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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_mpl1r_wp154

Request ID: cder_mpl1r_wp154_nsdv_v01

Request Description: The purpose of this request was to evaluate dispensing patterns among patients with exposure to ustekinumab (Stelara) or four comparator drugs in the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1

Data Source: We distributed this request to 17 Sentinel Data Partners on September 18, 2019. The study period included data from January 1, 2010 to April 30, 2019. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We designed this request to evaluate dispensing patterns of ustekinumab and four comparator drugs. For each of the five drugs, there were four cohorts (twenty total):

Cohort #1 evaluated Healthcare Common Procedure Coding System (HCPCS) codes or National Drug Codes (NDCs) for the drug exposure of interest. We assigned each HCPCS or NDC a one-day supply value. There was no allowable episode treatment gap or extension.

Cohort #2 evaluated HCPCS for the drug exposure of interest. We assigned each HCPCS a one-day supply value. There was no allowable episode treatment gap or extension.

Cohort #3 evaluated HCPCS or NDC for the drug exposure of interest. We allowed each NDC to retain its reported days' supply. For HCPCS, we assigned a days' supply value reflecting the recommended spacing between maintenance doses of the particular drug. We used the same value of recommended days between doses as the allowable episode treatment gap and extension for all episodes in this cohort.

Cohort #4 evaluated NDCs for the drug exposure of interest, using the reported days' supply value for each dispensing. The allowable episode treatment gap and extension matched the days' supply value assigned to HCPCS in cohort #3.

All 20 patient cohorts shared the following characteristics:

1. We counted all valid exposures during the query period, but only applied washout criteria to assess incident treatment for the first valid exposure episode (index).
2. We defined incident treatment as no use of that treatment in the 183 days prior to index. This washout period looked back to assess evidence of dispensing date.
3. We censored follow-up time at the first evidence of death, Data Partner end date, query end date, disenrollment, or evidence of use of any study treatment other than the treatment being assessed.

Exposures of Interest: The exposures of interest were ustekinumab and comparator drugs infliximab, adalimumab, certolizumab pegol, and vedolizumab in any care setting. We defined these exposures using a combination of HCPCS procedure codes and NDCs. See Appendix B for a list of HCPCS codes and Appendix C for a list of generic and brand names of medical products used to define exposures.

Cohort Eligibility Criteria: Members included in the cohort were required to be continuously enrolled in health plans with both medical and drug coverage for at least 183 days prior to their exposure, during which gaps in coverage of up to 45 days were allowed. Individuals of all ages were included in this cohort. Patients were included in the analysis if they had evidence of Crohn's disease in the 183 days prior to their exposure. Patients were excluded from the analysis if they had evidence of alternative drug indications (including plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, juvenile rheumatoid arthritis, or hidradenitis suppurativa) in the 183 days prior to their exposure. See Appendix D for a list of codes used to define inclusions and Appendix E for a list of codes used to define exclusions in this request.

Please see Appendices F through H for detailed specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define events are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

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

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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 (cohort) 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.

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. Baseline Table (Ustekinumab NDC or HCPCS Codes (1 Day Episodes) - Cohort 1)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	6,122	
Demographics		
Mean Age	47.5	15.2
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	2,243	36.6%
Age: 40-54	1,604	26.2%
Age: 55-64	854	13.9%
Age: 65+	1,305	21.3%
Gender (Female)	3,523	57.5%
Gender (Male)	*****	*****
Gender (Other)	*****	*****
Race (Unknown)	3,150	51.5%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	37	0.6%
Race (Black or African American)	282	4.6%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	2,640	43.1%
Hispanic Origin	71	1.2%
Year (2014)	78	1.3%
Year (2015)	73	1.2%
Year (2016)	419	6.8%
Year (2017)	2,780	45.4%
Year (2018)	2,741	44.8%
Year (2019)	31	0.5%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 2. Baseline Table (Ustekinumab HCPCS Codes (1 Day Episodes) - Cohort 2)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	3,349	
Demographics		
Mean Age	50.8	15.2
Age: 0-5	0	0.0%
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	1,041	31.1%
Age: 40-54	796	23.8%
Age: 55-64	452	13.5%
Age: 65+	1,014	30.3%
Gender (Female)	1,927	57.5%
Gender (Male)	1,422	42.5%
Gender (Other)	0	0.0%
Race (Unknown)	1,414	42.2%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	160	4.8%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	1,747	52.2%
Hispanic Origin	32	1.0%
Year (2014)	*****	*****
Year (2015)	*****	*****
Year (2016)	106	3.2%
Year (2017)	1,237	36.9%
Year (2018)	1,967	58.7%
Year (2019)	24	0.7%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 3. Baseline Table (Ustekinumab NDC or HCPCS Codes - Cohort 3)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	6,122	
Demographics		
Mean Age	47.5	15.2
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	2,243	36.6%
Age: 40-54	1,604	26.2%
Age: 55-64	854	13.9%
Age: 65+	1,305	21.3%
Gender (Female)	3,523	57.5%
Gender (Male)	*****	*****
Gender (Other)	*****	*****
Race (Unknown)	3,150	51.5%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	37	0.6%
Race (Black or African American)	282	4.6%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	2,640	43.1%
Hispanic Origin	71	1.2%
Year (2014)	78	1.3%
Year (2015)	73	1.2%
Year (2016)	419	6.8%
Year (2017)	2,780	45.4%
Year (2018)	2,741	44.8%
Year (2019)	31	0.5%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 4. Baseline Table (Ustekinumab NDC Codes - Cohort 4)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	2,826	
Demographics		
Mean Age	43.6	14.7
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	1,219	43.1%
Age: 40-54	826	29.2%
Age: 55-64	409	14.5%
Age: 65+	301	10.7%
Gender (Female)	1,635	57.9%
Gender (Male)	*****	*****
Gender (Other)	*****	*****
Race (Unknown)	1,762	62.3%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	125	4.4%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (White)	917	32.4%
Hispanic Origin	40	1.4%
Year (2014)	70	2.5%
Year (2015)	*****	*****
Year (2016)	314	11.1%
Year (2017)	1,559	55.2%
Year (2018)	807	28.6%
Year (2019)	*****	*****

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 5. Baseline Table (Infliximab NDC or HCPCS Codes (1 Day Episodes) - Cohort 1)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	19,132	
Demographics		
Mean Age	44.1	16.5
Age: 0-5	41	0.2%
Age: 6-11	535	2.8%
Age: 12-17	1,720	9.0%
Age: 18-39	6,583	34.4%
Age: 40-54	3,752	19.6%
Age: 55-64	2,046	10.7%
Age: 65+	4,455	23.3%
Gender (Female)	10,013	52.3%
Gender (Male)	9,119	47.7%
Gender (Other)	0	0.0%
Race (Unknown)	10,196	53.3%
Race (American Indian or Alaska Native)	33	0.2%
Race (Asian)	150	0.8%
Race (Black or African American)	901	4.7%
Race (Native Hawaiian or Other Pacific Islander)	16	0.1%
Race (White)	7,836	41.0%
Hispanic Origin	242	1.3%
Year (2014)	4,367	22.8%
Year (2015)	3,710	19.4%
Year (2016)	3,922	20.5%
Year (2017)	3,791	19.8%
Year (2018)	3,281	17.1%
Year (2019)	61	0.3%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

Table 6. Baseline Table (Infliximab HCPCS Codes (1 Day Episodes) - Cohort 2)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	19,006	
Demographics		
Mean Age	44.2	16.5
Age: 0-5	40	0.2%
Age: 6-11	531	2.8%
Age: 12-17	1,698	8.9%
Age: 18-39	6,545	34.4%
Age: 40-54	3,714	19.5%
Age: 55-64	2,019	10.6%
Age: 65+	4,459	23.5%
Gender (Female)	9,966	52.4%
Gender (Male)	9,040	47.6%
Gender (Other)	0	0.0%
Race (Unknown)	10,112	53.2%
Race (American Indian or Alaska Native)	35	0.2%
Race (Asian)	150	0.8%
Race (Black or African American)	912	4.8%
Race (Native Hawaiian or Other Pacific Islander)	17	0.1%
Race (White)	7,780	40.9%
Hispanic Origin	232	1.2%
Year (2014)	4,327	22.8%
Year (2015)	3,687	19.4%
Year (2016)	3,893	20.5%
Year (2017)	3,750	19.7%
Year (2018)	3,289	17.3%
Year (2019)	60	0.3%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

