

## 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>	Diminished Visual Acuity 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"
<b>Request ID</b>	cder_mpl1r_wp259
<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 diminished visual acuity 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://sentinelinitiative.org/studies/drugs/individual-drug-analyses/cataracts-glaucoma-ocular-hypertension-diminished-visual">https://sentinelinitiative.org/studies/drugs/individual-drug-analyses/cataracts-glaucoma-ocular-hypertension-diminished-visual</a></p>
<b>Outcome</b>	Diminished visual acuity
<b>Algorithm to Define Outcome</b>	The diminished visual acuity outcome is defined as the presence of an ICD-9-CM or ICD-10-CM diagnosis 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).
<b>Query Period</b>	December 1, 2017 – January 31, 2024
<b>Request Send Date</b>	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 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 Diminished Visual Acuity in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
368.1	Subjective visual disturbances	Diagnosis	ICD-9-CM
368.10	Unspecified subjective visual disturbance	Diagnosis	ICD-9-CM
368.11	Sudden visual loss	Diagnosis	ICD-9-CM
368.12	Transient visual loss	Diagnosis	ICD-9-CM
368.13	Visual discomfort	Diagnosis	ICD-9-CM
368.14	Visual distortions of shape and size	Diagnosis	ICD-9-CM
368.15	Other visual distortions and entoptic phenomena	Diagnosis	ICD-9-CM
368.2	Diplopia	Diagnosis	ICD-9-CM
368.3	Other disorders of binocular vision	Diagnosis	ICD-9-CM
368.30	Unspecified binocular vision disorder	Diagnosis	ICD-9-CM
368.31	Suppression of binocular vision	Diagnosis	ICD-9-CM
368.32	Simultaneous visual perception without fusion	Diagnosis	ICD-9-CM
368.33	Fusion with defective stereopsis	Diagnosis	ICD-9-CM
368.34	Abnormal retinal correspondence	Diagnosis	ICD-9-CM
368.4	Visual field defects	Diagnosis	ICD-9-CM
368.40	Unspecified visual field defect	Diagnosis	ICD-9-CM
368.41	Scotoma involving central area in visual field	Diagnosis	ICD-9-CM
368.42	Scotoma of blind spot area in visual field	Diagnosis	ICD-9-CM
368.43	Sector or arcuate defects in visual field	Diagnosis	ICD-9-CM
368.44	Other localized visual field defect	Diagnosis	ICD-9-CM
368.45	Generalized contraction or constriction in visual field	Diagnosis	ICD-9-CM
368.46	Homonymous bilateral field defects in visual field	Diagnosis	ICD-9-CM
368.47	Heteronymous bilateral field defects in visual field	Diagnosis	ICD-9-CM
368.5	Color vision deficiencies	Diagnosis	ICD-9-CM
368.51	Protan defect in color vision	Diagnosis	ICD-9-CM
368.52	Deutan defect in color vision	Diagnosis	ICD-9-CM
368.53	Tritan defect in color vision	Diagnosis	ICD-9-CM
368.55	Acquired color vision deficiencies	Diagnosis	ICD-9-CM
368.59	Other color vision deficiencies	Diagnosis	ICD-9-CM
368.6	Night blindness	Diagnosis	ICD-9-CM
368.60	Unspecified night blindness	Diagnosis	ICD-9-CM
368.62	Acquired night blindness	Diagnosis	ICD-9-CM
368.63	Abnormal dark adaptation curve	Diagnosis	ICD-9-CM
368.69	Other night blindness	Diagnosis	ICD-9-CM
368.8	Other specified visual disturbances	Diagnosis	ICD-9-CM
368.9	Unspecified visual disturbance	Diagnosis	ICD-9-CM
H53.10	Unspecified subjective visual disturbances	Diagnosis	ICD-10-CM
H53.11	Day blindness	Diagnosis	ICD-10-CM
H53.121	Transient visual loss, right eye	Diagnosis	ICD-10-CM
H53.122	Transient visual loss, left eye	Diagnosis	ICD-10-CM
H53.123	Transient visual loss, bilateral	Diagnosis	ICD-10-CM

