

## **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	Diminished Visual Acuity 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	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) diagnosis codes and algorithms used to define diminished visual acuity in this request.  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		
Outcome	Diminished Visual Acuity		
Algorithm to Define Outcome	Evidence of an ICD-9-CM or ICD-10-CM diagnosis code used to define diminished visual acuity, in any care setting.		
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 Modication (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Diminished Visual Acuity in this Request

Code	Description	Code Type	Code Category
368	Visual disturbances	ICD-9-CM	Diagnosis
368.11	Sudden visual loss	ICD-9-CM	Diagnosis
368.12	Transient visual loss	ICD-9-CM	Diagnosis
368.8	Other specified visual disturbances	ICD-9-CM	Diagnosis
368.9	Unspecified visual disturbance	ICD-9-CM	Diagnosis
H53.041	Amblyopia suspect, right eye	ICD-10-CM	Diagnosis
H53.042	Amblyopia suspect, left eye	ICD-10-CM	Diagnosis
153.043	Amblyopia suspect, bilateral	ICD-10-CM	Diagnosis
<del>1</del> 53.049	Amblyopia suspect, unspecified eye	ICD-10-CM	Diagnosis
H53.121	Transient visual loss, right eye	ICD-10-CM	Diagnosis
H53.122	Transient visual loss, left eye	ICD-10-CM	Diagnosis
H53.123	Transient visual loss, bilateral	ICD-10-CM	Diagnosis
H53.129	Transient visual loss, unspecified eye	ICD-10-CM	Diagnosis
H53.131	Sudden visual loss, right eye	ICD-10-CM	Diagnosis
H53.132	Sudden visual loss, left eye	ICD-10-CM	Diagnosis
H53.133	Sudden visual loss, bilateral	ICD-10-CM	Diagnosis
H53.139	Sudden visual loss, unspecified eye	ICD-10-CM	Diagnosis
H53.71	Glare sensitivity	ICD-10-CM	Diagnosis
153.72	Impaired contrast sensitivity	ICD-10-CM	Diagnosis
153.8	Other visual disturbances	ICD-10-CM	Diagnosis
153.9	Unspecified visual disturbance	ICD-10-CM	Diagnosis