Table 7. Baseline Table (Infliximab NDC or HCPCS Codes - Cohort 3)

Characteristic	N/Mean	%/Std Dev¹
Number of unique patients	19,132	
Demographics		
Mean Age	44.1	16.5
Age: 0-5	41	0.2%
Age: 6-11	535	2.8%
Age: 12-17	1,720	9.0%
Age: 18-39	6,583	34.4%
Age: 40-54	3,752	19.6%
Age: 55-64	2,046	10.7%
Age: 65+	4,455	23.3%
Gender (Female)	10,013	52.3%
Gender (Male)	9,119	47.7%
Gender (Other)	0	0.0%
Race (Unknown)	10,196	53.3%
Race (American Indian or Alaska Native)	33	0.2%
Race (Asian)	150	0.8%
Race (Black or African American)	901	4.7%
Race (Native Hawaiian or Other Pacific Islander)	16	0.1%
Race (White)	7,836	41.0%
Hispanic Origin	242	1.3%
Year (2014)	4,367	22.8%
Year (2015)	3,710	19.4%
Year (2016)	3,922	20.5%
Year (2017)	3,791	19.8%
Year (2018)	3,281	17.1%
Year (2019)	61	0.3%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

Table 8. Baseline Table (Infliximab NDC Codes - Cohort 4)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	735	
Demographics		
Mean Age	44.8	16.3
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	278	37.8%
Age: 40-54	174	23.7%
Age: 55-64	100	13.6%
Age: 65+	136	18.5%
Gender (Female)	388	52.8%
Gender (Male)	347	47.2%
Gender (Other)	0	0.0%
Race (Unknown)	343	46.7%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	*****	*****
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (White)	348	47.3%
Hispanic Origin	16	2.2%
Year (2014)	211	28.7%
Year (2015)	133	18.1%
Year (2016)	141	19.2%
Year (2017)	136	18.5%
Year (2018)	*****	*****
Year (2019)	*****	*****

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 9. Baseline Table (Adalimumab NDC or HCPCS Codes (1 Day Episodes) - Cohort 1)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	21,627	
Demographics		
Mean Age	43.8	15.4
Age: 0-5	11	0.1%
Age: 6-11	187	0.9%
Age: 12-17	1,048	4.8%
Age: 18-39	8,566	39.6%
Age: 40-54	5,551	25.7%
Age: 55-64	2,971	13.7%
Age: 65+	3,293	15.2%
Gender (Female)	11,713	54.2%
Gender (Male)	*****	*****
Gender (Other)	*****	*****
Race (Unknown)	12,607	58.3%
Race (American Indian or Alaska Native)	39	0.2%
Race (Asian)	161	0.7%
Race (Black or African American)	967	4.5%
Race (Native Hawaiian or Other Pacific Islander)	16	0.1%
Race (White)	7,837	36.2%
Hispanic Origin	256	1.2%
Year (2014)	4,547	21.0%
Year (2015)	5,129	23.7%
Year (2016)	4,675	21.6%
Year (2017)	4,269	19.7%
Year (2018)	2,954	13.7%
Year (2019)	53	0.2%

¹Value represents standard deviation where no % follows the value

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Table 10. Baseline Table (Adalimumab HCPCS Codes (1 Day Episodes) - Cohort 2)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	209	
Demographics		
Mean Age	39.8	16.7
Age: 0-5	0	0.0%
Age: 6-11	*****	*****
Age: 12-17	29	13.9%
Age: 18-39	87	41.6%
Age: 40-54	39	18.7%
Age: 55-64	*****	*****
Age: 65+	33	15.8%
Gender (Female)	100	47.8%
Gender (Male)	109	52.2%
Gender (Other)	0	0.0%
Race (Unknown)	106	50.7%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	*****	*****
Race (Black or African American)	*****	*****
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	83	39.7%
Hispanic Origin	*****	*****
Year (2014)	80	38.3%
Year (2015)	41	19.6%
Year (2016)	41	19.6%
Year (2017)	24	11.5%
Year (2018)	23	11.0%
Year (2019)	0	0.0%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 11. Baseline Table (Adalimumab NDC or HCPCS Codes - Cohort 3)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	21,627	
Demographics		
Mean Age	43.8	15.4
Age: 0-5	11	0.1%
Age: 6-11	187	0.9%
Age: 12-17	1,048	4.8%
Age: 18-39	8,566	39.6%
Age: 40-54	5,551	25.7%
Age: 55-64	2,971	13.7%
Age: 65+	3,293	15.2%
Gender (Female)	11,713	54.2%
Gender (Male)	*****	*****
Gender (Other)	*****	*****
Race (Unknown)	12,607	58.3%
Race (American Indian or Alaska Native)	39	0.2%
Race (Asian)	161	0.7%
Race (Black or African American)	967	4.5%
Race (Native Hawaiian or Other Pacific Islander)	16	0.1%
Race (White)	7,837	36.2%
Hispanic Origin	256	1.2%
Year (2014)	4,547	21.0%
Year (2015)	5,129	23.7%
Year (2016)	4,675	21.6%
Year (2017)	4,269	19.7%
Year (2018)	2,954	13.7%
Year (2019)	53	0.2%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 12. Baseline Table (Adalimumab NDC Codes - Cohort 4)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	21,442	
Demographics		
Mean Age	43.8	15.4
Age: 0-5	11	0.1%
Age: 6-11	186	0.9%
Age: 12-17	1,020	4.8%
Age: 18-39	8,488	39.6%
Age: 40-54	5,516	25.7%
Age: 55-64	2,957	13.8%
Age: 65+	3,264	15.2%
Gender (Female)	11,626	54.2%
Gender (Male)	*****	*****
Gender (Other)	*****	*****
Race (Unknown)	12,507	58.3%
Race (American Indian or Alaska Native)	39	0.2%
Race (Asian)	154	0.7%
Race (Black or African American)	959	4.5%
Race (Native Hawaiian or Other Pacific Islander)	15	0.1%
Race (White)	7,768	36.2%
Hispanic Origin	253	1.2%
Year (2014)	4,471	20.9%
Year (2015)	5,092	23.7%
Year (2016)	4,643	21.7%
Year (2017)	4,250	19.8%
Year (2018)	2,933	13.7%
Year (2019)	53	0.2%

¹Value represents standard deviation where no % follows the value

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Table 13. Baseline Table (Certolizumab pegol NDC or HCPCS Codes (1 Day Episodes) - Cohort 1)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	3,646	
Demographics		
Mean Age	45.7	14.9
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	1,501	41.2%
Age: 40-54	987	27.1%
Age: 55-64	451	12.4%
Age: 65+	642	17.6%
Gender (Female)	2,339	64.2%
Gender (Male)	1,307	35.8%
Gender (Other)	0	0.0%
Race (Unknown)	1,934	53.0%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	175	4.8%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	1,515	41.6%
Hispanic Origin	32	0.9%
Year (2014)	1,253	34.4%
Year (2015)	853	23.4%
Year (2016)	693	19.0%
Year (2017)	480	13.2%
Year (2018)	*****	*****
Year (2019)	*****	*****

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 14. Baseline Table (Certolizumab pegol HCPCS Codes (1 Day Episodes) - Cohort 2)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	597	
Demographics		
Mean Age	61.3	13.1
Age: 0-5	0	0.0%
Age: 6-11	0	0.0%
Age: 12-17	*****	*****
Age: 18-39	92	15.4%
Age: 40-54	80	13.4%
Age: 55-64	*****	*****
Age: 65+	360	60.3%
Gender (Female)	385	64.5%
Gender (Male)	212	35.5%
Gender (Other)	0	0.0%
Race (Unknown)	141	23.6%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	*****	*****
Race (Black or African American)	*****	*****
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (White)	429	71.9%
Hispanic Origin	*****	*****
Year (2014)	179	30.0%
Year (2015)	135	22.6%
Year (2016)	114	19.1%
Year (2017)	92	15.4%
Year (2018)	77	12.9%
Year (2019)	0	0.0%