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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
H53.129	Transient visual loss, unspecified eye	Diagnosis	ICD-10-CM
H53.131	Sudden visual loss, right eye	Diagnosis	ICD-10-CM
H53.132	Sudden visual loss, left eye	Diagnosis	ICD-10-CM
H53.133	Sudden visual loss, bilateral	Diagnosis	ICD-10-CM
H53.139	Sudden visual loss, unspecified eye	Diagnosis	ICD-10-CM
H53.141	Visual discomfort, right eye	Diagnosis	ICD-10-CM
H53.142	Visual discomfort, left eye	Diagnosis	ICD-10-CM
H53.143	Visual discomfort, bilateral	Diagnosis	ICD-10-CM
H53.149	Visual discomfort, unspecified	Diagnosis	ICD-10-CM
H53.15	Visual distortions of shape and size	Diagnosis	ICD-10-CM
H53.19	Other subjective visual disturbances	Diagnosis	ICD-10-CM
H53.2	Diplopia	Diagnosis	ICD-10-CM
H53.30	Unspecified disorder of binocular vision	Diagnosis	ICD-10-CM
H53.31	Abnormal retinal correspondence	Diagnosis	ICD-10-CM
H53.32	Fusion with defective stereopsis	Diagnosis	ICD-10-CM
H53.33	Simultaneous visual perception without fusion	Diagnosis	ICD-10-CM
H53.34	Suppression of binocular vision	Diagnosis	ICD-10-CM
H53.40	Unspecified visual field defects	Diagnosis	ICD-10-CM
H53.411	Scotoma involving central area, right eye	Diagnosis	ICD-10-CM
H53.412	Scotoma involving central area, left eye	Diagnosis	ICD-10-CM
H53.413	Scotoma involving central area, bilateral	Diagnosis	ICD-10-CM
H53.419	Scotoma involving central area, unspecified eye	Diagnosis	ICD-10-CM
H53.421	Scotoma of blind spot area, right eye	Diagnosis	ICD-10-CM
H53.422	Scotoma of blind spot area, left eye	Diagnosis	ICD-10-CM
H53.423	Scotoma of blind spot area, bilateral	Diagnosis	ICD-10-CM
H53.429	Scotoma of blind spot area, unspecified eye	Diagnosis	ICD-10-CM
H53.431	Sector or arcuate defects, right eye	Diagnosis	ICD-10-CM
H53.432	Sector or arcuate defects, left eye	Diagnosis	ICD-10-CM
H53.433	Sector or arcuate defects, bilateral	Diagnosis	ICD-10-CM
H53.439	Sector or arcuate defects, unspecified eye	Diagnosis	ICD-10-CM
H53.451	Other localized visual field defect, right eye	Diagnosis	ICD-10-CM
H53.452	Other localized visual field defect, left eye	Diagnosis	ICD-10-CM
H53.453	Other localized visual field defect, bilateral	Diagnosis	ICD-10-CM
H53.459	Other localized visual field defect, unspecified eye	Diagnosis	ICD-10-CM
H53.461	Homonymous bilateral field defects, right side	Diagnosis	ICD-10-CM
H53.462	Homonymous bilateral field defects, left side	Diagnosis	ICD-10-CM
H53.469	Homonymous bilateral field defects, unspecified side	Diagnosis	ICD-10-CM
H53.47	Heteronymous bilateral field defects	Diagnosis	ICD-10-CM
H53.481	Generalized contraction of visual field, right eye	Diagnosis	ICD-10-CM
H53.482	Generalized contraction of visual field, left eye	Diagnosis	ICD-10-CM
H53.483	Generalized contraction of visual field, bilateral	Diagnosis	ICD-10-CM

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<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
H53.489	Generalized contraction of visual field, unspecified eye	Diagnosis	ICD-10-CM
H53.50	Unspecified color vision deficiencies	Diagnosis	ICD-10-CM
H53.52	Acquired color vision deficiency	Diagnosis	ICD-10-CM
H53.53	Deuteranomaly	Diagnosis	ICD-10-CM
H53.54	Protanomaly	Diagnosis	ICD-10-CM
H53.55	Tritanomaly	Diagnosis	ICD-10-CM
H53.59	Other color vision deficiencies	Diagnosis	ICD-10-CM
H53.60	Unspecified night blindness	Diagnosis	ICD-10-CM
H53.61	Abnormal dark adaptation curve	Diagnosis	ICD-10-CM
H53.62	Acquired night blindness	Diagnosis	ICD-10-CM
H53.69	Other night blindness	Diagnosis	ICD-10-CM
H53.71	Glare sensitivity	Diagnosis	ICD-10-CM
H53.72	Impaired contrast sensitivity	Diagnosis	ICD-10-CM
H53.8	Other visual disturbances	Diagnosis	ICD-10-CM
H53.9	Unspecified visual disturbance	Diagnosis	ICD-10-CM
R44.1	Visual hallucinations	Diagnosis	ICD-10-CM