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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 for Request: cder_mpl1p_wp239

Request ID: cder_mpl1r_wp239_mkscnr_v01

Date Run: January 17, 2023

Request Description: In this report, we compare the frequency of diagnosis codes for Crohn's disease to examine trends in code usage surrounding the October, 2015 transition from International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) to International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. We determined mappings by performing comprehensive code list searches in both the ICD-9 and ICD-10 eras and leveraging the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). We used forward-backward mapping as part of this comprehensive approach.¹

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 12.0.0.

Data Source: We ran this request against a 100% sample from the Merative™ MarketScan® Research Databases which includes ~155 million members. We included data from October 1, 2010 to December 31, 2021 in this report. This report includes several distinct time periods: 1) October 1, 2013 to September 30, 2014; 2) October 1, 2014 to September 30, 2015; 3) October 1, 2015 to September 30, 2016; 4) October 1, 2016 to September 30, 2017; 5) October 1, 2010 to December 31, 2021. See Appendix A for the dates of available data used in this report.

Study Design: We examined the incidence and prevalence of Crohn's disease across the ICD-9-CM era (October 2010-September 2015) and ICD-10-CM (October 2015-now) in data.

See Appendices B and C for specific codes used to define the Crohn's disease in this request.

Cohort Eligibility Criteria:

Incident Cohorts: We identified codes for Crohn's disease and set this as our index date. For the one-year time periods, we defined index events using only the relevant terminologies available for use during that window. For example, in the October 2014 to September 2015 window we defined index using ICD-9-CM codes only. In the October 2015 to September 2016 window we defined index using ICD-10-CM codes only. For the October 2010 to December 2021 time period, we created separate cohorts for ICD-9 era codes and ICD-10 era codes but looked for these across the full study period. We required cohort members be continuously enrolled in plans with at least medical coverage for the 183 days prior to index, during which gaps in coverage up to 45 days were allowed and considered continuous enrollment. We defined incidence as no prior evidence of any outcome-defining code (including ICD-9 and ICD-10 terminologies) in the 183 days prior to index. Cohort re-entry was allowed. See Appendix C for specific codes used to define incidence criteria in this request.

Prevalent Cohorts: We identified codes for Crohn's disease and set this as our index date. We created separate cohorts for ICD-9 era codes and ICD-10 era codes but looked for these across the full study period. We did not require any pre-index enrollment requirements for these cohorts. Cohort re-entry was allowed. We assessed prevalence only in the October 2010 to December 2021 time period.

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.

Please refer to Appendix D for detailed specifications of parameters used in the analyses for this request.

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.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

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

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). The Care Setting, along with the Principal Diagnosis Indicator (PDX), 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.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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 Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (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 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.

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

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.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

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. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021

	Number of Patients	Number of Episodes	Number of Eligible Members¹	Number of Exposed Members per 10,000 Eligible Members
<i>Crohn's Disease ICD-9-CM from 2013 to 2014</i>	63,235	65,585	49,359,012	12.81
<i>Crohn's Disease ICD-9-CM from 2014 to 2015</i>	47,649	49,247	45,266,547	10.53
<i>Crohn's Disease ICD-10-CM from 2015 to 2016</i>	63,599	67,566	29,531,980	21.54
<i>Crohn's Disease ICD-10-CM from 2016 to 2017</i>	34,213	35,562	29,823,780	11.47
<i>Crohn's Disease ICD-9-CM Incidence</i>	239,924	334,117	128,694,713	18.64
<i>Crohn's Disease ICD-10-CM Incidence</i>	137,707	210,208	128,694,713	10.70
<i>Crohn's Disease ICD-9-CM Prevalence</i>	339,521	2,542,399	149,022,924	22.78
<i>Crohn's Disease ICD-10-CM Prevalence</i>	203,880	2,219,594	149,022,924	13.68

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
Crohn's Disease ICD-9-CM Incidence				
<i>2010</i>				
October	5,905	5,905	43,707,243	1.35
November	6,097	6,097	43,187,482	1.41
December	5,856	5,856	44,036,649	1.33
<i>2011</i>				
January	5,490	5,490	38,205,776	1.44
February	5,157	5,157	37,642,288	1.37
March	5,949	5,949	37,807,420	1.57
April	5,296	5,296	37,912,089	1.40
May	5,392	5,392	37,881,846	1.42
June	5,556	5,556	37,866,372	1.47
July	6,490	6,490	47,459,111	1.37
August	7,489	7,489	47,789,444	1.57
September	6,976	6,976	47,044,452	1.48
October	6,991	6,991	47,447,519	1.47
November	6,838	6,838	46,923,740	1.46
December	6,983	6,983	47,911,547	1.46
<i>2012</i>				
January	6,687	6,687	43,092,145	1.55
February	6,448	6,448	42,544,771	1.52
March	6,458	6,458	42,526,069	1.52
April	6,197	6,197	42,391,831	1.46
May	6,501	6,501	42,382,400	1.53
June	6,306	6,306	42,339,217	1.49
July	6,873	6,873	47,559,404	1.45
August	7,468	7,468	47,879,510	1.56
September	6,517	6,517	47,174,395	1.38
October	7,231	7,231	47,583,374	1.52
November	6,993	6,993	47,073,392	1.49
December	6,341	6,341	47,986,441	1.32
<i>2013</i>				
January	5,463	5,463	33,253,697	1.64
February	4,623	4,623	32,902,513	1.41
March	4,824	4,824	33,075,475	1.46
April	5,184	5,184	33,151,266	1.56
May	5,134	5,134	33,160,269	1.55
June	4,780	4,780	33,037,426	1.45
July	5,688	5,688	37,818,536	1.50