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Table 15. Baseline Table (Certolizumab pegol NDC or HCPCS Codes - Cohort 3)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	3,647	
Demographics		
Mean Age	45.7	14.9
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	1,502	41.2%
Age: 40-54	987	27.1%
Age: 55-64	451	12.4%
Age: 65+	642	17.6%
Gender (Female)	2,339	64.1%
Gender (Male)	1,308	35.9%
Gender (Other)	0	0.0%
Race (Unknown)	1,935	53.1%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	175	4.8%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	1,515	41.5%
Hispanic Origin	32	0.9%
Year (2014)	1,254	34.4%
Year (2015)	853	23.4%
Year (2016)	693	19.0%
Year (2017)	480	13.2%
Year (2018)	*****	*****
Year (2019)	*****	*****

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 16. Baseline Table (Certolizumab pegol NDC Codes - Cohort 4)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	3,057	
Demographics		
Mean Age	42.6	14.2
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	*****	*****
Age: 18-39	1,411	46.2%
Age: 40-54	909	29.7%
Age: 55-64	391	12.8%
Age: 65+	285	9.3%
Gender (Female)	1,959	64.1%
Gender (Male)	1,098	35.9%
Gender (Other)	0	0.0%
Race (Unknown)	1,798	58.8%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	150	4.9%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	1,089	35.6%
Hispanic Origin	29	0.9%
Year (2014)	1,075	35.2%
Year (2015)	720	23.6%
Year (2016)	580	19.0%
Year (2017)	389	12.7%
Year (2018)	*****	*****
Year (2019)	*****	*****

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 17. Baseline Table (Vedolizumab NDC or HCPCS Codes (1 Day Episodes) - Cohort 1)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	10,996	
Demographics		
Mean Age	52.0	15.6
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	160	1.5%
Age: 18-39	3,176	28.9%
Age: 40-54	2,534	23.0%
Age: 55-64	1,479	13.5%
Age: 65+	3,625	33.0%
Gender (Female)	6,263	57.0%
Gender (Male)	4,733	43.0%
Gender (Other)	0	0.0%
Race (Unknown)	4,654	42.3%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	59	0.5%
Race (Black or African American)	453	4.1%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	5,795	52.7%
Hispanic Origin	107	1.0%
Year (2014)	536	4.9%
Year (2015)	1,516	13.8%
Year (2016)	3,633	33.0%
Year (2017)	2,603	23.7%
Year (2018)	2,671	24.3%
Year (2019)	37	0.3%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 18. Baseline Table (Vedolizumab HCPCS Codes (1 Day Episodes) - Cohort 2)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	10,118	
Demographics		
Mean Age	52.4	15.5
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	144	1.4%
Age: 18-39	2,863	28.3%
Age: 40-54	2,288	22.6%
Age: 55-64	1,345	13.3%
Age: 65+	3,456	34.2%
Gender (Female)	5,763	57.0%
Gender (Male)	4,355	43.0%
Gender (Other)	0	0.0%
Race (Unknown)	4,225	41.8%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	55	0.5%
Race (Black or African American)	417	4.1%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	5,388	53.3%
Hispanic Origin	95	0.9%
Year (2014)	399	3.9%
Year (2015)	1,284	12.7%
Year (2016)	3,421	33.8%
Year (2017)	2,441	24.1%
Year (2018)	2,536	25.1%
Year (2019)	37	0.4%

¹Value represents standard deviation where no % follows the value

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Table 19. Baseline Table (Vedolizumab NDC or HCPCS Codes - Cohort 3)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	10,996	
Demographics		
Mean Age	52.0	15.6
Age: 0-5	*****	*****
Age: 6-11	*****	*****
Age: 12-17	160	1.5%
Age: 18-39	3,176	28.9%
Age: 40-54	2,534	23.0%
Age: 55-64	1,479	13.5%
Age: 65+	3,625	33.0%
Gender (Female)	6,263	57.0%
Gender (Male)	4,733	43.0%
Gender (Other)	0	0.0%
Race (Unknown)	4,654	42.3%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	59	0.5%
Race (Black or African American)	453	4.1%
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	5,795	52.7%
Hispanic Origin	107	1.0%
Year (2014)	536	4.9%
Year (2015)	1,516	13.8%
Year (2016)	3,633	33.0%
Year (2017)	2,603	23.7%
Year (2018)	2,671	24.3%
Year (2019)	37	0.3%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 20. Baseline Table (Vedolizumab NDC Codes - Cohort 4)

Characteristic	N/Mean	%/Std Dev ¹
Number of unique patients	915	
Demographics		
Mean Age	47.3	15.5
Age: 0-5	0	0.0%
Age: 6-11	0	0.0%
Age: 12-17	16	1.7%
Age: 18-39	330	36.1%
Age: 40-54	258	28.2%
Age: 55-64	137	15.0%
Age: 65+	174	19.0%
Gender (Female)	526	57.5%
Gender (Male)	389	42.5%
Gender (Other)	0	0.0%
Race (Unknown)	438	47.9%
Race (American Indian or Alaska Native)	*****	*****
Race (Asian)	*****	*****
Race (Black or African American)	*****	*****
Race (Native Hawaiian or Other Pacific Islander)	*****	*****
Race (White)	430	47.0%
Hispanic Origin	14	1.5%
Year (2014)	137	15.0%
Year (2015)	232	25.4%
Year (2016)	228	24.9%
Year (2017)	171	18.7%
Year (2018)	147	16.1%
Year (2019)	0	0.0%

¹Value represents standard deviation where no % follows the value

All metrics are based on total number of episodes per cohort, except for sex and race which are based on total number of unique patients; each baseline characteristic table represents one cohort.

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Table 21. Distribution of Days Supplied per Dispensing, by Length Categories

Exposures	Total Dispensings		0-1		2-7		8-21		22-35		36-49		50-63		64+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Ustekinumab																
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	35,954	100.0	35,893	99.8	61	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	7,280	100.0	7,280	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab NDC or HCPCS codes - Cohort 3	31,374	100.0	312	1.0	604.0	1.9	1,475	4.7	6,830	21.8	1,475	4.7	20,273	64.6	405	1.3
Ustekinumab NDC codes - Cohort 4	15,796	100.0	189	1.2	312.0	2.0	712	4.5	4,694	29.7	710	4.5	8,850	56.0	329	2.1
Infliximab																
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	182,322	100.0	182,322	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab HCPCS codes (1-day supply) - Cohort 2	179,892	100.0	179,892	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab NDC or HCPCS codes - Cohort 3	179,445	100.0	821	0.5	1,651	0.9	4,296	2.4	6,002	3.3	4,879	2.7	161,751	90.1	45	0.0
Infliximab NDC codes - Cohort 4	4,064	100.0	196	4.8	73	1.8	452	11.1	1,393	34.3	771	19.0	1,150	28.3	29	0.7
Adalimumab																
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	320,523	100.0	319,613	99.7	910	0.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab HCPCS codes (1-day supply) - Cohort 2	1,897	100.0	1,897	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab NDC or HCPCS codes - Cohort 3	292,467	100.0	451	0.2	2,786	1.0	11,663	4.0	268,048	91.7	472	0.2	1,785	0.6	7,262	2.5
Adalimumab NDC codes - Cohort 4	288,674	100.0	437	0.2	2,760	1.0	9,086	3.1	266,931	92.5	470	0.2	1,777	0.6	7,213	2.5
Certolizumab pegol																
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	45,382	100.0	45,282	99.8	100	0.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	8,999	100.0	8,999	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol NDC or HCPCS codes - Cohort 3	41,612	100.0	97	0.2	378	0.9	1,509	3.6	38,321	92.1	158	0.4	460	1.1	689	1.7
Certolizumab pegol NDC codes - Cohort 4	31,611	100.0	80	0.3	327	1.0	1,353	4.3	28,562	90.4	158	0.5	459	1.5	672	2.1

Table 21. Distribution of Days Supplied per Dispensing, by Length Categories

Exposures	Total Dispensings		0-1		2-7		8-21		22-35		36-49		50-63		64+		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
Vedolizumab																	
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	97,499	100.0	97,499	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0.0
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	88,806	100.0	88,806	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0.0
Vedolizumab NDC or HCPCS codes - Cohort 3	94,110	100.0	908	1.0	1,001	1.1	2,513	2.7	4,117	4.4	2,733	2.9	82,790	88.0	48	0.1	
Vedolizumab NDC codes - Cohort 4	5,528	100.0	455	8.2	76	1.4	369	6.7	1,573	28.5	600	10.9	2,407	43.5	48	0.9	

