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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 ulcerative colitis 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.<sup>1</sup>

**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 ulcerative colitis 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 ulcerative colitis in this request.

**Cohort Eligibility Criteria:**

*Incident Cohorts:* We identified codes for ulcerative colitis 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 ulcerative colitis 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.**

<sup>1</sup>Fung, 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](mailto: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.

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

**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.

**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 Ulcerative Colitis in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021**

	<b>Number of Patients</b>	<b>Number of Episodes</b>	<b>Number of Eligible Members<sup>1</sup></b>	<b>Number of Exposed Members per 10,000 Eligible Members</b>
<i>Ulcerative Colitis ICD-9-CM from 2013 to 2014</i>	81,958	85,000	49,370,755	16.60
<i>Ulcerative Colitis ICD-9-CM from 2014 to 2015</i>	63,673	65,907	45,276,434	14.06
<i>Ulcerative Colitis ICD-10-CM from 2015 to 2016</i>	78,634	83,454	29,532,505	26.63
<i>Ulcerative Colitis ICD-10-CM from 2016 to 2017</i>	54,803	56,749	29,829,930	18.37
<i>Ulcerative Colitis ICD-9-CM Incidence</i>	307,414	438,120	128,721,161	23.88
<i>Ulcerative Colitis ICD-10-CM Incidence</i>	227,784	334,924	128,721,161	17.70
<i>Ulcerative Colitis ICD-9-CM Prevalence</i>	390,703	1,850,108	149,022,924	26.22
<i>Ulcerative Colitis ICD-10-CM Prevalence</i>	288,718	1,726,792	149,022,924	19.37

<sup>1</sup>Eligible 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 Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
<b>Ulcerative Colitis ICD-9-CM Incidence</b>				
<i>2010</i>				
October	7,978	7,978	43,708,256	1.83
November	8,189	8,189	43,188,488	1.90
December	7,874	7,874	44,037,746	1.79
<i>2011</i>				
January	7,193	7,193	38,206,548	1.88
February	6,754	6,754	37,642,963	1.79
March	7,778	7,778	37,808,280	2.06
April	7,081	7,081	37,913,186	1.87
May	6,992	6,992	37,883,039	1.85
June	7,558	7,558	37,867,897	2.00
July	8,344	8,344	47,460,206	1.76
August	9,452	9,452	47,790,499	1.98
September	9,155	9,155	47,045,700	1.95
October	9,305	9,305	47,448,994	1.96
November	9,019	9,019	46,924,831	1.92
December	8,888	8,888	47,912,991	1.86
<i>2012</i>				
January	8,593	8,593	43,093,513	1.99
February	8,389	8,389	42,545,909	1.97
March	8,454	8,454	42,527,334	1.99
April	8,054	8,054	42,393,131	1.90
May	8,398	8,398	42,383,829	1.98
June	8,296	8,296	42,340,544	1.96
July	8,894	8,894	47,560,787	1.87
August	9,522	9,522	47,881,259	1.99
September	8,347	8,347	47,176,336	1.77
October	9,682	9,682	47,585,592	2.03
November	8,970	8,970	47,074,856	1.91
December	8,334	8,334	47,988,448	1.74
<i>2013</i>				
January	6,924	6,924	33,254,543	2.08
February	6,122	6,122	32,903,195	1.86
March	6,312	6,312	33,076,273	1.91
April	6,999	6,999	33,152,268	2.11

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
May	6,857	6,857	33,160,739	2.07
June	6,267	6,267	33,037,730	1.90
July	7,572	7,572	37,818,816	2.00
August	7,446	7,446	38,114,793	1.95
September	7,195	7,195	37,482,370	1.92
October	7,927	7,927	37,745,763	2.10
November	6,949	6,949	37,205,505	1.87
December	7,072	7,072	37,697,428	1.88
<b>2014</b>				
January	6,731	6,731	33,023,201	2.04
February	5,973	5,973	32,612,029	1.83
March	6,474	6,474	32,823,057	1.97
April	6,883	6,883	32,793,421	2.10
May	6,526	6,526	32,594,975	2.00
June	6,622	6,622	32,701,695	2.02
July	8,167	8,167	39,069,588	2.09
August	7,692	7,692	39,388,536	1.95
September	7,984	7,984	38,770,673	2.06
October	8,538	8,538	39,287,148	2.17
November	7,331	7,331	38,750,067	1.89
December	7,939	7,939	39,585,773	2.01
<b>2015</b>				
January	4,371	4,371	22,119,395	1.98
February	4,162	4,162	21,854,594	1.90
March	4,741	4,741	21,889,622	2.17
April	4,745	4,745	21,884,632	2.17
May	4,344	4,344	21,861,027	1.99
June	4,698	4,698	21,796,863	2.16
July	5,025	5,025	24,085,559	2.09
August	4,958	4,958	24,295,113	2.04
September	5,054	5,054	23,919,788	2.11
October	5	5	24,088,921	0.00
November	4	4	23,798,095	0.00
December	2	2	24,183,485	0.00
<b>2016</b>				
January	0	0	21,729,158	0.00



**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
February	0	0	21,477,951	0.00
March	1	1	21,539,996	0.00
April	1	1	21,561,282	0.00
May	0	0	21,528,346	0.00
June	1	1	21,480,630	0.00
July	1	1	24,021,934	0.00
August	2	2	24,205,806	0.00
September	0	0	23,835,286	0.00
October	0	0	23,965,632	0.00
November	0	0	23,633,883	0.00
December	0	0	23,973,995	0.00
<i>2017</i>				
January	0	0	19,161,908	0.00
February	0	0	18,933,120	0.00
March	1	1	18,980,513	0.00
April	0	0	18,970,435	0.00
May	0	0	18,935,476	0.00
June	1	1	18,869,610	0.00
July	1	1	22,243,080	0.00
August	0	0	22,408,481	0.00
September	0	0	22,073,493	0.00
October	0	0	22,240,799	0.00
November	0	0	21,788,570	0.00
December	0	0	22,061,522	0.00
<i>2018</i>				
January	0	0	17,928,934	0.00
February	1	1	17,723,352	0.00
March	0	0	17,758,237	0.00
April	0	0	17,744,521	0.00
May	1	1	17,728,135	0.00
June	0	0	17,659,397	0.00
July	0	0	22,022,934	0.00
August	1	1	22,208,896	0.00
September	0	0	21,836,214	0.00
October	0	0	22,011,613	0.00
November	0	0	21,700,276	0.00

