

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 Bleeding Algorithm Defined in "Thromboembolic Stroke, Intracranial Hemorrhage, Gastrointestinal Bleeding, and Major Extracranial Bleeding following Dabigatran, Rivaroxaban, and Apixaban Use in Patients with Atrial Fibrillation: A Propensity Score Matched Analysis"
Request ID	cder_mpl2p_wp025
Description	<p>This report lists International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) diagnosis codes and algorithms used to define gastrointestinal bleeding 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/thromboembolic-stroke-intracranial-hemorrhage-gastrointestinal-bleeding-and-major</p>
Outcome	Gastrointestinal bleeding
Algorithm to Define Outcome	The gastrointestinal bleeding outcome is defined as either 1) evidence of one ICD-9-CM or ICD-10-CM diagnosis code from Code List 1 that is the primary diagnosis from an inpatient encounter OR 2) one ICD-9-CM or ICD-10-CM code from Code List 2 that is the primary diagnosis from an inpatient encounter AND one code from Code List 1 that is the secondary or unspecified diagnosis from an inpatient encounter on the same day.
Query Period	October 19, 2010 - February 29, 2020
Request Send Date	September 1, 2020

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

Code List 1. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Gastrointestinal Bleeding in this Request

Code	Description	Code Type	Code Category
455.2	Internal hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.5	External hemorrhoids with other complication	ICD-9-CM	Diagnosis
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM	Diagnosis
456	Esophageal varices with bleeding	ICD-9-CM	Diagnosis
456.2	Esophageal varices with bleeding in diseases classified elsewhere	ICD-9-CM	Diagnosis
459	Unspecified hemorrhage	ICD-9-CM	Diagnosis
530.7	Gastroesophageal laceration-hemorrhage syndrome	ICD-9-CM	Diagnosis
530.82	Esophageal hemorrhage	ICD-9-CM	Diagnosis
531	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.2	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
531.4	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
531.6	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM	Diagnosis
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.2	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
532.4	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM	Diagnosis
532.6	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.2	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
533.4	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
533.6	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
534	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.2	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis

Code List 1. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Gastrointestinal Bleeding in this Request

Code	Description	Code Type	Code Category
534.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM	Diagnosis
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM	Diagnosis
534.6	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM	Diagnosis
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM	Diagnosis
535.01	Acute gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.11	Atrophic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.21	Gastric mucosal hypertrophy with hemorrhage	ICD-9-CM	Diagnosis
535.31	Alcoholic gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.41	Other specified gastritis with hemorrhage	ICD-9-CM	Diagnosis
535.51	Unspecified gastritis and gastroduodenitis with hemorrhage	ICD-9-CM	Diagnosis
535.61	Duodenitis with hemorrhage	ICD-9-CM	Diagnosis
537.83	Angiodysplasia of stomach and duodenum with hemorrhage	ICD-9-CM	Diagnosis
562.02	Diverticulosis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.03	Diverticulitis of small intestine with hemorrhage	ICD-9-CM	Diagnosis
562.12	Diverticulosis of colon with hemorrhage	ICD-9-CM	Diagnosis
562.13	Diverticulitis of colon with hemorrhage	ICD-9-CM	Diagnosis
568.81	Hemoperitoneum (nontraumatic)	ICD-9-CM	Diagnosis
569.3	Hemorrhage of rectum and anus	ICD-9-CM	Diagnosis
569.85	Angiodysplasia of intestine with hemorrhage	ICD-9-CM	Diagnosis
578	Hematemesis	ICD-9-CM	Diagnosis
578.1	Blood in stool	ICD-9-CM	Diagnosis
578.9	Hemorrhage of gastrointestinal tract, unspecified	ICD-9-CM	Diagnosis
I85.01	Esophageal varices with bleeding	ICD-10-CM	Diagnosis
I85.11	Secondary esophageal varices with bleeding	ICD-10-CM	Diagnosis
K22.6	Gastro-esophageal laceration-hemorrhage syndrome	ICD-10-CM	Diagnosis
K22.8	Other specified diseases of esophagus	ICD-10-CM	Diagnosis
K25.0	Acute gastric ulcer with hemorrhage	ICD-10-CM	Diagnosis
K25.2	Acute gastric ulcer with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K25.4	Chronic or unspecified gastric ulcer with hemorrhage	ICD-10-CM	Diagnosis
K25.6	Chronic or unspecified gastric ulcer with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K26.0	Acute duodenal ulcer with hemorrhage	ICD-10-CM	Diagnosis
K26.2	Acute duodenal ulcer with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K26.4	Chronic or unspecified duodenal ulcer with hemorrhage	ICD-10-CM	Diagnosis
K26.6	Chronic or unspecified duodenal ulcer with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K27.0	Acute peptic ulcer, site unspecified, with hemorrhage	ICD-10-CM	Diagnosis
K27.2	Acute peptic ulcer, site unspecified, with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K27.4	Chronic or unspecified peptic ulcer, site unspecified, with hemorrhage	ICD-10-CM	Diagnosis
K27.6	Chronic or unspecified peptic ulcer, site unspecified, with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K28.0	Acute gastrojejunal ulcer with hemorrhage	ICD-10-CM	Diagnosis
K28.2	Acute gastrojejunal ulcer with both hemorrhage and perforation	ICD-10-CM	Diagnosis

