

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	Ocular Hypertension 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 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 ocular hypertension 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	Ocular hypertension
Algorithm to Define Outcome	The ocular hypertension 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).
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 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 Ocular Hypertension in this Request

Code	Description	Code Category	Code Type
365.0	Borderline glaucoma (glaucoma suspect)	Diagnosis	ICD-9-CM
365.00	Unspecified preglaucoma	Diagnosis	ICD-9-CM
365.01	Borderline glaucoma, open angle with borderline findings, low risk	Diagnosis	ICD-9-CM
365.02	Borderline glaucoma with anatomical narrow angle	Diagnosis	ICD-9-CM
365.03	Borderline glaucoma with steroid responders	Diagnosis	ICD-9-CM
365.04	Borderline glaucoma with ocular hypertension	Diagnosis	ICD-9-CM
365.05	Open angle with borderline findings, high risk	Diagnosis	ICD-9-CM
H40.00	Preglaucoma, unspecified	Diagnosis	ICD-10-CM
H40.001	Preglaucoma, unspecified, right eye	Diagnosis	ICD-10-CM
H40.002	Preglaucoma, unspecified, left eye	Diagnosis	ICD-10-CM
H40.003	Preglaucoma, unspecified, bilateral	Diagnosis	ICD-10-CM
H40.009	Preglaucoma, unspecified, unspecified eye	Diagnosis	ICD-10-CM
H40.01	Open angle with borderline findings, low risk	Diagnosis	ICD-10-CM
H40.011	Open angle with borderline findings, low risk, right eye	Diagnosis	ICD-10-CM
H40.012	Open angle with borderline findings, low risk, left eye	Diagnosis	ICD-10-CM
H40.013	Open angle with borderline findings, low risk, bilateral	Diagnosis	ICD-10-CM
H40.019	Open angle with borderline findings, low risk, unspecified eye	Diagnosis	ICD-10-CM
H40.02	Open angle with borderline findings, high risk	Diagnosis	ICD-10-CM
H40.021	Open angle with borderline findings, high risk, right eye	Diagnosis	ICD-10-CM
H40.022	Open angle with borderline findings, high risk, left eye	Diagnosis	ICD-10-CM
H40.023	Open angle with borderline findings, high risk, bilateral	Diagnosis	ICD-10-CM
H40.029	Open angle with borderline findings, high risk, unspecified eye	Diagnosis	ICD-10-CM
H40.04	Steroid responder	Diagnosis	ICD-10-CM
H40.041	Steroid responder, right eye	Diagnosis	ICD-10-CM
H40.042	Steroid responder, left eye	Diagnosis	ICD-10-CM
H40.043	Steroid responder, bilateral	Diagnosis	ICD-10-CM
H40.049	Steroid responder, unspecified eye	Diagnosis	ICD-10-CM
H40.05	Ocular hypertension	Diagnosis	ICD-10-CM
H40.051	Ocular hypertension, right eye	Diagnosis	ICD-10-CM
H40.052	Ocular hypertension, left eye	Diagnosis	ICD-10-CM
H40.053	Ocular hypertension, bilateral	Diagnosis	ICD-10-CM
H40.059	Ocular hypertension, unspecified eye	Diagnosis	ICD-10-CM