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
August	5,672	5,672	38,114,346	1.49
September	5,408	5,408	37,482,107	1.44
October	6,016	6,016	37,745,362	1.59
November	5,426	5,426	37,205,303	1.46
December	5,339	5,339	37,696,913	1.42
<i>2014</i>				
January	5,274	5,274	33,022,131	1.60
February	4,723	4,723	32,611,026	1.45
March	5,110	5,110	32,821,807	1.56
April	5,316	5,316	32,791,872	1.62
May	4,986	4,986	32,593,277	1.53
June	5,021	5,021	32,700,123	1.54
July	6,299	6,299	39,067,621	1.61
August	5,880	5,880	39,386,698	1.49
September	6,195	6,195	38,769,182	1.60
October	6,469	6,469	39,285,626	1.65
November	5,609	5,609	38,749,036	1.45
December	5,767	5,767	39,584,265	1.46
<i>2015</i>				
January	3,479	3,479	22,118,535	1.57
February	3,157	3,157	21,853,749	1.44
March	3,466	3,466	21,888,888	1.58
April	3,371	3,371	21,883,955	1.54
May	3,231	3,231	21,860,806	1.48
June	3,562	3,562	21,796,589	1.63
July	3,865	3,865	24,085,339	1.60
August	3,667	3,667	24,294,775	1.51
September	3,604	3,604	23,919,507	1.51
October	2	2	24,088,941	0.00
November	6	6	23,798,929	0.00
December	4	4	24,184,888	0.00
<i>2016</i>				
January	0	0	21,731,240	0.00
February	0	0	21,480,469	0.00
March	1	1	21,543,050	0.00
April	0	0	21,564,347	0.00
May	0	0	21,531,524	0.00
June	1	1	21,483,610	0.00
July	0	0	24,025,306	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
August	0	0	24,209,174	0.00
September	0	0	23,838,918	0.00
October	3	3	23,969,167	0.00
November	0	0	23,637,686	0.00
December	0	0	23,977,641	0.00
<i>2017</i>				
January	0	0	19,165,051	0.00
February	0	0	18,936,479	0.00
March	0	0	18,983,797	0.00
April	0	0	18,973,821	0.00
May	0	0	18,938,762	0.00
June	0	0	18,872,839	0.00
July	1	1	22,246,745	0.00
August	0	0	22,412,075	0.00
September	0	0	22,077,261	0.00
October	1	1	22,244,539	0.00
November	0	0	21,792,536	0.00
December	0	0	22,065,305	0.00
<i>2018</i>				
January	0	0	17,932,330	0.00
February	0	0	17,726,853	0.00
March	0	0	17,761,416	0.00
April	0	0	17,747,673	0.00
May	1	1	17,731,139	0.00
June	0	0	17,662,292	0.00
July	0	0	22,026,500	0.00
August	0	0	22,212,468	0.00
September	0	0	21,839,979	0.00
October	1	1	22,015,376	0.00
November	0	0	21,704,270	0.00
December	0	0	22,067,241	0.00
<i>2019</i>				
January	0	0	18,668,007	0.00
February	0	0	18,431,740	0.00
March	0	0	18,501,194	0.00
April	0	0	18,414,922	0.00
May	1	1	18,397,585	0.00
June	0	0	18,314,601	0.00
July	1	1	20,023,234	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
August	0	0	20,206,507	0.00
September	0	0	19,842,670	0.00
October	0	0	20,064,821	0.00
November	0	0	19,773,960	0.00
December	0	0	20,118,383	0.00
<i>2020</i>				
January	0	0	16,803,851	0.00
February	0	0	16,601,972	0.00
March	0	0	16,675,995	0.00
April	0	0	16,719,062	0.00
May	0	0	16,726,303	0.00
June	0	0	16,695,742	0.00
July	0	0	19,740,144	0.00
August	0	0	19,922,211	0.00
September	0	0	19,596,303	0.00
October	0	0	19,679,999	0.00
November	0	0	19,415,235	0.00
December	0	0	19,638,594	0.00
<i>2021</i>				
January	0	0	16,440,405	0.00
February	0	0	16,247,176	0.00
March	1	1	16,257,238	0.00
April	0	0	16,232,263	0.00
May	0	0	16,196,066	0.00
June	0	0	16,108,967	0.00
July	0	0	17,788,941	0.00
August	0	0	17,882,856	0.00
September	0	0	17,524,817	0.00
October	0	0	17,684,720	0.00
November	0	0	17,387,107	0.00
December	0	0	17,651,737	0.00
Crohn's Disease ICD-10-CM Incidence				
<i>2010</i>				
October	0	0	43,707,243	0.00
November	0	0	43,187,482	0.00
December	0	0	44,036,649	0.00
<i>2011</i>				
January	0	0	38,205,776	0.00
February	0	0	37,642,288	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
March	0	0	37,807,420	0.00
April	0	0	37,912,089	0.00
May	0	0	37,881,846	0.00
June	0	0	37,866,372	0.00
July	0	0	47,459,111	0.00
August	0	0	47,789,444	0.00
September	0	0	47,044,452	0.00
October	0	0	47,447,519	0.00
November	0	0	46,923,740	0.00
December	0	0	47,911,547	0.00
<i>2012</i>				
January	0	0	43,092,145	0.00
February	0	0	42,544,771	0.00
March	0	0	42,526,069	0.00
April	0	0	42,391,831	0.00
May	0	0	42,382,400	0.00
June	0	0	42,339,217	0.00
July	0	0	47,559,404	0.00
August	0	0	47,879,510	0.00
September	0	0	47,174,395	0.00
October	0	0	47,583,374	0.00
November	0	0	47,073,392	0.00
December	0	0	47,986,441	0.00
<i>2013</i>				
January	0	0	33,253,697	0.00
February	0	0	32,902,513	0.00
March	0	0	33,075,475	0.00
April	0	0	33,151,266	0.00
May	0	0	33,160,269	0.00
June	0	0	33,037,426	0.00
July	0	0	37,818,536	0.00
August	0	0	38,114,346	0.00
September	0	0	37,482,107	0.00
October	0	0	37,745,362	0.00
November	0	0	37,205,303	0.00
December	0	0	37,696,913	0.00
<i>2014</i>				
January	0	0	33,022,131	0.00
February	0	0	32,611,026	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
March	0	0	32,821,807	0.00
April	0	0	32,791,872	0.00
May	0	0	32,593,277	0.00
June	0	0	32,700,123	0.00
July	0	0	39,067,621	0.00
August	0	0	39,386,698	0.00
September	0	0	38,769,182	0.00
October	0	0	39,285,626	0.00
November	0	0	38,749,036	0.00
December	0	0	39,584,265	0.00
<i>2015</i>				
January	0	0	22,118,535	0.00
February	1	1	21,853,749	0.00
March	0	0	21,888,888	0.00
April	0	0	21,883,955	0.00
May	0	0	21,860,806	0.00
June	0	0	21,796,589	0.00
July	1	1	24,085,339	0.00
August	0	0	24,294,775	0.00
September	52	52	23,919,507	0.02
October	3,763	3,763	24,088,941	1.56
November	3,482	3,482	23,798,929	1.46
December	3,577	3,577	24,184,888	1.48
<i>2016</i>				
January	3,185	3,185	21,731,240	1.47
February	3,137	3,137	21,480,469	1.46
March	3,300	3,300	21,543,050	1.53
April	3,033	3,033	21,564,347	1.41
May	3,038	3,038	21,531,524	1.41
June	3,233	3,233	21,483,610	1.50
July	3,164	3,164	24,025,306	1.32
August	3,690	3,690	24,209,174	1.52
September	3,462	3,462	23,838,918	1.45
October	3,362	3,362	23,969,167	1.40
November	3,433	3,433	23,637,686	1.45
December	3,340	3,340	23,977,641	1.39
<i>2017</i>				
January	2,840	2,840	19,165,051	1.48
February	2,543	2,543	18,936,479	1.34

