



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	Hypoglycemia Algorithm Defined in "Testing Routine Querying Tools with Known Positive Exposure-Outcome Associations: Hypoglycemia Events After Use of Glyburide versus Glipizide"
Request ID	to16_cap_mpl2r_wp001
Description	<p>This report lists International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM) diagnosis codes and algorithms used to define hypoglycemia 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 Modular Program report here: https://www.sentinelinitiative.org/sentinel/methods/testing-routine-querying-tools-known-positive-exposure-outcome-associations.</p>
Outcome	Severe hypoglycemia
Algorithms to Define Outcome	<p>Algorithm A: Evidence of an ICD-9-CM code used to define hypoglycemia in the Emergency Department care setting or in the Inpatient care setting in the principal diagnosis position, or an ICD-9-CM code to define diabetes with other specified manifestations in the Emergency Department care setting or in the Inpatient care setting in the principal diagnosis position without an ICD-9-CM to define a co-diagnosis of secondary diabetic glycosuria, diabetic lipodystrophy, cellulitis, ulcers of the lower extremity, Oppenheim-Urbach syndrome, or osteomyelitis present during the same visit.</p> <p>Algorithm B: Evidence of an ICD-9-CM code used to define hypoglycemia in the Emergency Department care setting, or an ICD-9-CM code to define diabetes with other specified manifestations in the Emergency Department care setting without an ICD-9-CM to define a co-diagnosis of secondary diabetic glycosuria, diabetic lipodystrophy, cellulitis, ulcers of the lower extremity, Oppenheim-Urbach syndrome, or osteomyelitis present during the same visit. This algorithm is adapted from the validated algorithm proposed by Ginde et al¹.</p> <p>Please see the Modular Program reports to determine which algorithm was used in each comparison.</p>
Query Period	January 1, 2008 - September 30, 2014
Request Send Date	February 24, 2015

¹Ginde, A. A., et al. (2008). "Validation of ICD-9-CM coding algorithm for improved identification of hypoglycemia visits." BMC Endocrine Disorders 8(1): 4.



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)

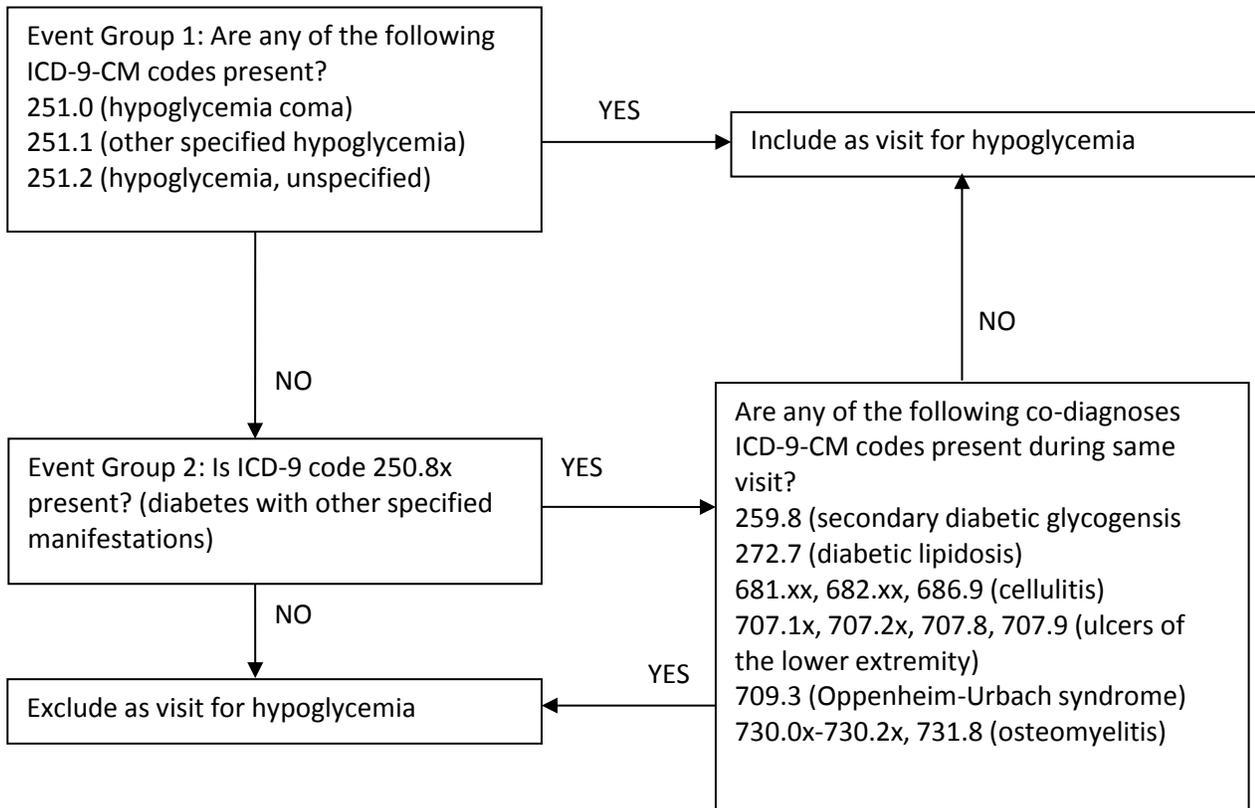
Outcome - outcome of interest (either primary or secondary)

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 and Algorithm Used to Define Hypoglycemia in this Request



Note 1: Event care setting and diagnosis position is restricted for both Event Groups 1 and 2:

Primary Outcome of Interest: Any diagnosis position for Emergency Department care setting or principal diagnosis position for Inpatient care setting

Secondary Outcome of Interest: Any diagnosis position for Emergency Department care setting

Note 2: Exact code matches are to be used unless followed by an “x.” Use “starts with” when an “x” is used to include all subcodes.