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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_wp165

Request ID: cder_mpl1r_wp165_nsdv_v01

Request Description: In this request, we investigated severe uterine bleeding (SUB) among new users of oral anticoagulants (rivaroxaban, apixaban, dabigatran, and warfarin) in the Sentinel Distributed Database (SDD).

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

Data Source: We included new users between October 19, 2010 and September 30, 2015 from 17 Data Partners contributing to the Sentinel Distributed Database (SDD) in this report. This request was distributed on September 17, 2019. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: We designed this request to use a retrospective cohort design and estimated SUB incidence rates amongst warfarin and novel oral anticoagulants (NOAC) new users overall and stratified by age group and oral anticoagulant category.

Exposures of Interest: Our exposures of interest were rivaroxaban, apixaban, dabigatran, and warfarin, which were defined using National Drug Codes (NDCs) recorded in outpatient pharmacy dispensings (index). Please see Appendix B for a list of generic and brand names of medical products used to define the exposures of interest in this request.

Cohort Eligibility Criteria: We required eligible members to be female and continuously enrolled in plans with medical and drug coverage for at least 183 days prior to their index dispensing date, during which gaps in coverage of up to 45 days were allowed. Members were excluded if they had either an exposure of interest or edoxaban in the 183 days prior to the index date. Edoxaban use was defined using NDCs. Age groups of interest were: 0-50 and 51+ years.

Inclusion and Exclusion Criteria: We required inclusion and exclusion criteria for the five cohorts to be evaluated in the 183 days prior to and including the index dispensing date. All cohorts required the inclusion of atrial fibrillation or flutter, deep vein thrombosis or pulmonary embolism. All cohorts required the exclusion of hysterectomy, joint replacement, and the medical, transfusion, and surgical managements used to define the SUB outcomes. Definition of each management was as follows:

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

We used International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes, Healthcare Common Procedure Coding System (HCPCS) codes, Current Procedural Terminology, Fourth Edition (CPT-4) and Third Edition (CPT Category III) codes, and Revenue Center codes to define the inclusion and exclusion criteria. Please refer to Appendix C for a list of diagnosis and procedure codes used to define inclusion and exclusion criteria in this request.

Follow-Up Time: We followed the new users of oral anticoagulant based on their first continuous exposure episode, defined using outpatient pharmacy dispensing days supplied with a maximum allowable gap of three days between dispensings. Follow-up began on the day on which the first exposure of interest was dispensed and continued until exhaustion of days supply of the last dispensing plus a three-day extension period, or until the first occurrence of: 1) disenrollment; 2) recorded death; 3) the end date of the data provided by each Data Partner; 4) the end of the query period (September 30, 2015); or 5) the outcome of interest. Only the first valid oral anticoagulant exposure episode per patient entered the analysis.

Overview for Request: cder_mpl1r_wp165

Outcomes of Interest: We adopted three different definitions of SUB, each defined as a combination of vaginal bleed and either medical, transfusion, or surgical management in non-institutional (non-IS) care settings. The SUB definitions used for each cohort were defined as below.

- 1) Vaginal bleed and medical management occurring on the same day (See Appendix J, Figure 1)
- 2) Vaginal bleed followed by medical management occurring within 5 days, except for vaginal packing management, which was required occurring on the same day (See Appendix J, Figure 2)
- 3) Vaginal bleed and transfusion management occurring on the same day (See Appendix J, Figure 1)
- 4) Vaginal bleed followed by surgical management occurring within 30 days (See Appendix J, Figure 2)
- 5) Vaginal bleed followed by surgical management occurring within 60 days (See Appendix J, Figure 2)

Please see Appendix D for a list of ICD-9-CM diagnosis codes used to define vaginal bleed. Please refer to Appendix E for a list of ICD-9-CM, HCPCS, CPT-4, CPT Category III, and Revenue Center diagnosis and procedure codes, and Appendix F for generic and brand names of medical products used to define medical and transfusion management in this request.

Baseline Characteristics: We assessed demographics on the index dispensing date: age and calendar year. The following characteristics were assessed in the 183 days prior to and including the index dispensing date: comorbidity score (Combined Comorbidity Index)^a, health service and drug utilization, cardiovascular and antidiabetic agents, medications that increase bleeding risk, medications that are inducers, inhibitors or substrates listed on label as having clinically significant interactions with warfarin or NOACs, same-day dispensing of warfarin, same-day dispensing of NOACs, severe anemia, gynecological disorders, vaginal bleed, and SUB. Severe anemia and gynecological disorder were captured from any care setting, and vaginal bleed and SUB codes were captured from non-IS care settings. Please see Appendix G for a list of diagnosis and procedure codes, Appendix H for a list of generic and brand names of medical products, and Appendix K for list of conditions used to define baseline characteristics in this request.

Please see Appendix I for the specifications of parameters used in the analyses for this request.

Limitations: 1) As with all observational studies, this evaluation was limited in its ability to control for all sources of potential bias. 2) Exposures, outcome, exclusions, censoring/episode truncation criteria, and characteristics are subject to misclassifications. Therefore, data should be interpreted with this limitation in mind.

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

^aGagne 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). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms

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

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

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

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

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

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

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

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

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

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"

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

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

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

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

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

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition

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

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

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

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

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

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

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

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

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

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 1. Baseline Characteristics for New Users of Warfarin or Novel Oral Anticoagulants in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015

Characteristics	Number	
Number of episodes	1,050,192	
Number of unique patients	1,050,192	
Demographics	Mean	Standard Deviation
Mean Age (Years)	75.3	11.5
	Number	Percent
Age (Years)		
0-50	50,317	4.8%
51+	999,875	95.2%
Sex		
Female	1,050,192	100.0%
Year		
2010	37,795	3.6%
2011	194,595	18.5%
2012	197,689	18.8%
2013	211,483	20.1%
2014	228,833	21.8%
2015	179,797	17.1%
Recorded history of:	Mean	Standard Deviation
Prior combined comorbidity raw score	3.3	2.9
	Number	Percent
Cardiovascular and antidiabetic agents	962,346	91.6%
Bleed risk medication	616,093	58.7%
Inhibitors/substrates of cytochrome P450 3A4	690,979	65.8%
Inducers of cytochrome P450 3A4	65,097	6.2%
Severe anemia	0	0.0%
Gynecological disorders	29,837	2.8%
Vaginal bleed	14,497	1.4%
Severe uterine bleed (medical management, transfusion management, surgical management within 30 days of vaginal bleed)	23	0.0%
Index Exposure Novel Oral Anticoagulants	352,822	33.6%
Index Exposure Warfarin	697,836	66.4%
Health Service Utilization Intensity:	Mean	Standard Deviation
Mean number of ambulatory encounters (AV)	14.1	13.6
Mean number of emergency department encounters (ED)	0.6	1.3
Mean number of inpatient hospital encounters (IP)	0.9	1
Mean number of non-acute institutional encounters (IS)	0.3	0.8
Mean number of other ambulatory encounters (OA)	9.6	14.1
Mean number of filled prescriptions	8.5	4.8
Mean number of generics	9.1	5.4
Mean number of unique drug classes	23.5	19.3

Table 2. Summary of New Use of Novel Oral Anticoagulants and Warfarin and Severe Uterine Bleeding (SUB) Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, Overall

Level	New Users	Years at Risk	Dispensing per User	Days Supplied per User	Days Supplied per Dispensing	New Episodes with an Event	New Episodes with an Event per 10,000 Years at Risk
Medical Management							
Medical Management	1,050,192	502,870.0	5.05	174.51	34.59	307	6.10
Medical Management within Five Days of Vaginal Bleed	1,050,192	502,861.7	5.05	174.51	34.59	329	6.54
Transfusion Management							
Transfusion Management	1,050,192	502,711.8	5.05	174.51	34.59	832	16.55
Surgical Management							
Surgical Management within 30 Days of Vaginal Bleed	1,050,192	501,584.6	5.05	174.51	34.59	2,507	49.98
Surgical Management within 60 Days of Vaginal Bleed	1,050,192	501,509.8	5.05	174.51	34.59	2,652	52.88

Table 3. Summary of New Use of Novel Oral Anticoagulants and Warfarin and Severe Uterine Bleeding Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Age Group

Age Group	New Users	Years at Risk	Dispensing per User	Days Supplied per User	Days Supplied per Dispensing	New Episodes with an Event	New Episodes with an Event per 10,000 Years at Risk
Medical Management							
Medical Management							
0-50 years	50,317	19,346.2	4.24	140.83	33.25	229	118.37
51+ years	999,875	483,523.9	5.09	176.21	34.64	78	1.61
Medical Management within Five Days of Vaginal Bleed							
0-50 years	50,317	19,338.0	4.24	140.83	33.25	248	128.24
51+ years	999,875	483,523.7	5.09	176.21	34.64	81	1.68
Transfusion Management							
Transfusion Management							
0-50 years	50,317	19,340.1	4.24	140.83	33.25	265	137.02
51+ years	999,875	483,371.7	5.09	176.21	34.64	567	11.73
Surgical Management							
Surgical Management within 30 Days of Vaginal Bleed							
0-50 years	50,317	19,081.9	4.24	140.83	33.25	630	330.16
51+ years	999,875	482,502.7	5.09	176.21	34.64	1,877	38.90
Surgical Management within 60 Days of Vaginal Bleed							
0-50 years	50,317	19,072.0	4.24	140.83	33.25	649	340.29
51+ years	999,875	482,437.8	5.09	176.21	34.64	2,003	41.52

Table 4. Summary of New Use of Novel Oral Anticoagulants and Warfarin and Severe Uterine Bleeding Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Index Exposure Novel Oral Anticoagulants and Age Group

Age Group	New Users	Years at Risk	Dispensing per User	Days Supplied per User	Days Supplied per Dispensing	New Episodes with an Event	New Episodes with an Event per 10,000 Years at Risk
Medical Management							
Medical Management							
No evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	39,404	16,662.1	4.59	155.30	33.85	178	106.83
51+ years	657,966	352,302.9	5.67	195.75	34.53	53	1.50
Evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	10,913	2,684.1	2.96	88.58	29.90	51	190.01
51+ years	341,909	131,221.0	3.97	138.59	34.95	25	1.91
Medical Management within 5 Days of Vaginal Bleed							
No evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	39,404	16,654.5	4.59	155.30	33.85	192	115.28
51+ years	657,966	352,302.7	5.67	195.75	34.53	55	1.56
Evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	10,913	2,683.5	2.96	88.58	29.90	56	208.68
51+ years	341,909	131,221.0	3.97	138.59	34.95	26	1.98
Transfusion Management							
Transfusion Management							
No evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	39,404	16,659.7	4.59	155.30	33.85	189	113.45
51+ years	657,966	352,164.6	5.67	195.75	34.53	425	12.07
Evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	10,913	2,680.4	2.96	88.58	29.90	76	283.54
51+ years	341,909	131,207.0	3.97	138.59	34.95	142	10.82

Table 4. Summary of New Use of Novel Oral Anticoagulants and Warfarin and Severe Uterine Bleeding Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Index Exposure Novel Oral Anticoagulants and Age Group

Age Group	New Users	Years at Risk	Dispensing per User	Days Supplied per User	Days Supplied per Dispensing	New Episodes with an Event	New Episodes with an Event per 10,000 Years at Risk
Surgical Management							
Surgical Management within 30 Days of Vaginal Bleed							
No evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	39,404	16,416.5	4.59	155.30	33.85	496	302.14
51+ years	657,966	351,496.2	5.67	195.75	34.53	1,247	35.48
Evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	10,913	2,665.5	2.96	88.58	29.90	134	502.72
51+ years	341,909	131,006.5	3.97	138.59	34.95	630	48.09
Surgical Management within 60 Days of Vaginal Bleed							
No evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	39,404	16,408.4	4.59	155.30	33.85	510	310.82
51+ years	657,966	351,441.5	5.67	195.75	34.53	1,338	38.07
Evidence of Index Exposure Novel Oral Anticoagulants							
0-50 years	10,913	2,663.5	2.96	88.58	29.90	139	521.87
51+ years	341,909	130,996.3	3.97	138.59	34.95	665	50.76

Table 5. Summary of New Use of Novel Oral Anticoagulants and Warfarin and Severe Uterine Bleeding Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Index Exposure of Warfarin and Age Group

Age Group	New Users	Years at Risk	Dispensing per User	Days Supplied per User	Days Supplied per Dispensing	New Episodes with an Event	New Episodes with an Event per 10,000 Years at Risk
Medical Management							
Medical Management							
No evidence of Index Exposure Warfarin							
0-50 years	10,880	2,676.9	2.96	88.53	29.92	51	190.52
51+ years	341,476	131,026.3	3.96	138.53	34.96	25	1.91
Evidence of Index Exposure Warfarin							
0-50 years	39,437	16,669.2	4.59	155.25	33.85	178	106.78
51+ years	658,399	352,497.6	5.67	195.74	34.53	53	1.50
Medical Management within 5 Days of Vaginal Bleed							
No evidence of Index Exposure Warfarin							
0-50 years	10,880	2,676.4	2.96	88.53	29.92	56	209.24
51+ years	341,476	131,026.3	3.96	138.53	34.96	26	1.98
Evidence of Index Exposure Warfarin							
0-50 years	39,437	16,661.6	4.59	155.25	33.85	192	115.24
51+ years	658,399	352,497.5	5.67	195.74	34.53	55	1.56
Transfusion Management							
Transfusion Management							
No evidence of Index Exposure Warfarin							
0-50 years	10,880	2,673.3	2.96	88.53	29.92	76	284.29
51+ years	341,476	131,012.4	3.96	138.53	34.96	141	10.76
Evidence of Index Exposure Warfarin							
0-50 years	39,437	16,666.8	4.59	155.25	33.85	189	113.40
51+ years	658,399	352,359.3	5.67	195.74	34.53	426	12.09

Table 5. Summary of New Use of Novel Oral Anticoagulants and Warfarin and Severe Uterine Bleeding Outcome in the Sentinel Distributed Database (SDD) between October 19, 2010 and September 30, 2015, by Index Exposure of Warfarin and Age Group

