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 "Testing Routine Querying Tools with Known Positive Exposure-Outcome Associations: Gastrointestinal (GI) Bleeding Following New Use of Warfarin Compared with Statins"
Request ID	to16_cap_mpl2r_wp008_nsdp_v02
Description	This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define gastrointestinal bleeding 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/sentinel/methods/gastrointestinal-gi-bleeding-following-new-use-of-warfarin-compared-with-statins.
Outcome	Gastrointestinal bleeding
Algorithm to Define Outcome	Evidence of an ICD-9-CM code used to define gastrointestinal bleeding as the principal diagnosis in the Inpatient care setting.
Query Period	January 1, 2012 - September 30, 2015
Request Send Date	July 12, 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 Gastrointestinal Bleeding in this Request

ICD-9-CM Codes	Description
455.2	Internal hemorrhoids with other complication
455.5	External hemorrhoids with other complication
455.8	Unspecified hemorrhoids with other complication
456.0	Esophageal varices with bleeding
456.20	Esophageal varices with bleeding in diseases classified elsewhere
530.21	Ulcer of esophagus with bleeding
530.7	Gastroesophageal laceration-hemorrhage syndrome
530.82	Esophageal hemorrhage
531.00	Acute gastric ulcer with hemorrhage, without mention of obstruction
531.0	Acute gastric ulcer with hemorrhage
531.01	Acute gastric ulcer with hemorrhage and obstruction
531.10	Acute gastric ulcer with perforation, without mention of obstruction
531.1	Acute gastric ulcer with perforation
531.11	Acute gastric ulcer with perforation and obstruction
531.20	Acute gastric ulcer with hemorrhage and perforation, without mention of obstruction
531.2	Acute gastric ulcer with hemorrhage and perforation
531.21	Acute gastric ulcer with hemorrhage, perforation, and obstruction
531.40	Chronic or unspecified gastric ulcer with hemorrhage, without mention of obstruction
531.4	Chronic or unspecified gastric ulcer with hemorrhage
531.41	Chronic or unspecified gastric ulcer with hemorrhage and obstruction
531.60	Chronic or unspecified gastric ulcer with hemorrhage and perforation, without mention of obstruction
531.6	Chronic or unspecified gastric ulcer with hemorrhage and perforation
531.61	Chronic or unspecified gastric ulcer with hemorrhage, perforation, and obstruction
532.00	Acute duodenal ulcer with hemorrhage, without mention of obstruction
532.0	Acute duodenal ulcer with hemorrhage
532.01	Acute duodenal ulcer with hemorrhage and obstruction
532.10	Acute duodenal ulcer with perforation, without mention of obstruction
532.1	Acute duodenal ulcer with perforation
532.11	Acute duodenal ulcer with perforation and obstruction
532.20	Acute duodenal ulcer with hemorrhage and perforation, without mention of obstruction
532.2	Acute duodenal ulcer with hemorrhage and perforation
532.21	Acute duodenal ulcer with hemorrhage, perforation, and obstruction
532.40	Duodenal ulcer, chronic or unspecified, with hemorrhage, without mention of obstruction
532.4	Chronic or unspecified duodenal ulcer with hemorrhage
532.41	Chronic or unspecified duodenal ulcer with hemorrhage and obstruction
532.60	Chronic or unspecified duodenal ulcer with hemorrhage and perforation, without mention of obstruction
532.6	Chronic or unspecified duodenal ulcer with hemorrhage and perforation
532.61	Chronic or unspecified duodenal ulcer with hemorrhage, perforation, and obstruction

ICD-9-CM Codes	Description
533.00	Acute peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction
533.0	Acute peptic ulcer, unspecified site, with hemorrhage
533.01	Acute peptic ulcer, unspecified site, with hemorrhage and obstruction
533.10	Acute peptic ulcer, unspecified site, with perforation, without mention of obstruction
533.1	Acute peptic ulcer, unspecified site, with perforation
533.11	Acute peptic ulcer, unspecified site, with perforation and obstruction
533.20	Acute peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction
533.2	Acute peptic ulcer, unspecified site, with hemorrhage and perforation
533.21	Acute peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction
533.40	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, without mention of obstruction
533.4	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage
533.41	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and obstruction
533.60	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation, without mention of obstruction
533.6	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage and perforation
533.61	Chronic or unspecified peptic ulcer, unspecified site, with hemorrhage, perforation, and obstruction
534.00	Acute gastrojejunal ulcer with hemorrhage, without mention of obstruction
534.0	Acute gastrojejunal ulcer with hemorrhage
534.01	Acute gastrojejunal ulcer, with hemorrhage and obstruction
534.10	Acute gastrojejunal ulcer with perforation, without mention of obstruction
534.1	Acute gastrojejunal ulcer with perforation
534.11	Acute gastrojejunal ulcer with perforation and obstruction
534.20	Acute gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction
534.2	Acute gastrojejunal ulcer with hemorrhage and perforation
534.21	Acute gastrojejunal ulcer with hemorrhage, perforation, and obstruction
534.40	Chronic or unspecified gastrojejunal ulcer with hemorrhage, without mention of obstruction
534.4	Chronic or unspecified gastrojejunal ulcer with hemorrhage
534.41	Chronic or unspecified gastrojejunal ulcer, with hemorrhage and obstruction
534.60	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation, without mention of obstruction
534.6	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation
534.61	Chronic or unspecified gastrojejunal ulcer with hemorrhage, perforation, and obstruction
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

ICD-9-CM Codes	Description
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
569.85	Angiodysplasia of intestine with hemorrhage
569.86	Dieulafoy lesion (hemorrhagic) of intestine
578.0	Hematemesis
578	Gastrointestinal hemorrhage
578.1	Blood in stool
578.9	Hemorrhage of gastrointestinal tract, unspecified