



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 "Risk of Stroke, Gastrointestinal Bleeding, and Intracranial Hemorrhage Following Apixaban or Warfarin Use in Patients with Non-Valvular Atrial Fibrillation"
Request ID	cder_mpl2p_wp009_nsdp_v01
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 bleed 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/drugs/assessments/risk-stroke-gastrointestinal-bleeding-and-intracranial-hemorrhage-following.</p>
Outcome	Gastrointestinal bleed
Algorithm to Define Outcome	Evidence of an ICD-9-CM or ICD-10-CM code used to define gastrointestinal bleed as the principal diagnosis in the Inpatient care setting from Code List 1 OR evidence of an ICD-9-CM or ICD-10-CM code used to define gastrointestinal bleed in the secondary or unspecified diagnosis position in the Inpatient care setting from Code List 1 AND evidence of an ICD-9-CM or ICD-10-CM code used to define gastrointestinal bleed as the principal diagnosis in the Inpatient care setting from Code List 2.
Query Period	December 28, 2012 - January 22, 2019
Request Send Date	January 22, 2019



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: International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM) Diagnosis Codes Used to Define Gastrointestinal Bleed in this Request

Codes	Description	Code Type
455.2	Internal hemorrhoids with other complication	ICD-9-CM
455.5	External hemorrhoids with other complication	ICD-9-CM
455.8	Unspecified hemorrhoids with other complication	ICD-9-CM
456.0	Esophageal varices with bleeding	ICD-9-CM
456.20	Esophageal varices with bleeding in diseases classified elsewhere	ICD-9-CM
459.0	Unspecified hemorrhage	ICD-9-CM
530.7	Gastroesophageal laceration-hemorrhage syndrome	ICD-9-CM
530.82	Esophageal hemorrhage	ICD-9-CM
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
531.01	Acute gastric ulcer with hemorrhage and obstruction	ICD-9-CM
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction	ICD-9-CM
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation	ICD-9-CM
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
532.01	Acute duodenal ulcer with hemorrhage and obstruction	ICD-9-CM
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction	ICD-9-CM
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction	ICD-9-CM
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction	ICD-9-CM
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction	ICD-9-CM
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction	ICD-9-CM
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction	ICD-9-CM
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction	ICD-9-CM
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction	ICD-9-CM
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction	ICD-9-CM
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction	ICD-9-CM

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

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



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

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

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