Age Group	New Users	Years at Risk	Dispensing per User	Days Supplied per User	Days Supplied per Dispensing	New Episodes with an Event	New Episodes with an Event per 10,000 Years at Risk
Surgical Management							
Surgical Management within 30 Days of Vaginal Bleed							
No evidence of Index Exposure Warfarin							
0-50 years	10,880	2,658.5	2.96	88.53	29.92	133	500.28
51+ years	341,476	130,811.8	3.96	138.53	34.96	629	48.08
Evidence of Index Exposure Warfarin							
0-50 years	39,437	16,423.4	4.59	155.25	33.85	497	302.62
51+ years	658,399	351,690.9	5.67	195.74	34.53	1,248	35.49
Surgical Management within 60 Days of Vaginal Bleed							
No evidence of Index Exposure Warfarin							
0-50 years	10,880	2,656.6	2.96	88.53	29.92	138	519.46
51+ years	341,476	130,801.6	3.96	138.53	34.96	664	50.76
Evidence of Index Exposure Warfarin							
0-50 years	39,437	16,415.4	4.59	155.25	33.85	511	311.29
51+ years	658,399	351,636.2	5.67	195.74	34.53	1,339	38.08



Appendix A. Dates of Available Data for Each Data Partner (DP) in the Sentinel Distributed Database (SDD) as of Request Distribution Date (September 17, 2019)

DP ID	DP Start Date*	DP End Date*
DP01	06/01/2007	01/31/2019
DP02	01/01/2000	02/28/2019
DP03	01/01/2000	04/30/2019
DP04	01/01/2008	11/30/2018
DP05	01/01/2006	12/31/2018
DP06	01/01/2000	12/31/2017
DP07	01/01/2008	06/30/2018
DP08	01/01/2010	12/31/2018
DP09	01/01/2005	07/31/2018
DP10	01/01/2000	03/31/2016
DP11	01/01/2000	04/30/2018
DP12	01/01/2000	01/31/2019
DP13	01/01/2000	12/31/2018
DP14	01/01/2000	06/30/2018
DP15	01/01/2004	03/31/2019
DP16	01/01/2000	03/31/2018
DP17	01/01/2012	06/30/2017

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

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

Generic Name	Brand Name
Exposure and Incidence Criteria	
apixaban	Eliquis
dabigatran etexilate mesylate	Pradaxa
rivaroxaban	Xarelto
warfarin sodium	Coumadin
warfarin sodium	Warfarin
warfarin sodium	Jantoven
Incidence Criteria Only	
edoxaban tosylate	Savaysa

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

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

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

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

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

Code	Code Category	Code Type	Description
01215	Procedure	CPT-4	Anesthesia for open procedures involving hip joint; revision of total hip arthroplasty
01402	Procedure	CPT-4	Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty
27125	Procedure	CPT-4	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)
27130	Procedure	CPT-4	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Procedure	CPT-4	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Procedure	CPT-4	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Procedure	CPT-4	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Procedure	CPT-4	Revision of total hip arthroplasty; femoral component only, with or without allograft
27265	Procedure	CPT-4	Closed treatment of post hip arthroplasty dislocation; without anesthesia
27266	Procedure	CPT-4	Closed treatment of post hip arthroplasty dislocation; requiring regional or general anesthesia
27437	Procedure	CPT-4	Arthroplasty, patella; without prosthesis
27438	Procedure	CPT-4	Arthroplasty, patella; with prosthesis
27440	Procedure	CPT-4	Arthroplasty, knee, tibial plateau;
27441	Procedure	CPT-4	Arthroplasty, knee, tibial plateau; with debridement and partial synovectomy
27442	Procedure	CPT-4	Arthroplasty, femoral condyles or tibial plateau(s), knee;
27443	Procedure	CPT-4	Arthroplasty, femoral condyles or tibial plateau(s), knee; with debridement and partial synovectomy
27445	Procedure	CPT-4	Arthroplasty, knee, hinge prosthesis (eg, Walldius type)
27446	Procedure	CPT-4	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment
27447	Procedure	CPT-4	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
27486	Procedure	CPT-4	Revision of total knee arthroplasty, with or without allograft; 1 component
27487	Procedure	CPT-4	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component
29862	Procedure	CPT-4	Arthroscopy, hip, surgical; with debridement/shaving of articular cartilage (chondroplasty), abrasion arthroplasty, and/or resection of labrum
29879	Procedure	CPT-4	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
81.5	Procedure	ICD-9-CM	Joint replacement of lower extremity
Hysterectomy			
00846	Procedure	CPT-4	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy
00855	Procedure	CPT-4	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy
00944	Procedure	CPT-4	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy
01962	Procedure	CPT-4	Anesthesia for urgent hysterectomy following delivery
01963	Procedure	CPT-4	Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care
01969	Procedure	CPT-4	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure performed)
51925	Procedure	CPT-4	closure of vesicouterine fistula; w/hysterectomy

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

Code	Code Category	Code Type	Description
58150	Procedure	CPT-4	tah w/wo removal of tube w/wo removal of ovary;
58152	Procedure	CPT-4	tah; w/wo remv tube-ovry w/colpo-urethrocystopex
58180	Procedure	CPT-4	supracerv abd hysterectomy w/wo remov tube-ovary
58200	Procedure	CPT-4	tah incl part vaginect w/pelv lymph node sampl
58205	Procedure	CPT-4	Total Hysterectomy, Extended, Corpus Cancer, Including Partial
58210	Procedure	CPT-4	rad abd hyst w/bilat tot pelvic lymphadenect bx
58260	Procedure	CPT-4	vag hyst 250 gm/<
58262	Procedure	CPT-4	vag hyst 250 gm/< w/rmvl tube&/ovary
58263	Procedure	CPT-4	vag hyst 250 gm/< w/rmvl tube ovary w/rpr ntrcl
58265	Procedure	CPT-4	Vaginal Hysterectomy With Plastic Repair Of Vagina, Anterior
58267	Procedure	CPT-4	vag hyst 250 gm/< w/colpo-urtcstopexy
58270	Procedure	CPT-4	vag hyst 250 gm/< w/rpr ntrcl
58275	Procedure	CPT-4	vag hyst with total or partial vaginectomy;
58280	Procedure	CPT-4	vag hyst w/tot/part vaginectomy; w/repr enterocl
58285	Procedure	CPT-4	vaginal hysterectomy radical
58290	Procedure	CPT-4	vag hyst for uterus greater than 250 grams;
58291	Procedure	CPT-4	vag hyst utrus >250 gms; w/remv tube &/ ovary
58292	Procedure	CPT-4	vag hyst utrus>250 gms; remv t&/o rep enterocl
58293	Procedure	CPT-4	vag hyst utrus > 250 gms; w/colpo-urethrocytProcedurey
58294	Procedure	CPT-4	vag hyst uterus > 250 grams; w/repair enterocele
58541	Procedure	CPT-4	laps supracrv hyst 250 g/<
58542	Procedure	CPT-4	laps supracrv hyst 250 g/< rmvl tube/ovary
58543	Procedure	CPT-4	laps supracrv hyst >250 g
58544	Procedure	CPT-4	laps supracrv hyst >250 g rmvl tube/ovary
58548	Procedure	CPT-4	laps w/rad hyst w/bilat lmpadec rmvl tube/ovary
58550	Procedure	CPT-4	laparscpy surg w/vag hyst uterus 250 gms/less;
58552	Procedure	CPT-4	lap vag hyst utrus 250 gms/<; w/remv tube&/ovry
58553	Procedure	CPT-4	laparscpy surgical w/vag hyst uterus > 250 gms;
58554	Procedure	CPT-4	lap w/vag hyst utrus >250 gms; w/remv tube&/ovry
58570	Procedure	CPT-4	laparoscopy w total hysterectomy uterus 250 g/<
58571	Procedure	CPT-4	laps total hysterectomy 250 g/<w tube/ovary
58572	Procedure	CPT-4	laparoscopy total hysterectomy uterus>250 g
58573	Procedure	CPT-4	laparoscopy tot hysterectomy >250 g w tube/ovary
58951	Procedure	CPT-4	rescj prim prtl mal w/bso&omntc tah&lmpadec
58953	Procedure	CPT-4	bilat s-o w/omentect tah&radl dissect debulking;
58954	Procedure	CPT-4	bil s-o w/omentect tah&radl dbulk; pelv lymphect
58956	Procedure	CPT-4	bil salpingooophorect w/tot omentect tah malig
59100	Procedure	CPT-4	hysterotomy abdominal
59135	Procedure	CPT-4	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy
59525	Procedure	CPT-4	subtotal/total hysterectomy after c-sect deliv
59560	Procedure	CPT-4	Cesarean Section With Hysterectomy, Subtotal, Including
59561	Procedure	CPT-4	Cesarean Section With Hysterectomy, Subtotal, Including
59580	Procedure	CPT-4	Cesarean Section With Hysterectomy, Total, Including
59581	Procedure	CPT-4	Cesarean Section With Hysterectomy, Total, Including

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

Code	Code Category	Code Type	Description
S2078	Procedure	HCPCS	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
68.3	Procedure	ICD-9-CM	Subtotal abdominal hysterectomy
68.31	Procedure	ICD-9-CM	Laparoscopic supracervical hysterectomy [LSH]
68.39	Procedure	ICD-9-CM	Other and unspecified subtotal abdominal hysterectomy
68.4	Procedure	ICD-9-CM	Total abdominal hysterectomy
68.41	Procedure	ICD-9-CM	Laparoscopic total abdominal hysterectomy
68.49	Procedure	ICD-9-CM	Other and unspecified total abdominal hysterectomy
68.5	Procedure	ICD-9-CM	Vaginal hysterectomy
68.51	Procedure	ICD-9-CM	Laparoscopically assisted vaginal hysterectomy (LAVH)
68.59	Procedure	ICD-9-CM	Other and unspecified vaginal hysterectomy
68.6	Procedure	ICD-9-CM	Radical abdominal hysterectomy
68.61	Procedure	ICD-9-CM	Laparoscopic radical abdominal hysterectomy
68.69	Procedure	ICD-9-CM	Other and unspecified radical abdominal hysterectomy
68.7	Procedure	ICD-9-CM	Radical vaginal hysterectomy
68.71	Procedure	ICD-9-CM	Laparoscopic radical vaginal hysterectomy [LRVH]
68.79	Procedure	ICD-9-CM	Other and unspecified radical vaginal hysterectomy
68.9	Procedure	ICD-9-CM	Other and unspecified hysterectomy
618.5	Diagnosis	ICD-9-CM	Prolapse of vaginal vault after hysterectomy
68.8	Procedure	ICD-9-CM	pelvic evisceration

Medical Management

See Appendix E for diagnosis and procedure codes for medical management.

See Appendix F for generic and brand names of medical products used to define medical management.

Transfusion Management

See Appendix E for procedure codes for transfusion management.

See Appendix F for generic and brand names of medical products used to define transfusion management.

Surgical Management

See Appendix E for diagnosis and procedure codes for surgical management.

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

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

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

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

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

Code	Code Category	Code Type	Description
Surgical Managements			
Hysteroscopic Polypectomy			
58558	Procedure	CPT-4	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C
Hysteroscopic/Laparoscopic/Abdominal Myomectomy			
218.0	Diagnosis	ICD-9-CM ^A	Submucous leiomyoma of uterus
218	Diagnosis	ICD-9-CM ^A	Uterine leiomyoma
218.1	Diagnosis	ICD-9-CM ^A	Intramural leiomyoma of uterus
218.2	Diagnosis	ICD-9-CM ^A	Subserous leiomyoma of uterus
218.9	Diagnosis	ICD-9-CM ^A	Leiomyoma of uterus, unspecified
56309	Procedure	CPT-4	LAP SURG; W/REMOV LEIOMYOMATA (SINGL/MX)
56354	Procedure	CPT-4	HYSTEROSCOPY SURG; W/REMOV LEIOMYOMATA
58140	Procedure	CPT-4	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
58145	Procedure	CPT-4	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
58146	Procedure	CPT-4	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
58545	Procedure	CPT-4	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas
58546	Procedure	CPT-4	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g
58561	Procedure	CPT-4	Hysteroscopy, surgical; with removal of leiomyomata
58994	Procedure	CPT-4	Hysteroscopy; With Removal Of Submucous Leiomyomata (any Method)
68.19	Procedure	ICD-9-CM ^B	Other diagnostic procedures on uterus and supporting structures
68.29	Procedure	ICD-9-CM ^B	Other excision or destruction of lesion of uterus
69.19	Procedure	ICD-9-CM ^B	Other excision or destruction of uterus and supporting structures
^A Myomectomy diagnosis codes and ^B myomectomy procedure codes are used in combination to detect myomectomy.			
Dilation and Curettage (with or without hysteroscopy)			
57558	Procedure	CPT-4	Dilation and curettage of cervical stump
57820	Procedure	CPT-4	Dilation and curettage of cervical stump
58120	Procedure	CPT-4	Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical)
69.0	Procedure	ICD-9-CM	Dilation and curettage of uterus
69.09	Procedure	ICD-9-CM	Other dilation and curettage of uterus
69.5	Procedure	ICD-9-CM	Aspiration curettage of uterus
69.59	Procedure	ICD-9-CM	Other aspiration curettage of uterus
Hysteroscopy (Not Listed in Other Surgical Managements)			
00952	Procedure	CPT-4	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); hysteroscopy and/or hysterosalpingography
56352	Procedure	CPT-4	HYSTEROSCOPY SURG; W/LYSIS INTRAUTERINE ADHESION
56353	Procedure	CPT-4	HYSTEROSCOPY SURG; W/DIVIS/RESECT SEPTUM
56355	Procedure	CPT-4	HYSTEROSCOPY SURG; W/REMOV IMPACTED F B

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

Code	Code Category	Code Type	Description
56399	Procedure	CPT-4	UNLISTED PROC-LAP/HYSTEROSCOPY
58559	Procedure	CPT-4	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)
58560	Procedure	CPT-4	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)
58562	Procedure	CPT-4	Hysteroscopy, surgical; with removal of impacted foreign body
58565	Procedure	CPT-4	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
58992	Procedure	CPT-4	Hysteroscopy; With Lysis Of Intrauterine Adhesions Or Resection Of Intrauterine Septum (any Method)
58995	Procedure	CPT-4	Hysteroscopy
G9823	Procedure	HCPCS	Endometrial sampling or hysteroscopy with biopsy and results documented
G9824	Procedure	HCPCS	Endometrial sampling or hysteroscopy with biopsy and results not documented
S2255	Procedure	HCPCS	Hysteroscopy, surgical; with occlusion of oviducts bilaterally by micro-inserts for permanent sterilization
68.12	Procedure	ICD-9-CM	Hysteroscopy
68.14	Procedure	ICD-9-CM	Open biopsy of uterine ligaments
68.16	Procedure	ICD-9-CM	Closed biopsy of uterine ligaments
Hysterectomy			
68.3	Diagnosis	ICD-9-CM	Subtotal abdominal hysterectomy
68.31	Diagnosis	ICD-9-CM	Laparoscopic supracervical hysterectomy [LSH]
68.39	Diagnosis	ICD-9-CM	Other and unspecified subtotal abdominal hysterectomy
68.4	Diagnosis	ICD-9-CM	Total abdominal hysterectomy
68.41	Diagnosis	ICD-9-CM	Laparoscopic total abdominal hysterectomy
68.49	Diagnosis	ICD-9-CM	Other and unspecified total abdominal hysterectomy
68.5	Diagnosis	ICD-9-CM	Vaginal hysterectomy
68.51	Diagnosis	ICD-9-CM	Laparoscopically assisted vaginal hysterectomy (LAVH)
68.59	Diagnosis	ICD-9-CM	Other and unspecified vaginal hysterectomy
68.6	Diagnosis	ICD-9-CM	Radical abdominal hysterectomy
68.61	Diagnosis	ICD-9-CM	Laparoscopic radical abdominal hysterectomy
68.69	Diagnosis	ICD-9-CM	Other and unspecified radical abdominal hysterectomy
68.7	Diagnosis	ICD-9-CM	Radical vaginal hysterectomy
68.71	Diagnosis	ICD-9-CM	Laparoscopic radical vaginal hysterectomy [LRVH]
68.79	Diagnosis	ICD-9-CM	Other and unspecified radical vaginal hysterectomy
68.9	Diagnosis	ICD-9-CM	Other and unspecified hysterectomy
618.5	Diagnosis	ICD-9-CM	Prolapse of vaginal vault after hysterectomy
00846	Procedure	CPT-4	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy
00855	Procedure	CPT-4	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy
00944	Procedure	CPT-4	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy
01962	Procedure	CPT-4	Anesthesia for urgent hysterectomy following delivery
01963	Procedure	CPT-4	Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care

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

Code	Code Category	Code Type	Description
01969	Procedure	CPT-4	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure
51925	Procedure	CPT-4	closure of vesicouterine fistula; w/hysterectomy
58150	Procedure	CPT-4	tah w/wo removal of tube w/wo removal of ovary;
58152	Procedure	CPT-4	tah; w/wo remv tube-ovry w/colpo-urethrocytopex
58180	Procedure	CPT-4	supracerv abd hysterectomy w/wo remov tube-ovary
58200	Procedure	CPT-4	tah incl part vaginect w/pelv lymph node sampl
58205	Procedure	CPT-4	Total Hysterectomy, Extended, Corpus Cancer, Including Partial
58210	Procedure	CPT-4	rad abd hyst w/bilat tot pelvic lymphadenect bx
58260	Procedure	CPT-4	vag hyst 250 gm/<
58262	Procedure	CPT-4	vag hyst 250 gm/< w/rmvl tube&/ovary
58263	Procedure	CPT-4	vag hyst 250 gm/< w/rmvl tube ovary w/rpr ntrcl
58265	Procedure	CPT-4	Vaginal Hysterectomy With Plastic Repair Of Vagina, Anterior
58267	Procedure	CPT-4	vag hyst 250 gm/< w/colpo-urtcstopexy
58270	Procedure	CPT-4	vag hyst 250 gm/< w/rpr ntrcl
58275	Procedure	CPT-4	vag hyst with total or partial vaginectomy;
58280	Procedure	CPT-4	vag hyst w/tot/part vaginectomy; w/repr enterocl
58285	Procedure	CPT-4	vaginal hysterectomy radical
58290	Procedure	CPT-4	vag hyst for uterus greater than 250 grams;
58291	Procedure	CPT-4	vag hyst utrus >250 gms; w/remv tube &/ ovary
58292	Procedure	CPT-4	vag hyst utrus>250 gms; remv t&/o rep enterocl
58293	Procedure	CPT-4	vag hyst utrus > 250 gms; w/colpo-urethrocytopexy
58294	Procedure	CPT-4	vag hyst uterus > 250 grams; w/repair enterocele
58541	Procedure	CPT-4	laps supracrv hyst 250 g/<
58542	Procedure	CPT-4	laps supracrv hyst 250 g/< rmvl tube/ovary
58543	Procedure	CPT-4	laps supracrv hyst >250 g
58544	Procedure	CPT-4	laps supracrv hyst >250 g rmvl tube/ovary
58548	Procedure	CPT-4	laps w/rad hyst w/bilat lmpadec rmvl tube/ovary
58550	Procedure	CPT-4	laparscpy surg w/vag hyst uterus 250 gms/less;
58552	Procedure	CPT-4	lap vag hyst utrus 250 gms/<; w/remv tube&/ovry
58553	Procedure	CPT-4	laparscpy surgical w/vag hyst uterus > 250 gms;
58554	Procedure	CPT-4	lap w/vag hyst utrus >250 gms; w/remv tube&/ovry
58570	Procedure	CPT-4	laparoscopy w total hysterectomy uterus 250 g/<
58571	Procedure	CPT-4	laps total hysterectomy 250 g/<w tube/ovary
58572	Procedure	CPT-4	laparoscopy total hysterectomy uterus>250 g
58573	Procedure	CPT-4	laparoscopy tot hysterectomy >250 g w tube/ovary
58951	Procedure	CPT-4	rescj prim prtl mal w/bso&omntc tah&lmpadec
58953	Procedure	CPT-4	bilat s-o w/omentect tah&radl dissect debulking;
58954	Procedure	CPT-4	bil s-o w/omentect tah&radl dbulk; pelv lymphect
58956	Procedure	CPT-4	bil salpingoophorect w/tot omentect tah malig
59100	Procedure	CPT-4	hysterotomy abdominal
59135	Procedure	CPT-4	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy
59525	Procedure	CPT-4	subtotal/total hysterectomy after c-sect deliv

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

Code	Code Category	Code Type	Description
59560	Procedure	CPT-4	Cesarean Section With Hysterectomy, Subtotal, Including
59561	Procedure	CPT-4	Cesarean Section With Hysterectomy, Subtotal, Including
59580	Procedure	CPT-4	Cesarean Section With Hysterectomy, Total, Including
59581	Procedure	CPT-4	Cesarean Section With Hysterectomy, Total, Including
S2078	Procedure	HCPCS	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
683	Procedure	ICD-9-CM	subtotal abdominal hysterectomy
684	Procedure	ICD-9-CM	total abdominal hysterectomy
685	Procedure	ICD-9-CM	vaginal hysterectomy
686	Procedure	ICD-9-CM	radical abdominal hysterectomy
687	Procedure	ICD-9-CM	radical vaginal hysterectomy
688	Procedure	ICD-9-CM	pelvic evisceration
689	Procedure	ICD-9-CM	hysterectomy nos
6831	Procedure	ICD-9-CM	laparoscopic supracervical hysterectomy
6839	Procedure	ICD-9-CM	other and unspecified subtotal abdominal hysterect
6841	Procedure	ICD-9-CM	laparoscopic total abdominal hysterectomy
6849	Procedure	ICD-9-CM	other and unspecified total abdominal hysterectomy
6851	Procedure	ICD-9-CM	laparoscopically assisted vaginal hysterectomy
6859	Procedure	ICD-9-CM	other and unspecified vaginal hysterectomy
6861	Procedure	ICD-9-CM	laparoscopic radical abdominal hysterectomy
6869	Procedure	ICD-9-CM	other and unspecified radical abdominal hysterecto
6871	Procedure	ICD-9-CM	laparoscopic radical vaginal hysterectomy
6879	Procedure	ICD-9-CM	other and unspecified radical vaginal hysterectomy
<i>Endometrial Ablation (Thermal, Cryo, Section)</i>			
0009T	Procedure	CPT Category III	Endometrial cryoablation with ultrasonic guidance
56351	Procedure	CPT-4	HYSTEROSCOPY SURG; W/SAMPL ENDOMETRIUM W/WO D&C
56356	Procedure	CPT-4	HYSTEROSCOPY SURG; W/ENDOMETRIAL ABLATION
58353	Procedure	CPT-4	Endometrial ablation, thermal, without hysteroscopic guidance
58356	Procedure	CPT-4	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed
58558	Procedure	CPT-4	HYSTEROSCOPY BX ENDOMETRIUM&/POLYPC W/WO D&C
58563	Procedure	CPT-4	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)
58996	Procedure	CPT-4	Hysteroscopy; With Endometrial Ablation (any Method)
68.23	Procedure	ICD-9-CM	Endometrial ablation
<i>Uterine Artery Embolization</i>			
37210	Procedure	CPT-4	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
S2250	Procedure	HCPCS	Uterine artery embolization for uterine fibroids
68.24	Procedure	ICD-9-CM	Uterine artery embolization [UAE] with coils
68.25	Procedure	ICD-9-CM	Uterine artery embolization [UAE] without coils

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Medical and Transfusion Management in this Request

Generic Name	Brand Name
Medical Managements	
<i>Levonorgestrel Intrauterine System Device (IUD)</i>	
levonorgestrel	Kyleena
levonorgestrel	Liletta
levonorgestrel	Mirena
levonorgestrel	Skyla
<i>Antifibrinolytic</i>	
desmopressin acetate	Ddavn
desmopressin acetate	Desmopressin
desmopressin acetate	Stimate
aminocaproic acid	Amicar
aminocaproic acid	Aminocaproic Acid
tranexamic acid	Cyklokapron
tranexamic acid	Lysteda
tranexamic acid	Tranexamic Acid
<i>Contraception (Combined Oral Contraceptives and Progestin-only Contraceptives)</i>	
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)
drospirenone/ethinyl estradiol/levomefolate calcium	Drospirenone-E.Estradiol-Lm.Fa
drospirenone/ethinyl estradiol/levomefolate calcium	Beyaz
drospirenone/ethinyl estradiol/levomefolate calcium	Rajani
drospirenone/ethinyl estradiol/levomefolate calcium	Safyral
estradiol valerate/dienogest	Natazia
ethinyl estradiol/drospirenone	Gianvi (28)
ethinyl estradiol/drospirenone	Loryna (28)
ethinyl estradiol/drospirenone	Yaz (28)

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Medical and Transfusion Management in this Request

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	Vienna
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)

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Medical and Transfusion Management in this Request

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

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Medical and Transfusion Management in this Request

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-Ligest 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)

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Medical and Transfusion Management in this Request

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)
Transfusion Managements	
<i>Conjugated Estrogen</i>	
estrogens, conjugated, synthetic a	Cenestin

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Medical and Transfusion Management in this Request

Generic Name	Brand Name
estrogens, conjugated, synthetic b	Enjuvia
estrogens, conjugated	Premarin
estrogens, conjugated/medroxyprogesterone acetate	Prempro
estrogens, conjugated/bazedoxifene acetate	Duavee
estrogens, conjugated/medroxyprogesterone acetate	Premphase

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes, Healthcare Common Procedure Coding System (HCPCS) Procedure Codes, and Revenue Center Procedure Codes Used to Define Baseline Characteristics in this Request

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

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes, Healthcare Common Procedure Coding System (HCPCS) Procedure Codes, and Revenue Center Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Code Category	Code Type	Description
236.0	Diagnosis	ICD-9-CM	Neoplasm of uncertain behavior of uterus
236.2	Diagnosis	ICD-9-CM	Neoplasm of uncertain behavior of ovary
236.3	Diagnosis	ICD-9-CM	Neoplasm of uncertain behavior of other and unspecified female genital organs
Ovarian Cyst			
620.0	Diagnosis	ICD-9-CM	Follicular cyst of ovary
620.1	Diagnosis	ICD-9-CM	Corpus luteum cyst or hematoma
620.2	Diagnosis	ICD-9-CM	Other and unspecified ovarian cyst
Uterine Fibroids/Leiomyoma			
218	Diagnosis	ICD-9-CM	UTERINE LEIOMYOMA
218.0	Diagnosis	ICD-9-CM	SUBMUCOUS LEIOMYOMA OF UTERUS
218	Diagnosis	ICD-9-CM	UTERINE LEIOMYOMA
218.0	Diagnosis	ICD-9-CM	SUBMUCOUS LEIOMYOMA OF UTERUS
218.1	Diagnosis	ICD-9-CM	INTRAMURAL LEIOMYOMA OF UTERUS
218.1	Diagnosis	ICD-9-CM	INTRAMURAL LEIOMYOMA OF UTERUS
218.2	Diagnosis	ICD-9-CM	SUBSEROUS LEIOMYOMA OF UTERUS
218.2	Diagnosis	ICD-9-CM	SUBSEROUS LEIOMYOMA OF UTERUS
218.9	Diagnosis	ICD-9-CM	LEIOMYOMA OF UTERUS UNSPECIFIED
218.9	Diagnosis	ICD-9-CM	LEIOMYOMA OF UTERUS UNSPECIFIED
Uterine or Cervical Polyp			
621.0	Diagnosis	ICD-9-CM	Polyp of corpus uteri
622.7	Diagnosis	ICD-9-CM	Mucous polyp of cervix
Von Willebrand's Disease			
286.4	Diagnosis	ICD-9-CM	Von Willebrand's disease
Severe Anemia			
C1010	Procedure	HCPCS	Whole blood or red blood cells, leukoreduced, cmv negative, each unit
C1016	Procedure	HCPCS	Whole blood or red blood cells, leukoreduced, frozen, deglycerol, washed, each unit
C1020	Procedure	HCPCS	Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated,
C1021	Procedure	HCPCS	Red blood cells, leukocyte-reduced, cmv negative, irradiated, each unit
P9016	Procedure	HCPCS	Red blood cells, leukocytes reduced, each unit
P9021	Procedure	HCPCS	Red blood cells, each unit
P9022	Procedure	HCPCS	Red blood cells, washed, each unit
P9038	Procedure	HCPCS	Red blood cells, irradiated, each unit
P9039	Procedure	HCPCS	Red blood cells, deglycerolized, each unit
P9040	Procedure	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit
P9051	Procedure	HCPCS	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit
P9054	Procedure	HCPCS	Each unit whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed,
P9057	Procedure	HCPCS	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit
P9058	Procedure	HCPCS	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit
9904	Procedure	ICD-9-CM	transfusion of packed cells
0381	Procedure	Revenue Center	Blood and blood products-packed red cells
Vaginal Bleed			
623.8	Diagnosis	ICD-9-CM	Other specified noninflammatory disorder of vagina
623.9	Diagnosis	ICD-9-CM	Unspecified noninflammatory disorder of vagina

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes, Healthcare Common Procedure Coding System (HCPCS) Procedure Codes, and Revenue Center Procedure Codes Used to Define Baseline Characteristics in this Request

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

Severe Uterine Bleed (SUB)

SUB is defined as a vaginal bleed diagnosis (defined above) and medical, transfusion or surgical management. Medical and transfusion management are taken to occur on the same day as vaginal bleed diagnosis. Surgical management is taken to occur within 30 days of vaginal bleed diagnosis. Please refer to Appendix E for diagnosis and procedure codes for medical, transfusion, or surgical managements. Please refer to Appendix F for generic and brand names of medical products used to define these managements.