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
December	0	0	22,062,887	0.00
<i>2019</i>				
January	0	0	18,664,430	0.00
February	0	0	18,427,997	0.00
March	0	0	18,497,719	0.00
April	0	0	18,411,525	0.00
May	1	1	18,394,182	0.00
June	1	1	18,311,429	0.00
July	0	0	20,020,001	0.00
August	0	0	20,203,245	0.00
September	0	0	19,839,227	0.00
October	0	0	20,061,546	0.00
November	0	0	19,770,477	0.00
December	0	0	20,114,405	0.00
<i>2020</i>				
January	0	0	16,800,574	0.00
February	0	0	16,598,617	0.00
March	0	0	16,672,514	0.00
April	0	0	16,716,072	0.00
May	0	0	16,724,464	0.00
June	0	0	16,694,515	0.00
July	0	0	19,738,674	0.00
August	0	0	19,920,978	0.00
September	0	0	19,594,801	0.00
October	0	0	19,677,287	0.00
November	0	0	19,411,690	0.00
December	0	0	19,635,000	0.00
<i>2021</i>				
January	0	0	16,438,047	0.00
February	1	1	16,244,767	0.00
March	0	0	16,255,031	0.00
April	0	0	16,230,204	0.00
May	0	0	16,194,033	0.00
June	0	0	16,107,035	0.00
July	0	0	17,786,122	0.00
August	0	0	17,879,792	0.00

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
September	0	0	17,521,501	0.00
October	1	1	17,681,572	0.00
November	0	0	17,383,717	0.00
December	0	0	17,648,030	0.00
<b>Ulcerative Colitis ICD-10-CM Incidence</b>				
<i>2010</i>				
October	0	0	43,708,256	0.00
November	0	0	43,188,488	0.00
December	0	0	44,037,746	0.00
<i>2011</i>				
January	0	0	38,206,548	0.00
February	0	0	37,642,963	0.00
March	0	0	37,808,280	0.00
April	0	0	37,913,186	0.00
May	0	0	37,883,039	0.00
June	0	0	37,867,897	0.00
July	0	0	47,460,206	0.00
August	0	0	47,790,499	0.00
September	0	0	47,045,700	0.00
October	0	0	47,448,994	0.00
November	0	0	46,924,831	0.00
December	0	0	47,912,991	0.00
<i>2012</i>				
January	0	0	43,093,513	0.00
February	0	0	42,545,909	0.00
March	0	0	42,527,334	0.00
April	0	0	42,393,131	0.00
May	0	0	42,383,829	0.00
June	0	0	42,340,544	0.00
July	0	0	47,560,787	0.00
August	0	0	47,881,259	0.00
September	0	0	47,176,336	0.00
October	0	0	47,585,592	0.00
November	0	0	47,074,856	0.00
December	0	0	47,988,448	0.00
<i>2013</i>				

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
January	0	0	33,254,543	0.00
February	0	0	32,903,195	0.00
March	0	0	33,076,273	0.00
April	0	0	33,152,268	0.00
May	0	0	33,160,739	0.00
June	0	0	33,037,730	0.00
July	0	0	37,818,816	0.00
August	0	0	38,114,793	0.00
September	0	0	37,482,370	0.00
October	0	0	37,745,763	0.00
November	0	0	37,205,505	0.00
December	0	0	37,697,428	0.00
<i>2014</i>				
January	0	0	33,023,201	0.00
February	0	0	32,612,029	0.00
March	0	0	32,823,057	0.00
April	0	0	32,793,421	0.00
May	0	0	32,594,975	0.00
June	0	0	32,701,695	0.00
July	0	0	39,069,588	0.00
August	0	0	39,388,536	0.00
September	0	0	38,770,673	0.00
October	0	0	39,287,148	0.00
November	0	0	38,750,067	0.00
December	0	0	39,585,773	0.00
<i>2015</i>				
January	0	0	22,119,395	0.00
February	0	0	21,854,594	0.00
March	0	0	21,889,622	0.00
April	0	0	21,884,632	0.00
May	0	0	21,861,027	0.00
June	0	0	21,796,863	0.00
July	2	2	24,085,559	0.00
August	2	2	24,295,113	0.00
September	46	46	23,919,788	0.02
October	5,799	5,799	24,088,921	2.41

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
November	5,373	5,373	23,798,095	2.26
December	5,660	5,660	24,183,485	2.34
<i>2016</i>				
January	4,690	4,690	21,729,158	2.16
February	4,909	4,909	21,477,951	2.29
March	5,075	5,075	21,539,996	2.36
April	4,846	4,846	21,561,282	2.25
May	4,814	4,814	21,528,346	2.24
June	5,012	5,012	21,480,630	2.33
July	4,942	4,942	24,021,934	2.06
August	5,718	5,718	24,205,806	2.36
September	5,446	5,446	23,835,286	2.28
October	5,382	5,382	23,965,632	2.25
November	5,448	5,448	23,633,883	2.31
December	5,412	5,412	23,973,995	2.26
<i>2017</i>				
January	4,433	4,433	19,161,908	2.31
February	3,969	3,969	18,933,120	2.10
March	4,487	4,487	18,980,513	2.36
April	3,984	3,984	18,970,435	2.10
May	4,450	4,450	18,935,476	2.35
June	4,527	4,527	18,869,610	2.40
July	4,652	4,652	22,243,080	2.09
August	5,230	5,230	22,408,481	2.33
September	4,775	4,775	22,073,493	2.16
October	5,297	5,297	22,240,799	2.38
November	5,025	5,025	21,788,570	2.31
December	4,873	4,873	22,061,522	2.21
<i>2018</i>				
January	4,031	4,031	17,928,934	2.25
February	3,713	3,713	17,723,352	2.09
March	3,949	3,949	17,758,237	2.22
April	3,935	3,935	17,744,521	2.22
May	4,123	4,123	17,728,135	2.33
June	3,973	3,973	17,659,397	2.25
July	4,925	4,925	22,022,934	2.24

