

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 [Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data](#) guidance document provided by the FDA.

Overview

Title	Nasal Septal Perforation Defined in "Glaucoma, Cataracts, Diminished Visual Acuity, and Nasal Septal Perforation following Mometasone Sinus Implant Use in Patients with Nasal Polyposis: A Descriptive Analysis"
Request ID	cder_mpl1r_wp157, cder_mpl1r_wp172, cder_mpl1r_wp176
Description	<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), and Current Procedural Terminology, Fourth Edition (CPT-4) diagnosis and procedure codes and algorithms used to define nasal septal perforation 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 descriptive analysis, see the analysis page here: https://www.sentinelinitiative.org/assessments/drugs/adverse-ocular-events-nasal-septal-perforation-mometasone-sinus-implant</p>
Outcome	Nasal Septal Perforation
Algorithm to Define Outcome	<p>Definition 1: Evidence of an ICD-9-CM or ICD-10-CM diagnosis code used to define nasal septal perforation AND evidence of a CPT-4 procedure code for nasal septal perforation repair within 90 days of the nasal septal perforation diagnosis. Both conditions may occur in any care setting. The final nasal septal perforation outcome date is set to the date of the diagnosis code.</p> <p>Definition 2: Evidence of an ICD-9-CM or ICD-10-CM diagnosis code used to define nasal septal perforation AND evidence of a CPT-4 procedure code for nasal septal perforation repair within 180 days of the nasal septal perforation diagnosis. Both conditions may occur in any care setting. The final nasal septal perforation outcome date is set to the date of the diagnosis code.</p>
Query Period	January 1, 2016 - April 30, 2019 (cder_mpl1r_wp157); January 1, 2016 - September 30, 2019 (cder_mpl1r_wp172, cder_mpl1r_wp176)
Request Send Date	November 12, 2019 (cder_mpl1r_wp157); March 12, 2020 (cder_mpl1r_wp172, cder_mpl1r_wp176)

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), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Nasal Septal Perforation in this Request

Code	Description	Code Type	Code Category
478.19	Other diseases of nasal cavity and sinuses	ICD-9-CM	Diagnosis
748.1	Other congenital anomaly of nose	ICD-9-CM	Diagnosis
Q30.3	Congenital perforated nasal septum	ICD-10-CM	Diagnosis
J34.89	Other specified disorders of nose and nasal sinuses	ICD-10-CM	Diagnosis
30630	Repair nasal septal perforations	CPT-4	Procedure