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

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

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

Generic Name	Brand Name
<i>Aldosterone Receptor Antagonist</i>	
eplerenone	Eplerenone
eplerenone	Inspira
spironolactone	Aldactone
spironolactone	Spironolactone
spironolactone/hydrochlorothiazide	Aldactazide
spironolactone/hydrochlorothiazide	Spironolacton-Hydrochlorothiaz
<i>Angiotensin II Receptor Blocker</i>	
amlodipine besylate/olmesartan medoxomil	Amlodipine-Olmesartan
amlodipine besylate/olmesartan medoxomil	Azor
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan	Exforge
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge Hct
azilsartan medoxomil	Edarbi
azilsartan medoxomil/chlorthalidone	Edarbyclor
candesartan cilexetil	Atacand
candesartan cilexetil	Candesartan
candesartan cilexetil/hydrochlorothiazide	Atacand Hct
candesartan cilexetil/hydrochlorothiazide	Candesartan-Hydrochlorothiazid
eprosartan mesylate	Eprosartan
eprosartan mesylate	Teveten
eprosartan mesylate/hydrochlorothiazide	Teveten Hct
irbesartan	Avapro
irbesartan	Irbesartan
irbesartan/hydrochlorothiazide	Avalide
irbesartan/hydrochlorothiazide	Irbesartan-Hydrochlorothiazide
losartan potassium	Cozaar
losartan potassium	Losartan
losartan potassium/hydrochlorothiazide	Hyzaar
losartan potassium/hydrochlorothiazide	Losartan-Hydrochlorothiazide
nebivolol hcl/valsartan	Byvalson
olmesartan medoxomil	Benicar
olmesartan medoxomil	Olmesartan
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Tribenzor
olmesartan medoxomil/hydrochlorothiazide	Benicar Hct
olmesartan medoxomil/hydrochlorothiazide	Olmesartan-Hydrochlorothiazide
sacubitril/valsartan	Entresto
telmisartan	Micardis
telmisartan	Telmisartan
telmisartan/amlodipine besylate	Telmisartan-Amlodipine
telmisartan/amlodipine besylate	Twynsta
telmisartan/hydrochlorothiazide	Micardis Hct
telmisartan/hydrochlorothiazide	Telmisartan-Hydrochlorothiazid
valsartan	Diovan
valsartan	Valsartan

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

Generic Name	Brand Name
valsartan/hydrochlorothiazide	Diovan Hct
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Antianginal Vasodilator	
amyl nitrite	Amyl Nitrite
isosorbide dinitrate	Dilatrate-Sr
isosorbide dinitrate	Isochron
isosorbide dinitrate	Isoditrate
isosorbide dinitrate	Isordil
isosorbide dinitrate	Isordil Titradose
isosorbide dinitrate	Isosorbide Dinitrate
isosorbide dinitrate/hydralazine hcl	Bidil
isosorbide mononitrate	Imdur
isosorbide mononitrate	Ismo
isosorbide mononitrate	Isosorbide Mononitrate
isosorbide mononitrate	Monoket
nitroglycerin	Gonitro
nitroglycerin	Minitran
nitroglycerin	Nitro-Bid
nitroglycerin	Nitro-Dur
nitroglycerin	Nitroglycerin
nitroglycerin	Nitrolingual
nitroglycerin	Nitromist
nitroglycerin	Nitronol
nitroglycerin	Nitroquick
nitroglycerin	Nitrostat
nitroglycerin	Nitro-Time
nitroglycerin in 5 % dextrose in water	Nitroglycerin In 5 % Dextrose
Beta Blocker	
acebutolol hcl	Acebutolol
acebutolol hcl	Sectral
atenolol	Atenolol
atenolol	Senormin
atenolol	Tenormin
atenolol/chlorthalidone	Atenolol-Chlorthalidone
atenolol/chlorthalidone	Tenoretic 100
atenolol/chlorthalidone	Tenoretic 50
betaxolol hcl	Betaxolol
betaxolol hcl	Kerlone
bisoprolol fumarate	Bisoprolol Fumarate
bisoprolol fumarate	Zebeta
bisoprolol fumarate/hydrochlorothiazide	Bisoprolol-Hydrochlorothiazide
bisoprolol fumarate/hydrochlorothiazide	Ziac
carteolol hcl	Cartrol
carvedilol	Carvedilol
carvedilol	Coreg
carvedilol phosphate	Coreg Cr
esmolol hcl	Brevibloc

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

Generic Name	Brand Name
esmolol hcl	Esmolol
esmolol hcl in sodium chloride, iso-osmotic	Brevibloc In Nacl (Iso-Osm)
labetalol hcl	Labetalol
labetalol hcl	Normodyne
labetalol hcl	Trandate
metoprolol succinate	Metoprolol Succinate
metoprolol succinate	Toprol XI
metoprolol succinate/hydrochlorothiazide	Dutoprol
metoprolol succinate/hydrochlorothiazide	Metoprolol Su-Hydrochlorothiaz
metoprolol tartrate	Lopressor
metoprolol tartrate	Metoprolol Tartrate
metoprolol tartrate/dietary supplement,comb.10	Hypertensolol
metoprolol tartrate/hydrochlorothiazide	Lopressor Hct
metoprolol tartrate/hydrochlorothiazide	Metoprolol Ta-Hydrochlorothiaz
nadolol	Corgard
nadolol	Nadolol
nadolol/bendroflumethiazide	Corzide
nadolol/bendroflumethiazide	Nadolol-Bendroflumethiazide
nebivolol hcl	Bystolic
penbutolol sulfate	Levatol
pindolol	Pindolol
pindolol	Visken
propranolol hcl	Hemangeol
propranolol hcl	Inderal
propranolol hcl	Inderal La
propranolol hcl	Inderal XI
propranolol hcl	Innopran XI
propranolol hcl	Propanolol
propranolol hcl/hydrochlorothiazide	Propanolol-Hydrochlorothiazid
sotalol hcl	Betapace
sotalol hcl	Betapace Af
sotalol hcl	Sorine
sotalol hcl	Sotalol
sotalol hcl	Sotalol Af
sotalol hcl	Sotyliza
timolol maleate	Blocadren
timolol maleate	Timolol Maleate
Calcium Channel Blocker	
aliskiren hemifumarate/amlodipine besylate	Tekamlo
aliskiren hemifumarate/amlodipine/hydrochlorothiazide	Amturnide
amlodipine besylate	Amlodipine
amlodipine besylate	Norvasc
amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
amlodipine besylate/atorvastatin calcium	Caduet
amlodipine besylate/benazepril hcl	Amlodipine-Benazepril
amlodipine besylate/benazepril hcl	Lotrel
amlodipine besylate/olmesartan medoxomil	Amlodipine-Olmesartan

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

Generic Name	Brand Name
amlodipine besylate/olmesartan medoxomil	Azor
amlodipine besylate/valsartan	Amlodipine-Valsartan
amlodipine besylate/valsartan	Exforge
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge Hct
clevidipine butyrate	Cleviprex
diltiazem hcl	Cardizem
diltiazem hcl	Cardizem Cd
diltiazem hcl	Cardizem La
diltiazem hcl	Cartia Xt
diltiazem hcl	Dilacor Xr
diltiazem hcl	Dilt-Cd
diltiazem hcl	Diltia Xt
diltiazem hcl	Diltiazem Hcl
diltiazem hcl	Dilt-Xr
diltiazem hcl	Diltzac Er
diltiazem hcl	Matzim La
diltiazem hcl	Taztia Xt
diltiazem hcl	Tiazac
diltiazem hcl in 0.9 % sodium chloride	Diltiazem Hcl In 0.9% Nacl
diltiazem hcl/dextrose 5 % in water	Diltiazem In Dextrose 5 %
felodipine	Felodipine
isradipine	Dynacirc Cr
isradipine	Isradipine
nicardipine hcl	Cardene Iv
nicardipine hcl	Cardene Sr
nicardipine hcl	Nicardipine
nicardipine hcl in 0.9 % sodium chloride	Nicardipine In 0.9 % Nacl
nicardipine in 5 % dextrose in water	Nicardipine In 5 % Dextrose
nicardipine in dextrose, iso-osmotic	Cardene Iv In Dextrose
nicardipine in sodium chloride, iso-osmotic	Cardene Iv In Sodium Chloride
nifedipine	Adalat Cc
nifedipine	Afeditab Cr
nifedipine	Nifediac Cc
nifedipine	Nifedical XI
nifedipine	Nifedipine
nifedipine	Procardia
nifedipine	Procardia XI
nimodipine	Nimodipine
nimodipine	Nymalize
nisoldipine	Nisoldipine
nisoldipine	Sular
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Tribenzor
perindopril arginine/amlodipine besylate	Prestalia
telmisartan/amlodipine besylate	Telmisartan-Amlodipine
telmisartan/amlodipine besylate	Twynsta

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

Generic Name	Brand Name
trandolapril/verapamil hcl	Tarka
trandolapril/verapamil hcl	Trandolapril-Verapamil
verapamil hcl	Calan
verapamil hcl	Calan Sr
verapamil hcl	Covera-Hs
verapamil hcl	Isoptin Sr
verapamil hcl	Verapamil
verapamil hcl	Verelan
verapamil hcl	Verelan Pm
ziconotide acetate	Prialt
Diuretic	
acetazolamide	Acetazolamide
acetazolamide	Diamox Sequels
acetazolamide sodium	Acetazolamide Sodium
aliskiren hemifumarate/hydrochlorothiazide	Tekturna Hct
amiloride hcl	Amiloride
amiloride hcl	Midamor
amiloride hcl/hydrochlorothiazide	Amiloride-Hydrochlorothiazide
amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
amlodipine besylate/valsartan/hydrochlorothiazide	Exforge Hct
ammonium chloride	Ammonium Chloride
atenolol/chlorthalidone	Atenolol-Chlorthalidone
atenolol/chlorthalidone	Tenoretic 100
atenolol/chlorthalidone	Tenoretic 50
azilsartan medoxomil/chlorthalidone	Edarbyclor
benazepril hcl/hydrochlorothiazide	Benazepril-Hydrochlorothiazide
benazepril hcl/hydrochlorothiazide	Lotensin Hct
bisoprolol fumarate/hydrochlorothiazide	Bisoprolol-Hydrochlorothiazide
bisoprolol fumarate/hydrochlorothiazide	Ziac
bumetanide	Bumetanide
candesartan cilexetil/hydrochlorothiazide	Atacand Hct
candesartan cilexetil/hydrochlorothiazide	Candesartan-Hydrochlorothiazid
captopril/hydrochlorothiazide	Captopril-Hydrochlorothiazide
chlorothiazide	Chlorothiazide
chlorothiazide	Diuril
chlorothiazide sodium	Chlorothiazide Sodium
chlorothiazide sodium	Diuril Iv
chlorthalidone	Chlorthalidone
chlorthalidone	Thalitone
clonidine hcl/chlorthalidone	Clorpres
conivaptan hcl/dextrose 5 % in water	Vaprisol
enalapril maleate/hydrochlorothiazide	Enalapril-Hydrochlorothiazide
enalapril maleate/hydrochlorothiazide	Vaseretic
eplerenone	Eplerenone
eplerenone	Inspra
eprosartan mesylate/hydrochlorothiazide	Teveten Hct
ethacrynate sodium	Ethacrynate Sodium

