otherwise listed), uterine artery embolization)
	Care Setting/PDX	Any	Any	Any
	Event Incidence with Respect to	N/A	N/A	N/A
	Event Incidence Criteria Care Setting / PDX	N/A	N/A	N/A
	Event Washout (days)	0 days	0 days	0 days
	Blackout Period	0 days	0 days	0 days

Appendix H.4. Specifications Defining Parameters in this Request: Scenarios 10-12

		Scenario 10 Reference Population, 30-Day Gap Surgical Management	Scenario 11 OAC-exposure Population, 30-Day Gap Surgical Management	Scenario 12 OAC-exposure Population, 30-Day Gap Surgical Management, Washout
Inclusion/Exclusion Criteria	**Conditions**	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	Joint replacement (knee or hip)	Joint replacement (knee or hip)	Joint replacement (knee or hip)
	Include or Exclude	Exclusion	Exclusion	Exclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	N/A	N/A	N/A
	Lookback Period	(0, 0)	(0, 0)	(-183, 0)
	Number of Code Occurrences	1	1	1

Appendix H.4. Specifications Defining Parameters in this Request: Scenarios 10-12

		Scenario 10 Reference Population, 30-Day Gap Surgical Management	Scenario 11 OAC-exposure Population, 30-Day Gap Surgical Management	Scenario 12 OAC-exposure Population, 30-Day Gap Surgical Management, Washout
Baseline Covariates / Health Services Utilization / Comorbidity Score	**Covariates**	See Appendix I	See Appendix I	See Appendix I
	Care Setting/PDX	See Appendix I	See Appendix I	See Appendix I
	Covariate Evaluation Window (days)	See Appendix I	See Appendix I	See Appendix I
	Comorbidity Score Evaluation window (days)	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Care setting	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED
	Drug Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)

Appendix H.5. Specifications Defining Parameters in this Request: Scenarios 13-15

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to provide background incidence of severe uterine bleed outcomes for a previous request (cder_mpl1r_wp165_nsdp_v02). These estimates are for populations of women exposed to oral anticoagulants (OACs) or of women with no indication for atrial fibrillation (AF) or deep vein thrombosis (DVT)/pulmonary embolism (PE) and no exposure to OACs. Information on types of surgical outcomes was also obtained.

Query Period: October 19, 2010 - Spetember 30, 2015
Coverage Requirement: Medical and Drug Coverage
Pre-exposure Enrollment (days): 6 months (183 days)
Enrollment Gap: 45 days
Sex: Female only
Age Groups: 00-17, 18-50, 51+ years
Patient-level Return: No
Envelope Macro Use: Yes
Create/Run on Frozen Data: No
Subgroups: Age group (00-17 18-50 51+)
Presence of gynecological disorder (Y/N)
Evidence of IUD use (Y/N)
Evidence of oral contraceptive use (Y/N)
Age group * gynecological disorder
Age group * IUD
Age group * oral contraceptive
Calendar year
Additional Output: Code index distribution tool, censoring table

	Scenario 13 Reference Population, 60-Day Gap Surgical Management	Scenario 14 OAC-exposure Population, 60-Day Gap Surgical Management	Scenario 15 OAC-exposure Population, 60-Day Gap Surgical Management, Washout
Exposure	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	Inpatient Hospital Stay (IP*), Emergency Stay (ED*), Ambulatory Visit (AV*), or Other Ambulatory Visit (OA*)	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Fixed Episode Duration (ITT Days)	60 days	60 days	60 days
Incidence with Respect to	Vaginal bleed	Vaginal bleed	Vaginal bleed
Care Setting / Principal Diagnosis	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*	IP*, ED*, AV*, or OA*
Washout (days)	183 days	183 days	183 days

Appendix H.5. Specifications Defining Parameters in this Request: Scenarios 13-15

		Scenario 13	Scenario 14	Scenario 15
		Reference Population, 60-Day Gap Surgical Management	**OAC-exposure Population, 60-Day Gap Surgical Management**	**OAC-exposure Population, 60-Day Gap Surgical Management, Washout**
Drug/Exposure Definition	**Exposure Episode Truncation Criteria**	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (60 days) *Occurrence of first surgical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (60 days) *Occurrence of first surgical management	*Death *Query end date *Data end date *Disenrollment *End of fixed episode duration (60 days) *Occurrence of first surgical management
	Cohort Definition	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)	Only the first valid treatment episode during the query period (01)
	Exposure Episode Gap	0 days	0 days	0 days
	Exposure Extension Period	0 days	0 days	0 days
Outcome Definition	**Event/Outcome**	Surgical management (Dilation and curettage, Thermal/cryo/section endometrial ablation, hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, hysterectomy, hysteroscopy (not otherwise listed), uterine artery embolization)	Surgical management (Dilation and curettage, Thermal/cryo/section endometrial ablation, hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, hysterectomy, hysteroscopy (not otherwise listed), uterine artery embolization)	Surgical management (Dilation and curettage, Thermal/cryo/section endometrial ablation, hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, hysterectomy, hysteroscopy (not otherwise listed), uterine artery embolization)
	Care Setting/PDX	Any	Any	Any
	Event Incidence with Respect to	N/A	N/A	N/A
	Event Incidence Criteria Care Setting / PDX	N/A	N/A	N/A
	Event Washout (days)	0 days	0 days	0 days
	Blackout Period	0 days	0 days	0 days

