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	Intracranial Hemorrhage Algorithm Defined in "PROMPT: Rivaroxaban Surveillance, Intracranial Hemorrhage"
Request ID	riva_mpl2r_wp003_nsdp_v01
Description	This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define intracranial hemorrhage 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 Modular Program report here: https://www.sentinelinitiative.org/drugs/assessments/prompt-rivaroxaban-surveillance.
Outcome	Intracranial hemorrhage
Algorithm to Define Outcome	Evidence of an ICD-9-CM code used to define intracranial hemorrhage as the prinicipal discharge diagnosis in the Inpatient care setting.
Query Period	November 1, 2011 - April 30, 2015
Request Send Date	June 9, 2016

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 Intracranial Hemorrhage in this Request

ICD-9-CM Codes	Description
430	Subarachnoid hemorrhage
431	Intracerebral hemorrhage
432	Other and unspecified intracranial hemorrhage
432*	Other and unspecified intracranial hemorrhage
432**	Other and unspecified intracranial hemorrhage
852.0	Subarachnoid hemorrhage following injury without mention of open intracranial wound
852.0*	Subarachnoid hemorrhage following injury without mention of open intracranial wound
852.2	Subdural hemorrhage following injury without mention of open intracranial wound
852.2*	Subdural hemorrhage following injury without mention of open intracranial wound
852.4	Extradural hemorrhage following injury without mention of open intracranial wound
852.4*	Extradural hemorrhage following injury without mention of open intracranial wound
853.0	Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wound
853.0*	Other and unspecified intracranial hemorrhage following injury without mention of open intracranial wound

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.