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
August	5,250	5,250	22,208,896	2.36
September	4,633	4,633	21,836,214	2.12
October	5,595	5,595	22,011,613	2.54
November	5,153	5,153	21,700,276	2.37
December	4,652	4,652	22,062,887	2.11
<i>2019</i>				
January	4,411	4,411	18,664,430	2.36
February	3,915	3,915	18,427,997	2.12
March	4,099	4,099	18,497,719	2.22
April	4,307	4,307	18,411,525	2.34
May	4,143	4,143	18,394,182	2.25
June	4,040	4,040	18,311,429	2.21
July	4,719	4,719	20,020,001	2.36
August	4,702	4,702	20,203,245	2.33
September	4,372	4,372	19,839,227	2.20
October	5,049	5,049	20,061,546	2.52
November	4,589	4,589	19,770,477	2.32
December	4,499	4,499	20,114,405	2.24
<i>2020</i>				
January	3,907	3,907	16,800,574	2.33
February	3,624	3,624	16,598,617	2.18
March	2,976	2,976	16,672,514	1.78
April	2,251	2,251	16,716,072	1.35
May	2,716	2,716	16,724,464	1.62
June	3,849	3,849	16,694,515	2.31
July	4,585	4,585	19,738,674	2.32
August	4,586	4,586	19,920,978	2.30
September	4,907	4,907	19,594,801	2.50
October	4,915	4,915	19,677,287	2.50
November	4,263	4,263	19,411,690	2.20
December	4,342	4,342	19,635,000	2.21
<i>2021</i>				
January	3,555	3,555	16,438,047	2.16
February	3,382	3,382	16,244,767	2.08
March	3,803	3,803	16,255,031	2.34
April	3,704	3,704	16,230,204	2.28

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
May	3,443	3,443	16,194,033	2.13
June	3,841	3,841	16,107,035	2.38
July	4,148	4,148	17,786,122	2.33
August	4,295	4,295	17,879,792	2.40
September	4,147	4,147	17,521,501	2.37
October	4,237	4,237	17,681,572	2.40
November	4,260	4,260	17,383,717	2.45
December	4,133	4,133	17,648,030	2.34
<b>Ulcerative Colitis ICD-9-CM Prevalence</b>				
<i>2010</i>				
October	22,350	28,588	47,783,732	4.68
November	22,869	29,098	47,714,965	4.79
December	22,546	29,005	47,760,109	4.72
<i>2011</i>				
January	24,568	32,076	52,274,120	4.70
February	23,480	30,036	52,038,076	4.51
March	27,157	35,775	51,957,287	5.23
April	25,143	32,467	51,860,782	4.85
May	25,005	32,345	51,769,930	4.83
June	26,625	34,898	51,756,451	5.14
July	24,136	31,034	51,804,123	4.66
August	26,621	35,088	51,756,708	5.14
September	25,713	33,457	51,699,947	4.97
October	26,327	34,206	51,652,144	5.10
November	26,117	33,797	51,621,813	5.06
December	26,218	34,193	51,691,308	5.07
<i>2012</i>				
January	26,957	35,427	52,576,934	5.13
February	26,520	34,455	52,397,697	5.06
March	27,414	36,198	52,177,387	5.25
April	26,416	34,371	51,958,063	5.08
May	27,272	35,825	51,927,518	5.25
June	26,981	35,289	51,845,618	5.20
July	26,393	34,586	51,815,509	5.09
August	28,105	37,169	51,942,235	5.41
September	25,245	32,777	52,013,540	4.85

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
October	28,259	37,375	52,041,223	5.43
November	27,009	35,145	52,036,409	5.19
December	25,776	33,348	52,143,790	4.94
<i>2013</i>				
January	22,987	30,367	41,330,662	5.56
February	20,936	27,000	41,267,747	5.07
March	21,945	28,731	41,223,201	5.32
April	23,037	30,293	41,169,578	5.60
May	23,171	30,774	41,107,177	5.64
June	21,725	28,261	41,036,151	5.29
July	22,821	30,134	40,989,887	5.57
August	22,695	29,925	40,976,506	5.54
September	21,942	28,627	41,041,550	5.35
October	23,962	31,651	41,017,147	5.84
November	21,725	27,963	41,146,809	5.28
December	22,316	29,191	41,022,577	5.44
<i>2014</i>				
January	24,528	32,637	43,473,954	5.64
February	22,714	29,630	43,277,665	5.25
March	24,710	32,930	43,280,753	5.71
April	25,380	33,787	43,218,379	5.87
May	24,408	32,248	43,004,996	5.68
June	25,062	33,000	42,964,110	5.83
July	25,898	34,871	43,114,303	6.01
August	24,742	32,590	43,028,459	5.75
September	25,165	33,470	43,006,724	5.85
October	27,052	36,197	42,978,610	6.29
November	23,832	31,039	42,927,741	5.55
December	25,695	33,940	42,855,039	6.00
<i>2015</i>				
January	15,359	20,507	26,489,481	5.80
February	14,773	19,398	26,451,586	5.58
March	16,359	21,950	26,381,863	6.20
April	16,370	21,973	26,312,168	6.22
May	15,745	20,958	26,259,467	6.00
June	16,659	22,509	26,200,289	6.36



**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
July	16,529	22,347	26,155,278	6.32
August	15,911	21,299	26,077,047	6.10
September	16,302	21,746	26,022,688	6.26
October	28	28	26,017,688	0.01
November	8	9	25,965,811	0.00
December	16	17	25,926,759	0.01
<i>2016</i>				
January	1	1	26,171,554	0.00
February	2	2	26,153,287	0.00
March	3	3	26,148,283	0.00
April	4	4	26,106,323	0.00
May	1	1	26,053,425	0.00
June	7	8	26,012,490	0.00
July	1	1	25,987,259	0.00
August	3	5	25,915,857	0.00
September	1	1	25,860,540	0.00
October	2	2	25,753,179	0.00
November	1	1	25,666,896	0.00
December	1	1	25,603,634	0.00
<i>2017</i>				
January	1	1	24,253,479	0.00
February	0	0	24,209,651	0.00
March	1	1	24,184,192	0.00
April	0	0	24,121,539	0.00
May	0	0	24,077,422	0.00
June	1	2	24,025,177	0.00
July	3	3	23,948,148	0.00
August	0	0	23,901,232	0.00
September	1	2	23,861,833	0.00
October	1	1	23,830,784	0.00
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	1	1	24,278,968	0.00
March	0	0	24,232,276	0.00