Code List 1. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Gastrointestinal Bleeding in this Request

Code	Description	Code Type	Code Category
K28.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage	ICD-10-CM	Diagnosis
K28.6	Chronic or unspecified gastrojejunal ulcer with both hemorrhage and perforation	ICD-10-CM	Diagnosis
K29.01	Acute gastritis with bleeding	ICD-10-CM	Diagnosis
K29.21	Alcoholic gastritis with bleeding	ICD-10-CM	Diagnosis
K29.31	Chronic superficial gastritis with bleeding	ICD-10-CM	Diagnosis
K29.41	Chronic atrophic gastritis with bleeding	ICD-10-CM	Diagnosis
K29.51	Unspecified chronic gastritis with bleeding	ICD-10-CM	Diagnosis
K29.61	Other gastritis with bleeding	ICD-10-CM	Diagnosis
K29.71	Gastritis, unspecified, with bleeding	ICD-10-CM	Diagnosis
K29.81	Duodenitis with bleeding	ICD-10-CM	Diagnosis
K29.91	Gastroduodenitis, unspecified, with bleeding	ICD-10-CM	Diagnosis
K31.811	Angiodysplasia of stomach and duodenum with bleeding	ICD-10-CM	Diagnosis
K55.21	Angiodysplasia of colon with hemorrhage	ICD-10-CM	Diagnosis
K56.699	Other intestinal obstruction unspecified as to partial versus complete obstruction	ICD-10-CM	Diagnosis
K57.01	Diverticulitis of small intestine with perforation and abscess with bleeding	ICD-10-CM	Diagnosis
K57.11	Diverticulosis of small intestine without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.13	Diverticulitis of small intestine without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.21	Diverticulitis of large intestine with perforation and abscess with bleeding	ICD-10-CM	Diagnosis
K57.31	Diverticulosis of large intestine without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.33	Diverticulitis of large intestine without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.41	Diverticulitis of both small and large intestine with perforation and abscess with bleeding	ICD-10-CM	Diagnosis
K57.51	Diverticulosis of both small and large intestine without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.53	Diverticulitis of both small and large intestine without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.81	Diverticulitis of intestine, part unspecified, with perforation and abscess with bleeding	ICD-10-CM	Diagnosis
K57.91	Diverticulosis of intestine, part unspecified, without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K57.93	Diverticulitis of intestine, part unspecified, without perforation or abscess with bleeding	ICD-10-CM	Diagnosis
K62.5	Hemorrhage of anus and rectum	ICD-10-CM	Diagnosis
K64.0	First degree hemorrhoids	ICD-10-CM	Diagnosis
K64.1	Second degree hemorrhoids	ICD-10-CM	Diagnosis
K64.2	Third degree hemorrhoids	ICD-10-CM	Diagnosis
K64.3	Fourth degree hemorrhoids	ICD-10-CM	Diagnosis
K64.4	Residual hemorrhoidal skin tags	ICD-10-CM	Diagnosis
K64.8	Other hemorrhoids	ICD-10-CM	Diagnosis
K66.1	Hemoperitoneum	ICD-10-CM	Diagnosis
K92.0	Hematemesis	ICD-10-CM	Diagnosis
K92.1	Melena	ICD-10-CM	Diagnosis
K92.2	Gastrointestinal hemorrhage, unspecified	ICD-10-CM	Diagnosis
R58	Hemorrhage, not elsewhere classified	ICD-10-CM	Diagnosis

Code List 2. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Gastrointestinal Bleeding in this Request