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
March	2,879	2,879	18,983,797	1.52
April	2,498	2,498	18,973,821	1.32
May	2,729	2,729	18,938,762	1.44
June	2,746	2,746	18,872,839	1.46
July	2,978	2,978	22,246,745	1.34
August	3,300	3,300	22,412,075	1.47
September	2,913	2,913	22,077,261	1.32
October	3,169	3,169	22,244,539	1.42
November	3,158	3,158	21,792,536	1.45
December	2,977	2,977	22,065,305	1.35
2018				
January	2,614	2,614	17,932,330	1.46
February	2,291	2,291	17,726,853	1.29
March	2,483	2,483	17,761,416	1.40
April	2,491	2,491	17,747,673	1.40
May	2,642	2,642	17,731,139	1.49
June	2,470	2,470	17,662,292	1.40
July	2,949	2,949	22,026,500	1.34
August	3,165	3,165	22,212,468	1.42
September	2,803	2,803	21,839,979	1.28
October	3,421	3,421	22,015,376	1.55
November	3,161	3,161	21,704,270	1.46
December	2,888	2,888	22,067,241	1.31
2019				
January	2,772	2,772	18,668,007	1.48
February	2,447	2,447	18,431,740	1.33
March	2,536	2,536	18,501,194	1.37
April	2,613	2,613	18,414,922	1.42
May	2,575	2,575	18,397,585	1.40
June	2,586	2,586	18,314,601	1.41
July	2,941	2,941	20,023,234	1.47
August	2,993	2,993	20,206,507	1.48
September	2,775	2,775	19,842,670	1.40
October	3,034	3,034	20,064,821	1.51
November	2,650	2,650	19,773,960	1.34
December	2,676	2,676	20,118,383	1.33
2020				
January	2,486	2,486	16,803,851	1.48
February	2,219	2,219	16,601,972	1.34

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
March	1,797	1,797	16,675,995	1.08
April	1,681	1,681	16,719,062	1.01
May	1,825	1,825	16,726,303	1.09
June	2,413	2,413	16,695,742	1.45
July	2,952	2,952	19,740,144	1.50
August	3,010	3,010	19,922,211	1.51
September	3,047	3,047	19,596,303	1.55
October	3,077	3,077	19,679,999	1.56
November	2,659	2,659	19,415,235	1.37
December	2,725	2,725	19,638,594	1.39
2021				
January	2,358	2,358	16,440,405	1.43
February	2,289	2,289	16,247,176	1.41
March	2,488	2,488	16,257,238	1.53
April	2,409	2,409	16,232,263	1.48
May	2,211	2,211	16,196,066	1.37
June	2,449	2,449	16,108,967	1.52
July	2,416	2,416	17,788,941	1.36
August	2,615	2,615	17,882,856	1.46
September	2,681	2,681	17,524,817	1.53
October	2,556	2,556	17,684,720	1.45
November	2,514	2,514	17,387,107	1.45
December	2,372	2,372	17,651,737	1.34
Crohn's Disease ICD-9-CM Prevalence				
2010				
October	28,230	40,448	47,783,732	5.91
November	28,317	40,537	47,714,965	5.93
December	28,651	41,145	47,760,109	6.00
2011				
January	30,859	44,907	52,274,120	5.90
February	29,770	42,160	52,038,076	5.72
March	33,987	49,919	51,957,287	6.54
April	31,045	44,368	51,860,782	5.99
May	31,370	45,138	51,769,930	6.06
June	32,717	47,396	51,756,451	6.32
July	30,483	43,391	51,804,123	5.88
August	33,495	49,279	51,756,708	6.47
September	31,838	46,071	51,699,947	6.16
October	32,163	46,677	51,652,144	6.23

