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Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview

Date Run: October 19, 2017

Request Description: The purpose of this report was to compare the frequency of diagnoses for cataracts using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. ICD-10-CM code definitions were determined by mapping from ICD-9-CM code definitions using the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). Forward-backward mapping (FBM) was used to map ICD-9-CM to ICD-10-CM codes.¹

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.0.4

Data Source: This request was run against the IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 121 million members. Data from October 1, 2010 to September 30, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 30, 2016, 2) April 1, 2015 to September 30, 2015, and 3) April 1, 2016 to September 30, 2016. See Appendix A for the dates of available data used in this report.

Study Design: We examined the incidence and prevalence of cataracts across the ICD-9-CM era (October 2010 to September 2015) and ICD-10-CM era (October 2015 to September 2016) in the US. Incidence was additionally evaluated from April 2015 to September 2015 and April 2016 to September 2016. See Appendix B for specific codes used to define cataracts in this request.

Cohort Eligibility Criteria: Members included in the cohorts were required to be enrolled in health plans with medical and drug coverage. The following age groups were included in the cohorts: 0-18, 19-24, 25-64, and 65+ years

Incident Cohorts: Members included in the incident cohorts were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to cataracts diagnosis, during which gaps in coverage of up to 45 days were allowed. Incident cataracts was defined as no previous cataracts diagnosis in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

Prevalent Cohorts: There was no enrollment time requirement for members in the prevalent cohorts. All qualifying diagnosis codes that occurred between October 1, 2010 and September 30, 2016 were included.

Please see Appendix C for detailed specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define outcomes are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind. The MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented.²

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

¹Fung, K. W., et al. (2016). "Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions." EGEMS (Wash DC) 4(1): 1211.

²IBM Watson Health (2018). [online] ibm.com. Available at: <https://www.ibm.com/downloads/cas/OWZWJ0QO> [Accessed 01 Mar. 2019].

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Glossary of Terms for Analyses Using Cohort Identification and Descriptive Analysis (CIDA) Tool*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

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). Along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: (1): Cohort includes only the first valid treatment episode during the query period; (2): Cohort includes all valid treatment episodes during the query period; (3): Cohort includes all valid treatment episodes during the query period until an event occurs.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the MP algorithm: (0): Counts all occurrences of an HOI during an exposure episode; (1): de-duplicates occurrences of the same HOI code and code type on the same day; (2): de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions days are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

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.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1. Comparison of Incident* Cataracts Diagnoses in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016)

	Members with Diagnosis	Eligible Members	Members with Diagnosis per 1,000 Eligible Members
Cataracts			
ICD-9-CM: April 1, 2015 - September 30, 2015	462,245	23,823,863	19.40
ICD-10-CM: April 1, 2016 - September 30, 2016	469,274	23,584,600	19.90

* Incidence defined by 183 day washout

Figure 1. Incidence of Cataracts Diagnoses per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout

