



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 refer to the [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 Transfusion Management Algorithm Defined in "Severe Uterine Bleed following Novel Oral Anticoagulants Use: a Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp007
Description	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), Healthcare Common Procedure Coding System (HCPCS), and Revenue Center codes and algorithms used to define severe uterine bleed with transfusion management in this request.</p> <p>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/drugs/assessments/severe-uterine-bleed-following-novel-oral-anticoagulants-use-propensity-score</p>
Outcome	Severe uterine bleed with transfusion management
Algorithm to Define Outcome	Evidence of an ICD-9-CM code used to define vaginal bleed in any non-institutional (IS) care setting in any diagnosis position AND evidence of a HCPCS, ICD-9-CM, or Revenue Center code to define red blood cell transfusion management in any non-IS care setting on the same day as the vaginal bleed diagnosis.
Query Period	October 19, 2010 - September 30, 2015
Request Send Date	February 21, 2019



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



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



Healthcare Common Procedure Coding System (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and Revenue Center Codes Used to Define Transfusion Management in this Request

Red Blood Cell-Only Transfusion

Code	Description	Code Category	Code Type
C1010	Whole blood or red blood cells, leukoreduced, cmv negative, each unit	Procedure	HCPCS
C1016	Whole blood or red blood cells, leukoreduced, frozen, deglycerol, washed, each unit	Procedure	HCPCS
C1020	Each unit red blood cells, frozen/deglycerolized/washed, leukocyte-reduced, irradiated,	Procedure	HCPCS
C1021	Red blood cells, leukocyte-reduced, cmv negative, irradiated, each unit	Procedure	HCPCS
P9016	Red blood cells, leukocytes reduced, each unit	Procedure	HCPCS
P9021	Red blood cells, each unit	Procedure	HCPCS
P9022	Red blood cells, washed, each unit	Procedure	HCPCS
P9038	Red blood cells, irradiated, each unit	Procedure	HCPCS
P9039	Red blood cells, deglycerolized, each unit	Procedure	HCPCS
P9040	Red blood cells, leukocytes reduced, irradiated, each unit	Procedure	HCPCS
P9051	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit	Procedure	HCPCS
P9054	Each unit whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed,	Procedure	HCPCS
P9057	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit	Procedure	HCPCS
P9058	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit	Procedure	HCPCS
9904	Transfusion of packed cells	Procedure	ICD-9-CM
0381	Blood and blood products-packed red cells	Procedure	Revenue Center