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

Generic Name	Brand Name
ethacrynate sodium	Sodium Edecrin
ethacrynic acid	Edecrin
ethacrynic acid	Ethacrynic Acid
fosinopril sodium/hydrochlorothiazide	Fosinopril-Hydrochlorothiazide
furosemide	Furosemide
furosemide	Lasix
furosemide in 0.9 % sodium chloride	Furosemide In 0.9 % Nacl
furosemide/dextrose 5 % in water	Furosemide In Dextrose 5 %
glycerin	Intral
hydrochlorothiazide	Hydrochlorothiazide
hydrochlorothiazide	Microzide
indapamide	Indapamide
irbesartan/hydrochlorothiazide	Avalide
irbesartan/hydrochlorothiazide	Irbesartan-Hydrochlorothiazide
lisinopril/hydrochlorothiazide	Lisinopril-Hydrochlorothiazide
lisinopril/hydrochlorothiazide	Prinzide
lisinopril/hydrochlorothiazide	Zestoretic
losartan potassium/hydrochlorothiazide	Hyzaar
losartan potassium/hydrochlorothiazide	Losartan-Hydrochlorothiazide
mannitol	Mannitol 10 %
mannitol	Mannitol 15 %
mannitol	Mannitol 20 %
mannitol	Mannitol 25 %
mannitol	Mannitol 5 %
mannitol	Osmitrol 10 %
mannitol	Osmitrol 15 %
mannitol	Osmitrol 20 %
mannitol	Osmitrol 5 %
methazolamide	Methazolamide
methazolamide	Neptazane
methyclothiazide	Enduron
methyclothiazide	Methyclothiazide
methylodopa/hydrochlorothiazide	Methylodopa-Hydrochlorothiazide
metolazone	Metolazone
metolazone	Zaroxolyn
metoprolol succinate/hydrochlorothiazide	Dutoprol
metoprolol succinate/hydrochlorothiazide	Metoprolol Su-Hydrochlorothiaz
metoprolol tartrate/hydrochlorothiazide	Lopressor Hct
metoprolol tartrate/hydrochlorothiazide	Metoprolol Ta-Hydrochlorothiaz
moexipril hcl/hydrochlorothiazide	Moexipril-Hydrochlorothiazide
moexipril hcl/hydrochlorothiazide	Uniretic
nadolol/bendroflumethiazide	Corzide
nadolol/bendroflumethiazide	Nadolol-Bendroflumethiazide
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid
olmesartan medoxomil/amlodipine besylate/hydrochlorothiazide	Tribenzor
olmesartan medoxomil/hydrochlorothiazide	Benicar Hct
olmesartan medoxomil/hydrochlorothiazide	Olmesartan-Hydrochlorothiazide

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

Generic Name	Brand Name
propranolol hcl/hydrochlorothiazide	Propranolol-Hydrochlorothiazid
quinapril hcl/hydrochlorothiazide	Accuretic
quinapril hcl/hydrochlorothiazide	Quinapril-Hydrochlorothiazide
spironolactone	Aldactone
spironolactone	Spironolactone
spironolactone/hydrochlorothiazide	Aldactazide
spironolactone/hydrochlorothiazide	Spironolacton-Hydrochlorothiaz
telmisartan/hydrochlorothiazide	Micardis Hct
telmisartan/hydrochlorothiazide	Telmisartan-Hydrochlorothiazid
tolvaptan	Samsca
toremide	Demadex
toremide	Toremide
triamterene	Dyrenium
triamterene/hydrochlorothiazide	Dyazide
triamterene/hydrochlorothiazide	Maxzide
triamterene/hydrochlorothiazide	Maxzide-25Mg
triamterene/hydrochlorothiazide	Triamterene-Hydrochlorothiazid
valsartan/hydrochlorothiazide	Diovan Hct
valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide
Insulin	
insulin aspart	Novolog
insulin aspart	Novolog Flexpen
insulin aspart	Novolog Penfill
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 Flexpen
insulin degludec	Tresiba Flextouch U-100
insulin degludec	Tresiba Flextouch U-200
insulin detemir	Levemir
insulin detemir	Levemir Flexpen
insulin detemir	Levemir Flextouch
insulin glargine,human recombinant analog	Basaglar Kwikpen
insulin glargine,human recombinant analog	Lantus
insulin glargine,human recombinant analog	Lantus Solostar
insulin glargine,human recombinant analog	Toujeo Solostar
insulin glulisine	Apidra
insulin glulisine	Apidra Solostar
insulin lispro	Humalog
insulin lispro	Humalog Kwikpen
insulin lispro	Humalog Pen
insulin lispro protamine and insulin lispro	Humalog Mix 50-50
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Kwikpen
insulin lispro protamine and insulin lispro	Humalog Mix 75-25
insulin lispro protamine and insulin lispro	Humalog Mix 75-25 Kwikpen
insulin regular, human	Afrezza
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Humulin R U-500 (Concentrated)
Non-statin Lipid Lowering Drug	

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

Generic Name	Brand Name
alirocumab	Praluent Pen
alirocumab	Praluent Syringe
colesevelam hcl	Welchol
colestipol hcl	Colestid
colestipol hcl	Colestipol
evolocumab	Repatha Pushtronex
evolocumab	Repatha Sureclick
evolocumab	Repatha Syringe
ezetimibe	Ezetimibe
ezetimibe	Zetia
fenofibrate	Fenofibrate
fenofibrate	Fenoglide
fenofibrate	Lipofen
fenofibrate	Lofibra
fenofibrate nanocrystallized	Fenofibrate Nanocrystallized
fenofibrate nanocrystallized	Tricor
fenofibrate nanocrystallized	Triglide
fenofibrate,micronized	Antara
fenofibrate,micronized	Fenofibrate Micronized
fenofibrate,micronized	Lofibra
fenofibric acid	Fenofibric Acid
fenofibric acid	Fibricor
fenofibric acid (choline)	Fenofibric Acid (Choline)
fenofibric acid (choline)	Trilipix
fish oil/omega-3 fatty acids/vit e/folic acid/b6-b12	Cardiovid Plus
gemfibrozil	Gemfibrozil
gemfibrozil	Lopid
icosapent ethyl	Vascepa
lomitapide mesylate	Juxtapid
methionine/inositol/choline/folic acid	Lipochol Plus
mipomersen sodium	Kynamro
niacin	Niacin
niacin	Niacor
niacin	Niaspan Extended-Release
omega-3 acid ethyl esters	Lovaza
omega-3 acid ethyl esters	Omega-3 Acid Ethyl Esters
Oral Antidiabetic Agent	
acarbose	Acarbose
acarbose	Precose
alogliptin benzoate	Alogliptin
alogliptin benzoate	Nesina
alogliptin benzoate/metformin hcl	Alogliptin-Metformin
alogliptin benzoate/metformin hcl	Kazano
alogliptin benzoate/pioglitazone hcl	Alogliptin-Pioglitazone
alogliptin benzoate/pioglitazone hcl	Oseni
bromocriptine mesylate	Cycloset
canagliflozin	Invokana

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

Generic Name	Brand Name
canagliflozin/metformin hcl	Invokamet
canagliflozin/metformin hcl	Invokamet Xr
chlorpropamide	Chlorpropamide
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/metformin hcl	Xigduo Xr
empagliflozin	Jardiance
empagliflozin/linagliptin	Glyxambi
empagliflozin/metformin hcl	Synjardy
empagliflozin/metformin hcl	Synjardy Xr
glimepiride	Amaryl
glimepiride	Glimepiride
glipizide	Glipizide
glipizide	Glucotrol
glipizide	Glucotrol Xl
glipizide/metformin hcl	Glipizide-Metformin
glipizide/metformin hcl	Metaglip
glyburide	Diabeta
glyburide	Glyburide
glyburide,micronized	Glyburide Micronized
glyburide,micronized	Glynase
glyburide/metformin hcl	Glucovance
glyburide/metformin hcl	Glyburide-Metformin
linagliptin	Tradjenta
linagliptin/metformin hcl	Jentadueto
linagliptin/metformin hcl	Jentadueto Xr
metformin hcl	Fortamet
metformin hcl	Glucophage
metformin hcl	Glucophage Xr
metformin hcl	Glumetza
metformin hcl	Metformin
metformin hcl	Riomet
metformin/amino acids comb. #7/herbal comb.#125/choline	Appformin-D
metformin/caffeine/amino acids#7/herbal comb#125/choline bit	Appformin
mifepristone	Korlym
miglitol	Glyset
miglitol	Miglitol
nateglinide	Nateglinide
nateglinide	Starlix
pioglitazone hcl	Actos
pioglitazone hcl	Pioglitazone
pioglitazone hcl/glimepiride	Duetact
pioglitazone hcl/glimepiride	Pioglitazone-Glimepiride
pioglitazone hcl/metformin hcl	Actoplus Met
pioglitazone hcl/metformin hcl	Actoplus Met Xr
pioglitazone hcl/metformin hcl	Pioglitazone-Metformin
repaglinide	Prandin
repaglinide	Repaglinide

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

Generic Name	Brand Name
repaglinide/metformin hcl	Prandimet
repaglinide/metformin hcl	Repaglinide-Metformin
rosiglitazone maleate	Avandia
rosiglitazone maleate/glimepiride	Avandaryl
rosiglitazone maleate/metformin hcl	Avandamet
saxagliptin hcl	Onglyza
saxagliptin hcl/metformin hcl	Kombiglyze Xr
sitagliptin phosphate	Januvia
sitagliptin phosphate/metformin hcl	Janumet
sitagliptin phosphate/metformin hcl	Janumet Xr
sitagliptin phosphate/simvastatin	Juvisync
tolazamide	Tolazamide
tolbutamide	Tolbutamide
<i>Other Antihypertensive Medication</i>	
aliskiren hemifumarate	Tekturna
aliskiren hemifumarate/amlodipine besylate	Tekamlo
aliskiren hemifumarate/amlodipine/hydrochlorothiazide	Amturnide
aliskiren hemifumarate/hydrochlorothiazide	Tekturna Hct
aliskiren/valsartan	Valturna
ambrisentan	Letairis
bosentan	Tracleer
clonidine	Catapres-Tts-1
clonidine	Catapres-Tts-2
clonidine	Catapres-Tts-3
clonidine	Clonidine
clonidine hcl	Catapres
clonidine hcl	Clonidine Hcl
clonidine hcl	Nexiclon Xr
clonidine hcl/chlorthalidone	Clorpres
doxazosin mesylate	Cardura
doxazosin mesylate	Cardura XI
doxazosin mesylate	Doxazosin
epoprostenol sodium (arginine)	Veletri
epoprostenol sodium (glycine)	Epoprostenol (Glycine)
epoprostenol sodium (glycine)	Flolan
fenoldopam mesylate	Corlopam
fenoldopam mesylate	Fenoldopam
guanabenz acetate	Guanabenz
guanfacine hcl	Guanfacine
guanfacine hcl	Tenex
hydralazine hcl	Hydralazine
iloprost tromethamine	Ventavis
isosorbide dinitrate/hydralazine hcl	Bidil
isoxsuprine hcl	Isoxsuprine
macitentan	Opsumit
mecamylamine hcl	Vecamyl
methyl dopa	Methyl dopa

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

Generic Name	Brand Name
methyldopa/hydrochlorothiazide	Methyldopa-Hydrochlorothiazide
methyldopate hcl	Methyldopate
metyrosine	Demser
minoxidil	Minoxidil
nitroprusside sodium	Nitropress
nitroprusside sodium	Sodium Nitroprusside
nitroprusside sodium in 0.9 % sodium chloride	Nipride Rtu
papaverine hcl	Papaverine
phenoxybenzamine hcl	Dibenzyline
phenoxybenzamine hcl	Phenoxybenzamine
phentolamine mesylate	Phentolamine
prazosin hcl	Minipress
prazosin hcl	Prazosin
reserpine	Reserpine
riociguat	Adempas
selexipag	Uptravi
sildenafil citrate	Revatio
sildenafil citrate	Sildenafil
tadalafil	Adcirca
terazosin hcl	Hytrin
terazosin hcl	Terazosin
treprostinil	Tyvaso
treprostinil diolamine	Orenitram
treprostinil sodium	Remodulin
treprostinil/nebulizer accessories	Tyvaso Refill Kit
treprostinil/nebulizer and accessories	Tyvaso Institutional Start Kit
treprostinil/nebulizer and accessories	Tyvaso Starter Kit
Statin	
amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
amlodipine besylate/atorvastatin calcium	Caduet
atorvastatin calcium	Atorvastatin
atorvastatin calcium	Lipitor
ezetimibe/atorvastatin calcium	Liptruzet
ezetimibe/simvastatin	Ezetimibe-Simvastatin
ezetimibe/simvastatin	Vytorin 10-10
ezetimibe/simvastatin	Vytorin 10-20
ezetimibe/simvastatin	Vytorin 10-40
ezetimibe/simvastatin	Vytorin 10-80
fluvastatin sodium	Fluvastatin
fluvastatin sodium	Lescol
fluvastatin sodium	Lescol XI
lovastatin	Altoprev
lovastatin	Lovastatin
lovastatin	Mevacor
niacin/lovastatin	Advicor
niacin/simvastatin	Simcor
pitavastatin calcium	Livalo

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

Generic Name	Brand Name
pravastatin sodium	Pravachol
pravastatin sodium	Pravastatin
rosuvastatin calcium	Crestor
rosuvastatin calcium	Rosuvastatin
simvastatin	Simvastatin
simvastatin	Zocor

Medications that Increase Bleeding Risk

Antiplatelet Agent

abciximab	Reopro
anagrelide hcl	Agrylin
anagrelide hcl	Anagrelide
aspirin	Durlaza
aspirin/dipyridamole	Aggrenox
aspirin/dipyridamole	Aspirin-Dipyridamole
aspirin/omeprazole	Yosprala
cangrelor tetrasodium	Kengreal
cilostazol	Cilostazol
cilostazol	Pletal
clopidogrel bisulfate	Clopidogrel
clopidogrel bisulfate	Plavix
dipyridamole	Dipyridamole
dipyridamole	Persantine
eptifibatide	Eptifibatide
eptifibatide	Integrilin
prasugrel hcl	Effient
ticagrelor	Brilinta
ticlopidine hcl	Ticlopidine
tirofiban hcl monohydrate	Aggrastat Concentrate
tirofiban hcl monohydrate in 0.9 % sodium chloride	Aggrastat In Sodium Chloride
vorapaxar sulfate	Zontivity