Table 22. Descriptive Statistics of Days Supplied per Dispensing

Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Ustekinumab								
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	35,954	1	0.04	1	1	1	1	2
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	7,280	1	0	1	1	1	1	1
Ustekinumab NDC or HCPCS codes - Cohort 3	31,374	46.41	16.4	1	30	56	56	564
Ustekinumab NDC codes - Cohort 4	15,796	44.52	17.76	1	30	56	56	564
Infliximab								
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	182,322	1	0	1	1	1	1	1
Infliximab HCPCS codes (1-day supply) - Cohort 2	179,892	1	0	1	1	1	1	1
Infliximab NDC or HCPCS codes - Cohort 3	179,445	52.99	10.04	1	56	56	56	118
Infliximab NDC codes - Cohort 4	4,064	36.29	16.99	1	28	30	56	118
Adalimumab								
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	320,523	1	0.05	1	1	1	1	4
Adalimumab HCPCS codes (1-day supply) - Cohort 2	1,897	1	0	1	1	1	1	1
Adalimumab NDC or HCPCS codes - Cohort 3	292,467	28.86	9.95	1	28	28	28	300
Adalimumab NDC codes - Cohort 4	288,674	28.99	9.88	1	28	28	28	300
Certolizumab pegol								
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	45,382	1	0.05	1	1	1	1	2
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	8,999	1	0	1	1	1	1	1
Certolizumab pegol NDC or HCPCS codes - Cohort 3	41,612	28.72	8.67	1	28	28	28	140
Certolizumab pegol NDC codes - Cohort 4	31,611	29.03	9.72	1	28	28	28	140
Vedolizumab								
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	97,499	1	0	1	1	1	1	1
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	88,806	1	0	1	1	1	1	1
Vedolizumab NDC or HCPCS codes - Cohort 3	94,110	52.23	11.3	1	56	56	56	98
Vedolizumab NDC codes - Cohort 4	5,528	38.95	18.85	1	28	42	56	98

Table 23. Descriptive Statistics of the Length of the First Gap Between Treatment Episodes, in Days

Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Ustekinumab								
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	5,048	49.33	46.88	1	27	49	58	972
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	909	81.76	84.23	1	55	55	62	667
Ustekinumab NDC or HCPCS codes - Cohort 3	570	92.02	153.59	1	10	32	102	1,290
Ustekinumab NDC codes - Cohort 4	353	89.90	168.04	1	10	26	84	1,290
Infliximab								
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	17,247	32.67	76.99	1	13	13	28	1,721
Infliximab HCPCS codes (1-day supply) - Cohort 2	17,131	33.01	76.47	1	13	13	28	1,721
Infliximab NDC or HCPCS codes - Cohort 3	2,427	190.74	282.27	1	18	69	226	1,634
Infliximab NDC codes - Cohort 4	134	97.54	187.80	1	9	22	87	1,292
Adalimumab								
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	19,838	33.53	49.79	1	21	25	32	1,624
Adalimumab HCPCS codes (1-day supply) - Cohort 2	140	27.26	51.33	4	13	20	27	601
Adalimumab NDC or HCPCS codes - Cohort 3	7,800	57.37	133.04	1	6	14	41	1,583
Adalimumab NDC codes - Cohort 4	7,676	57.20	132.41	1	6	15	41	1,583
Certolizumab pegol								
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	3,171	44.78	62.29	1	20	32	53	1,076
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	547	23.37	48.53	6	13	13	18	742
Certolizumab pegol NDC or HCPCS codes - Cohort 3	1,258	66.02	139.45	1	7	20	58	1,339
Certolizumab pegol NDC codes - Cohort 4	1,075	66.34	140.92	1	7	20	58	1,339
Vedolizumab								
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	10,292	27.49	49.09	1	13	13	27	1,233
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	9,487	25.77	44.96	1	13	13	20	1,126
Vedolizumab NDC or HCPCS codes - Cohort 3	1,319	132.72	181.64	1	16	63	173	1,371
Vedolizumab NDC codes - Cohort 4	171	84.01	171.92	1	7	23	83	1,153

Table 24. Descriptive Statistics of the Length of Second and Subsequent Gaps Between Treatment Episodes, in Days

Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Ustekinumab								
supply) - Cohort 1	23,701	50.26	31.26	1	36	53	59	1,318
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	2,999	55.89	28.74	3	54	55	56	854
	93	60.39	103.69	1	9	26	63	801
Ustekinumab NDC or HCPCS codes - Cohort 3								
Ustekinumab NDC codes - Cohort 4	63	63.03	116.90	2	11	28	63	801
Infliximab								
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	139,303	53.15	45.71	1	41	55	55	1,658
Infliximab HCPCS codes (1-day supply) - Cohort 2	137,106	53.33	41.27	1	41	55	55	1,658
Infliximab NDC or HCPCS codes - Cohort 3	711	129.24	165.61	1	20	63	175	1,137
Infliximab NDC codes - Cohort 4	48	48.98	81.39	1	6	14	34	387
Adalimumab								
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	271,246	30.48	32.35	1	22	27	31	1,571
Adalimumab HCPCS codes (1-day supply) - Cohort 2	1,547	24.38	35.32	4	13	20	27	888
Adalimumab NDC or HCPCS codes - Cohort 3	10,292	40.84	88.38	1	6	15	38	1,383
Adalimumab NDC codes - Cohort 4	9,905	41.79	89.92	1	7	15	38	1,383
Certolizumab pegol								
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	37,754	31.74	33.89	1	23	27	32	1,364
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	7,824	29.09	27.45	1	26	27	29	1,232
Certolizumab pegol NDC or HCPCS codes - Cohort 3	961	53.96	110.77	1	8	21	48	1,108
Certolizumab pegol NDC codes - Cohort 4	827	54.11	112.47	1	8	21	47	1,108
Vedolizumab								
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	76,052	50.39	33.73	1	31	55	55	1,482
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	69,122	50.65	33.22	1	32	55	55	1,482
	309	79.35	103.74	1	7	42	110	747
Vedolizumab NDC or HCPCS codes - Cohort 3								
Vedolizumab NDC codes - Cohort 4	68	32.87	67.62	1	3	7	39	466

Table 25. Distribution of First Exposure Episode Duration, by Length Categories, in Days

Exposures	Total Episodes		1-30		31-90		91-180		181-270		271-365		366+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Ustekinumab														
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	6,122	100.0	6,122	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	3,349	100.0	3,349	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab NDC or HCPCS codes - Cohort 3	6,122	100.0	712	11.6	817	13.3	1,541	25.2	881	14.4	743	12.1	1,428	23.3
Ustekinumab NDC codes - Cohort 4	2,826	100.0	403	14.3	363	12.8	579	20.5	377	13.3	342	12.1	762	27.0
Infliximab														
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	19,132	100.0	19,132	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab HCPCS codes (1-day supply) - Cohort 2	19,006	100.0	19,006	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab NDC or HCPCS codes - Cohort 3	19,132	100.0	1,181	6.2	1,686	8.8	4,710	24.6	2,474	12.9	1,897	9.9	7,184	37.5
Infliximab NDC codes - Cohort 4	735	100.0	46	6.3	163	22.2	229	31.2	121	16.5	55	7.5	121	16.5
Adalimumab														
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	21,627	100.0	21,627	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab HCPCS codes (1-day supply) - Cohort 2	209	100.0	209	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab NDC or HCPCS codes - Cohort 3	21,627	100.0	993	4.6	6,274	29.0	4,112	19.0	2,831	13.1	1,922	8.9	5,495	25.4
Adalimumab NDC codes - Cohort 4	21,442	100.0	933	4.4	6,218	29.0	4,082	19.0	2,819	13.1	1,914	8.9	5,476	25.5

Table 25. Distribution of First Exposure Episode Duration, by Length Categories, in Days

Exposures	Total Episodes		1-30		31-90		91-180		181-270		271-365		366+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Certolizumab pegol														
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	3,646	100.0	3,646	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	597	100.0	597	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol NDC or HCPCS codes - Cohort 3	3,647	100.0	246	6.7	1,241	34.0	719	19.7	426	11.7	269	7.4	746	20.5
Certolizumab pegol NDC codes - Cohort 4	3,057	100.0	227	7.4	1,131	37.0	583	19.1	344	11.3	216	7.1	556	18.2
Vedolizumab														
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	10,996	100.0	10,996	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	10,118	100.0	10,118	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vedolizumab NDC or HCPCS codes - Cohort 3	10,996	100.0	779	7.1	1,028	9.3	2,475	22.5	1,528	13.9	1,225	11.1	3,961	36.0
Vedolizumab NDC codes - Cohort 4	915	100.0	76	8.3	137	15.0	291	31.8	126	13.8	84	9.2	201	22.0

