

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	Cataracts 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), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) codes and algorithms used to define cataracts 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	Cataracts
Algorithm to Define Outcome	The cataracts outcome is defined as the presence of an ICD-9-CM or ICD-10-CM diagnosis code, or ICD-9-CM or CPT-4 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 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) Codes Used to Define Cataracts in this Request

Code	Description	Code Category	Code Type
13.41	Phacoemulsification and aspiration of cataract	Procedure	ICD-9-CM
13.42	Mechanical phacofragmentation and aspiration of cataract by posterior route	Procedure	ICD-9-CM
13.43	Mechanical phacofragmentation and other aspiration of cataract	Procedure	ICD-9-CM
13.6	Other cataract extraction	Procedure	ICD-9-CM
13.64	Dissection of secondary membrane (after cataract)	Procedure	ICD-9-CM
13.66	Mechanical fragmentation of secondary membrane (after cataract)	Procedure	ICD-9-CM
13.69	Other cataract extraction	Procedure	ICD-9-CM
366.00	Unspecified nonsenile cataract	Diagnosis	ICD-9-CM
366.02	Posterior subcapsular polar cataract, nonsenile	Diagnosis	ICD-9-CM
366.09	Other and combined forms of nonsenile cataract	Diagnosis	ICD-9-CM
366.12	Incipient cataract	Diagnosis	ICD-9-CM
366.14	Posterior subcapsular polar senile cataract	Diagnosis	ICD-9-CM
366.15	Cortical senile cataract	Diagnosis	ICD-9-CM
366.19	Other and combined forms of senile cataract	Diagnosis	ICD-9-CM
366.30	Unspecified cataracta complicata	Diagnosis	ICD-9-CM
366.4	Cataract associated with other disorders	Diagnosis	ICD-9-CM
366.50	Unspecified after-cataract	Diagnosis	ICD-9-CM
366.52	Other after-cataract, not obscuring vision	Diagnosis	ICD-9-CM
366.8	Other cataract	Diagnosis	ICD-9-CM
366.9	Unspecified cataract	Diagnosis	ICD-9-CM
66820	Dissection of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); stab incision technique (Ziegler or Wheeler knife)	Procedure	CPT-4
66821	Dissection of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); laser surgery (eg, YAG laser) (1 or more stages)	Procedure	CPT-4
66825	Repositioning of intraocular lens prosthesis, requiring an incision (separate procedure)	Procedure	CPT-4
66830	Removal of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid) with corneo-scleral section, with or without iridectomy (iridocapsulotomy, iridocapsulectomy)	Procedure	CPT-4
66840	Removal of lens material; aspiration technique, 1 or more stages	Procedure	CPT-4
66850	Removal of lens material; phacofragmentation technique (mechanical or ultrasonic) (eg, phacoemulsification), with aspiration	Procedure	CPT-4
66852	Removal of lens material; pars plana approach, with or without vitrectomy	Procedure	CPT-4
66920	Removal of lens material; intracapsular	Procedure	CPT-4
66930	Removal of lens material; intracapsular, for dislocated lens	Procedure	CPT-4
66940	Removal of lens material; extracapsular (other than 66840, 66850, 66852)	Procedure	CPT-4

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Code	Description	Code Category	Code Type
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage	Procedure	CPT-4
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)	Procedure	CPT-4
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification)	Procedure	CPT-4
H25.011	Cortical age-related cataract, right eye	Diagnosis	ICD-10-CM
H25.012	Cortical age-related cataract, left eye	Diagnosis	ICD-10-CM
H25.013	Cortical age-related cataract, bilateral	Diagnosis	ICD-10-CM
H25.019	Cortical age-related cataract, unspecified eye	Diagnosis	ICD-10-CM
H25.041	Posterior subcapsular polar age-related cataract, right eye	Diagnosis	ICD-10-CM
H25.042	Posterior subcapsular polar age-related cataract, left eye	Diagnosis	ICD-10-CM
H25.043	Posterior subcapsular polar age-related cataract, bilateral	Diagnosis	ICD-10-CM
H25.049	Posterior subcapsular polar age-related cataract, unspecified eye	Diagnosis	ICD-10-CM
H25.9	Unspecified age-related cataract	Diagnosis	ICD-10-CM
H26.001	Unspecified infantile and juvenile cataract, right eye	Diagnosis	ICD-10-CM
H26.002	Unspecified infantile and juvenile cataract, left eye	Diagnosis	ICD-10-CM
H26.003	Unspecified infantile and juvenile cataract, bilateral	Diagnosis	ICD-10-CM
H26.009	Unspecified infantile and juvenile cataract, unspecified eye	Diagnosis	ICD-10-CM
H26.051	Posterior subcapsular polar infantile and juvenile cataract, right eye	Diagnosis	ICD-10-CM
H26.052	Posterior subcapsular polar infantile and juvenile cataract, left eye	Diagnosis	ICD-10-CM
H26.053	Posterior subcapsular polar infantile and juvenile cataract, bilateral	Diagnosis	ICD-10-CM
H26.059	Posterior subcapsular polar infantile and juvenile cataract, unspecified eye	Diagnosis	ICD-10-CM
H26.09	Other infantile and juvenile cataract	Diagnosis	ICD-10-CM
H26.20	Unspecified complicated cataract	Diagnosis	ICD-10-CM
H26.30	Drug-induced cataract, unspecified eye	Diagnosis	ICD-10-CM
H26.31	Drug-induced cataract, right eye	Diagnosis	ICD-10-CM
H26.32	Drug-induced cataract, left eye	Diagnosis	ICD-10-CM
H26.33	Drug-induced cataract, bilateral	Diagnosis	ICD-10-CM
H26.40	Unspecified secondary cataract	Diagnosis	ICD-10-CM
H26.491	Other secondary cataract, right eye	Diagnosis	ICD-10-CM
H26.492	Other secondary cataract, left eye	Diagnosis	ICD-10-CM
H26.493	Other secondary cataract, bilateral	Diagnosis	ICD-10-CM
H26.499	Other secondary cataract, unspecified eye	Diagnosis	ICD-10-CM
H26.8	Other specified cataract	Diagnosis	ICD-10-CM
H26.9	Unspecified cataract	Diagnosis	ICD-10-CM