Aspirin

aspirin	Aspirin
aspirin	Durlaza
aspirin	Easprin
aspirin	Zorprin
aspirin/caffeine/dihydrocodeine bitartrate	Aspirin-Caffeine-Dihydrocodein
aspirin/caffeine/dihydrocodeine bitartrate	Synalgos-Dc
aspirin/dipyridamole	Aggrenox
aspirin/dipyridamole	Aspirin-Dipyridamole
aspirin/omeprazole	Yosprala
aspirin/salicylamide/acetaminophen/caffeine	Levacet
butalbital/aspirin/caffeine	Butalbital Compound
butalbital/aspirin/caffeine	Butalbital-Aspirin-Caffeine
butalbital/aspirin/caffeine	Fiorinal
carisoprodol/aspirin	Carisoprodol Compound
carisoprodol/aspirin	Carisoprodol-Aspirin
carisoprodol/aspirin/codeine phosphate	Carisoprodol Compound-Codeine

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

Generic Name	Brand Name
carisoprodol/aspirin/codeine phosphate	Carisoprodol-Asa-Codeine
choline salicylate/magnesium salicylate	Choline,Magnesium Salicylate
choline salicylate/magnesium salicylate	Choline-Mag Trisalicylate
codeine phosphate/butalbital/aspirin/caffeine	Ascomp With Codeine
codeine phosphate/butalbital/aspirin/caffeine	Butalbital Compound W/Codeine
codeine phosphate/butalbital/aspirin/caffeine	Butalbital Compound-Codeine
codeine phosphate/butalbital/aspirin/caffeine	Codeine-Butalbital-Asa-Caff
codeine phosphate/butalbital/aspirin/caffeine	Fiorinal-Codeine #3
diflunisal	Diflunisal
magnesium salicylate	Mst 600
orphenadrine citrate/aspirin/caffeine	Norgesic Forte
orphenadrine citrate/aspirin/caffeine	Orphenadrine Compound
orphenadrine citrate/aspirin/caffeine	Orphenadrine Compound Forte
orphenadrine citrate/aspirin/caffeine	Orphenadrine Compound-Ds
orphenadrine citrate/aspirin/caffeine	Orphenadrine-Asa-Caffeine
oxycodone hcl/aspirin	Endodan
oxycodone hcl/aspirin	Oxycodone-Aspirin
oxycodone hcl/aspirin	Percodan
oxycodone hcl/oxycodone terephthalate/aspirin	Oxycodone Hcl-Oxycodone-Asa
salicylamide/acetaminophen	Frenadol
salicylamide/acetaminophen/phenyltoloxamine	Anabar
salicylamide/acetaminophen/phenyltoloxamine	Be-Flex Plus
salicylamide/acetaminophen/phenyltoloxamine	Duraxin
salicylamide/acetaminophen/phenyltoloxamine	Ed-Flex
salicylamide/acetaminophen/phenyltoloxamine/caffeine	Cafgesic
salicylamide/acetaminophen/phenyltoloxamine/caffeine	Durabac
salsalate	Disalcid
salsalate	Salsalate
sodium thiosalicylate	Thiocyl
<i>Cephalosporin Antibiotic</i>	
cefaclor	Ceclor
cefaclor	Cefaclor
cefadroxil	Cefadroxil
cefadroxil	Duricef
cefazolin sodium	Cefazolin
cefazolin sodium in 0.9 % sodium chloride	Cefazolin In 0.9% Sod Chloride
cefazolin sodium/dextrose 5 % in water	Cefazolin In Dextrose 5 %
cefazolin sodium/dextrose, iso-osmotic	Cefazolin In Dextrose (Iso-Os)
cefazolin sodium/water for injection,sterile	Cefazolin In Sterile Water
cefdinir	Cefdinir
cefdinir	Omnicef
cefditoren pivoxil	Cefditoren Pivoxil
cefditoren pivoxil	Spectracef
cefepime hcl	Cefepime
cefepime hcl	Maxipime
cefepime hcl in dextrose 5 % in water	Cefepime In Dextrose 5 %
cefepime hcl in iso-osmotic dextrose	Cefepime In Dextrose,Iso-Osm

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

Generic Name	Brand Name
cefixime	Cefixime
cefixime	Suprax
cefotaxime sodium	Cefotaxime
cefotaxime sodium	Claforan
cefotaxime sodium/dextrose, iso-osmotic	Claforan In Dextrose(Iso-Osm)
cefotetan disodium	Cefotan
cefotetan disodium	Cefotetan
cefotetan disodium in iso-osmotic dextrose	Cefotetan In Dextrose, Iso-Osm
cefoxitin sodium	Cefoxitin
cefoxitin sodium/dextrose 5 % in water	Mefoxin In Dextrose (Iso-Osm)
cefoxitin sodium/dextrose, iso-osmotic	Cefoxitin In Dextrose, Iso-Osm
cefpodoxime proxetil	Cefpodoxime
cefprozil	Cefprozil
ceftaroline fosamil acetate	Teflaro
ceftazidime	Ceftazidime
ceftazidime	Fortaz
ceftazidime	Tazicef
ceftazidime in dextrose 5% and water	Ceftazidime In D5W
ceftazidime sodium in iso-osmotic dextrose	Fortaz In Dextrose 5 %
ceftazidime/avibactam sodium	Avycaz
ceftibuten	Cedax
ceftibuten	Ceftibuten
ceftolozane sulfate/tazobactam sodium	Zerbaxa
ceftriaxone sodium	Ceftriaxone
ceftriaxone sodium	Rocephin
ceftriaxone sodium in iso-osmotic dextrose	Ceftriaxone In Dextrose,Iso-Os
cefuroxime axetil	Ceftin
cefuroxime axetil	Cefuroxime Axetil
cefuroxime sodium	Cefuroxime Sodium
cefuroxime sodium	Zinacef
cefuroxime sodium/dextrose, iso-osmotic	Cefuroxime-Dextrose (Iso-Osm)
cefuroxime sodium/dextrose, iso-osmotic	Zinacef In Dextrose (Iso-Osm)
cefuroxime sodium/water for injection,sterile	Zinacef In Sterile Water
cephalexin	Cephalexin
cephalexin	Daxbia
cephalexin	Keflex
<i>Cyclooxygenase-2 (COX-2) Inhibitors</i>	
celecoxib	Celebrex
celecoxib	Celecoxib
<i>Fondaparinux</i>	
fondaparinux sodium	Arixtra
fondaparinux sodium	Fondaparinux
<i>Heparin and Low Molecular Weight Heparin</i>	
dalteparin sodium,porcine	Fragmin
enoxaparin sodium	Enoxaparin
enoxaparin sodium	Lovenox
heparin sodium,porcine	Heparin (Porcine)

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

Generic Name	Brand Name
heparin sodium,porcine	Heparin Lock
heparin sodium,porcine	Heparin Lock Flush
heparin sodium,porcine	Heparin Lock Flush (Porcine)
heparin sodium,porcine	Hep-Lock Flush
heparin sodium,porcine in 0.45 % sodium chloride	Heparin(Porcine) In 0.45% Nacl
heparin sodium,porcine in 0.9 % sodium chloride	Heparin (Porcine) In 0.9% Nacl
heparin sodium,porcine in 0.9 % sodium chloride/pf	Heparin (Porcine) In Nacl (Pf)
heparin sodium,porcine/dextrose 5 % in water	Heparin (Porcine) In 5 % Dex
heparin sodium,porcine/dextrose 5 % in water/pf	Heparin (Porcine) In D5W (Pf)
heparin sodium,porcine/pf	Hep Flush-10 (Pf)
heparin sodium,porcine/pf	Heparin Lockflush(Porcine)(Pf)
heparin sodium,porcine/pf	Heparin, Porcine (Pf)
heparin sodium,porcine/pf	Hep-Lock U/P Pf
heparin sodium,porcine/pf	Monoject Prefill (Pf)
heparin sodium,porcine/pf	Monoject Prefill Advanced (Pf)
tinzaparin sodium,porcine	Innohep
Prescription Non-steroidal Anti-inflammatory Drug (NSAID)	
celecoxib	Celebrex
celecoxib	Celecoxib
diclofenac epolamine	Flector
diclofenac potassium	Cambia
diclofenac potassium	Cataflam
diclofenac potassium	Diclofenac Potassium
diclofenac potassium	Zipsor
diclofenac sodium	Diclofenac Sodium
diclofenac sodium	Dyloject
diclofenac sodium	Voltaren
diclofenac sodium	Voltaren-Xr
diclofenac sodium/misoprostol	Arthrotec 50
diclofenac sodium/misoprostol	Arthrotec 75
diclofenac sodium/misoprostol	Diclofenac-Misoprostol
diclofenac submicronized	Zorvolex
etodolac	Etodolac
etodolac	Lodine
fenoprofen calcium	Fenoprofen
fenoprofen calcium	Fenortho
fenoprofen calcium	Nalfon
flurbiprofen	Ansaid
flurbiprofen	Flurbiprofen
hydrocodone/ibuprofen	Hydrocodone-Ibuprofen
hydrocodone/ibuprofen	Ibudone
hydrocodone/ibuprofen	Reprexain
hydrocodone/ibuprofen	Vicoprofen
hydrocodone/ibuprofen	Xylon 10
ibuprofen	Caldolor
ibuprofen	Ibuprofen
ibuprofen	Motrin

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

Generic Name	Brand Name
ibuprofen lysine/pf	Ibuprofen Lysine (Pf)
ibuprofen lysine/pf	Neoprofen (Ibuprofen Lysn)(Pf)
ibuprofen/caffeine/vitamins b1, b2, b6, & b12	Ic400
ibuprofen/caffeine/vitamins b1, b2, b6, & b12	Ic800
ibuprofen/dietary supplement,misc. cb.11	Theraprofen-60
ibuprofen/dietary supplement,misc. cb.11	Theraprofen-90
ibuprofen/famotidine	Duexis
ibuprofen/oxycodone hcl	Combunox
ibuprofen/oxycodone hcl	Ibuprofen-Oxycodone
indomethacin	Indocin
indomethacin	Indomethacin
indomethacin sodium	Indocin
indomethacin sodium	Indomethacin Sodium
indomethacin, submicronized	Tivorbex
ketoprofen	Ketoprofen
ketorolac tromethamine	Ketorolac
ketorolac tromethamine	Readysharp Ketorolac
ketorolac tromethamine	Sprix
ketorolac tromethamine	Toradol
meclofenamate sodium	Meclofenamate
mefenamic acid	Mefenamic Acid
mefenamic acid	Ponstel
meloxicam	Meloxicam
meloxicam	Mobic
meloxicam, submicronized	Vivlodex
nabumetone	Nabumetone
nabumetone	Relafen
naproxen	Ec-Naprosyn
naproxen	Naprosyn
naproxen	Naproxen
naproxen sodium	Anaprox
naproxen sodium	Anaprox Ds
naproxen sodium	Naprelan Cr
naproxen sodium	Naprelan Cr Dose Card
naproxen sodium	Naproxen Sodium
naproxen/dietary supplement,misc. cb.11	Theraproxen
naproxen/dietary supplement,misc. cb.11	Theraproxen-90
naproxen/esomeprazole magnesium	Vimovo
oxaprozin	Daypro
oxaprozin	Oxaprozin
piroxicam	Feldene
piroxicam	Piroxicam
piroxicam/dietary supplement,misc. cb.11	Therapfeldamine
sulindac	Clinoril
sulindac	Sulindac
sumatriptan succinate/naproxen sodium	Treximet
tolmetin sodium	Tolmetin

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

Generic Name	Brand Name
<i>Serotonin–Norepinephrine Reuptake Inhibitor (SNRI)</i>	
desvenlafaxine	Desvenlafaxine
desvenlafaxine	Khedeza
desvenlafaxine fumarate	Desvenlafaxine Fumarate
desvenlafaxine succinate	Pristiq
duloxetine hcl	Cymbalta
duloxetine hcl	Duloxetine
duloxetine hcl	Irenka
levomilnacipran hcl	Fetzima
milnacipran hcl	Savella
venlafaxine hcl	Effexor
venlafaxine hcl	Effexor Xr
venlafaxine hcl	Venlafaxine
<i>Selective Serotonin Reuptake Inhibitor (SSRI)</i>	
citalopram hydrobromide	Celexa
citalopram hydrobromide	Citalopram
escitalopram oxalate	Escitalopram Oxalate
escitalopram oxalate	Lexapro
fluoxetine hcl	Fluoxetine
fluoxetine hcl	Prozac
fluoxetine hcl	Prozac Weekly
fluoxetine hcl	Rapiflux
fluoxetine hcl	Sarafem
fluoxetine hcl	Selfemra
fluoxetine hcl/dietary supplement,misc comb17	Gaboxetine
fluoxetine hcl/dietary supplement,misc.combo8	Sentroxatine
fluvoxamine maleate	Fluvoxamine
fluvoxamine maleate	Luvox Cr
paroxetine hcl	Paroxetine Hcl
paroxetine hcl	Paxil
paroxetine hcl	Paxil Cr
paroxetine mesylate	Pexeva
sertraline hcl	Sertraline
sertraline hcl	Zoloft
Medications Listed on Label as Having Clinically Significant Interactions with Warfarin or Novel Oral Anticoagulants (NOACs) (Inhibitors and Substrates)	
<i>Cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) Inhibitors and Substrates</i>	
atazanavir sulfate	Reyataz
atazanavir sulfate/cobicistat	Evotaz
chloramphenicol sod succinate	Chloramphenicol Sod Succinate
conivaptan hcl/dextrose 5 % in water	Vaprisol
darunavir ethanolate	Prezista
darunavir ethanolate/cobicistat	Prezcobix
fluconazole	Diflucan
fluconazole	Fluconazole
fluconazole in dextrose, iso-osmotic	Diflucan In Dextrose (Iso-Osm)
fluconazole in dextrose, iso-osmotic	Fluconazole In Dextrose(Iso-O)