Appendix H.5. Specifications Defining Parameters in this Request: Scenarios 13-15

		Scenario 13 Reference Population, 60-Day Gap Surgical Management	Scenario 14 OAC-exposure Population, 60-Day Gap Surgical Management	Scenario 15 OAC-exposure Population, 60-Day Gap Surgical Management, Washout
Inclusion/Exclusion Criteria	**Conditions**	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))	OAC use indications (Atrial fibrillation (AF) or atrial flutter, deep vein thrombosis / pulmonary embolism (DVT/PE))
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	Joint replacement (knee or hip)	Joint replacement (knee or hip)	Joint replacement (knee or hip)
	Include or Exclude	Exclusion	Exclusion	Exclusion
	Care Setting/PDX	Any	Any	Any
	Lookback Period	(-183, 0)	(-183, 0)	(-183, 0)
	Number of Code Occurrences	1 instance	1 instance	1 instance
Inclusion/Exclusion Criteria	**Conditions**	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)	OAC (Novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban, edoxaban), warfarin) (evidence of days supply)
	Include or Exclude	Exclusion	Inclusion	Inclusion
	Care Setting/PDX	N/A	N/A	N/A
	Lookback Period	(0, 0)	(0, 0)	(-183, 0)
	Number of Code Occurrences	1	1	1

Appendix H.5. Specifications Defining Parameters in this Request: Scenarios 13-15

		Scenario 13 Reference Population, 60-Day Gap Surgical Management	Scenario 14 OAC-exposure Population, 60-Day Gap Surgical Management	Scenario 15 OAC-exposure Population, 60-Day Gap Surgical Management, Washout
Baseline Covariates / Health Services Utilization / Comorbidity Score	**Covariates**	See Appendix I	See Appendix I	See Appendix I
	Care Setting/PDX	See Appendix I	See Appendix I	See Appendix I
	Covariate Evaluation Window (days)	See Appendix I	See Appendix I	See Appendix I
	Comorbidity Score Evaluation window (days)	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)
	Medical Utilization Care setting	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED	IP, IS, AV, OA, ED
	Drug Utilization Evaluation Window	(-183, 0)	(-183, 0)	(-183, 0)

Appendix I. Specifications Defining Characteristics in this Request

Group	Covariate	Care Setting	Covariate Window
Gynecological disorders of interest	Uterine myoma	Any	(-183, 0)
	Endometrial hyperplasia	Any	(-183, 0)
	Endometriosis	Any	(-183, 0)
	Ovarian cyst	Any	(-183, 0)
	Uterine or cervical polyp	Any	(-183, 0)
	Adenomyosis	Any	(-183, 0)
	Uterine, ovarian or cervical cancer	Any	(-183, 0)
	Any gynecological disorder of interest	Any	(-183, 0)
Medical managements	Insertion of intrauterine system device	Inpatient Hospital Stay (IP*), Emergency Stay (ED*), Ambulatory Visit (AV*), or Other Ambulatory Visit (OA*)	(-183, 0)
	Initiation of contraception (combined oral contraceptives and progestin-only contraceptives)	IP*, ED*, AV*, or OA*	(-183, 0)
	Vaginal packing	IP*, ED*, AV*, or OA*	(-183, 0)
	Initiation of an antifibrinolytic drug (tranexamic acid, aminocaproic acid, aprotinin, desmopressin)	IP*, ED*, AV*, or OA*	(-183, 0)
	Any medical management	IP*, ED*, AV*, or OA*	(-183, 0)
Oral Anticoagulants (OAC) indications	Deep vein thrombosis (DVT) / pulmonary embolism (PE)	Any	(-183, 0)
	Atrial fibrillation or atrial flutter (AF)	Any	(-183, 0)
OACs	Rivaroxaban	N/A	(0, 0)
	Dabigatran	N/A	(0, 0)
	Apixaban	N/A	(0, 0)
	Any novel oral anticoagulant (NOAC) (rivaroxaban, dabigatran, apixaban)	N/A	(0, 0)
	Warfarin	N/A	(0, 0)
Demographics	Race/ethnicity	N/A	(0, 0)
	Continuous age	N/A	(0, 0)
	Age groups (00-17, 18-50, 51+ years)	N/A	(0, 0)
	Calendar year	N/A	(0, 0)
Comorbidity Score	Comorbidity score	N/A	(-183, 0)
Utilization	Number of inpatient hospital (IP) encounters	IP*	(-183, 0)
	Number of ambulatory (AV) encounters	AV*	(-183, 0)
	Number of non-acute institutional (IS) encounters	IS*	(-183, 0)
	Number of emergency department (ED) encounters	ED*	(-183, 0)
	Number of other ambulatory (OA) encounters	OA*	(-183, 0)
	Number of generics dispensed	N/A	(-183, 0)
	Number of unique drug classes dispensed	N/A	(-183, 0)
	Number of filled prescriptions dispensed	N/A	(-183, 0)