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
April	0	0	24,185,445	0.00
May	2	3	24,113,466	0.00
June	1	3	24,057,211	0.00
July	1	1	24,006,160	0.00
August	1	1	23,997,638	0.00
September	1	1	23,972,867	0.00
October	0	0	23,920,988	0.00
November	1	1	23,871,095	0.00
December	1	1	23,802,676	0.00
<i>2019</i>				
January	2	2	22,188,245	0.00
February	1	1	22,171,940	0.00
March	1	1	22,140,668	0.00
April	0	0	22,036,744	0.00
May	1	1	22,002,830	0.00
June	2	2	21,951,062	0.00
July	1	1	21,892,323	0.00
August	1	1	21,865,062	0.00
September	1	1	21,824,448	0.00
October	1	1	21,811,664	0.00
November	0	0	21,762,917	0.00
December	2	2	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
November	0	0	20,952,934	0.00
December	0	0	20,915,869	0.00

2021

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
January	0	0	19,598,561	0.00
February	2	3	19,570,182	0.00
March	0	0	19,535,326	0.00
April	0	0	19,519,760	0.00
May	2	2	19,569,498	0.00
June	3	4	19,536,298	0.00
July	2	2	19,471,442	0.00
August	1	1	19,448,365	0.00
September	0	0	19,411,991	0.00
October	2	3	19,339,254	0.00
November	2	2	19,299,376	0.00
December	1	1	19,262,996	0.00
<b>Ulcerative Colitis ICD-10-CM Prevalence</b>				
<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 Ulcerative Colitis 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 <sup>1</sup>	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
<b>2013</b>				
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
<b>2014</b>				
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
<b>2015</b>				
January	0	0	26,489,481	0.00
February	0	0	26,451,586	0.00

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
March	0	0	26,381,863	0.00
April	0	0	26,312,168	0.00
May	1	1	26,259,467	0.00
June	0	0	26,200,289	0.00
July	2	2	26,155,278	0.00
August	5	7	26,077,047	0.00
September	156	198	26,022,688	0.06
October	17,093	22,745	26,017,688	6.57
November	16,328	21,329	25,965,811	6.29
December	17,680	23,644	25,926,759	6.82
<i>2016</i>				
January	16,294	21,724	26,171,554	6.23
February	16,771	22,530	26,153,287	6.41
March	18,136	24,572	26,148,283	6.94
April	17,116	22,881	26,106,323	6.56
May	17,173	22,972	26,053,425	6.59
June	18,137	24,491	26,012,490	6.97
July	16,461	22,035	25,987,259	6.33
August	18,397	25,220	25,915,857	7.10
September	17,573	23,718	25,860,540	6.80
October	17,430	23,168	25,753,179	6.77
November	18,025	24,086	25,666,896	7.02
December	18,040	24,201	25,603,634	7.05
<i>2017</i>				
January	16,524	22,080	24,253,479	6.81
February	15,725	20,740	24,209,651	6.50
March	17,568	23,962	24,184,192	7.26
April	15,908	21,092	24,121,539	6.59
May	17,324	23,505	24,077,422	7.20
June	17,492	23,620	24,025,177	7.28
July	15,941	21,353	23,948,148	6.66
August	17,584	23,826	23,901,232	7.36
September	16,295	21,990	23,861,833	6.83
October	17,537	23,744	23,830,784	7.36
November	17,196	22,868	23,610,075	7.28
December	16,996	22,564	23,562,154	7.21

**Table 2. Summary of Ulcerative Colitis in the Merative MarketScan Research Databases from October 1, 2010 to December 31, 2021, by Year and Month**

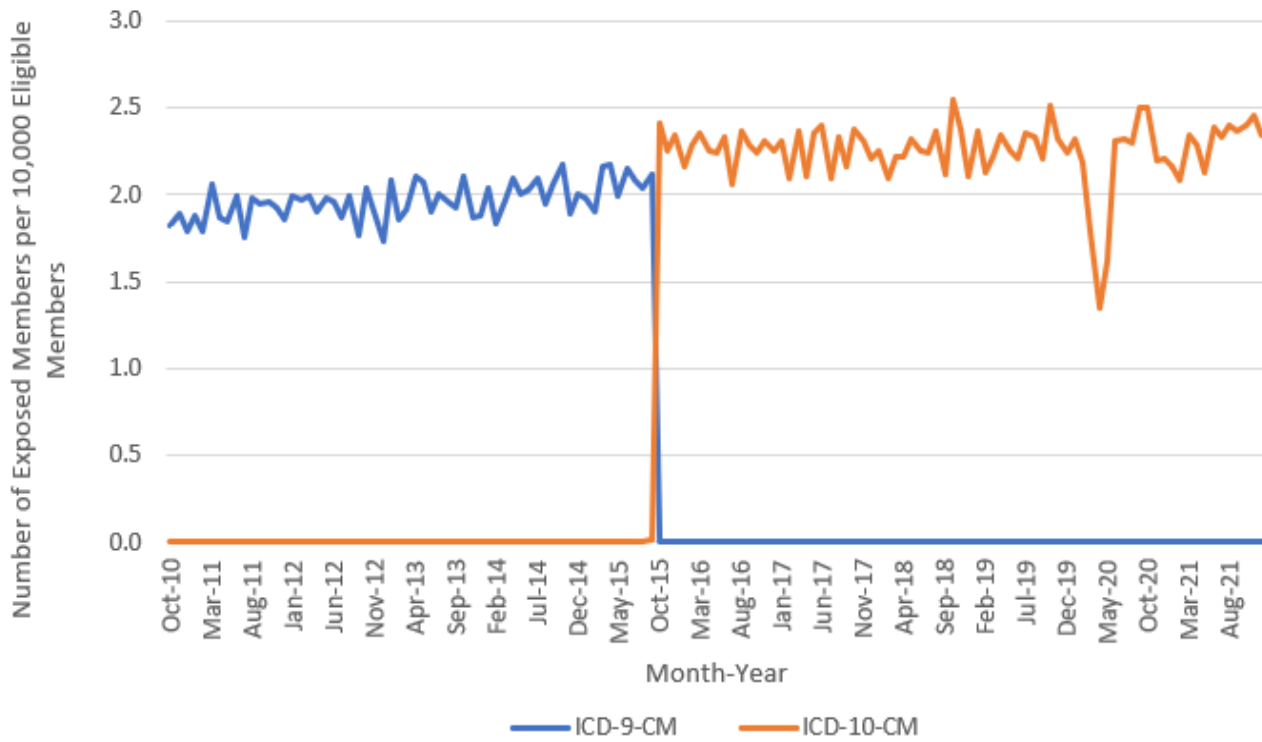
	Number of Patients	Number of Episodes	Number of Eligible Members <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
<i>2018</i>				
January	17,201	23,410	24,301,121	7.08
February	16,496	21,913	24,278,968	6.79
March	17,637	24,080	24,232,276	7.28
April	17,027	23,065	24,185,445	7.04
May	17,994	24,686	24,113,466	7.46
June	17,141	23,140	24,057,211	7.13
July	17,352	23,626	24,006,160	7.23
August	18,403	25,661	23,997,638	7.67
September	16,675	22,455	23,972,867	6.96
October	19,226	26,450	23,920,988	8.04
November	18,260	24,630	23,871,095	7.65
December	17,403	23,258	23,802,676	7.31
<i>2019</i>				
January	17,136	23,427	22,188,245	7.72
February	15,526	20,782	22,171,940	7.00
March	16,699	22,770	22,140,668	7.54
April	17,100	23,259	22,036,744	7.76
May	17,210	23,613	22,002,830	7.82
June	16,133	21,780	21,951,062	7.35
July	17,397	23,749	21,892,323	7.95
August	17,250	23,630	21,865,062	7.89
September	16,738	22,599	21,824,448	7.67
October	18,251	25,155	21,811,664	8.37
November	16,985	22,807	21,762,917	7.80
December	17,197	23,607	21,731,070	7.91
<i>2020</i>				
January	17,484	24,147	21,597,091	8.10
February	16,301	22,091	21,553,960	7.56
March	14,865	20,114	21,530,147	6.90
April	12,799	17,639	21,487,224	5.96
May	14,073	19,781	21,424,880	6.57
June	17,039	24,274	21,388,355	7.97
July	16,942	24,008	21,236,324	7.98
August	16,712	23,546	21,180,862	7.89
September	17,387	24,238	21,097,793	8.24

