

## 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

<b>Title</b>	Diabetic Ketoacidosis Algorithm Defined in "Rates of Diabetic Ketoacidosis (DKA) by Chronic Kidney Disease (CKD) Stage Among Patients with Type 1 Diabetes Mellitus (T1DM): A Propensity Score Matched Analysis"
<b>Request ID</b>	cder_mpl2p_wp060
<b>Description</b>	<p>This report lists International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes and algorithms used to define diabetic ketoacidosis in this request.</p> <p>For additional information about the algorithm and how it was defined relative to the cohort and exposure(s) of interest in the analysis, refer to the analysis webpage here: <a href="https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/rates-diabetic-ketoacidosis-dka-chronic-kidney-disease-ckd">https://www.sentinelinitiative.org/studies/drugs/individual-drug-analyses/rates-diabetic-ketoacidosis-dka-chronic-kidney-disease-ckd</a></p>
<b>Outcome</b>	Diabetic ketoacidosis
<b>Algorithm to Define Outcome</b>	The diabetic ketoacidosis outcome is defined as an ICD-9-CM or ICD-10-CM diagnosis code for diabetic ketoacidosis in the inpatient or emergency department care settings.
<b>Query Period</b>	March 1, 2013 - February 29, 2024
<b>Request Send Date</b>	November 21, 2024

## 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

**List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Diabetic Ketoacidosis in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E13.10	Other specified diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E13.11	Other specified diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM