

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	Nasal Septal Perforation Algorithm Defined in "Cataracts, Glaucoma, Ocular Hypertension, Diminished Visual Acuity, and Nasal Septal Perforation Following Sinuva and Propel (Mometasone Furoate Sinus Implants) Use: A Descriptive Analysis"
Request ID	cder_mpl1r_wp259
Description	<p>This report lists Current Procedural Terminology, Fourth Edition (CPT-4) and Healthcare Common Procedure Coding System, Level II (HCPCS) 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 exposure(s) of interest in the analysis, refer to the analysis webpage here: https://sentinelinitiative.org/studies/drugs/individual-drug-analyses/cataracts-glaucoma-ocular-hypertension-diminished-visual</p>
Outcome	Nasal septal perforation
Algorithm to Define Outcome	The nasal septal perforation outcome is defined as the presence of a CPT-4 or HCPCS procedure code in any care setting over the specified follow-up time (one year for the primary and sensitivity analyses as well as two years for the secondary analysis).
Query Period	December 1, 2017 – January 31, 2024
Request Send Date	July 22, 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

Code List 1. List of Current Procedural Terminology, Fourth Edition (CPT-4) and Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Nasal Septal Perforation in this Request

Code	Description	Code Category	Code Type
30220	Insertion Nasal Septal Prosthesis Button	Procedure	CPT-4
30630	Repair nasal septal perforations	Procedure	CPT-4
L8047	Nasal Septal Prosthesis	Procedure	HCPCS