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
November	32,095	45,976	51,621,813	6.22
December	32,943	47,028	51,691,308	6.37
<i>2012</i>				
January	33,419	48,529	52,576,934	6.36
February	32,924	47,553	52,397,697	6.28
March	34,200	49,913	52,177,387	6.55
April	32,601	46,719	51,958,063	6.27
May	34,072	49,547	51,927,518	6.56
June	33,672	48,437	51,845,618	6.49
July	32,859	47,518	51,815,509	6.34
August	35,055	51,510	51,942,235	6.75
September	31,597	44,778	52,013,540	6.07
October	34,760	50,868	52,041,223	6.68
November	33,831	48,418	52,036,409	6.50
December	32,203	46,008	52,143,790	6.18
<i>2013</i>				
January	28,042	41,038	41,330,662	6.78
February	25,570	36,393	41,267,747	6.20
March	27,098	38,892	41,223,201	6.57
April	27,924	40,702	41,169,578	6.78
May	28,216	41,205	41,107,177	6.86
June	26,760	38,247	41,036,151	6.52
July	28,046	40,752	40,989,887	6.84
August	27,769	40,261	40,976,506	6.78
September	26,728	38,219	41,041,550	6.51
October	28,801	42,516	41,017,147	7.02
November	26,612	37,847	41,146,809	6.47
December	27,467	39,589	41,022,577	6.70
<i>2014</i>				
January	30,497	44,826	43,473,954	7.02
February	28,587	41,247	43,277,665	6.61
March	30,786	45,139	43,280,753	7.11
April	31,414	46,491	43,218,379	7.27
May	30,193	44,280	43,004,996	7.02
June	30,723	45,301	42,964,110	7.15
July	32,042	47,751	43,114,303	7.43
August	30,620	45,384	43,028,459	7.12
September	31,378	46,402	43,006,724	7.30
October	33,070	49,849	42,978,610	7.69

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
November	29,630	42,673	42,927,741	6.90
December	31,489	46,951	42,855,039	7.35
<i>2015</i>				
January	19,381	29,133	26,489,481	7.32
February	18,255	26,958	26,451,586	6.90
March	20,227	30,821	26,381,863	7.67
April	20,117	30,320	26,312,168	7.65
May	19,089	28,189	26,259,467	7.27
June	20,378	30,572	26,200,289	7.78
July	20,511	31,031	26,155,278	7.84
August	19,693	29,580	26,077,047	7.55
September	19,696	29,462	26,022,688	7.57
October	21	25	26,017,688	0.01
November	20	24	25,965,811	0.01
December	13	15	25,926,759	0.01
<i>2016</i>				
January	1	1	26,171,554	0.00
February	0	0	26,153,287	0.00
March	1	1	26,148,283	0.00
April	4	4	26,106,323	0.00
May	4	5	26,053,425	0.00
June	9	10	26,012,490	0.00
July	0	0	25,987,259	0.00
August	0	0	25,915,857	0.00
September	0	0	25,860,540	0.00
October	4	4	25,753,179	0.00
November	2	2	25,666,896	0.00
December	0	0	25,603,634	0.00
<i>2017</i>				
January	0	0	24,253,479	0.00
February	1	1	24,209,651	0.00
March	1	1	24,184,192	0.00
April	1	1	24,121,539	0.00
May	1	1	24,077,422	0.00
June	2	2	24,025,177	0.00
July	7	7	23,948,148	0.00
August	0	0	23,901,232	0.00
September	0	0	23,861,833	0.00
October	1	1	23,830,784	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
November	0	0	23,610,075	0.00
December	0	0	23,562,154	0.00
<i>2018</i>				
January	0	0	24,301,121	0.00
February	0	0	24,278,968	0.00
March	0	0	24,232,276	0.00
April	0	0	24,185,445	0.00
May	1	1	24,113,466	0.00
June	0	0	24,057,211	0.00
July	0	0	24,006,160	0.00
August	0	0	23,997,638	0.00
September	0	0	23,972,867	0.00
October	1	1	23,920,988	0.00
November	0	0	23,871,095	0.00
December	0	0	23,802,676	0.00
<i>2019</i>				
January	1	1	22,188,245	0.00
February	1	1	22,171,940	0.00
March	2	2	22,140,668	0.00
April	0	0	22,036,744	0.00
May	1	1	22,002,830	0.00
June	1	1	21,951,062	0.00
July	2	2	21,892,323	0.00
August	2	3	21,865,062	0.00
September	0	0	21,824,448	0.00
October	1	1	21,811,664	0.00
November	0	0	21,762,917	0.00
December	2	4	21,731,070	0.00
<i>2020</i>				
January	0	0	21,597,091	0.00
February	0	0	21,553,960	0.00
March	0	0	21,530,147	0.00
April	0	0	21,487,224	0.00
May	0	0	21,424,880	0.00
June	0	0	21,388,355	0.00
July	0	0	21,236,324	0.00
August	0	0	21,180,862	0.00
September	0	0	21,097,793	0.00
October	0	0	21,002,571	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
November	0	0	20,952,934	0.00
December	0	0	20,915,869	0.00
<i>2021</i>				
January	0	0	19,598,561	0.00
February	1	1	19,570,182	0.00
March	2	3	19,535,326	0.00
April	2	2	19,519,760	0.00
May	0	0	19,569,498	0.00
June	1	3	19,536,298	0.00
July	1	1	19,471,442	0.00
August	2	2	19,448,365	0.00
September	0	0	19,411,991	0.00
October	3	5	19,339,254	0.00
November	0	0	19,299,376	0.00
December	0	0	19,262,996	0.00
Crohn's Disease ICD-10-CM Prevalence				
<i>2010</i>				
October	0	0	47,783,732	0.00
November	0	0	47,714,965	0.00
December	0	0	47,760,109	0.00
<i>2011</i>				
January	0	0	52,274,120	0.00
February	0	0	52,038,076	0.00
March	0	0	51,957,287	0.00
April	0	0	51,860,782	0.00
May	0	0	51,769,930	0.00
June	0	0	51,756,451	0.00
July	0	0	51,804,123	0.00
August	0	0	51,756,708	0.00
September	0	0	51,699,947	0.00
October	0	0	51,652,144	0.00
November	0	0	51,621,813	0.00
December	0	0	51,691,308	0.00
<i>2012</i>				
January	0	0	52,576,934	0.00
February	0	0	52,397,697	0.00
March	0	0	52,177,387	0.00
April	0	0	51,958,063	0.00
May	0	0	51,927,518	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
June	0	0	51,845,618	0.00
July	0	0	51,815,509	0.00
August	0	0	51,942,235	0.00
September	0	0	52,013,540	0.00
October	0	0	52,041,223	0.00
November	0	0	52,036,409	0.00
December	0	0	52,143,790	0.00
<i>2013</i>				
January	0	0	41,330,662	0.00
February	0	0	41,267,747	0.00
March	0	0	41,223,201	0.00
April	0	0	41,169,578	0.00
May	0	0	41,107,177	0.00
June	0	0	41,036,151	0.00
July	0	0	40,989,887	0.00
August	0	0	40,976,506	0.00
September	0	0	41,041,550	0.00
October	0	0	41,017,147	0.00
November	0	0	41,146,809	0.00
December	0	0	41,022,577	0.00
<i>2014</i>				
January	0	0	43,473,954	0.00
February	0	0	43,277,665	0.00
March	0	0	43,280,753	0.00
April	0	0	43,218,379	0.00
May	0	0	43,004,996	0.00
June	0	0	42,964,110	0.00
July	0	0	43,114,303	0.00
August	0	0	43,028,459	0.00
September	0	0	43,006,724	0.00
October	0	0	42,978,610	0.00
November	0	0	42,927,741	0.00
December	0	0	42,855,039	0.00
<i>2015</i>				
January	1	1	26,489,481	0.00
February	1	1	26,451,586	0.00
March	0	0	26,381,863	0.00
April	0	0	26,312,168	0.00
May	0	0	26,259,467	0.00