Table 26. Descriptive Statistics of First Exposure Episode Duration, in Days

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Ustekinumab								
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	6,122	1.03	0.21	1	1	1	1	4
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	3,349	1	0.02	1	1	1	1	2
Ustekinumab NDC or HCPCS codes - Cohort 3	6,122	238.98	201.52	1	91	180	347	1,349
Ustekinumab NDC codes - Cohort 4	2,826	259.04	224.73	1	86	193	392	1,349
Infliximab								
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	19,132	1	0.03	1	1	1	1	2
Infliximab HCPCS codes (1-day supply) - Cohort 2	19,006	1	0.02	1	1	1	1	2
Infliximab NDC or HCPCS codes - Cohort 3	19,132	396.59	390.32	1	113	253	545	1,904
Infliximab NDC codes - Cohort 4	735	233.98	268.92	1	86	146	257	1,788
Adalimumab								
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	21,627	1.06	0.29	1	1	1	1	5
Adalimumab HCPCS codes (1-day supply) - Cohort 2	209	1	0.07	1	1	1	1	2
Adalimumab NDC or HCPCS codes - Cohort 3	21,627	278.28	309.15	1	70	160	372	1,860
Adalimumab NDC codes - Cohort 4	21,442	279.4	309.48	1	70	161	374	1,860
Certolizumab pegol								
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	3,646	1.04	0.25	1	1	1	1	4
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	597	1	0	1	1	1	1	1
Certolizumab pegol NDC or HCPCS codes - Cohort 3	3,647	241.47	287.72	1	58	126	303	1,813
Certolizumab pegol NDC codes - Cohort 4	3,057	221.33	267.09	1	56	112	274	1,813
Vedolizumab								
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	10,996	1	0.03	1	1	1	1	2
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	10,118	1	0.02	1	1	1	1	2
Vedolizumab NDC or HCPCS codes - Cohort 3	10,996	358.19	319.08	1	121	255	506	1,581
Vedolizumab NDC codes - Cohort 4	915	255.06	260.64	1	98	155	330	1,551

Table 27. Distribution of Second and Subsequent Exposure Episode Duration, by Length Categories, in Days

Exposures	Total Episodes		1-30		31-90		91-180		181-270		271-365		366+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Ustekinumab														
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	28,749	100.0	28,749	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	3,908	100.0	3,908	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab NDC or HCPCS codes - Cohort 3	663	100.0	51	7.7	136	20.5	191	28.8	103	15.5	76	11.5	106	16.0
Ustekinumab NDC codes - Cohort 4	416	100.0	22	5.3	85	20.4	107	25.7	78	18.8	44	10.6	80	19.2
Infliximab														
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	156,550	100.0	156,550	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab HCPCS codes (1-day supply) - Cohort 2	154,237	100.0	154,237	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab NDC or HCPCS codes - Cohort 3	3,138	100.0	194	6.2	345	11.0	1,142	36.4	380	12.1	310	9.9	767	24.4
Infliximab NDC codes - Cohort 4	182	100.0	*****	*****	41	22.5	54	29.7	*****	*****	21	11.5	40	22.0
Adalimumab														
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	291,084	100.0	291,084	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab HCPCS codes (1-day supply) - Cohort 2	1,687	100.0	1,687	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab NDC or HCPCS codes - Cohort 3	18,092	100.0	1,216	6.7	8,197	45.3	3,810	21.1	1,738	9.6	1,008	5.6	2,123	11.7
Adalimumab NDC codes - Cohort 4	17,581	100.0	1,008	5.7	8,044	45.8	3,728	21.2	1,713	9.7	994	5.7	2,094	11.9
Certolizumab pegol														
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	40,925	100.0	40,925	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	8,371	100.0	8,371	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol NDC or HCPCS codes - Cohort 3	2,219	100.0	105	4.7	751	33.8	546	24.6	254	11.4	174	7.8	389	17.5
Certolizumab pegol NDC codes - Cohort 4	1,902	100.0	96	5.0	646	34.0	464	24.4	216	11.4	153	8.0	327	17.2
Vedolizumab														
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	86,344	100.0	86,344	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	78,609	100.0	78,609	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vedolizumab NDC or HCPCS codes - Cohort 3	1,628	100.0	103	6.3	211	13.0	481	29.5	226	13.9	171	10.5	436	26.8
Vedolizumab NDC codes - Cohort 4	239	100.0	*****	*****	53	22.2	71	29.7	28	11.7	*****	*****	59	24.7

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 28. Distribution of All Exposure Episode Durations, by Length Categories, in Days

Exposures	Total Episodes		1-30		31-90		91-180		181-270		271-365		366+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Ustekinumab														
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	34,871	100.0	34,871	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	7,257	100.0	7,257	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ustekinumab NDC or HCPCS codes - Cohort 3	6,785	100.0	763	11.2	953	14.0	1,732	25.5	984	14.5	819	12.1	1,534	22.6
Ustekinumab NDC codes - Cohort 4	3,242	100.0	425	13.1	448	13.8	686	21.2	455	14.0	386	11.9	842	26.0
Infliximab														
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	175,682	100.0	175,682	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab HCPCS codes (1-day supply) - Cohort 2	173,243	100.0	173,243	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infliximab NDC or HCPCS codes - Cohort 3	22,270	100.0	1,375	6.2	2,031	9.1	5,852	26.3	2,854	12.8	2,207	9.9	7,951	35.7
Infliximab NDC codes - Cohort 4	917	100.0	51	5.6	204	22.2	283	30.9	142	15.5	76	8.3	161	17.6
Adalimumab														
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	312,711	100.0	312,711	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab HCPCS codes (1-day supply) - Cohort 2	1,896	100.0	1,896	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Adalimumab NDC or HCPCS codes - Cohort 3	39,719	100.0	2,209	5.6	14,471	36.4	7,922	19.9	4,569	11.5	2,930	7.4	7,618	19.2
Adalimumab NDC codes - Cohort 4	39,023	100.0	1,941	5.0	14,262	36.5	7,810	20.0	4,532	11.6	2,908	7.5	7,570	19.4
Certolizumab pegol														
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	44,571	100.0	44,571	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	8,968	100.0	8,968	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Certolizumab pegol NDC or HCPCS codes - Cohort 3	5,866	100.0	351	6.0	1,992	34.0	1,265	21.6	680	11.6	443	7.6	1,135	19.3
Certolizumab pegol NDC codes - Cohort 4	4,959	100.0	323	6.5	1,777	35.8	1,047	21.1	560	11.3	369	7.4	883	17.8

Table 28. Distribution of All Exposure Episode Durations, by Length Categories, in Days

Exposures	Total Episodes		1-30		31-90		91-180		181-270		271-365		366+	
Vedolizumab														
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	97,340	100.0	97,340	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	88,727	100.0	88,727	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vedolizumab NDC or HCPCS codes - Cohort 3	12,624	100.0	882	7.0	1,239	9.8	2,956	23.4	1,754	13.9	1,396	11.1	4,397	34.8
Vedolizumab NDC codes - Cohort 4	1,154	100.0	84	7.3	190	16.5	362	31.4	154	13.3	104	9.0	260	22.5

