



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	Venous Thromboembolism Algorithm Defined in "Venous Thromboembolism after Continuous or Extended Cycle Contraceptive Use"
Request ID	cder_mpl2p_wp001_nsdv_v01
Description	<p>This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define venous thromboembolism (VTE) 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 Modular Program reports here: https://www.sentinelinitiative.org/drugs/assessments/venous-thromboembolism-after-continuous-extended-cycle-contraceptive.</p>
Outcome	Venous thromboembolism
Algorithms to Define Outcome	<p>Algorithm A: Evidence of an ICD-9-CM code used to define VTE in the Inpatient care setting in any diagnosis position.</p> <p>Algorithm B: Evidence of an ICD-9-CM code used to define VTE in the Outpatient or Other Ambulatory care setting plus anticoagulant treatment within four weeks following the Outpatient or Other Ambulatory VTE diagnosis.</p> <p>Please see the Modular Program reports to determine which algorithm was used in each comparison.</p>
Query Period	May 22, 2007 - September 30, 2015
Request Send Date	March 28, 2017



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 Edition, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Venous Thromboembolism in this Request

ICD-9-CM Codes	Description
415.1	Pulmonary embolism and infarction
415.1*	Pulmonary embolism and infarction
453	Other venous embolism and thrombosis
453*	Other venous embolism and thrombosis
453**	Other venous embolism and thrombosis

Note: Codes containing "*" indicate wildcards. Wildcards are used to represent a digit 0-9 or a letter A-Z. Wildcards are always indicative of one character. For example, "250*" will always expand into a four-digit code, never a five-digit code, while "250**" will always expand into a five-digit code.



Generic and Brand Names used to Define Anticoagulant Treatment in this Request

Generic Name	Brand Name
APIXABAN	Eliquis
FONDAPARINUX SODIUM	Arixtra
ARGATROBAN	argatroban
DALTEPARIN SODIUM,PORCINE	Fragmin
WARFARIN SODIUM	Coumadin
HEPARIN SODIUM,PORCINE/PF	heparin, porcine (PF)
HEPARIN SODIUM,PORCINE	heparin (porcine)
HEPARIN SODIUM,PORCINE	heparin lock flush (porcine)
HEPARIN SODIUM,PORCINE/DEXTROSE 5 % IN WATER	heparin (porcine) in 5 % dex
ENOXAPARIN SODIUM	Lovenox
WARFARIN SODIUM	warfarin
DESIRUDIN	lprivask
HEPARIN SODIUM,PORCINE IN 0.9 % SODIUM CHLORIDE/PF	heparin (porcine) in NaCl (PF)
HEPARIN SODIUM,PORCINE	Heparin Lock
HEPARIN SODIUM,PORCINE	heparin lock flush
HEPARIN SODIUM,PORCINE IN 0.45 % SODIUM CHLORIDE	heparin(porcine) in 0.45% NaCl
BIVALIRUDIN	bivalirudin
ENOXAPARIN SODIUM	enoxaparin
DABIGATRAN ETEXILATE MESYLATE	Pradaxa
HEPARIN SODIUM,PORCINE/PF	Hep-Lock U/P PF
HEPARIN SODIUM,PORCINE	Hep-Lock Flush
HEPARIN SODIUM,PORCINE	Hep-Lock
ARGATROBAN IN 0.9 % SODIUM CHLORIDE	argatroban in 0.9 % sod chlor
ARGATROBAN IN SODIUM CHLORIDE, ISO-OSMOTIC	argatroban in NaCl (iso-os)
WARFARIN SODIUM	Jantoven
HEPARIN SODIUM,PORCINE/PF	Heparin LockFlush(Porcine)(PF)
HEPARIN SODIUM,PORCINE IN 0.9 % SODIUM CHLORIDE	Heparin Flush
HEPARIN SODIUM,PORCINE IN 0.9 % SODIUM CHLORIDE	heparin flush(porcine)-0.9NaCl
HEPARIN SODIUM,PORCINE/PF	Monoject Prefill Advanced (PF)
HEPARIN SODIUM,PORCINE/PF	Monoject Prefill (PF)
HEPARIN SODIUM,PORCINE/DEXTROSE 5 % IN WATER/PF	heparin (porcine) in D5W (PF)
RIVAROXABAN	Xarelto
HEPARIN SODIUM,PORCINE	heparin (porcine) (bulk)
WARFARIN SODIUM	warfarin (bulk)
TINZAPARIN SODIUM,PORCINE	Innohep
LEPIRUDIN,RECOMBINANT	Refludan
DICUMAROL	dicumarol (bulk)
ANISINDIONE	anisindione (bulk)
PHENINDIONE	phenindione (bulk)
HEPARIN SODIUM,PORCINE IN 0.9 % SODIUM CHLORIDE	heparin (porcine) in 0.9% NaCl
FONDAPARINUX SODIUM	fondaparinux
HEPARIN SODIUM,PORCINE/PF	Hep Flush-10 (PF)
BIVALIRUDIN	Angiomax
EDOXABAN TOSYLATE	Savaysa