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

Generic Name	Brand Name
fluconazole in sodium chloride, iso-osmotic	Diflucan In Nacl (Iso-Osm)
fluconazole in sodium chloride, iso-osmotic	Fluconazole In Nacl (Iso-Osm)
fosamprenavir calcium	Lexiva
indinavir sulfate	Crixivan
itraconazole	Itraconazole
itraconazole	Onmel
itraconazole	Sporanox
itraconazole	Sporanox Pulsepak
ketoconazole	Ketoconazole
ketoconazole	Nizoral
lopinavir/ritonavir	Kaletra
lopinavir/ritonavir	Lopinavir-Ritonavir
midazolam hcl	Midazolam
midazolam hcl in 0.9 % sodium chloride	Midazolam In 0.9 % Nacl
midazolam hcl in 0.9 % sodium chloride/pf	Midazolam (Pf) In 0.9 % Nacl
midazolam hcl in dextrose 5% in water	Midazolam In Dextrose 5 %
midazolam hcl/dextrose 5%-water/pf	Midazolam In Dextrose 5 % (Pf)
midazolam hcl/pf	Midazolam (Pf)
nefazodone hcl	Nefazodone
nelfinavir mesylate	Viracept
ritonavir	Norvir
ritonavir	Norvir Soft Gelatin
saquinavir mesylate	Invirase
tipranavir	Aptivus
tipranavir/vitamin e tpgs	Aptivus
trandolapril/verapamil hcl	Tarka
trandolapril/verapamil hcl	Trandolapril-Verapamil
triazolam	Halcion
triazolam	Triazolam
verapamil hcl	Calan
verapamil hcl	Calan Sr
verapamil hcl	Covera-Hs
verapamil hcl	Isoptin Sr
verapamil hcl	Verapamil
verapamil hcl	Verelan
verapamil hcl	Verelan Pm
Fibrate	
fenofibrate	Fenofibrate
fenofibrate	Fenoglide
fenofibrate	Lipofen
fenofibrate	Lofibra
fenofibrate nanocrystallized	Fenofibrate Nanocrystallized
fenofibrate nanocrystallized	Tricor
fenofibrate nanocrystallized	Triglide
fenofibrate,micronized	Antara
fenofibrate,micronized	Fenofibrate Micronized
fenofibrate,micronized	Lofibra

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

Generic Name	Brand Name
fenofibric acid	Fenofibric Acid
fenofibric acid	Fibricor
fenofibric acid (choline)	Fenofibric Acid (Choline)
fenofibric acid (choline)	Trilipix
gemfibrozil	Gemfibrozil
gemfibrozil	Lopid
Statin	
amlodipine besylate/atorvastatin calcium	Amlodipine-Atorvastatin
amlodipine besylate/atorvastatin calcium	Caduet
atorvastatin calcium	Atorvastatin
atorvastatin calcium	Lipitor
ezetimibe/atorvastatin calcium	Liptruzet
ezetimibe/simvastatin	Ezetimibe-Simvastatin
ezetimibe/simvastatin	Vytorin 10-10
ezetimibe/simvastatin	Vytorin 10-20
ezetimibe/simvastatin	Vytorin 10-40
ezetimibe/simvastatin	Vytorin 10-80
fluvastatin sodium	Fluvastatin
fluvastatin sodium	Lescol
fluvastatin sodium	Lescol Xi
lovastatin	Altoprev
lovastatin	Lovastatin
lovastatin	Mevacor
niacin/lovastatin	Advicor
niacin/simvastatin	Simcor
pitavastatin calcium	Livalo
pravastatin sodium	Pravachol
pravastatin sodium	Pravastatin
rosuvastatin calcium	Crestor
rosuvastatin calcium	Rosuvastatin
simvastatin	Simvastatin
simvastatin	Zocor
Other Medications that Inhibit CYP3A4, P-gp, Cytochrome P450 2C9 (CYP2C9), or Cytochrome P450 1A2 (CYP1A2)	
amiodarone hcl	Amiodarone
amiodarone hcl	Cordarone
amiodarone hcl	Pacerone
amiodarone hcl/dextrose 5 % in water	Amiodarone In Dextrose 5 %
amiodarone in dextrose, iso-osmotic	Nexterone
cimetidine	Cimetidine
cimetidine	Tagamet
cimetidine hcl	Cimetidine Hcl
ciprofloxacin	Cipro
ciprofloxacin	Ciprofloxacin
ciprofloxacin hcl	Cipro
ciprofloxacin hcl	Ciprofloxacin Hcl
ciprofloxacin hcl	Proquin Xr
ciprofloxacin lactate	Ciprofloxacin Lactate

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

Generic Name	Brand Name
ciprofloxacin lactate/dextrose 5 % in water	Cipro In D5W
ciprofloxacin lactate/dextrose 5 % in water	Ciprofloxacin In 5 % Dextrose
ciprofloxacin/ciprofloxacin hcl	Cipro Xr
ciprofloxacin/ciprofloxacin hcl	Ciprofloxacin (Mixture)
clarithromycin	Biaxin
clarithromycin	Biaxin XI
clarithromycin	Biaxin XI Pak
clarithromycin	Clarithromycin
erythromycin base	E-Mycin
erythromycin base	Ery-Tab
erythromycin base	Erythromycin
erythromycin base	Pce
erythromycin ethylsuccinate	E.E.S. 200
erythromycin ethylsuccinate	E.E.S. 400
erythromycin ethylsuccinate	E.E.S. Granules
erythromycin ethylsuccinate	Eryped
erythromycin ethylsuccinate	Eryped 200
erythromycin ethylsuccinate	Eryped 400
erythromycin ethylsuccinate	Erythromycin Ethylsuccinate
erythromycin ethylsuccinate/sulfisoxazole acetyl	Erythromycin-Sulfisoxazole
erythromycin lactobionate	Erythrocin
erythromycin stearate	Erythrocin (As Stearate)
erythromycin stearate	Erythromycin Stearate
lansoprazole/amoxicillin trihydrate/clarithromycin	Amoxicil-Clarithromy-Lansopraz
lansoprazole/amoxicillin trihydrate/clarithromycin	Prevpac
sulfamethoxazole/trimethoprim	Bactrim
sulfamethoxazole/trimethoprim	Bactrim Ds
sulfamethoxazole/trimethoprim	Septra
sulfamethoxazole/trimethoprim	Septra Ds
sulfamethoxazole/trimethoprim	Smz-Tmp Ds
sulfamethoxazole/trimethoprim	Sulfamethoxazole-Trimethoprim
sulfamethoxazole/trimethoprim	Sulfatrim
trimethoprim	Primsol
trimethoprim	Trimethoprim

Medications Listed on Label as Having Clinically Significant Interactions with Warfarin or NOACs (Inducers)

CYP3A4 and P-gp Inducers	
carbamazepine	Carbamazepine
carbamazepine	Carbatrol
carbamazepine	Epitol
carbamazepine	Equetro
carbamazepine	Tegretol
carbamazepine	Tegretol Xr
omacetaxine mepesuccinate	Synribo
phenytoin	Dilantin Infatabs
phenytoin	Dilantin-125
phenytoin	Phenytoin
phenytoin sodium	Phenytoin Sodium

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

Generic Name	Brand Name
phenytoin sodium extended	Dilantin
phenytoin sodium extended	Dilantin Extended
phenytoin sodium extended	Dilantin Kapseal
phenytoin sodium extended	Phenytek
phenytoin sodium extended	Phenytoin Sodium Extended
rifampin	Rifadin
rifampin	Rifampin
rifampin	Rimactane
rifampin/isoniazid	Isonarif
rifampin/isoniazid	Rifamate
rifampin/isoniazid/pyrazinamide	Rifater
CYP2C9 Inducers	
bosentan	Tracleer
phenobarbital	Phenobarbital
phenobarbital sodium	Luminal
phenobarbital sodium	Phenobarbital Sodium
phenobarbital sodium in 0.9 % sodium chloride	Phenobarbital In 0.9 % Sod Chl
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Antispasmodic
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	B-Donna
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Belladonna-Phenobarbital
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Donnatal
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Donnatal Extentabs
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Me-Pb-Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Pb-Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Phenobarb-Hyoscy-Atropine-Scop
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Phenohtro
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Quadrapax
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Re-Pb Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Se-Donna Pb Hyos
phenobarbital/hyoscyamine sulf/atropine sulf/scopolamine hb	Servira
CYP1A2 Inducers	
aspirin/omeprazole	Yosprala
montelukast sodium	Montelukast
montelukast sodium	Singulair
omeprazole/clarithromycin/amoxicillin trihydrate	Omeclamox-Pak
omeprazole/sodium bicarbonate	Omeprazole-Sodium Bicarbonate
omeprazole/sodium bicarbonate	Zegerid

Appendix I. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to investigate the incidence rate of severe uterine bleeding (SUB) among users of oral anticoagulants (rivaroxaban, apixaban, dabigatran, and warfarin) in preparation for a risk assessment amongst warfarin and novel oral anticoagulants (NOAC) users.

Query Period: October 19, 2010 to September 30, 2015
Coverage Requirement: Medical and Drug
Pre-Exposure Enrollment (days): 183
Enrollment Gap: 45 days
Sex: Female
Age Groups: 0-50, 51+ years
Additional Output: Code distribution

Drug/Exposure

Scenario	Exposure	Incident with respect to:	Washout (days)	Cohort Definition	Exposure Episode Gap	Exposure Extension Period	Minimum Episode Duration	Minimum Days Supplied	Exposure Episode Truncation Criteria
1	Rivaroxaban, apixaban, dabigatran, or warfarin	Rivaroxaban, apixaban, dabigatran, edoxaban, or warfarin	183	Only the first valid treatment episode during the query period	3	3	1	1	End of treatment episode, identification of health outcome of interest (HOI), disenrollment, death, end of available data, query end date
2	Rivaroxaban, apixaban, dabigatran, or warfarin	Rivaroxaban, apixaban, dabigatran, edoxaban, or warfarin	183	Only the first valid treatment episode during the query period	3	3	1	1	End of treatment episode, identification of HOI, disenrollment, death, end of available data, query end date
3	Rivaroxaban, apixaban, dabigatran, or warfarin	Rivaroxaban, apixaban, dabigatran, edoxaban, or warfarin	183	Only the first valid treatment episode during the query period	3	3	1	1	End of treatment episode, identification of HOI, disenrollment, death, end of available data, query end date
4	Rivaroxaban, apixaban, dabigatran, or warfarin	Rivaroxaban, apixaban, dabigatran, edoxaban, or warfarin	183	Only the first valid treatment episode during the query period	3	3	1	1	End of treatment episode, identification of HOI, disenrollment, death, end of available data, query end date
5	Rivaroxaban, apixaban, dabigatran, or warfarin	Rivaroxaban, apixaban, dabigatran, edoxaban, or warfarin	183	Only the first valid treatment episode during the query period	3	3	1	1	End of treatment episode, identification of HOI, disenrollment, death, end of available data, query end date

Appendix I. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to investigate the incidence rate of severe uterine bleeding (SUB) among users of oral anticoagulants (rivaroxaban, apixaban, dabigatran, and warfarin) in preparation for a risk assessment amongst warfarin and novel oral anticoagulants (NOAC) users.

Inclusion/Exclusion Criteria

Scenario	Inclusion/Exclusion	Criteria	Care Setting	Lookback Period (Start, End)
1	Deep vein thrombosis (DVT) / pulmonary embolism (PE); atrial fibrillation (AF) or atrial flutter	Inclusion	Any	-183, 0
	Hysterectomy; vaginal bleeding (VB) managements under medical managements outcome (i.e., IUD, contraceptives, antifibrinolytics, vaginal packing; Vaginal bleeding (VB) managements under transfusion managements outcome (i.e., RBC-specific transfusion); Vaginal bleeding (VB) managements under surgical managements outcome (i.e., hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, dilation and curettage (D&C) with or without hysteroscopy, hysterectomy, hysteroscopy (not listed in other surgical managements), endometrial ablation (thermal, cryo, and section), uterine artery embolization); Joint Replacement	Exclusion	Any	-183, 0
2	DVT/PE; AF or atrial flutter	Inclusion	Any	-183, 0
	Hysterectomy; VB managements under medical managements outcome (i.e., IUD, contraceptives, antifibrinolytics, vaginal packing; VB managements under transfusion managements outcome (i.e., RBC-specific transfusion); VB managements under surgical managements outcome (i.e., hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, D&C with or without hysteroscopy, hysterectomy, hysteroscopy (not listed in other surgical managements), endometrial ablation (thermal, cryo, and section), uterine artery embolization); Joint Replacement	Exclusion	Any	-183, 0
3	DVT /PE; AF or atrial flutter	Inclusion	Any	-183, 0
	Hysterectomy; VB managements under medical managements outcome (i.e., IUD, contraceptives, antifibrinolytics, vaginal packing; VB managements under transfusion managements outcome (i.e., RBC-specific transfusion); VB managements under surgical managements outcome (i.e., hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, D&C with or without hysteroscopy, hysterectomy, hysteroscopy (not listed in other surgical managements), endometrial ablation (thermal, cryo, and section), uterine artery embolization); Joint Replacement	Exclusion	Any	-183, 0

Appendix I. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to investigate the incidence rate of severe uterine bleeding (SUB) among users of oral anticoagulants (rivaroxaban, apixaban, dabigatran, and warfarin) in preparation for a risk assessment amongst warfarin and novel oral anticoagulants (NOAC) users.

Inclusion/Exclusion Criteria

Scenario	Inclusion/Exclusion	Criteria	Care Setting	Lookback Period (Start, End)
	DVT/ PE; AF or atrial flutter	Inclusion	Any	-183, 0
4	Hysterectomy; VB managements under medical managements outcome (i.e., IUD, contraceptives, antifibrinolytics, vaginal packing; VB managements under transfusion managements outcome (i.e., RBC-specific transfusion);			
	VB managements under surgical managements outcome (i.e., hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, D&C with or without hysteroscopy, hysterectomy, hysteroscopy (not listed in other surgical managements), endometrial ablation (thermal, cryo, and section), uterine artery embolization);	Exclusion	Any	-183, 0
	Joint Replacement			
	DVT/ PE; AF or atrial flutter	Inclusion	Any	-183, 0
5	Hysterectomy; VB managements under medical managements outcome (i.e., IUD, contraceptives, antifibrinolytics, vaginal packing; VB managements under transfusion managements outcome (i.e., RBC-specific transfusion);			
	VB managements under surgical managements outcome (i.e., hysteroscopic polypectomy, hysteroscopic/laparoscopic/abdominal myomectomy, D&C with or without hysteroscopy, hysterectomy, hysteroscopy (not listed in other surgical managements), endometrial ablation (thermal, cryo, and section), uterine artery embolization);	Exclusion	Any	-183, 0
	Joint Replacement			

Appendix I. Specifications Defining Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 7.3.4, to investigate the incidence rate of severe uterine bleeding (SUB) among users of oral anticoagulants (rivaroxaban, apixaban, dabigatran, and warfarin) in preparation for a risk assessment amongst warfarin and novel oral anticoagulants (NOAC) users.

