Disclaimer

The FDA chose a specific outcome algorithm that met its need for a given medical product-outcome assessment. The use of a specific outcome algorithm in a Sentinel assessment should not be interpreted as an endorsement from FDA to use the algorithm for all safety assessments. Investigators should always consider the objective, study design, analytic approach, and data source of a given medical product safety assessment when choosing the outcome algorithm. The suitability of an outcome algorithm may change when applied to different scenarios. For additional information, please Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data guidance document provided by the FDA.

Overview

Title	Severe Uterine Bleed with Surgical Management Algorithm Defined in "Severe Uterine Bleed following Novel Oral Anticoagulants Use: a Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp007, cder_mpl2p_wp018
Description	This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes and algorithms used to define severe uterine bleed with surgical management in this request. For additional information about the algorithm and how it was defined relative to the cohort and exposures of interest in the inferential analysis, see the analysis page here: https://www.sentinelinitiative.org/assessments/drugs/severe-uterine-bleed-following-novel-oral-anticogulants-use-propensity-score
Outcome	Severe uterine bleed with surgical management
Algorithm to Define Outcome	Evidence of an ICD-9-CM diagnosis code used to define vaginal bleed **AND** evidence of a CPT-4, HCPCS, ICD-9-CM procedure or ICD-9-CM diagnosis code used to define surgical management within 60 days of the vaginal bleed diagnosis. Both conditions must occur in non-institutional stay (IS) care settings in any position. The final severe uterine bleed diagnosis date is set to the date of the surgical management.
Query Period	October 19, 2010 - September 30, 2015 (cder_mpl2p_wp007, cder_mpl2p_wp018)
Request Send Date	February 21, 2019 (cder_mpl2p_wp007); December 30, 2019 (cder_mpl2p_wp018)

Glossary

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)

Outcome - outcome of interest (either primary or secondary)

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

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

Request Send Date - date the request was sent to Sentinel Data Partners

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

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

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

Code	Description	Code Type	Code Category
Hysteroscopic Polypectomy			
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C	CPT-4	Procedure
Hysteroscopic/Laparoscopic/Abdominal Myomectomy			
218.0	Submucous leiomyoma of uterus	ICD-9-CM[1]	Diagnosis
218	Uterine leiomyoma	ICD-9-CM[1]	Diagnosis
218.1	Intramural leiomyoma of uterus	ICD-9-CM[1]	Diagnosis
218.2	Subserous leiomyoma of uterus	ICD-9-CM[1]	Diagnosis
218.9	Leiomyoma of uterus, unspecified	ICD-9-CM[1]	Diagnosis
56309	LAP SURG; W/REMOV LEIOMYOMATA (SINGL/MX)	CPT-4	Procedure
56354	HYSTEROSCOPY SURG; W/REMOV LEIOMYOMATA	CPT-4	Procedure
58140	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with	CPT-4	Procedure
58145	Myomectomy, excision of fibroid tumor(s) of uterus, 1 to 4 intramural myoma(s) with	CPT-4	Procedure
58146	Myomectomy, excision of fibroid tumor(s) of uterus, 5 or more intramural myomas	CPT-4	Procedure
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas	CPT-4	Procedure
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g	CPT-4	Procedure
58561	Hysteroscopy, surgical; with removal of leiomyomata	CPT-4	Procedure
58994	Hysteroscopy; With Removal Of Submucous Leiomyomata (any Method)	CPT-4	Procedure
68.19	Other diagnostic procedures on uterus and supporting structures	ICD-9-CM[2]	Procedure
68.29	Other excision or destruction of lesion of uterus	ICD-9-CM[2]	Procedure
69.19	Other excision or destruction of uterus and supporting structures	ICD-9-CM[2]	Procedure
Dilation and Curettage (with or without Hysteroscopy)			
57558	Dilation and curettage of cervical stump	CPT-4	Procedure
57820	Dilation and curettage of cervical stump	CPT-4	Procedure
58120	Dilation and curettage, diagnostic and/or therapeutic (nonobstetrical)	CPT-4	Procedure
69.0	Dilation and curettage of uterus	ICD-9-CM	Procedure
69.09	Other dilation and curettage of uterus	ICD-9-CM	Procedure
69.5	Aspiration curettage of uterus	ICD-9-CM	Procedure
69.59	Other aspiration curettage of uterus	ICD-9-CM	Procedure
Hysteroscopy (Not Listed in Other Surgical Managements)			
00952	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); hysteroscopy and/or hysterosalpingography	CPT-4	Procedure
56352	HYSTEROSCOPY SURG; W/LYSIS INTRAUTERINE ADHESION	CPT-4	Procedure
56353	HYSTEROSCOPY SURG; W/DIVIS/RESECT SEPTUM	CPT-4	Procedure
56355	HYSTEROSCOPY SURG; W/REMOV IMPACTED F B	CPT-4	Procedure
56399	UNLISTED PROC-LAP/HYSTEROSCOPY	CPT-4	Procedure
58559	Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)	CPT-4	Procedure
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)	CPT-4	Procedure
58562	Hysteroscopy, surgical; with removal of impacted foreign body	CPT-4	Procedure
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants	CPT-4	Procedure