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
June	0	0	26,200,289	0.00
July	1	1	26,155,278	0.00
August	8	10	26,077,047	0.00
September	187	225	26,022,688	0.07
October	20,158	30,490	26,017,688	7.75
November	19,214	28,853	25,965,811	7.40
December	20,673	31,683	25,926,759	7.97
<i>2016</i>				
January	19,414	29,235	26,171,554	7.42
February	19,669	29,531	26,153,287	7.52
March	21,398	33,232	26,148,283	8.18
April	19,995	30,400	26,106,323	7.66
May	20,120	30,627	26,053,425	7.72
June	21,194	32,205	26,012,490	8.15
July	19,565	29,356	25,987,259	7.53
August	21,475	33,221	25,915,857	8.29
September	20,494	31,250	25,860,540	7.92
October	20,052	30,481	25,753,179	7.79
November	20,689	31,077	25,666,896	8.06
December	20,859	31,743	25,603,634	8.15
<i>2017</i>				
January	19,225	29,290	24,253,479	7.93
February	18,328	27,261	24,209,651	7.57
March	20,269	31,347	24,184,192	8.38
April	18,471	27,694	24,121,539	7.66
May	20,028	30,650	24,077,422	8.32
June	20,039	30,404	24,025,177	8.34
July	18,847	28,217	23,948,148	7.87
August	20,367	31,384	23,901,232	8.52
September	18,794	27,793	23,861,833	7.88
October	19,824	30,113	23,830,784	8.32
November	19,804	29,645	23,610,075	8.39
December	19,388	29,157	23,562,154	8.23
<i>2018</i>				
January	20,051	30,667	24,301,121	8.25
February	18,663	27,950	24,278,968	7.69
March	20,225	31,042	24,232,276	8.35
April	19,733	29,661	24,185,445	8.16
May	20,457	31,277	24,113,466	8.48

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members ¹	Number of Exposed Members per 10,000 Eligible Members
June	20,091	30,390	24,057,211	8.35
July	19,809	30,238	24,006,160	8.25
August	20,868	32,106	23,997,638	8.70
September	18,988	28,376	23,972,867	7.92
October	21,396	33,124	23,920,988	8.94
November	20,680	31,288	23,871,095	8.66
December	19,815	29,705	23,802,676	8.32
<i>2019</i>				
January	19,647	30,150	22,188,245	8.85
February	18,072	26,879	22,171,940	8.15
March	19,247	29,469	22,140,668	8.69
April	19,407	29,844	22,036,744	8.81
May	19,627	30,073	22,002,830	8.92
June	18,861	28,472	21,951,062	8.59
July	19,674	30,313	21,892,323	8.99
August	19,770	30,452	21,865,062	9.04
September	18,895	28,529	21,824,448	8.66
October	20,320	31,407	21,811,664	9.32
November	18,870	28,291	21,762,917	8.67
December	19,363	29,545	21,731,070	8.91
<i>2020</i>				
January	19,847	30,650	21,597,091	9.19
February	18,492	27,753	21,553,960	8.58
March	17,471	26,226	21,530,147	8.11
April	15,748	23,762	21,487,224	7.33
May	16,778	25,791	21,424,880	7.83
June	19,286	30,525	21,388,355	9.02
July	19,365	30,529	21,236,324	9.12
August	19,117	29,224	21,180,862	9.03
September	19,081	29,594	21,097,793	9.04
October	19,868	31,529	21,002,571	9.46
November	18,366	28,193	20,952,934	8.77
December	19,654	31,138	20,915,869	9.40
<i>2021</i>				
January	17,673	27,291	19,598,561	9.02
February	17,180	25,860	19,570,182	8.78
March	19,396	30,748	19,535,326	9.93
April	18,700	29,194	19,519,760	9.58
May	17,922	27,372	19,569,498	9.16

