

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 Transfusion 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 | <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/assessments/drugs/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 (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 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

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