Table 29. Descriptive Statistics of All Exposure Episode Durations, in Days

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Ustekinumab								
Ustekinumab NDC or HCPCS codes (1-day supply) - Cohort 1	34,871	1.03	0.19	1	1	1	1	4
Ustekinumab HCPCS codes (1-day supply) - Cohort 2	7,257	1	0.02	1	1	1	1	2
Ustekinumab NDC or HCPCS codes - Cohort 3	6,785	236.55	201.07	1	90	176	342	1,588
Ustekinumab NDC codes - Cohort 4	3,242	256.09	222.42	1	86	191	379	1,588
Infliximab								
Infliximab NDC or HCPCS codes (1-day supply) - Cohort 1	175,682	1	0.08	1	1	1	1	29
Infliximab HCPCS codes (1-day supply) - Cohort 2	173,243	1	0.07	1	1	1	1	29
Infliximab NDC or HCPCS codes - Cohort 3	22,270	379.41	378.36	1	112	235	512	1,904
Infliximab NDC codes - Cohort 4	917	235.83	258.59	1	86	152	278	1,788
Adalimumab								
Adalimumab NDC or HCPCS codes (1-day supply) - Cohort 1	312,711	1.03	0.18	1	1	1	1	7
Adalimumab HCPCS codes (1-day supply) - Cohort 2	1,896	1	0.02	1	1	1	1	2
Adalimumab NDC or HCPCS codes - Cohort 3	39,719	227.64	276.12	1	42	115	291	1,860
Adalimumab NDC codes - Cohort 4	39,023	229.62	277.01	1	42	118	294	1,860
Certolizumab pegol								
Certolizumab pegol NDC or HCPCS codes (1-day supply) - Cohort 1	44,571	1.02	0.2	1	1	1	1	29
Certolizumab pegol HCPCS codes (1-day supply) - Cohort 2	8,968	1	0.3	1	1	1	1	29
Certolizumab pegol NDC or HCPCS codes - Cohort 3	5,866	232.88	273.34	1	57	123	293	1,813
Certolizumab pegol NDC codes - Cohort 4	4,959	218.95	258.29	1	56	114	274	1,813
Vedolizumab								
Vedolizumab NDC or HCPCS codes (1-day supply) - Cohort 1	97,340	1	0.04	1	1	1	1	5
Vedolizumab HCPCS codes (1-day supply) - Cohort 2	88,727	1	0.02	1	1	1	1	2
Vedolizumab NDC or HCPCS codes - Cohort 3	12,624	348.9	313.46	1	112	243	491	1,581
Vedolizumab NDC codes - Cohort 4	1,154	253.76	255.82	1	96	157	331	1,551

Table 30. Full Code Distribution of Ustekinumab NDCs (with 1-Day Supply) or HCPCS Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Encounter Care Setting	Overall Counts
ustekinumab	Generic Name	NDC	N/A	2784
J3358	Procedure	HCPCS	AV	1800
Q9989	Procedure	HCPCS	AV	665
J3357	Procedure	HCPCS	AV	490
C9487	Procedure	HCPCS	AV	*****
J3358	Procedure	HCPCS	OA	73
Q9989	Procedure	HCPCS	OA	*****
J3357	Procedure	HCPCS	OA	31
ustekinumab	Generic Name	NDC	N/A	18
J3358	Procedure	HCPCS	AV	
ustekinumab	Generic Name	NDC	N/A	*****
Q9989	Procedure	HCPCS	AV	*****
J3358	Procedure	HCPCS	AV	*****
J3357	Procedure	HCPCS	AV	*****
ustekinumab	Generic Name	NDC	N/A	*****
J3357	Procedure	HCPCS	AV	*****
J3358	Procedure	HCPCS	IP	*****
J3358	Procedure	HCPCS	ED	*****
Q9989	Procedure	HCPCS	AV	*****
J3357	Procedure	HCPCS	AV	*****
ustekinumab	Generic Name	NDC	N/A	*****
J3357	Procedure	HCPCS	OA	*****
ustekinumab	Generic Name	NDC	N/A	*****
C9487	Procedure	HCPCS	AV	*****
J3358	Procedure	HCPCS	OA	*****
J3357	Procedure	HCPCS	OA	*****
J3357	Procedure	HCPCS	IP	*****
J3357	Procedure	HCPCS	ED	*****
J3357	Procedure	HCPCS	AV	*****
J3357	Procedure	HCPCS	OA	*****
J3357	Procedure	HCPCS	AV	*****
C9487	Procedure	HCPCS	AV	*****
J3358	Procedure	HCPCS	IPX	*****
J3358	Procedure	HCPCS	IS	*****
Q9989	Procedure	HCPCS	IS	*****
Q9989	Procedure	HCPCS	ED	*****

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 31. Total Code Counts of Ustekinumab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Overall Counts¹
ustekinumab	Generic Name	NDC	2817
J3358	Procedure	HCPCS	1906
Q9989	Procedure	HCPCS	711
J3357	Procedure	HCPCS	542
C9487	Procedure	HCPCS	190

¹Total overall counts may exceed total index episodes in cases where two different codes occur on the same day and encounter setting

Table 32. Full Code Distribution of Infliximab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Encounter Care Setting	Overall Counts
J1745	Procedure	HCPCS	AV	16512
infliximab	Generic Name	NDC	N/A	*****
Q5103	Procedure	HCPCS	AV	*****
S9359	Procedure	HCPCS	OA	311
J1745	Procedure	HCPCS	OA	
J1745	Procedure	HCPCS	OA	294
Q5102	Procedure	HCPCS	AV	*****
S9359	Procedure	HCPCS	OA	213
S9359	Procedure	HCPCS	AV	150
J1745	Procedure	HCPCS	AV	
J1745	Procedure	HCPCS	IS	68
J1745	Procedure	HCPCS	ED	49
S9359	Procedure	HCPCS	AV	47
J1745	Procedure	HCPCS	IP	40
J1745	Procedure	HCPCS	IPX	28
Q5104	Procedure	HCPCS	AV	*****
S9359	Procedure	HCPCS	OA	*****
J1745	Procedure	HCPCS	AV	
S9359	Procedure	HCPCS	OA	*****
J1745	Procedure	HCPCS	AV	
J1745	Procedure	HCPCS	OA	
S9359	Procedure	HCPCS	OA	*****
Q5103	Procedure	HCPCS	OA	
infliximabdyb	Generic Name	NDC	N/A	*****
J1745	Procedure	HCPCS	AV	*****
J1745	Procedure	HCPCS	OA	
S9359	Procedure	HCPCS	AV	*****
S9359	Procedure	HCPCS	OA	
J1745	Procedure	HCPCS	OA	
J1745	Procedure	HCPCS	AV	
infliximab	Generic Name	NDC	N/A	*****
J1745	Procedure	HCPCS	AV	
J1745	Procedure	HCPCS	AV	*****
J1745	Procedure	HCPCS	ED	
Q5102	Procedure	HCPCS	AV	*****
J1745	Procedure	HCPCS	AV	
Q5103	Procedure	HCPCS	AV	*****
Q5102	Procedure	HCPCS	AV	
J1745	Procedure	HCPCS	AV	
S9359	Procedure	HCPCS	AV	*****
S9359	Procedure	HCPCS	OA	
J1745	Procedure	HCPCS	AV	
infliximab	Generic Name	NDC	N/A	*****
J1745	Procedure	HCPCS	OA	
Q5102	Procedure	HCPCS	IPX	*****
Q5102	Procedure	HCPCS	IS	*****

Table 32. Full Code Distribution of Infliximab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Encounter Care Setting	Overall Counts
Q5102	Procedure	HCPCS	OA	*****
S9359	Procedure	HCPCS	OA	*****
Q5102	Procedure	HCPCS	OA	*****
infliximababda	Generic Name	NDC	N/A	*****
infliximab	Generic Name	NDC	N/A	*****
infliximab	Generic Name	NDC	N/A	*****
J1745	Procedure	HCPCS	IPX	*****
S9359	Procedure	HCPCS	AV	*****
Q5103	Procedure	HCPCS	AV	*****
Q5103	Procedure	HCPCS	OA	*****
Q5104	Procedure	HCPCS	IP	*****
Q5104	Procedure	HCPCS	IS	*****
S9359	Procedure	HCPCS	IPX	*****
S9359	Procedure	HCPCS	IS	*****
S9359	Procedure	HCPCS	AV	*****
S9359	Procedure	HCPCS	OA	*****

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 33. Total Code Counts of Infliximab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Overall Counts ¹
J1745	Procedure	HCPCS	17481
S9359	Procedure	HCPCS	745
infiximab	Generic Name	NDC	719
Q5103	Procedure	HCPCS	371
Q5102	Procedure	HCPCS	289
Q5104	Procedure	HCPCS	22
infiximabdyyb	Generic Name	NDC	*****
infiximababda	Generic Name	NDC	*****

¹Total overall counts may exceed total index episodes in cases where two different codes occur on the same day and encounter setting
 *****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 34. Full Code Distribution of Adalimumab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Encounter Care Setting	Overall Counts
adalimumab	Generic Name	NDC	N/A	21421
J0135	Procedure	HCPCS	AV	138
J0135	Procedure	HCPCS	OA	44
adalimumab	Generic Name	NDC	N/A	*****
J0135	Procedure	HCPCS	AV	*****
J0135	Procedure	HCPCS	IP	*****
J0135	Procedure	HCPCS	ED	*****
adalimumab	Generic Name	NDC	N/A	*****
J0135	Procedure	HCPCS	OA	*****
J0135	Procedure	HCPCS	IPX	*****