Table 2. Summary of Crohn's Disease in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month

	Number of Patients	Number of Episodes	Number of Eligible Members¹	Number of Exposed Members per 10,000 Eligible Members
June	18,956	29,494	19,536,298	9.70
July	18,321	28,125	19,471,442	9.41
August	18,653	28,517	19,448,365	9.59
September	18,593	28,037	19,411,991	9.58
October	18,465	28,167	19,339,254	9.55
November	18,294	27,858	19,299,376	9.48
December	18,363	28,192	19,262,996	9.53

¹Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

Figure 1. Incidence of Crohn's Disease (183 Days Washout) per 10,000 Eligible Members from October 2010 to December 2021 by Code Type

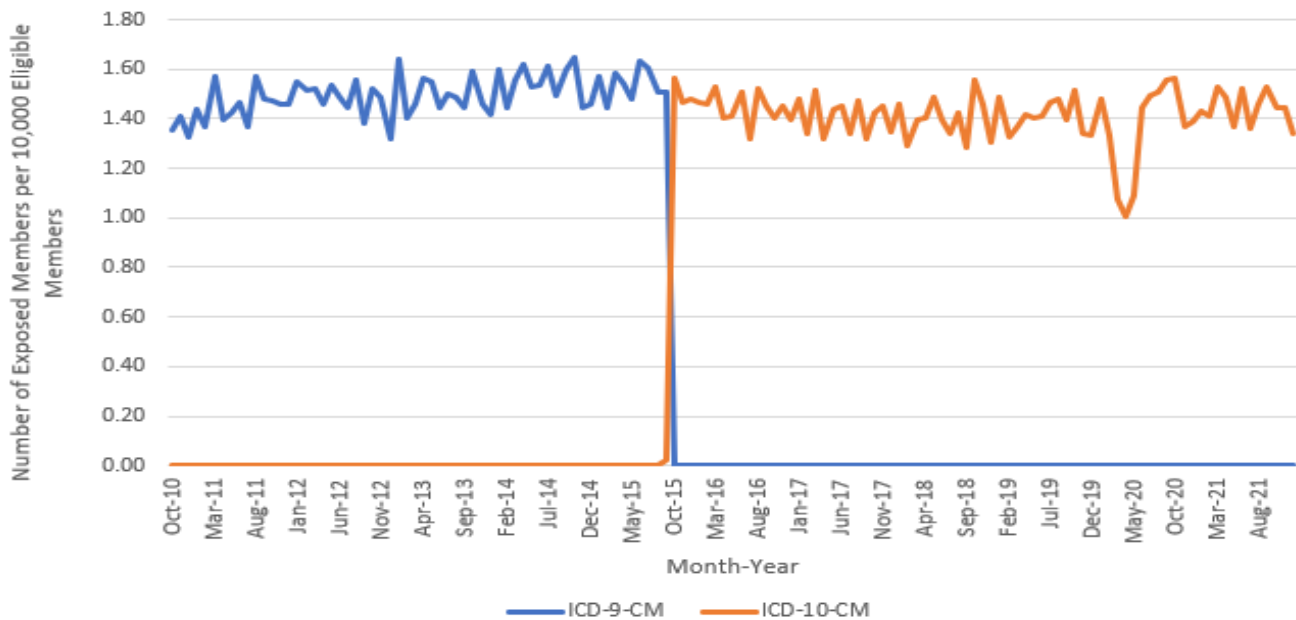
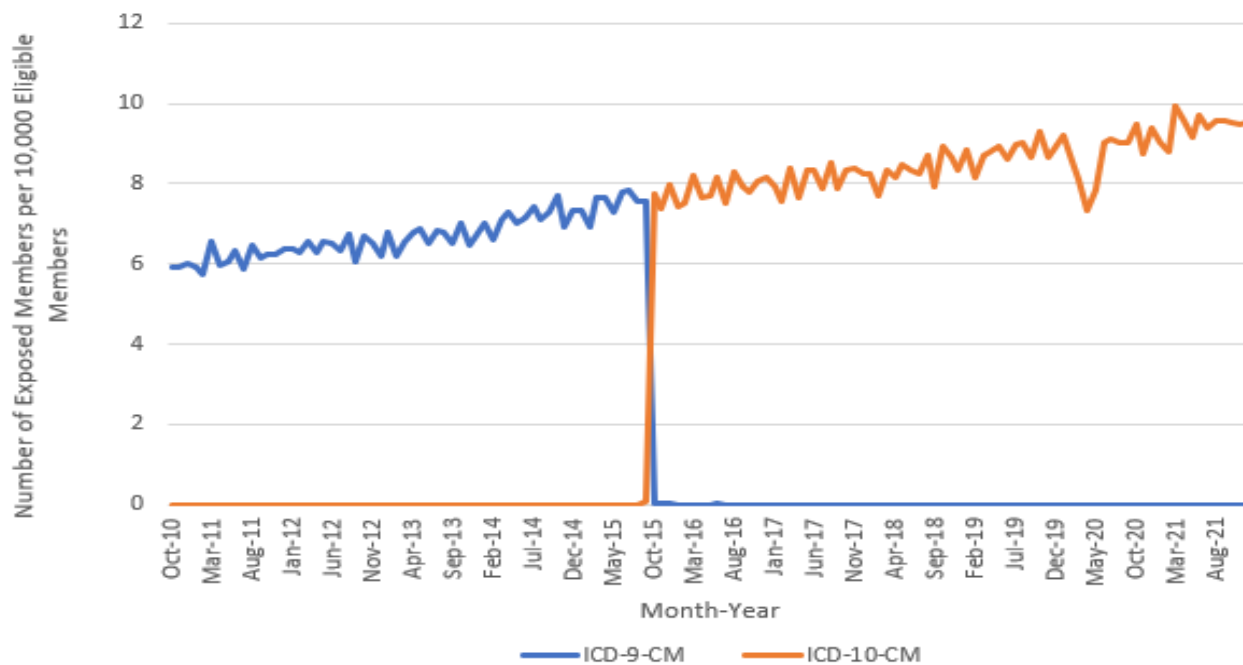


