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	Gastrointestinal Bleed Algorithm Defined in "PROMPT: Rivaroxaban Surveillance, Gastrointestinal Bleed"
Request ID	riva_mpl2r_wp002_nsdp_v01
Description	This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define gastrointestinal bleed 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	Gastrointestinal bleed
Algorithm to Define Outcome	Evidence of an ICD-9-CM code used to define gastrointestinal bleed as the principal 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

ICD-9-CM Codes	Description
455.2	Internal hemorrhoids with other complication
455.2*	Internal hemorrhoids with other complication
455.5	External hemorrhoids with other complication
455.5*	External hemorrhoids with other complication
455.8	Unspecified hemorrhoids with other complication
455.8*	Unspecified hemorrhoids with other complication
456.0	Esophageal varices with bleeding
456.0*	Esophageal varices with bleeding
456.20	Esophageal varices in diseases classified elsewhere, with bleeding
530.21	Ulcer of esophagus with bleeding
530.7	Gastroesophageal laceration-hemorrhage syndrome
530.7*	Gastroesophageal laceration-hemorrhage syndrome
530.82	Esophageal hemorrhage
531.0	Acute gastric ulcer with hemorrhage
531.0*	Acute gastric ulcer with hemorrhage
531.1	Acute gastric ulcer with perforation
531.1*	Acute gastric ulcer with perforation
531.2	Acute gastric ulcer with hemorrhage and perforation
531.2*	Acute gastric ulcer with hemorrhage and perforation
531.4	Chronic or unspecified gastric ulcer with hemorrhage
531.4*	Chronic or unspecified gastric ulcer with hemorrhage
531.6	Chronic or unspecified gastric ulcer with hemorrhage and perforation
531.6*	Chronic or unspecified gastric ulcer with hemorrhage and perforation
532.0	Acute duodenal ulcer with hemorrhage
532.0*	Acute duodenal ulcer with hemorrhage
532.1	Acute duodenal ulcer with perforation
532.1*	Acute duodenal ulcer with perforation
532.2	Acute duodenal ulcer with hemorrhage and perforation
532.2*	Acute duodenal ulcer with hemorrhage and perforation
532.4	Chronic or unspecified duodenal ulcer with hemorrhage
532.4*	Chronic or unspecified duodenal ulcer with hemorrhage
532.6	Chronic or unspecified duodenal ulcer with hemorrhage and perforation
532.6*	Chronic or unspecified duodenal ulcer with hemorrhage and perforation
533.0	Acute peptic ulcer of unspecified site with hemorrhage
533.0*	Acute peptic ulcer of unspecified site with hemorrhage
533.1	Acute peptic ulcer of unspecified site with perforation
533.1*	Acute peptic ulcer of unspecified site with perforation
533.2	Acute peptic ulcer of unspecified site with hemorrhage and perforation
533.2*	Acute peptic ulcer of unspecified site with hemorrhage and perforation
533.4	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage

ICD-9-CM Codes	Description
533.4*	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage
533.6	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation
533.6*	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation
534.0	Acute gastrojejunal ulcer with hemorrhage
534.0*	Acute gastrojejunal ulcer with hemorrhage
534.1	Acute gastrojejunal ulcer with perforation
534.1*	Acute gastrojejunal ulcer with perforation
534.2	Acute gastrojejunal ulcer with hemorrhage and perforation
534.2*	Acute gastrojejunal ulcer with hemorrhage and perforation
534.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage
534.4*	Chronic or unspecified gastrojejunal ulcer with hemorrhage
534.6	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation
534.6*	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation
535.01	Acute gastritis with hemorrhage
535.11	Atrophic gastritis with hemorrhage
535.21	Gastric mucosal hypertrophy with hemorrhage
535.31	Alcoholic gastritis with hemorrhage
535.41	Other specified gastritis with hemorrhage
535.51	Unspecified gastritis and gastroduodenitis, with hemorrhage
535.61	Duodenitis with hemorrhage
537.83	Angiodysplasia of stomach and duodenum with hemorrhage
537.84	Dieulafoy lesion (hemorrhagic) of stomach and duodenum
562.02	Diverticulosis of small intestine with hemorrhage
562.03	Diverticulitis of small intestine with hemorrhage
562.12	Diverticulosis of colon with hemorrhage
562.13	Diverticulitis of colon with hemorrhage
568.81	Hemoperitoneum (nontraumatic)
569.3	Hemorrhage of rectum and anus
569.3*	Hemorrhage of rectum and anus
569.85	Angiodysplasia of intestine with hemorrhage
569.86	Dieulafoy lesion (hemorrhagic) of intestine
578	Gastrointestinal hemorrhage
578.*	Gastrointestinal hemorrhage
578.**	Gastrointestinal hemorrhage

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.