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Code	Description	Code Type	Code Category
58992	Hysteroscopy; With Lysis Of Intrauterine Adhesions Or Resection Of Intrauterine Septum (any Method)	CPT-4	Procedure
58995	Hysteroscopy	CPT-4	Procedure
G9823	Endometrial sampling or hysteroscopy with biopsy and results documented	HCPCS	Procedure
G9824	Endometrial sampling or hysteroscopy with biopsy and results not documented	HCPCS	Procedure
S2255	Hysteroscopy, surgical; with occlusion of oviducts bilaterally by micro-inserts for permanent sterilization	HCPCS	Procedure
68.12	Hysteroscopy	ICD-9-CM	Procedure
68.14	Open biopsy of uterine ligaments	ICD-9-CM	Procedure
68.16	Closed biopsy of uterine ligaments	ICD-9-CM	Procedure
Hysterectomy			
68.3	Subtotal abdominal hysterectomy	ICD-9-CM	Diagnosis
68.31	Laparoscopic supracervical hysterectomy [LSH]	ICD-9-CM	Diagnosis
68.39	Other and unspecified subtotal abdominal hysterectomy	ICD-9-CM	Diagnosis
68.4	Total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.41	Laparoscopic total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.49	Other and unspecified total abdominal hysterectomy	ICD-9-CM	Diagnosis
68.5	Vaginal hysterectomy	ICD-9-CM	Diagnosis
68.51	Laparoscopically assisted vaginal hysterectomy (LAVH)	ICD-9-CM	Diagnosis
68.59	Other and unspecified vaginal hysterectomy	ICD-9-CM	Diagnosis
68.6	Radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.61	Laparoscopic radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.69	Other and unspecified radical abdominal hysterectomy	ICD-9-CM	Diagnosis
68.7	Radical vaginal hysterectomy	ICD-9-CM	Diagnosis
68.71	Laparoscopic radical vaginal hysterectomy [LRVH]	ICD-9-CM	Diagnosis
68.79	Other and unspecified radical vaginal hysterectomy	ICD-9-CM	Diagnosis
68.9	Other and unspecified hysterectomy	ICD-9-CM	Diagnosis
618.5	Prolapse of vaginal vault after hysterectomy	ICD-9-CM	Diagnosis
00846	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; radical hysterectomy	CPT-4	Procedure
00855	Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; cesarean hysterectomy	CPT-4	Procedure
00944	Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy	CPT-4	Procedure
01962	Anesthesia for urgent hysterectomy following delivery	CPT-4	Procedure
01963	Anesthesia for cesarean hysterectomy without any labor analgesia/anesthesia care	CPT-4	Procedure
01969	Anesthesia for cesarean hysterectomy following neuraxial labor analgesia/anesthesia (List separately in addition to code for primary procedure performed)	CPT-4	Procedure
51925	closure of vesicouterine fistula; w/hysterectomy	CPT-4	Procedure
58150	tah w/wo removal of tube w/wo removal of ovary;	CPT-4	Procedure
58152	tah; w/wo remv tube-ovry w/colpo-urethrocystopex	CPT-4	Procedure
58180	supracerv abd hysterectomy w/wo remov tube-ovary	CPT-4	Procedure
58200	tah incl part vaginect w/pelv lymph node sampl	CPT-4	Procedure