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 35. Total Code Counts of Adalimumab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Overall Counts¹
adalimumab	Generic Name	NDC	21435
J0135	Procedure	HCPCS	206

¹Total overall counts may exceed total index episodes in cases where two different codes occur on the same day and encounter setting

**Table 36. Full Code Distribution of Certolizumab pegol NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply)
- Cohort 1**

Code	Code Category	Code Type	Encounter Care Setting	Overall Counts
certolizumab pegol	Generic Name	NDC	N/A	*****
J0717	Procedure	HCPCS	AV	579
J0717	Procedure	HCPCS	OA	*****
J0717	Procedure	HCPCS	IPX	*****
J0717	Procedure	HCPCS	ED	*****
J0717	Procedure	HCPCS	IS	*****
certolizumab pegol	Generic Name	NDC	N/A	*****
J0717	Procedure	HCPCS	AV	*****

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 37. Total Code Counts of Certolizumab pegol NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Overall Counts¹
certolizumab pegol	Generic Name	NDC	3054
J0717	Procedure	HCPCS	593

¹Total overall counts may exceed total index episodes in cases where two different codes occur on the same day and encounter setting

Table 38. Full Code Distribution of Vedolizumab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Encounter Care Setting	Overall Counts
J3380	Procedure	HCPCS	AV	7940
C9026	Procedure	HCPCS	AV	1648
vedolizumab	Generic Name	NDC	N/A	902
J3380	Procedure	HCPCS	OA	405
J3380	Procedure	HCPCS	IS	41
C9026	Procedure	HCPCS	IS	14
C9026	Procedure	HCPCS	OA	*****
J3380	Procedure	HCPCS	ED	*****
J3380	Procedure	HCPCS	IPX	*****
J3380	Procedure	HCPCS	IP	*****
C9026	Procedure	HCPCS	ED	*****
J3380	Procedure	HCPCS	AV	*****
J3380	Procedure	HCPCS	OA	*****
C9026	Procedure	HCPCS	IPX	*****
C9026	Procedure	HCPCS	IP	*****
J3380	Procedure	HCPCS	OA	*****
J3380	Procedure	HCPCS	IS	*****
J3380	Procedure	HCPCS	AV	*****

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 39. Total Code Counts of Vedolizumab NDCs (with 1-Day Supply) or Procedure Codes (with 1-Day Supply) - Cohort 1

Code	Code Category	Code Type	Overall Counts¹
J3380	Procedure	HCPCS	8417
C9026	Procedure	HCPCS	1682
vedolizumab	Generic Name	NDC	902

¹Total overall counts may exceed total index episodes in cases where two different codes occur on the same day and encounter setting

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (September 18, 2019)

DP ID	Start Date ¹	End Date ¹
DP01	06/01/2007	01/31/2019
DP02	01/01/2000	02/28/2019
DP03	01/01/2000	04/30/2019
DP04	01/01/2006	12/31/2018
DP05	01/01/2010	12/31/2018
DP06	01/01/2000	12/31/2017
DP07	01/01/2008	06/30/2018
DP08	01/01/2012	06/30/2017
DP09	01/01/2005	07/31/2018
DP10	01/01/2000	03/31/2016
DP11	01/01/2000	04/30/2018
DP12	01/01/2000	01/31/2019
DP13	01/01/2000	12/31/2018
DP14	01/01/2000	06/30/2018
DP15	01/01/2004	03/31/2019
DP16	01/01/2000	03/31/2018
DP17	01/01/2008	11/30/2018

¹The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Ustekinumab and Comparator Drugs in this Request

Code	Description	Code Type	Code Category
Ustekinumab			
C9487	Ustekinumab, for intravenous injection, 1 mg	HCPCS	Procedure
J3358	Ustekinumab, for intravenous injection, 1 mg	HCPCS	Procedure
Q9989	Ustekinumab, for intravenous injection, 1 mg	HCPCS	Procedure
J3357	Ustekinumab, for subcutaneous injection, 1 mg	HCPCS	Procedure
Infliximab			
S9359	Home infusion therapy, antitumor necrosis factor intravenous therapy; (e.g., Infliximab); administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment, per diem	HCPCS	Procedure
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg	HCPCS	Procedure
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg	HCPCS	Procedure
Q5109	Injection, infliximab-qbtx, biosimilar, (Ixifi), 10 mg	HCPCS	Procedure
Q5102	Injection, infliximab, biosimilar, 10 mg	HCPCS	Procedure
J1745	Injection, infliximab, excludes biosimilar, 10 mg	HCPCS	Procedure
Adalimumab			
J0135	Injection, adalimumab, 20 mg	HCPCS	Procedure
Certolizumab Pegol			
J0717	Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered)	HCPCS	Procedure
J0718	Injection, certolizumab pegol, 1 mg	HCPCS	Procedure
Vedolizumab			
C9026	Injection, vedolizumab, 1 mg	HCPCS	Procedure
J3380	Injection, vedolizumab, 1 mg	HCPCS	Procedure

Appendix C. Generic and Brand Names of Medical Products Used to Define Ustekinumab and Comparator Drugs in this Request

Generic Name	Brand Name
Ustekinumab	Stelara
Infliximab-dyyb	Inflectra
Infliximab-abda	Renflexis
Infliximab	Remicade
Adalimumab	Humira
Adalimumab	Humira Pediatric Crohns Start
Adalimumab	Humira Pen
Adalimumab	Humira Pen Crohns-UC-HS Start
Adalimumab	Humira Pen Psor-Uveits-Adol HS
Adalimumab	Humira(CF)
Adalimumab	Humira(CF) Pen
Adalimumab	Humira(CF) Pedi Crohns Starter
Adalimumab	Humira(CF) Pen Crohns-UC-HS
Adalimumab	Humira(CF) Pen Psor-Uv-Adol HS
Certolizumab pegol	Cimzia Powder for Reconst
Certolizumab pegol	Cimzia
Certolizumab pegol	Cimzia Starter Kit
Vedolizumab	Entyvio

Appendix D. 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) Diagnosis Codes Used to Define Inclusion Criteria