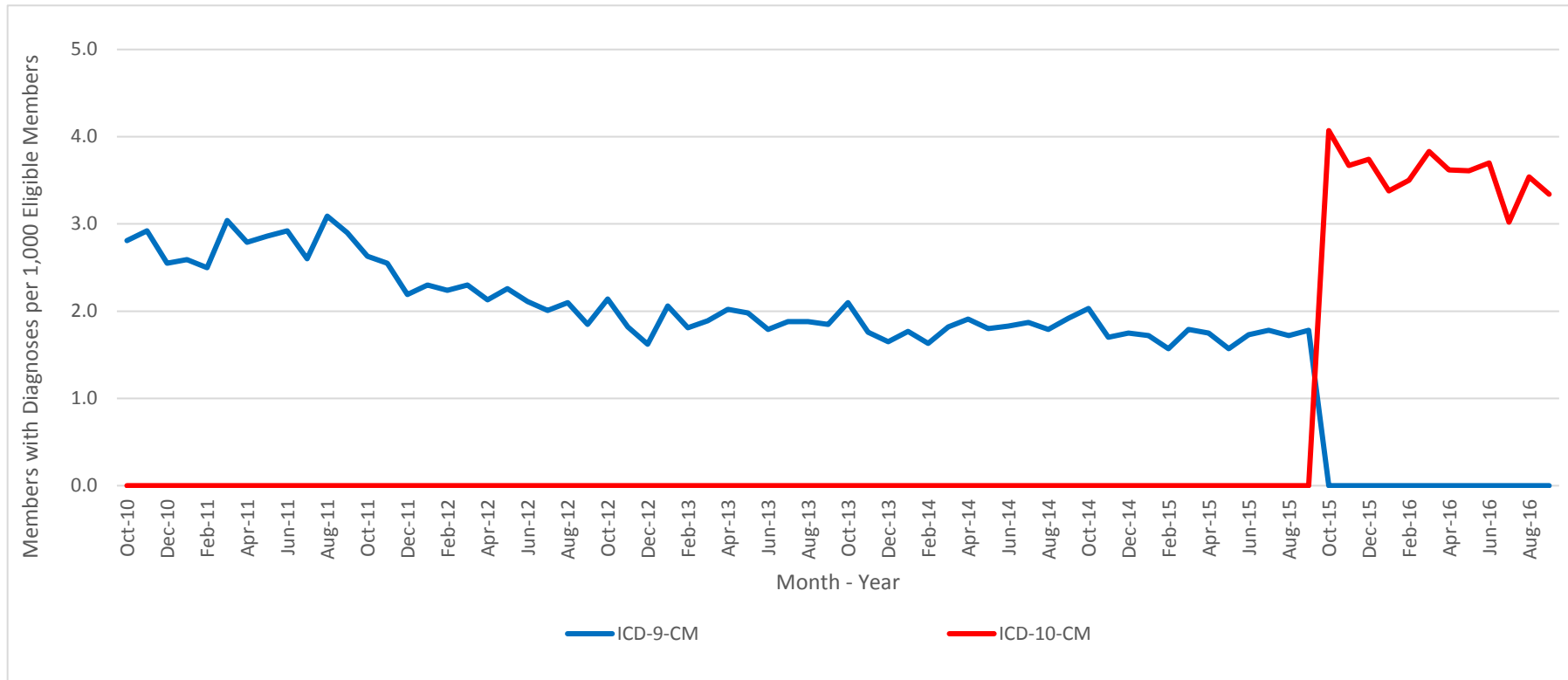
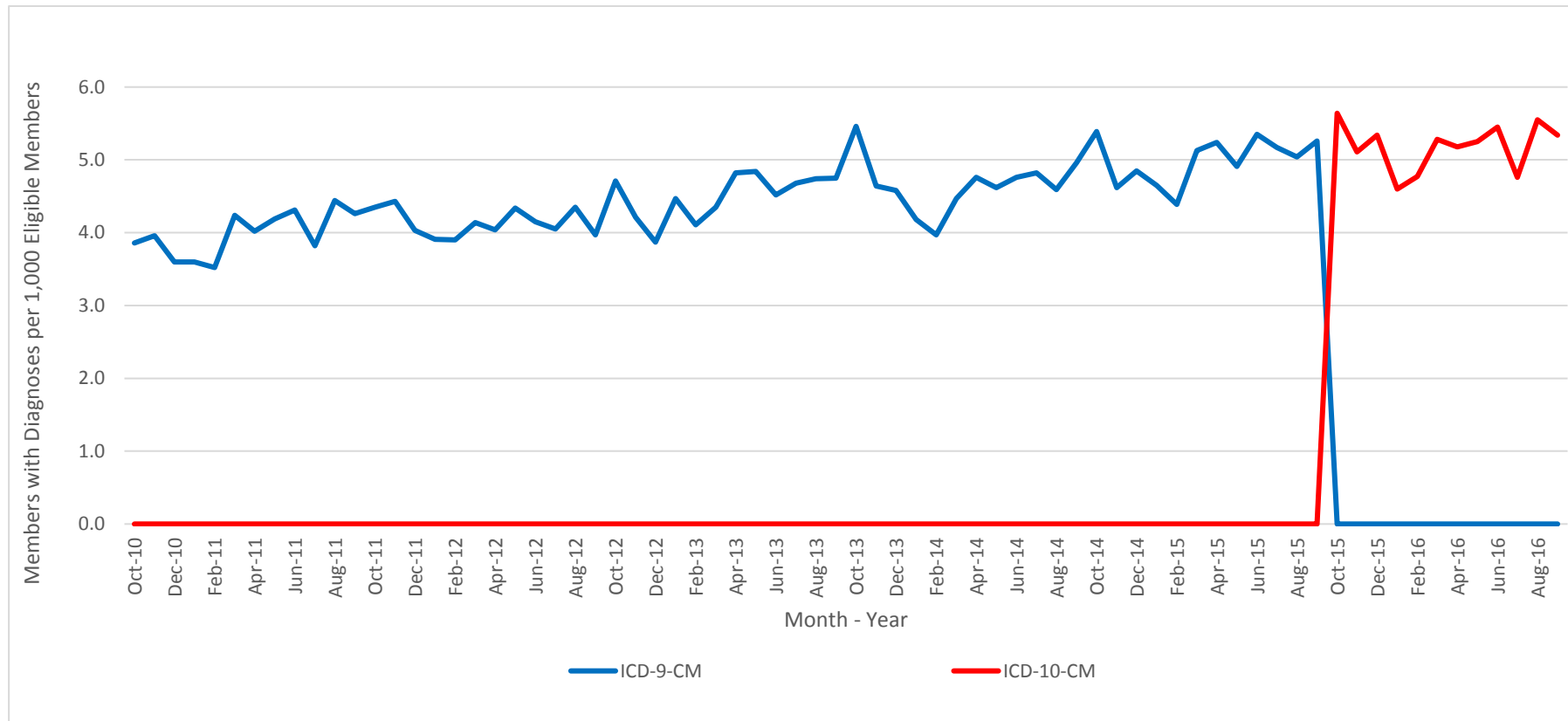