**Table 2. Summary of Ulcerative Colitis 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 <sup>1</sup>	Number of Exposed Members per 10,000 Eligible Members
October	17,734	24,690	21,002,571	8.44
November	16,364	22,304	20,952,934	7.81
December	17,460	24,678	20,915,869	8.35
<i>2021</i>				
January	15,428	21,468	19,598,561	7.87
February	14,906	20,485	19,570,182	7.62
March	16,990	24,234	19,535,326	8.70
April	16,349	22,785	19,519,760	8.38
May	15,729	21,799	19,569,498	8.04
June	16,814	23,499	19,536,298	8.61
July	16,258	22,322	19,471,442	8.35
August	16,646	23,071	19,448,365	8.56
September	16,355	22,765	19,411,991	8.43
October	16,590	22,916	19,339,254	8.58
November	16,346	22,404	19,299,376	8.47
December	16,496	23,114	19,262,996	8.56

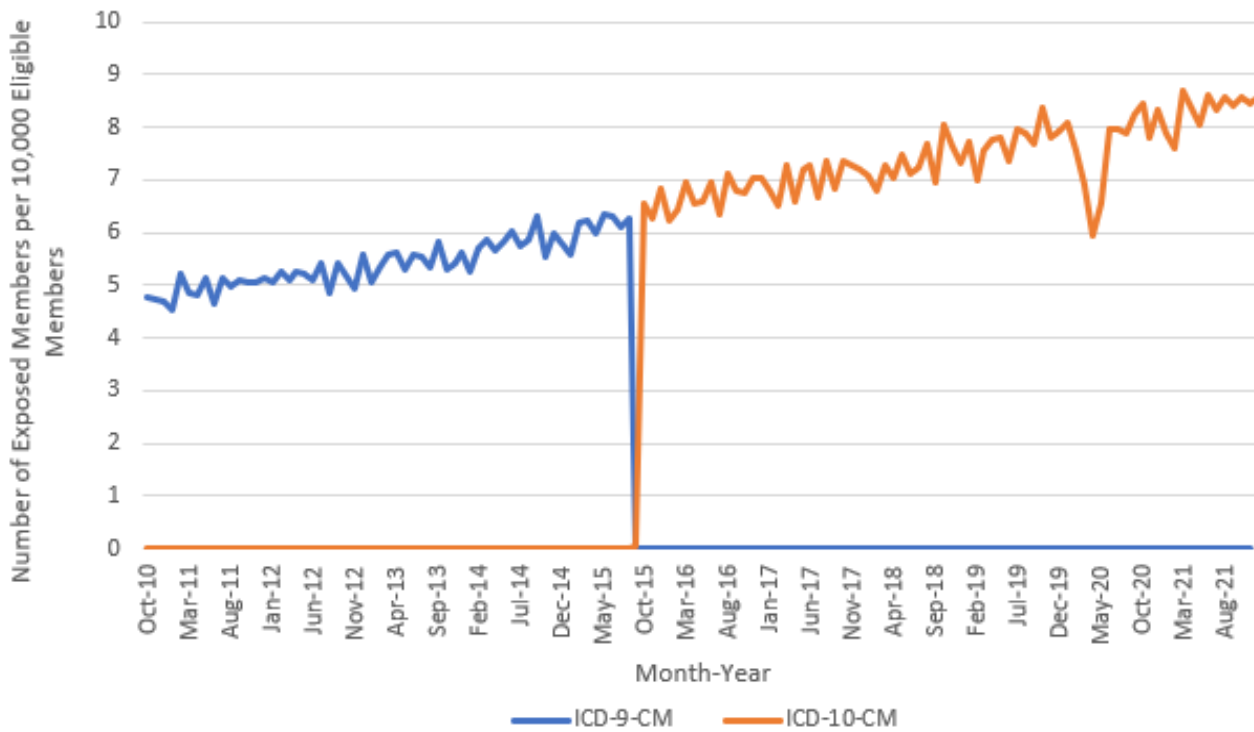
<sup>1</sup>Eligible Members are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period.

**Figure 1. Incidence of Ulcerative Colitis (183 Days Washout) per 10,000 Eligible Members from October 2010 to December 2021, by Code Type**





**Figure 2. Prevalence of Ulcerative Colitis (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)**

<b>Masked DP ID<sup>1</sup></b>	<b>DP Start Date</b>	<b>DP End Date<sup>2</sup></b>
DP01	01/01/2010	12/31/2021

<sup>1</sup>Participating Data Partner(s) include(s) Merative MarketScan Research Databases.