Scenario	Baseline Characteristics		Event/Outcome			
	Characteristics	Characteristics Evaluation Window (days)	Event/Outcome	Care Setting	Event Washout (days)	Blackout Period
1	See Appendix K	-183, 0	Medical Management Outcome, same day (see "Outcomes of Interest" in Overview and Figure 1 in Appendix J)	Inpatient Hospital Stay (IP), Emergency Department (ED), Ambulatory Visit (AV), or Other Ambulatory Visit (OA)	0	0
2	See Appendix K	-183, 0	Medical Management Outcome, 5-day gap allowed for Levonorgestrel IUD, contraceptives, antifibrinolytics (see "Outcomes of Interest" in Overview and Figure 2 in Appendix J)	IP, ED, AV, or OA	0	0
3	See Appendix K	-183, 0	Transfusion Management Outcome, same day, RBC-specific transfusion (see "Outcomes of Interest" in Overview and Figure 1 in Appendix J)	IP, ED, AV, or OA	0	0
4	See Appendix K	-183, 0	Surgical Management Outcome, 30-day gap (see "Outcomes of Interest" in Overview and Figure 2 in Appendix J)	IP, ED, AV, or OA	0	0
5	See Appendix K	-183, 0	Surgical Management Outcome, 60-day gap (see "Outcomes of Interest" in Overview and Figure 2 in Appendix J)	IP, ED, AV, or OA	0	0

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), Current Procedural Terminology, Fourth Edition (CPT-4), and Healthcare Common Procedure Coding System (HCPCS) codes are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings. NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix J. Pictorial Summary of Outcome Assessment

Note 1: Depending on the management outcome, the gap may be 5, 30 or 60 days.

Note 2: The follow-up will end if one of the following occurs: end of treatment episode, identification of Health Outcome of Interest (HOI), disenrollment, death, end of available data, or query end.

Note 3: Management event date is the date a patient is administered a management for vaginal bleed, and is taken as the date of Severe Uterine Bleed (SUB).

Note 4: SUB event date is taken as the date of HOI.

Figure 1.

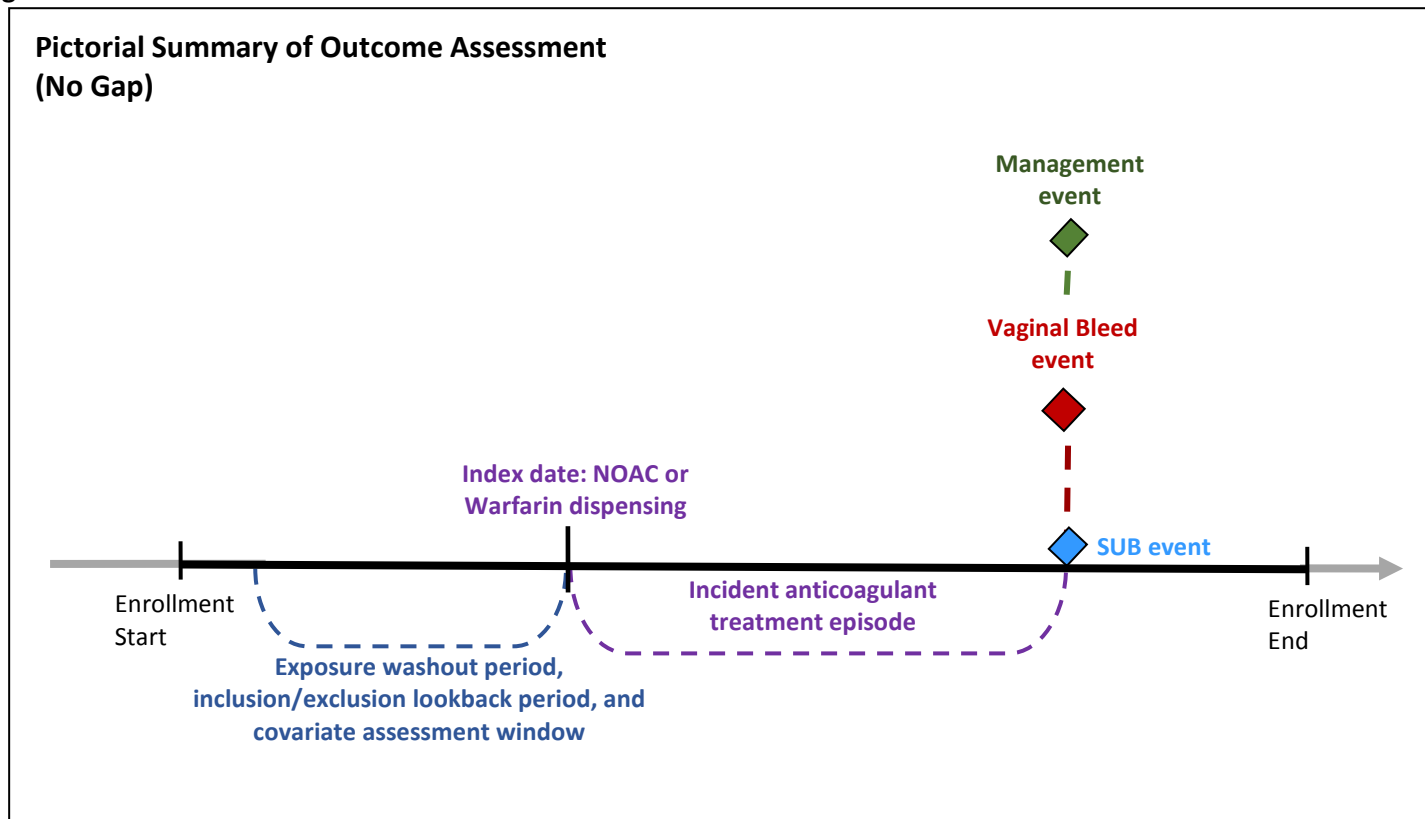
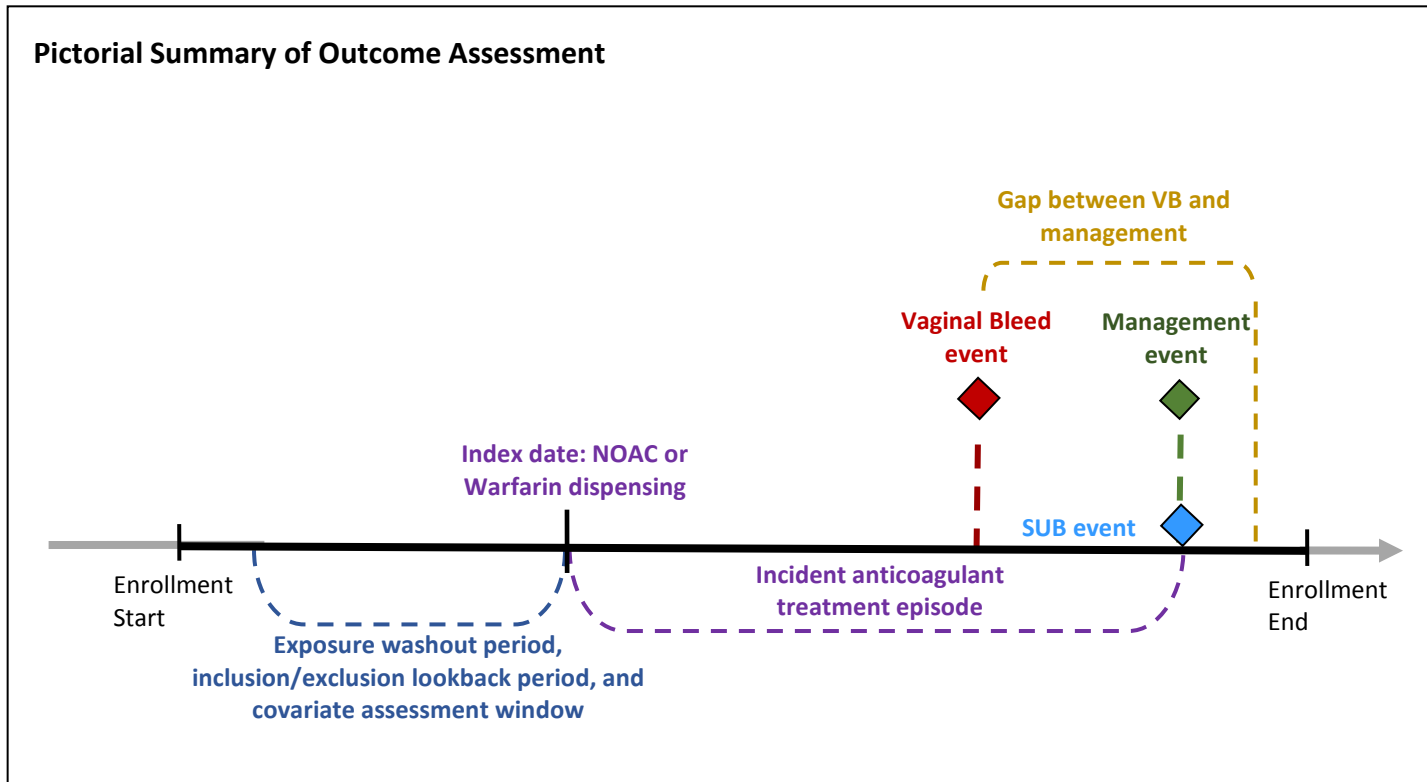


Figure 2.



Appendix K. List of Baseline Characteristics for this Request

Baseline Characteristics	Group	Care Setting
Cardiovascular and Antidiabetic Agents	Statins	NA
	Non-statin Lipid Lowering Agents	NA
	Angiotensin-Converting-Enzyme (ACE) Inhibitors	NA
	Angiotensin II Receptor Blockers	NA
	Aldosterone Receptor Antagonists	NA
	Beta Blockers	NA
	Calcium Channel Blockers	NA
	Diuretics	NA
	Other Antihypertensive Medication	NA
	Antianginal Vasodilator	NA
	Oral Antidiabetic Agent	NA
Insulin	NA	
Medications that Increase Bleeding Risk	Aspirin	NA
	Antiplatelet Agents	NA
	Prescription Non-steroidal Anti-inflammatory Drug (NSAID)	NA
	Cyclooxygenase-2 (COX-2) Inhibitors	NA
	Selective Serotonin Reuptake Inhibitor (SSRI)	NA
	Serotonin–Norepinephrine Reuptake Inhibitor (SNRI)	NA
	Heparin and Low Molecular Weight Heparin, Fondaparinux	NA
Cephalosporin Antibiotic	NA	
Medications Listed on Label as Having Clinically Significant Interactions with Warfarin or Novel Oral Anticoagulants (NOACs) (Inhibitors and Substrates)	Cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) Inhibitors and Substrates (protease inhibitors (atazanavir, darunavir, fosamprenavir, nelfinavir, saquinavir, tipranavir, lopinavir/ritonavir, indinavir), azole antifungals (ketoconazole, itraconazole, fluconazole), nefazodone, chloramphenicol, conivaptan, verapamil, midazolam, triazolam)	NA
	Fibrates	NA
	Statins	NA
	Other Medications that Inhibit CYP3A4, P-gp, Cytochrome P450 2C9 (CYP2C9), or Cytochrome P450 1A2 (CYP1A2) (amiodarone, cimetidine, ciprofloxacin, clopidogrel, co-trimoxazole (trimethoprim), erythromycin, clarithromycin)	NA
Medications Listed on Label as Having Clinically Significant Interactions with Warfarin or NOACs (Inducers, possibly decreasing bleeding/increasing clotting risk)	Cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) Inducers (rifampin, phenytoin, carbamazepine, omeprazole)	NA
	Cytochrome P450 2C9 (CYP2C9) Inducers (bosentan, phenobarbital)	NA
	Cytochrome P450 1A2 Inducers (montelukast, omeprazole)	NA
Severe Anemia (Any Caresetting)	Red Blood Cell Transfusion	Any
Healthcare / Medical Utilization	Number of Inpatient Hospital Encounters	IP
	Number of Non-Acute Institutional Encounters	IS
	Number of Emergency Department Encounters	ED
	Number of Ambulatory Encounters	AV
	Number of Other Ambulatory Encounters (includes other non overnight ambulatory encounters such as home health visits, telemedicine, telephone and email consultations)	OA

Appendix K. List of Baseline Characteristics for this Request

Baseline Characteristics	Group	Care Setting
Drug Utilization	Number of Dispensings	NA
	Number of Unique Generics Dispensed	NA
	Number of Unique Drug Classes Dispensed	NA
Gynecological Disorders of Interest	Indicator for any of the gynecological disorders listed below (Y/N)	Any
	Uterine Myoma	Any
	Endometrial Hyperplasia	Any
	Endometriosis	Any
	Ovarian Cyst	Any
	Uterine or Cervical Polyp	Any
	Adenomyosis	Any
	Uterine, Ovarian or Cervical Cancer	Any
	Von Willebrand's Disease	Any
Exposure of Interest on Index Date	Novel Oral Anticoagulants (rivaroxaban, dabigatran, apixaban)	NA
	Warfarin	NA
Vaginal Bleeding	Vaginal Bleeding	IP, ED, AV, or OA
Severe Uterine Bleeding	Medical Management Outcome	IP, ED, AV, or OA
	Transfusion Management Outcome	IP, ED, AV, or OA
	Surgical Management Outcome	IP, ED, AV, or OA

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