Figure 2. Prevalence of Cataracts Diagnoses per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout





Appendix A. Dates Available for IBM® MarketScan® Commercial and Medicare Supplemental Databases

Databases	Start Date	End Date
IBM MarketScan Commercial and Medicare Supplemental Databases ¹	1/1/2010	9/30/2016

¹ The IBM MarketScan Databases includes a sample of 121 million employees, dependents, and retirees in the United States with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans. The IBM MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented. For more information on the IBM MarketScan Databases, please review the White Paper here: <https://www.ibm.com/downloads/cas/OWZWJ0QO>

Appendix B. 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 Cataracts

Code	Description	Code Type
ICD-9-CM		
366	Cataract	ICD-9-CM Diagnosis
366.00	Unspecified nonsenile cataract	ICD-9-CM Diagnosis
366.01	Anterior subcapsular polar cataract, nonsenile	ICD-9-CM Diagnosis
366.02	Posterior subcapsular polar cataract, nonsenile	ICD-9-CM Diagnosis
366.03	Cortical, lamellar, or zonular cataract, nonsenile	ICD-9-CM Diagnosis
366.04	Nuclear cataract, nonsenile	ICD-9-CM Diagnosis
366.09	Other and combined forms of nonsenile cataract	ICD-9-CM Diagnosis
366.1	Senile cataract	ICD-9-CM Diagnosis
366.10	Unspecified senile cataract	ICD-9-CM Diagnosis
366.11	Pseudoexfoliation of lens capsule	ICD-9-CM Diagnosis
366.12	Incipient cataract	ICD-9-CM Diagnosis
366.13	Anterior subcapsular polar senile cataract	ICD-9-CM Diagnosis
366.14	Posterior subcapsular polar senile cataract	ICD-9-CM Diagnosis
366.15	Cortical senile cataract	ICD-9-CM Diagnosis
366.16	Nuclear sclerosis	ICD-9-CM Diagnosis
366.17	Total or mature senile cataract	ICD-9-CM Diagnosis
366.18	Hyper mature senile cataract	ICD-9-CM Diagnosis
366.19	Other and combined forms of senile cataract	ICD-9-CM Diagnosis
366.2	Traumatic cataract	ICD-9-CM Diagnosis
366.20	Unspecified traumatic cataract	ICD-9-CM Diagnosis
366.21	Localized traumatic opacities of cataract	ICD-9-CM Diagnosis
366.22	Total traumatic cataract	ICD-9-CM Diagnosis
366.23	Partially resolved traumatic cataract	ICD-9-CM Diagnosis
366.3	Cataract secondary to ocular disorders	ICD-9-CM Diagnosis
366.30	Unspecified cataracta complicata	ICD-9-CM Diagnosis
366.31	Cataract secondary to glaucomatous flecks (subcapsular)	ICD-9-CM Diagnosis
366.32	Cataract in inflammatory ocular disorders	ICD-9-CM Diagnosis
366.33	Cataract with ocular neovascularization	ICD-9-CM Diagnosis
366.34	Cataract in degenerative ocular disorders	ICD-9-CM Diagnosis
366.4	Cataract associated with other disorders	ICD-9-CM Diagnosis
366.50	Unspecified after-cataract	ICD-9-CM Diagnosis
366.52	Other after-cataract, not obscuring vision	ICD-9-CM Diagnosis
366.53	After-cataract, obscuring vision	ICD-9-CM Diagnosis
366.8	Other cataract	ICD-9-CM Diagnosis
366.9	Unspecified cataract	ICD-9-CM Diagnosis
ICD-10-CM		
H25.011	Cortical age-related cataract, right eye	ICD-10-CM Diagnosis
H25.012	Cortical age-related cataract, left eye	ICD-10-CM Diagnosis
H25.013	Cortical age-related cataract, bilateral	ICD-10-CM Diagnosis
H25.019	Cortical age-related cataract, unspecified eye	ICD-10-CM Diagnosis
H25.031	Anterior subcapsular polar age-related cataract, right eye	ICD-10-CM Diagnosis
H25.032	Anterior subcapsular polar age-related cataract, left eye	ICD-10-CM Diagnosis
H25.033	Anterior subcapsular polar age-related cataract, bilateral	ICD-10-CM Diagnosis