Figure 2. Prevalence of Crohn's Disease (0 Days Washout) per 10,000 Eligible Members from October 2010 to December 2021 by Code Type



Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (January 17, 2023)

Masked DP ID¹	DP Start Date	DP End Date²
DP01	01/01/2010	12/31/2021

¹Participating Data Partner(s) include(s) Merative MarketScan Research Databases.

²End Date represents the earliest of: (1) query end date, or (2) last day of the most recent month for which all of a Data Partner's data tables (enrollment, dispensing, etc.) have at least 80% of the record count relative to the prior month.

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 Crohn's Disease in this Request

Code	Description	Code Category	Code Type
Crohn's Disease			
555	Regional enteritis	Diagnosis	ICD-9-CM
555.0	Regional enteritis of small intestine	Diagnosis	ICD-9-CM
555.1	Regional enteritis of large intestine	Diagnosis	ICD-9-CM
555.2	Regional enteritis of small intestine with large intestine	Diagnosis	ICD-9-CM
555.9	Regional enteritis of unspecified site	Diagnosis	ICD-9-CM
K50.00	Crohn's disease of small intestine without complications	Diagnosis	ICD-10-CM
K50.011	Crohn's disease of small intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.012	Crohn's disease of small intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.013	Crohn's disease of small intestine with fistula	Diagnosis	ICD-10-CM
K50.014	Crohn's disease of small intestine with abscess	Diagnosis	ICD-10-CM
K50.018	Crohn's disease of small intestine with other complication	Diagnosis	ICD-10-CM
K50.019	Crohn's disease of small intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.10	Crohn's disease of large intestine without complications	Diagnosis	ICD-10-CM
K50.111	Crohn's disease of large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.112	Crohn's disease of large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.113	Crohn's disease of large intestine with fistula	Diagnosis	ICD-10-CM
K50.114	Crohn's disease of large intestine with abscess	Diagnosis	ICD-10-CM
K50.118	Crohn's disease of large intestine with other complication	Diagnosis	ICD-10-CM
K50.119	Crohn's disease of large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.80	Crohn's disease of both small and large intestine without complications	Diagnosis	ICD-10-CM
K50.811	Crohn's disease of both small and large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.813	Crohn's disease of both small and large intestine with fistula	Diagnosis	ICD-10-CM
K50.814	Crohn's disease of both small and large intestine with abscess	Diagnosis	ICD-10-CM
K50.818	Crohn's disease of both small and large intestine with other complication	Diagnosis	ICD-10-CM
K50.819	Crohn's disease of both small and large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.90	Crohn's disease, unspecified, without complications	Diagnosis	ICD-10-CM
K50.911	Crohn's disease, unspecified, with rectal bleeding	Diagnosis	ICD-10-CM
K50.912	Crohn's disease, unspecified, with intestinal obstruction	Diagnosis	ICD-10-CM
K50.913	Crohn's disease, unspecified, with fistula	Diagnosis	ICD-10-CM
K50.914	Crohn's disease, unspecified, with abscess	Diagnosis	ICD-10-CM
K50.918	Crohn's disease, unspecified, with other complication	Diagnosis	ICD-10-CM
K50.919	Crohn's disease, unspecified, with unspecified complications	Diagnosis	ICD-10-CM
Crohn's Disease ICD-9-CM			
555	Regional enteritis	Diagnosis	ICD-9-CM
555.0	Regional enteritis of small intestine	Diagnosis	ICD-9-CM
555.1	Regional enteritis of large intestine	Diagnosis	ICD-9-CM
555.2	Regional enteritis of small intestine with large intestine	Diagnosis	ICD-9-CM
555.9	Regional enteritis of unspecified site	Diagnosis	ICD-9-CM
Crohn's Disease ICD-10-CM			
K50.00	Crohn's disease of small intestine without complications	Diagnosis	ICD-10-CM
K50.011	Crohn's disease of small intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.012	Crohn's disease of small intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.013	Crohn's disease of small intestine with fistula	Diagnosis	ICD-10-CM
K50.014	Crohn's disease of small intestine with abscess	Diagnosis	ICD-10-CM
K50.018	Crohn's disease of small intestine with other complication	Diagnosis	ICD-10-CM

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 Crohn's Disease in this Request

Code	Description	Code Category	Code Type
K50.019	Crohn's disease of small intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.10	Crohn's disease of large intestine without complications	Diagnosis	ICD-10-CM
K50.111	Crohn's disease of large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.112	Crohn's disease of large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.113	Crohn's disease of large intestine with fistula	Diagnosis	ICD-10-CM
K50.114	Crohn's disease of large intestine with abscess	Diagnosis	ICD-10-CM
K50.118	Crohn's disease of large intestine with other complication	Diagnosis	ICD-10-CM
K50.119	Crohn's disease of large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.80	Crohn's disease of both small and large intestine without complications	Diagnosis	ICD-10-CM
K50.811	Crohn's disease of both small and large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.813	Crohn's disease of both small and large intestine with fistula	Diagnosis	ICD-10-CM
K50.814	Crohn's disease of both small and large intestine with abscess	Diagnosis	ICD-10-CM
K50.818	Crohn's disease of both small and large intestine with other complication	Diagnosis	ICD-10-CM
K50.819	Crohn's disease of both small and large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.90	Crohn's disease, unspecified, without complications	Diagnosis	ICD-10-CM
K50.911	Crohn's disease, unspecified, with rectal bleeding	Diagnosis	ICD-10-CM
K50.912	Crohn's disease, unspecified, with intestinal obstruction	Diagnosis	ICD-10-CM
K50.913	Crohn's disease, unspecified, with fistula	Diagnosis	ICD-10-CM
K50.914	Crohn's disease, unspecified, with abscess	Diagnosis	ICD-10-CM
K50.918	Crohn's disease, unspecified, with other complication	Diagnosis	ICD-10-CM
K50.919	Crohn's disease, unspecified, with unspecified complications	Diagnosis	ICD-10-CM