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Code	Description	Code Type	Code Category
58205	Total Hysterectomy, Extended, Corpus Cancer, Including Partial	CPT-4	Procedure
58210	rad abd hyst w/bilat tot pelvic lymphadenect bx	CPT-4	Procedure
58260	vag hyst 250 gm/<	CPT-4	Procedure
58262	vag hyst 250 gm/< w/rmvl tube&/ovary	CPT-4	Procedure
58263	vag hyst 250 gm/< w/rmvl tube ovary w/rpr ntrcl	CPT-4	Procedure
58265	Vaginal Hysterectomy With Plastic Repair Of Vagina, Anterior	CPT-4	Procedure
58267	vag hyst 250 gm/< w/colpo-urtcstopexy	CPT-4	Procedure
58270	vag hyst 250 gm/< w/rpr ntrcl	CPT-4	Procedure
58275	vag hyst with total or partial vaginectomy;	CPT-4	Procedure
58280	vag hyst w/tot/part vaginectomy; w/repr enterocl	CPT-4	Procedure
58285	vaginal hysterectomy radical	CPT-4	Procedure
58290	vag hyst for uterus greater than 250 grams;	CPT-4	Procedure
58291	vag hyst utrus >250 gms; w/remv tube &/ ovary	CPT-4	Procedure
58292	vag hyst utrus>250 gms; remv t&/o rep enterocl	CPT-4	Procedure
58293	vag hyst utrus > 250 gms; w/colpo-urethrocystProcedurey	CPT-4	Procedure
58294	vag hyst uterus > 250 grams; w/repair enterocele	CPT-4	Procedure
58541	laps supracrv hyst 250 g/<	CPT-4	Procedure
58542	laps supracrv hyst 250 g/< rmvl tube/ovary	CPT-4	Procedure
58543	laps supracrv hyst >250 g	CPT-4	Procedure
58544	laps supracrv hyst >250 g rmvl tube/ovary	CPT-4	Procedure
58548	laps w/rad hyst w/bilat lmphadec rmvl tube/ovary	CPT-4	Procedure
58550	laparscpy surg w/vag hyst uterus 250 gms/less;	CPT-4	Procedure
58552	lap vag hyst utrus 250 gms/<; w/remv tube&/ovry	CPT-4	Procedure
58553	laparscpy surgical w/vag hyst uterus > 250 gms;	CPT-4	Procedure
58554	lap w/vag hyst utrus >250 gms; w/remv tube&/ovry	CPT-4	Procedure
58570	laparoscopy w total hysterectomy uterus 250 g/<	CPT-4	Procedure
58571	laps total hysterectomy 250 g/<w tube/ovary	CPT-4	Procedure
58572	laparoscopy total hysterectomy uterus>250 g	CPT-4	Procedure
58573	laparoscopy tot hysterectomy >250 g w tube/ovary	CPT-4	Procedure
58951	rescj prim prtl mal w/bso&omntc tah&lmphadec	CPT-4	Procedure
58953	bilat s-o w/omentect tah&radl dissect debulking;	CPT-4	Procedure
58954	bil s-o w/omentect tah&radl dbulk; pelv lymphect	CPT-4	Procedure
58956	bil salpingooophorect w/tot omentect tah malig	CPT-4	Procedure
59100	hysterotomy abdominal	CPT-4	Procedure
59135	Surgical treatment of ectopic pregnancy; interstitial, uterine pregnancy requiring total hysterectomy	CPT-4	Procedure
59525	subtotal/total hysterectomy after c-sect deliv	CPT-4	Procedure
59560	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59561	Cesarean Section With Hysterectomy, Subtotal, Including	CPT-4	Procedure
59580	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
59581	Cesarean Section With Hysterectomy, Total, Including	CPT-4	Procedure
S2078	Laparoscopic supracervical hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)	HCPCS	Procedure

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Code	Description	Code Type	Code Category
683	subtotal abdominal hysterectomy	ICD-9-CM	Procedure
684	total abdominal hysterectomy	ICD-9-CM	Procedure
685	vaginal hysterectomy	ICD-9-CM	Procedure
686	radical abdominal hysterectomy	ICD-9-CM	Procedure
687	radical vaginal hysterectomy	ICD-9-CM	Procedure
688	pelvic evisceration	ICD-9-CM	Procedure
689	hysterectomy nos	ICD-9-CM	Procedure
6831	laparoscopic supracervical hysterectomy	ICD-9-CM	Procedure
6839	other and unspecified subtotal abdominal hysterect	ICD-9-CM	Procedure
6841	laparoscopic total abdominal hysterectomy	ICD-9-CM	Procedure
6849	other and unspecified total abdoinal hysterectomy	ICD-9-CM	Procedure
6851	laparoscopically assisted vaginal hysterectomy	ICD-9-CM	Procedure
6859	other and unspecified vaginal hysterectomy	ICD-9-CM	Procedure
6861	laparoscopic radical abdominal hysterectomy	ICD-9-CM	Procedure
6869	other and unspecified radical abdominal hysterecto	ICD-9-CM	Procedure
6871	laparoscopic radical vaginal hysterectomy	ICD-9-CM	Procedure
6879	other and unspecified radical vaginal hysterectomy	ICD-9-CM	Procedure
Endometrial Ablation (Thermal, Cryo, Section)			
0009T	Endometrial cryoablation with ultrasonic guidance	CPT-4 Categc	Procedure
56351	HYSTEROSCOPY SURG; W/SAMPL ENDOMETRIUM W/WO D&C	CPT-4	Procedure
56356	HYSTEROSCOPY SURG; W/ENDOMETRIAL ABLATION	CPT-4	Procedure
58353	Endometrial ablation, thermal, without hysteroscopic guidance	CPT-4	Procedure
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed	CPT-4	Procedure
58558	HYSTEROSCOPY BX ENDOMETRIUM&/POLYPC W/WO D&C	CPT-4	Procedure
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)	CPT-4	Procedure
58996	Hysteroscopy; With Endometrial Ablation (any Method)	CPT-4	Procedure
68.23	Endometrial ablation	ICD-9-CM	Procedure
Uterine Artery Embolization			
37210	Uterine fibroid embolization (UFE, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the procedure	CPT-4	Procedure
S2250	Uterine artery embolization for uterine fibroids	HCPCS	Procedure
68.24	Uterine artery embolization [UAE] with coils	ICD-9-CM	Procedure
68.25	Uterine artery embolization [UAE] without coils	ICD-9-CM	Procedure

[1]Myomectomy diagnosis codes and [2]myomectomy procedure codes are used in combination to detect myomectomy.