Appendix B. 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 Cataracts

Code	Description	Code Type
H25.039	Anterior subcapsular polar age-related cataract, unspecified eye	ICD-10-CM Diagnosis
H25.041	Posterior subcapsular polar age-related cataract, right eye	ICD-10-CM Diagnosis
H25.042	Posterior subcapsular polar age-related cataract, left eye	ICD-10-CM Diagnosis
H25.043	Posterior subcapsular polar age-related cataract, bilateral	ICD-10-CM Diagnosis
H25.049	Posterior subcapsular polar age-related cataract, unspecified eye	ICD-10-CM Diagnosis
H25.091	Other age-related incipient cataract, right eye	ICD-10-CM Diagnosis
H25.092	Other age-related incipient cataract, left eye	ICD-10-CM Diagnosis
H25.093	Other age-related incipient cataract, bilateral	ICD-10-CM Diagnosis
H25.099	Other age-related incipient cataract, unspecified eye	ICD-10-CM Diagnosis
H25.10	Age-related nuclear cataract, unspecified eye	ICD-10-CM Diagnosis
H25.11	Age-related nuclear cataract, right eye	ICD-10-CM Diagnosis
H25.12	Age-related nuclear cataract, left eye	ICD-10-CM Diagnosis
H25.13	Age-related nuclear cataract, bilateral	ICD-10-CM Diagnosis
H25.20	Age-related cataract, morgagnian type, unspecified eye	ICD-10-CM Diagnosis
H25.21	Age-related cataract, morgagnian type, right eye	ICD-10-CM Diagnosis
H25.22	Age-related cataract, morgagnian type, left eye	ICD-10-CM Diagnosis
H25.23	Age-related cataract, morgagnian type, bilateral	ICD-10-CM Diagnosis
H25.811	Combined forms of age-related cataract, right eye	ICD-10-CM Diagnosis
H25.812	Combined forms of age-related cataract, left eye	ICD-10-CM Diagnosis
H25.813	Combined forms of age-related cataract, bilateral	ICD-10-CM Diagnosis
H25.819	Combined forms of age-related cataract, unspecified eye	ICD-10-CM Diagnosis
H25.89	Other age-related cataract	ICD-10-CM Diagnosis
H25.9	Unspecified age-related cataract	ICD-10-CM Diagnosis
H26.101	Unspecified traumatic cataract, right eye	ICD-10-CM Diagnosis
H26.102	Unspecified traumatic cataract, left eye	ICD-10-CM Diagnosis
H26.103	Unspecified traumatic cataract, bilateral	ICD-10-CM Diagnosis
H26.109	Unspecified traumatic cataract, unspecified eye	ICD-10-CM Diagnosis
H26.111	Localized traumatic opacities, right eye	ICD-10-CM Diagnosis
H26.112	Localized traumatic opacities, left eye	ICD-10-CM Diagnosis
H26.113	Localized traumatic opacities, bilateral	ICD-10-CM Diagnosis
H26.119	Localized traumatic opacities, unspecified eye	ICD-10-CM Diagnosis
H26.121	Partially resolved traumatic cataract, right eye	ICD-10-CM Diagnosis
H26.122	Partially resolved traumatic cataract, left eye	ICD-10-CM Diagnosis
H26.123	Partially resolved traumatic cataract, bilateral	ICD-10-CM Diagnosis
H26.129	Partially resolved traumatic cataract, unspecified eye	ICD-10-CM Diagnosis
H26.131	Total traumatic cataract, right eye	ICD-10-CM Diagnosis
H26.132	Total traumatic cataract, left eye	ICD-10-CM Diagnosis
H26.133	Total traumatic cataract, bilateral	ICD-10-CM Diagnosis
H26.139	Total traumatic cataract, unspecified eye	ICD-10-CM Diagnosis
H26.20	Unspecified complicated cataract	ICD-10-CM Diagnosis
H26.211	Cataract with neovascularization, right eye	ICD-10-CM Diagnosis
H26.212	Cataract with neovascularization, left eye	ICD-10-CM Diagnosis
H26.213	Cataract with neovascularization, bilateral	ICD-10-CM Diagnosis
H26.219	Cataract with neovascularization, unspecified eye	ICD-10-CM Diagnosis