<sup>2</sup>End 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 Ulcerative Colitis (UC) in this Request**

Code	Description	Code Category	Code Type
<b>Ulcerative Colitis</b>			
556	Ulcerative Colitis	Diagnosis	ICD-9-CM
556.0	Ulcerative (chronic) enterocolitis	Diagnosis	ICD-9-CM
556.1	Ulcerative (chronic) ileocolitis	Diagnosis	ICD-9-CM
556.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-9-CM
556.3	Ulcerative (chronic) proctosigmoiditis	Diagnosis	ICD-9-CM
556.4	Pseudopolyposis of colon	Diagnosis	ICD-9-CM
556.5	Left sided ulcerative (chronic) colitis	Diagnosis	ICD-9-CM
556.6	Universal ulcerative (chronic) colitis	Diagnosis	ICD-9-CM
556.8	Other ulcerative colitis	Diagnosis	ICD-9-CM
556.9	Unspecified ulcerative colitis	Diagnosis	ICD-9-CM
K51	Ulcerative colitis	Diagnosis	ICD-10-CM
K51.0	Ulcerative (chronic) pancolitis	Diagnosis	ICD-10-CM
K51.00	Ulcerative (chronic) pancolitis without complications	Diagnosis	ICD-10-CM
K51.01	Ulcerative (chronic) pancolitis with complications	Diagnosis	ICD-10-CM
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.013	Ulcerative (chronic) pancolitis with fistula	Diagnosis	ICD-10-CM
K51.014	Ulcerative (chronic) pancolitis with abscess	Diagnosis	ICD-10-CM
K51.018	Ulcerative (chronic) pancolitis with other complication	Diagnosis	ICD-10-CM
K51.019	Ulcerative (chronic) pancolitis with unspecified complications	Diagnosis	ICD-10-CM
K51.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-10-CM
K51.20	Ulcerative (chronic) proctitis without complications	Diagnosis	ICD-10-CM
K51.21	Ulcerative (chronic) proctitis with complications	Diagnosis	ICD-10-CM
K51.211	Ulcerative (chronic) proctitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.213	Ulcerative (chronic) proctitis with fistula	Diagnosis	ICD-10-CM
K51.214	Ulcerative (chronic) proctitis with abscess	Diagnosis	ICD-10-CM
K51.218	Ulcerative (chronic) proctitis with other complication	Diagnosis	ICD-10-CM
K51.219	Ulcerative (chronic) proctitis with unspecified complications	Diagnosis	ICD-10-CM
K51.3	Ulcerative (chronic) rectosigmoiditis	Diagnosis	ICD-10-CM
K51.30	Ulcerative (chronic) rectosigmoiditis without complications	Diagnosis	ICD-10-CM
K51.31	Ulcerative (chronic) rectosigmoiditis with complications	Diagnosis	ICD-10-CM
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding	Diagnosis	ICD-10-CM
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula	Diagnosis	ICD-10-CM
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess	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 Ulcerative Colitis (UC) in this Request**

Code	Description	Code Category	Code Type
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication	Diagnosis	ICD-10-CM
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications	Diagnosis	ICD-10-CM
K51.4	Inflammatory polyps of colon	Diagnosis	ICD-10-CM
K51.40	Inflammatory polyps of colon without complications	Diagnosis	ICD-10-CM
K51.41	Inflammatory polyps of colon with complications	Diagnosis	ICD-10-CM
K51.411	Inflammatory polyps of colon with rectal bleeding	Diagnosis	ICD-10-CM
K51.412	Inflammatory polyps of colon with intestinal obstruction	Diagnosis	ICD-10-CM
K51.413	Inflammatory polyps of colon with fistula	Diagnosis	ICD-10-CM
K51.414	Inflammatory polyps of colon with abscess	Diagnosis	ICD-10-CM
K51.418	Inflammatory polyps of colon with other complication	Diagnosis	ICD-10-CM
K51.419	Inflammatory polyps of colon with unspecified complications	Diagnosis	ICD-10-CM
K51.5	Left sided colitis	Diagnosis	ICD-10-CM
K51.50	Left sided colitis without complications	Diagnosis	ICD-10-CM
K51.51	Left sided colitis with complications	Diagnosis	ICD-10-CM
K51.511	Left sided colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.512	Left sided colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.513	Left sided colitis with fistula	Diagnosis	ICD-10-CM
K51.514	Left sided colitis with abscess	Diagnosis	ICD-10-CM
K51.518	Left sided colitis with other complication	Diagnosis	ICD-10-CM
K51.519	Left sided colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.8	Other ulcerative colitis	Diagnosis	ICD-10-CM
K51.80	Other ulcerative colitis without complications	Diagnosis	ICD-10-CM
K51.81	Other ulcerative colitis with complications	Diagnosis	ICD-10-CM
K51.811	Other ulcerative colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.812	Other ulcerative colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.813	Other ulcerative colitis with fistula	Diagnosis	ICD-10-CM
K51.814	Other ulcerative colitis with abscess	Diagnosis	ICD-10-CM
K51.818	Other ulcerative colitis with other complication	Diagnosis	ICD-10-CM
K51.819	Other ulcerative colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.9	Ulcerative colitis, unspecified	Diagnosis	ICD-10-CM
K51.90	Ulcerative colitis, unspecified, without complications	Diagnosis	ICD-10-CM
K51.91	Ulcerative colitis, unspecified, with complications	Diagnosis	ICD-10-CM
K51.911	Ulcerative colitis, unspecified with rectal bleeding	Diagnosis	ICD-10-CM
K51.912	Ulcerative colitis, unspecified with intestinal obstruction	Diagnosis	ICD-10-CM
K51.913	Ulcerative colitis, unspecified with fistula	Diagnosis	ICD-10-CM
K51.914	Ulcerative colitis, unspecified with abscess	Diagnosis	ICD-10-CM
K51.918	Ulcerative colitis, unspecified 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 Ulcerative Colitis (UC) in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
K51.919	Ulcerative colitis, unspecified with unspecified complications	Diagnosis	ICD-10-CM
<b>Ulcerative Colitis ICD-9-CM</b>			
556	Ulcerative Colitis	Diagnosis	ICD-9-CM
556.0	Ulcerative (chronic) enterocolitis	Diagnosis	ICD-9-CM
556.1	Ulcerative (chronic) ileocolitis	Diagnosis	ICD-9-CM
556.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-9-CM
556.3	Ulcerative (chronic) proctosigmoiditis	Diagnosis	ICD-9-CM
556.4	Pseudopolyposis of colon	Diagnosis	ICD-9-CM
556.5	Left sided ulcerative (chronic) colitis	Diagnosis	ICD-9-CM
556.6	Universal ulcerative (chronic) colitis	Diagnosis	ICD-9-CM
556.8	Other ulcerative colitis	Diagnosis	ICD-9-CM
556.9	Unspecified ulcerative colitis	Diagnosis	ICD-9-CM
<b>Ulcerative Colitis ICD-10-CM</b>			
K51	Ulcerative colitis	Diagnosis	ICD-10-CM
K51.0	Ulcerative (chronic) pancolitis	Diagnosis	ICD-10-CM
K51.00	Ulcerative (chronic) pancolitis without complications	Diagnosis	ICD-10-CM
K51.01	Ulcerative (chronic) pancolitis with complications	Diagnosis	ICD-10-CM
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.013	Ulcerative (chronic) pancolitis with fistula	Diagnosis	ICD-10-CM
K51.014	Ulcerative (chronic) pancolitis with abscess	Diagnosis	ICD-10-CM
K51.018	Ulcerative (chronic) pancolitis with other complication	Diagnosis	ICD-10-CM
K51.019	Ulcerative (chronic) pancolitis with unspecified complications	Diagnosis	ICD-10-CM
K51.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-10-CM
K51.20	Ulcerative (chronic) proctitis without complications	Diagnosis	ICD-10-CM
K51.21	Ulcerative (chronic) proctitis with complications	Diagnosis	ICD-10-CM
K51.211	Ulcerative (chronic) proctitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.213	Ulcerative (chronic) proctitis with fistula	Diagnosis	ICD-10-CM
K51.214	Ulcerative (chronic) proctitis with abscess	Diagnosis	ICD-10-CM
K51.218	Ulcerative (chronic) proctitis with other complication	Diagnosis	ICD-10-CM
K51.219	Ulcerative (chronic) proctitis with unspecified complications	Diagnosis	ICD-10-CM
K51.3	Ulcerative (chronic) rectosigmoiditis	Diagnosis	ICD-10-CM
K51.30	Ulcerative (chronic) rectosigmoiditis without complications	Diagnosis	ICD-10-CM
K51.31	Ulcerative (chronic) rectosigmoiditis with complications	Diagnosis	ICD-10-CM
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding	Diagnosis	ICD-10-CM
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction	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 Ulcerative Colitis (UC) in this Request**