Code	Description	Code Type	Code Category
455.0	Internal hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.1	Internal thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.3	External hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.4	External thrombosed hemorrhoids	ICD-9-CM	Diagnosis
455.6	Unspecified hemorrhoids without mention of complication	ICD-9-CM	Diagnosis
455.7	Unspecified thrombosed hemorrhoids	ICD-9-CM	Diagnosis
531.1	Acute gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.3	Acute gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.5	Chronic or unspecified gastric ulcer with perforation	ICD-9-CM	Diagnosis
531.7	Chronic gastric ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
531.9	Gastric ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.1	Acute duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.3	Acute duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.5	Chronic or unspecified duodenal ulcer with perforation	ICD-9-CM	Diagnosis
532.7	Chronic duodenal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
532.9	Duodenal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.1	Acute peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.3	Acute peptic ulcer, unspecified site, without mention of hemorrhage and perforation	ICD-9-CM	Diagnosis
533.5	Chronic or unspecified peptic ulcer, unspecified site, with perforation	ICD-9-CM	Diagnosis
533.7	Chronic peptic ulcer, unspecified site, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
533.9	Peptic ulcer, unspecified site, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.1	Acute gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.3	Acute gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.5	Chronic or unspecified gastrojejunal ulcer with perforation	ICD-9-CM	Diagnosis
534.7	Chronic gastrojejunal ulcer without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
534.9	Gastrojejunal ulcer, unspecified as acute or chronic, without mention of hemorrhage or perforation	ICD-9-CM	Diagnosis
535.00	Acute gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.10	Atrophic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.20	Gastric mucosal hypertrophy without mention of hemorrhage	ICD-9-CM	Diagnosis
535.30	Alcoholic gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.40	Other specified gastritis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.50	Unspecified gastritis and gastroduodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
535.60	Duodenitis without mention of hemorrhage	ICD-9-CM	Diagnosis
562.00	Diverticulosis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.01	Diverticulitis of small intestine (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.10	Diverticulosis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
562.11	Diverticulitis of colon (without mention of hemorrhage)	ICD-9-CM	Diagnosis
530.1	Esophagitis	ICD-9-CM	Diagnosis
K29.00	Acute gastritis without bleeding	ICD-10-CM	Diagnosis
K29.20	Alcoholic gastritis without bleeding	ICD-10-CM	Diagnosis

Code List 2. List of International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Gastrointestinal Bleeding in this Request

Code	Description	Code Type	Code Category
K29.30	Chronic superficial gastritis without bleeding	ICD-10-CM	Diagnosis
K29.40	Chronic atrophic gastritis without bleeding	ICD-10-CM	Diagnosis
K29.50	Unspecified chronic gastritis without bleeding	ICD-10-CM	Diagnosis
K29.60	Other gastritis without bleeding	ICD-10-CM	Diagnosis
K29.70	Gastritis, unspecified, without bleeding	ICD-10-CM	Diagnosis
K29.80	Duodenitis without bleeding	ICD-10-CM	Diagnosis
K29.90	Gastroduodenitis, unspecified, without bleeding	ICD-10-CM	Diagnosis
K57.00	Diverticulitis of small intestine with perforation and abscess without bleeding	ICD-10-CM	Diagnosis
K57.10	Diverticulosis of small intestine without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.12	Diverticulitis of small intestine without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.20	Diverticulitis of large intestine with perforation and abscess without bleeding	ICD-10-CM	Diagnosis
K57.30	Diverticulosis of large intestine without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.32	Diverticulitis of large intestine without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.40	Diverticulitis of both small and large intestine with perforation and abscess without bleeding	ICD-10-CM	Diagnosis
K57.50	Diverticulosis of both small and large intestine without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.52	Diverticulitis of both small and large intestine without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.80	Diverticulitis of intestine, part unspecified, with perforation and abscess without bleeding	ICD-10-CM	Diagnosis
K57.90	Diverticulosis of intestine, part unspecified, without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K57.92	Diverticulitis of intestine, part unspecified, without perforation or abscess without bleeding	ICD-10-CM	Diagnosis
K64.0	First degree hemorrhoids	ICD-10-CM	Diagnosis
K64.1	Second degree hemorrhoids	ICD-10-CM	Diagnosis
K64.2	Third degree hemorrhoids	ICD-10-CM	Diagnosis
K64.3	Fourth degree hemorrhoids	ICD-10-CM	Diagnosis
K64.4	Residual hemorrhoidal skin tags	ICD-10-CM	Diagnosis
K64.5	Perianal venous thrombosis	ICD-10-CM	Diagnosis
K64.8	Other hemorrhoids	ICD-10-CM	Diagnosis
K64.9	Unspecified hemorrhoids	ICD-10-CM	Diagnosis