Appendix C. 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 Crohn's Disease Incidence

Code	Description	Code Category	Code Type
555	Regional enteritis	Diagnosis	ICD-9-CM
555.0	Regional enteritis of small intestine	Diagnosis	ICD-9-CM
555.1	Regional enteritis of large intestine	Diagnosis	ICD-9-CM
555.2	Regional enteritis of small intestine with large intestine	Diagnosis	ICD-9-CM
555.9	Regional enteritis of unspecified site	Diagnosis	ICD-9-CM
K50.00	Crohn's disease of small intestine without complications	Diagnosis	ICD-10-CM
K50.011	Crohn's disease of small intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.012	Crohn's disease of small intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.013	Crohn's disease of small intestine with fistula	Diagnosis	ICD-10-CM
K50.014	Crohn's disease of small intestine with abscess	Diagnosis	ICD-10-CM
K50.018	Crohn's disease of small intestine with other complication	Diagnosis	ICD-10-CM
K50.019	Crohn's disease of small intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.10	Crohn's disease of large intestine without complications	Diagnosis	ICD-10-CM
K50.111	Crohn's disease of large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.112	Crohn's disease of large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.113	Crohn's disease of large intestine with fistula	Diagnosis	ICD-10-CM
K50.114	Crohn's disease of large intestine with abscess	Diagnosis	ICD-10-CM
K50.118	Crohn's disease of large intestine with other complication	Diagnosis	ICD-10-CM
K50.119	Crohn's disease of large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.80	Crohn's disease of both small and large intestine without complications	Diagnosis	ICD-10-CM
K50.811	Crohn's disease of both small and large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.813	Crohn's disease of both small and large intestine with fistula	Diagnosis	ICD-10-CM
K50.814	Crohn's disease of both small and large intestine with abscess	Diagnosis	ICD-10-CM
K50.818	Crohn's disease of both small and large intestine with other complication	Diagnosis	ICD-10-CM
K50.819	Crohn's disease of both small and large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.90	Crohn's disease, unspecified, without complications	Diagnosis	ICD-10-CM
K50.911	Crohn's disease, unspecified, with rectal bleeding	Diagnosis	ICD-10-CM
K50.912	Crohn's disease, unspecified, with intestinal obstruction	Diagnosis	ICD-10-CM
K50.913	Crohn's disease, unspecified, with fistula	Diagnosis	ICD-10-CM
K50.914	Crohn's disease, unspecified, with abscess	Diagnosis	ICD-10-CM
K50.918	Crohn's disease, unspecified, with other complication	Diagnosis	ICD-10-CM
K50.919	Crohn's disease, unspecified, with unspecified complications	Diagnosis	ICD-10-CM

Appendix D. Specifications of the Study Design and Parameters Used in this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool will be used to compare the frequency of diagnoses for a selection of health outcomes using ICD-9 versus ICD-10 codes

Coverage requirement: At least medical coverage
Enrollment gap: 45 Days
Enrollment Requirement: (See below)
Age groups: 0-106
Stratifications: (See below)

Exposure/Event

Scenario	Group	Event	Enrollment Requirement	Stratifications	Query Period Start	Query Period End	Monitoring File/Run #	Event Code Type	Incident Code Type	Cohort definition	Washout period	Care setting
1	CD_9_yr1	CD	183	None	10/1/2013	9/30/2014	1	ICD-9-CM, HCPCS/CPT	ICD-9-CM	02	183	Any care setting
2	CD_9_yr2	CD	183	None	10/1/2014	9/30/2015	2	ICD-9-CM	ICD-9-CM	02	183	Any care setting
3	CD_10_yr1	CD	183	None	10/1/2015	9/30/2016	3	ICD-10-CM	ICD-10-CM	02	183	Any care setting
4	CD_10_yr2	CD	183	None	10/1/2016	9/30/2017	4	ICD-10-CM	ICD-10-CM	02	183	Any care setting
5	CD_9_inc	CD	183	Year*Month	10/1/2010	12/31/2022	5	ICD-9-CM	ICD-9-CM, ICD-10-CM	02	183	Any care setting
6	CD_10_inc	CD	183	Year*Month	10/1/2010	12/31/2022	5	ICD-10-CM	ICD-9-CM, ICD-10-CM	02	183	Any care setting
7	CD_9_prev	CD	0	Year*Month	10/1/2010	12/31/2022	5	ICD-9-CM	N/A	02	0	Any care setting
8	CD_10_prev	CD	0	Year*Month	10/1/2010	12/31/2022	5	ICD-10-CM	N/A	02	0	Any care setting

ICD-9-CM and ICD-10-CM are provided by FDA. ICD-10-CM codes were mapped from ICD-9-CM codes and ICD-9-CM codes were mapped from ICD-10-CM. ☒

ICD-9, ICD-10, HCPCS, and CPT codes are provided by FDA.

NDC codes are checked against First Data Bank's FDB MedKnowledge®.