Code	Description	Code Category	Code Type
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula	Diagnosis	ICD-10-CM
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess	Diagnosis	ICD-10-CM
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication	Diagnosis	ICD-10-CM
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications	Diagnosis	ICD-10-CM
K51.4	Inflammatory polyps of colon	Diagnosis	ICD-10-CM
K51.40	Inflammatory polyps of colon without complications	Diagnosis	ICD-10-CM
K51.41	Inflammatory polyps of colon with complications	Diagnosis	ICD-10-CM
K51.411	Inflammatory polyps of colon with rectal bleeding	Diagnosis	ICD-10-CM
K51.412	Inflammatory polyps of colon with intestinal obstruction	Diagnosis	ICD-10-CM
K51.413	Inflammatory polyps of colon with fistula	Diagnosis	ICD-10-CM
K51.414	Inflammatory polyps of colon with abscess	Diagnosis	ICD-10-CM
K51.418	Inflammatory polyps of colon with other complication	Diagnosis	ICD-10-CM
K51.419	Inflammatory polyps of colon with unspecified complications	Diagnosis	ICD-10-CM
K51.5	Left sided colitis	Diagnosis	ICD-10-CM
K51.50	Left sided colitis without complications	Diagnosis	ICD-10-CM
K51.51	Left sided colitis with complications	Diagnosis	ICD-10-CM
K51.511	Left sided colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.512	Left sided colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.513	Left sided colitis with fistula	Diagnosis	ICD-10-CM
K51.514	Left sided colitis with abscess	Diagnosis	ICD-10-CM
K51.518	Left sided colitis with other complication	Diagnosis	ICD-10-CM
K51.519	Left sided colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.8	Other ulcerative colitis	Diagnosis	ICD-10-CM
K51.80	Other ulcerative colitis without complications	Diagnosis	ICD-10-CM
K51.81	Other ulcerative colitis with complications	Diagnosis	ICD-10-CM
K51.811	Other ulcerative colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.812	Other ulcerative colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.813	Other ulcerative colitis with fistula	Diagnosis	ICD-10-CM
K51.814	Other ulcerative colitis with abscess	Diagnosis	ICD-10-CM
K51.818	Other ulcerative colitis with other complication	Diagnosis	ICD-10-CM
K51.819	Other ulcerative colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.9	Ulcerative colitis, unspecified	Diagnosis	ICD-10-CM
K51.90	Ulcerative colitis, unspecified, without complications	Diagnosis	ICD-10-CM
K51.91	Ulcerative colitis, unspecified, with complications	Diagnosis	ICD-10-CM
K51.911	Ulcerative colitis, unspecified with rectal bleeding	Diagnosis	ICD-10-CM
K51.912	Ulcerative colitis, unspecified with intestinal obstruction	Diagnosis	ICD-10-CM
K51.913	Ulcerative colitis, unspecified with fistula	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 Ulcerative Colitis (UC) in this Request**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
K51.914	Ulcerative colitis, unspecified with abscess	Diagnosis	ICD-10-CM
K51.918	Ulcerative colitis, unspecified with other complication	Diagnosis	ICD-10-CM
K51.919	Ulcerative colitis, 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 Ulcerative Colitis (UC)**