Appendix B. 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 Cataracts

Code	Description	Code Type
H26.221	Cataract secondary to ocular disorders (degenerative) (inflammatory), right eye	ICD-10-CM Diagnosis
H26.222	Cataract secondary to ocular disorders (degenerative) (inflammatory), left eye	ICD-10-CM Diagnosis
H26.223	Cataract secondary to ocular disorders (degenerative) (inflammatory), bilateral	ICD-10-CM Diagnosis
H26.229	Cataract secondary to ocular disorders (degenerative) (inflammatory), unspecified eye	ICD-10-CM Diagnosis
H26.231	Glaucomatous flecks (subcapsular), right eye	ICD-10-CM Diagnosis
H26.232	Glaucomatous flecks (subcapsular), left eye	ICD-10-CM Diagnosis
H26.233	Glaucomatous flecks (subcapsular), bilateral	ICD-10-CM Diagnosis
H26.239	Glaucomatous flecks (subcapsular), unspecified eye	ICD-10-CM Diagnosis
H26.30	Drug-induced cataract, unspecified eye	ICD-10-CM Diagnosis
H26.31	Drug-induced cataract, right eye	ICD-10-CM Diagnosis
H26.32	Drug-induced cataract, left eye	ICD-10-CM Diagnosis
H26.33	Drug-induced cataract, bilateral	ICD-10-CM Diagnosis
H26.40	Unspecified secondary cataract	ICD-10-CM Diagnosis
H26.491	Other secondary cataract, right eye	ICD-10-CM Diagnosis
H26.492	Other secondary cataract, left eye	ICD-10-CM Diagnosis
H26.493	Other secondary cataract, bilateral	ICD-10-CM Diagnosis
H26.499	Other secondary cataract, unspecified eye	ICD-10-CM Diagnosis
H26.8	Other specified cataract	ICD-10-CM Diagnosis
H26.9	Unspecified cataract	ICD-10-CM Diagnosis
H28	Cataract in diseases classified elsewhere	ICD-10-CM Diagnosis

Appendix C. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.0.4 was used to compare the frequency of diagnoses for cataracts using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes.

Enrollment Gap: 45 days

Age Groups: 0-18, 19-24, 25-64, 65+ years

Enrollment Requirement: 183 days for incidence scenarios; 0 days for prevalence scenarios

Coverage Requirement: Medical and drug coverage

Event

Scenario	Query Start Date	Query End Date	Event	Incidence/ Prevalence Code Type	Incident with Respect To	Washout (days)	Cohort Definition	Care Setting
1	4/1/2015	9/30/2015	Cataract	ICD-9-CM	ICD-9-CM	183	First valid event only	Any
2	4/1/2016	9/30/2016	Cataract	ICD-10-CM	ICD-10-CM	183	First valid event only	Any
3	10/1/2010	9/30/2016	Cataract	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	Any
4	10/1/2010	9/30/2016	Cataract	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	Any
5	10/1/2010	9/30/2016	Cataract	ICD-9-CM	N/A	0	All valid events	Any
6	10/1/2010	9/30/2016	Cataract	ICD-10-CM	N/A	0	All valid events	Any

ICD-9-CM and ICD-10-CM are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.