**Incidence**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
556	Ulcerative Colitis	Diagnosis	ICD-9-CM
556.0	Ulcerative (chronic) enterocolitis	Diagnosis	ICD-9-CM
556.1	Ulcerative (chronic) ileocolitis	Diagnosis	ICD-9-CM
556.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-9-CM
556.3	Ulcerative (chronic) proctosigmoiditis	Diagnosis	ICD-9-CM
556.4	Pseudopolyposis of colon	Diagnosis	ICD-9-CM
556.5	Left sided ulcerative (chronic) colitis	Diagnosis	ICD-9-CM
556.6	Universal ulcerative (chronic) colitis	Diagnosis	ICD-9-CM
556.8	Other ulcerative colitis	Diagnosis	ICD-9-CM
556.9	Unspecified ulcerative colitis	Diagnosis	ICD-9-CM
K51	Ulcerative colitis	Diagnosis	ICD-10-CM
K51.0	Ulcerative (chronic) pancolitis	Diagnosis	ICD-10-CM
K51.00	Ulcerative (chronic) pancolitis without complications	Diagnosis	ICD-10-CM
K51.01	Ulcerative (chronic) pancolitis with complications	Diagnosis	ICD-10-CM
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.013	Ulcerative (chronic) pancolitis with fistula	Diagnosis	ICD-10-CM
K51.014	Ulcerative (chronic) pancolitis with abscess	Diagnosis	ICD-10-CM
K51.018	Ulcerative (chronic) pancolitis with other complication	Diagnosis	ICD-10-CM
K51.019	Ulcerative (chronic) pancolitis with unspecified complications	Diagnosis	ICD-10-CM
K51.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-10-CM
K51.20	Ulcerative (chronic) proctitis without complications	Diagnosis	ICD-10-CM
K51.21	Ulcerative (chronic) proctitis with complications	Diagnosis	ICD-10-CM
K51.211	Ulcerative (chronic) proctitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.213	Ulcerative (chronic) proctitis with fistula	Diagnosis	ICD-10-CM
K51.214	Ulcerative (chronic) proctitis with abscess	Diagnosis	ICD-10-CM
K51.218	Ulcerative (chronic) proctitis with other complication	Diagnosis	ICD-10-CM
K51.219	Ulcerative (chronic) proctitis with unspecified complications	Diagnosis	ICD-10-CM
K51.3	Ulcerative (chronic) rectosigmoiditis	Diagnosis	ICD-10-CM
K51.30	Ulcerative (chronic) rectosigmoiditis without complications	Diagnosis	ICD-10-CM
K51.31	Ulcerative (chronic) rectosigmoiditis with complications	Diagnosis	ICD-10-CM
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding	Diagnosis	ICD-10-CM
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula	Diagnosis	ICD-10-CM
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess	Diagnosis	ICD-10-CM
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication	Diagnosis	ICD-10-CM
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications	Diagnosis	ICD-10-CM
K51.4	Inflammatory polyps of colon	Diagnosis	ICD-10-CM
K51.40	Inflammatory polyps of colon without complications	Diagnosis	ICD-10-CM
K51.41	Inflammatory polyps of colon with complications	Diagnosis	ICD-10-CM
K51.411	Inflammatory polyps of colon with rectal bleeding	Diagnosis	ICD-10-CM
K51.412	Inflammatory polyps of colon with intestinal obstruction	Diagnosis	ICD-10-CM
K51.413	Inflammatory polyps of colon with fistula	Diagnosis	ICD-10-CM
K51.414	Inflammatory polyps of colon with abscess	Diagnosis	ICD-10-CM
K51.418	Inflammatory polyps of colon with other complication	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 Ulcerative Colitis (UC)**

**Incidence**

<b>Code</b>	<b>Description</b>	<b>Code Category</b>	<b>Code Type</b>
K51.419	Inflammatory polyps of colon with unspecified complications	Diagnosis	ICD-10-CM
K51.5	Left sided colitis	Diagnosis	ICD-10-CM
K51.50	Left sided colitis without complications	Diagnosis	ICD-10-CM
K51.51	Left sided colitis with complications	Diagnosis	ICD-10-CM
K51.511	Left sided colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.512	Left sided colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.513	Left sided colitis with fistula	Diagnosis	ICD-10-CM
K51.514	Left sided colitis with abscess	Diagnosis	ICD-10-CM
K51.518	Left sided colitis with other complication	Diagnosis	ICD-10-CM
K51.519	Left sided colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.8	Other ulcerative colitis	Diagnosis	ICD-10-CM
K51.80	Other ulcerative colitis without complications	Diagnosis	ICD-10-CM
K51.81	Other ulcerative colitis with complications	Diagnosis	ICD-10-CM
K51.811	Other ulcerative colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.812	Other ulcerative colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.813	Other ulcerative colitis with fistula	Diagnosis	ICD-10-CM
K51.814	Other ulcerative colitis with abscess	Diagnosis	ICD-10-CM
K51.818	Other ulcerative colitis with other complication	Diagnosis	ICD-10-CM
K51.819	Other ulcerative colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.9	Ulcerative colitis, unspecified	Diagnosis	ICD-10-CM
K51.90	Ulcerative colitis, unspecified, without complications	Diagnosis	ICD-10-CM
K51.91	Ulcerative colitis, unspecified, with complications	Diagnosis	ICD-10-CM
K51.911	Ulcerative colitis, unspecified with rectal bleeding	Diagnosis	ICD-10-CM
K51.912	Ulcerative colitis, unspecified with intestinal obstruction	Diagnosis	ICD-10-CM
K51.913	Ulcerative colitis, unspecified with fistula	Diagnosis	ICD-10-CM
K51.914	Ulcerative colitis, unspecified with abscess	Diagnosis	ICD-10-CM
K51.918	Ulcerative colitis, unspecified with other complication	Diagnosis	ICD-10-CM
K51.919	Ulcerative colitis, 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	UC_9_yr1	UC	183	None	10/1/2013	9/30/2014	1	ICD-9-CM	ICD-9-CM	02	183	Any care setting
2	UC_9_yr2	UC	183	None	10/1/2014	9/30/2015	2	ICD-9-CM	ICD-9-CM	02	183	Any care setting
3	UC_10_yr1	UC	183	None	10/1/2015	9/30/2016	3	ICD-10-CM	ICD-10-CM	02	183	Any care setting
4	UC_10_yr2	UC	183	None	10/1/2016	9/30/2017	4	ICD-10-CM	ICD-10-CM	02	183	Any care setting
5	UC_9_inc	UC	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	UC_10_inc	UC	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	UC_9_prev	UC	0	Year*Month	10/1/2010	12/31/2022	5	ICD-9-CM	N/A	02	0	Any care setting
8	UC_10_prev	UC	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®.