Code	Description	Code Type	Code Category
Crohn's Disease			
555	Regional enteritis	ICD-09-CM	Diagnosis
555.0	Regional enteritis of small intestine	ICD-09-CM	Diagnosis
555.1	Regional enteritis of large intestine	ICD-09-CM	Diagnosis
555.2	Regional enteritis of small intestine with large intestine	ICD-09-CM	Diagnosis
555.9	Regional enteritis of unspecified site	ICD-09-CM	Diagnosis
K50.0	Crohn's disease of small intestine	ICD-10-CM	Diagnosis
K50.00	Crohn's disease of small intestine without complications	ICD-10-CM	Diagnosis
K50.01	Crohn's disease of small intestine with complications	ICD-10-CM	Diagnosis
K50.011	Crohn's disease of small intestine with rectal bleeding	ICD-10-CM	Diagnosis
K50.012	Crohn's disease of small intestine with intestinal obstruction	ICD-10-CM	Diagnosis
K50.013	Crohn's disease of small intestine with fistula	ICD-10-CM	Diagnosis
K50.014	Crohn's disease of small intestine with abscess	ICD-10-CM	Diagnosis
K50.018	Crohn's disease of small intestine with other complication	ICD-10-CM	Diagnosis
K50.019	Crohn's disease of small intestine with unspecified complications	ICD-10-CM	Diagnosis
K50.1	Crohn's disease of large intestine	ICD-10-CM	Diagnosis
K50.10	Crohn's disease of large intestine without complications	ICD-10-CM	Diagnosis
K50.11	Crohn's disease of large intestine with complications	ICD-10-CM	Diagnosis
K50.111	Crohn's disease of large intestine with rectal bleeding	ICD-10-CM	Diagnosis
K50.112	Crohn's disease of large intestine with intestinal obstruction	ICD-10-CM	Diagnosis
K50.113	Crohn's disease of large intestine with fistula	ICD-10-CM	Diagnosis
K50.114	Crohn's disease of large intestine with abscess	ICD-10-CM	Diagnosis
K50.118	Crohn's disease of large intestine with other complication	ICD-10-CM	Diagnosis
K50.119	Crohn's disease of large intestine with unspecified complications	ICD-10-CM	Diagnosis
K50.8	Crohn's disease of both small and large intestine	ICD-10-CM	Diagnosis
K50.80	Crohn's disease of both small and large intestine without complications	ICD-10-CM	Diagnosis
K50.81	Crohn's disease of both small and large intestine with complications	ICD-10-CM	Diagnosis
K50.811	Crohn's disease of both small and large intestine with rectal bleeding	ICD-10-CM	Diagnosis
K50.812	Crohn's disease of both small and large intestine with intestinal	ICD-10-CM	Diagnosis
K50.813	Crohn's disease of both small and large intestine with fistula	ICD-10-CM	Diagnosis
K50.814	Crohn's disease of both small and large intestine with abscess	ICD-10-CM	Diagnosis
K50.818	Crohn's disease of both small and large intestine with other	ICD-10-CM	Diagnosis
K50.819	Crohn's disease of both small and large intestine with unspecified	ICD-10-CM	Diagnosis
K50.9	Crohn's disease, unspecified	ICD-10-CM	Diagnosis
K50.90	Crohn's disease, unspecified, without complications	ICD-10-CM	Diagnosis
K50.91	Crohn's disease, unspecified, with complications	ICD-10-CM	Diagnosis
K50.911	Crohn's disease, unspecified, with rectal bleeding	ICD-10-CM	Diagnosis
K50.912	Crohn's disease, unspecified, with intestinal obstruction	ICD-10-CM	Diagnosis
K50.913	Crohn's disease, unspecified, with fistula	ICD-10-CM	Diagnosis
K50.914	Crohn's disease, unspecified, with abscess	ICD-10-CM	Diagnosis
K50.918	Crohn's disease, unspecified, with other complication	ICD-10-CM	Diagnosis
K50.919	Crohn's disease, unspecified, with unspecified complications	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
Rheumatoid Arthritis			
714.0	Rheumatoid arthritis	ICD-9-CM	Diagnosis
714.2	Other rheumatoid arthritis with visceral or systemic involvement	ICD-9-CM	Diagnosis
714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified	ICD-9-CM	Diagnosis
714.31	Polyarticular juvenile rheumatoid arthritis, acute	ICD-9-CM	Diagnosis
714.32	Pauciarticular juvenile rheumatoid arthritis	ICD-9-CM	Diagnosis
714.33	Monoarticular juvenile rheumatoid arthritis	ICD-9-CM	Diagnosis
M05.1	Rheumatoid lung disease with rheumatoid arthritis	ICD-10-CM	Diagnosis
M05.10	Rheumatoid lung disease with rheumatoid arthritis of unspecified site	ICD-10-CM	Diagnosis
M05.11	Rheumatoid lung disease with rheumatoid arthritis of shoulder	ICD-10-CM	Diagnosis
M05.111	Rheumatoid lung disease with rheumatoid arthritis of right shoulder	ICD-10-CM	Diagnosis
M05.112	Rheumatoid lung disease with rheumatoid arthritis of left shoulder	ICD-10-CM	Diagnosis
M05.119	Rheumatoid lung disease with rheumatoid arthritis of unspecified shoulder	ICD-10-CM	Diagnosis
M05.12	Rheumatoid lung disease with rheumatoid arthritis of elbow	ICD-10-CM	Diagnosis
M05.121	Rheumatoid lung disease with rheumatoid arthritis of right elbow	ICD-10-CM	Diagnosis
M05.122	Rheumatoid lung disease with rheumatoid arthritis of left elbow	ICD-10-CM	Diagnosis
M05.129	Rheumatoid lung disease with rheumatoid arthritis of unspecified elbow	ICD-10-CM	Diagnosis
M05.13	Rheumatoid lung disease with rheumatoid arthritis of wrist	ICD-10-CM	Diagnosis
M05.131	Rheumatoid lung disease with rheumatoid arthritis of right wrist	ICD-10-CM	Diagnosis
M05.132	Rheumatoid lung disease with rheumatoid arthritis of left wrist	ICD-10-CM	Diagnosis
M05.139	Rheumatoid lung disease with rheumatoid arthritis of unspecified wrist	ICD-10-CM	Diagnosis
M05.14	Rheumatoid lung disease with rheumatoid arthritis of hand	ICD-10-CM	Diagnosis
M05.141	Rheumatoid lung disease with rheumatoid arthritis of right hand	ICD-10-CM	Diagnosis
M05.142	Rheumatoid lung disease with rheumatoid arthritis of left hand	ICD-10-CM	Diagnosis
M05.149	Rheumatoid lung disease with rheumatoid arthritis of unspecified hand	ICD-10-CM	Diagnosis
M05.15	Rheumatoid lung disease with rheumatoid arthritis of hip	ICD-10-CM	Diagnosis
M05.151	Rheumatoid lung disease with rheumatoid arthritis of right hip	ICD-10-CM	Diagnosis
M05.152	Rheumatoid lung disease with rheumatoid arthritis of left hip	ICD-10-CM	Diagnosis
M05.159	Rheumatoid lung disease with rheumatoid arthritis of unspecified hip	ICD-10-CM	Diagnosis
M05.16	Rheumatoid lung disease with rheumatoid arthritis of knee	ICD-10-CM	Diagnosis
M05.161	Rheumatoid lung disease with rheumatoid arthritis of right knee	ICD-10-CM	Diagnosis
M05.162	Rheumatoid lung disease with rheumatoid arthritis of left knee	ICD-10-CM	Diagnosis
M05.169	Rheumatoid lung disease with rheumatoid arthritis of unspecified knee	ICD-10-CM	Diagnosis
M05.17	Rheumatoid lung disease with rheumatoid arthritis of ankle and foot	ICD-10-CM	Diagnosis
M05.171	Rheumatoid lung disease with rheumatoid arthritis of right ankle and foot	ICD-10-CM	Diagnosis
M05.172	Rheumatoid lung disease with rheumatoid arthritis of left ankle and foot	ICD-10-CM	Diagnosis
M05.179	Rheumatoid lung disease with rheumatoid arthritis of unspecified ankle and foot	ICD-10-CM	Diagnosis
M05.19	Rheumatoid lung disease with rheumatoid arthritis of multiple sites	ICD-10-CM	Diagnosis
M05.2	Rheumatoid vasculitis with rheumatoid arthritis	ICD-10-CM	Diagnosis
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site	ICD-10-CM	Diagnosis
M05.21	Rheumatoid vasculitis with rheumatoid arthritis of shoulder	ICD-10-CM	Diagnosis
M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder	ICD-10-CM	Diagnosis
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder	ICD-10-CM	Diagnosis
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
M05.22	Rheumatoid vasculitis with rheumatoid arthritis of elbow	ICD-10-CM	Diagnosis
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow	ICD-10-CM	Diagnosis
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow	ICD-10-CM	Diagnosis
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow	ICD-10-CM	Diagnosis
M05.23	Rheumatoid vasculitis with rheumatoid arthritis of wrist	ICD-10-CM	Diagnosis
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist	ICD-10-CM	Diagnosis
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist	ICD-10-CM	Diagnosis
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist	ICD-10-CM	Diagnosis
M05.24	Rheumatoid vasculitis with rheumatoid arthritis of hand	ICD-10-CM	Diagnosis
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand	ICD-10-CM	Diagnosis
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand	ICD-10-CM	Diagnosis
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand	ICD-10-CM	Diagnosis
M05.25	Rheumatoid vasculitis with rheumatoid arthritis of hip	ICD-10-CM	Diagnosis
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip	ICD-10-CM	Diagnosis
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip	ICD-10-CM	Diagnosis
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip	ICD-10-CM	Diagnosis
M05.26	Rheumatoid vasculitis with rheumatoid arthritis of knee	ICD-10-CM	Diagnosis
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee	ICD-10-CM	Diagnosis
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee	ICD-10-CM	Diagnosis
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee	ICD-10-CM	Diagnosis
M05.27	Rheumatoid vasculitis with rheumatoid arthritis of ankle and foot	ICD-10-CM	Diagnosis
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot	ICD-10-CM	Diagnosis
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot	ICD-10-CM	Diagnosis
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot	ICD-10-CM	Diagnosis
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites	ICD-10-CM	Diagnosis
M05.3	Rheumatoid heart disease with rheumatoid arthritis	ICD-10-CM	Diagnosis
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site	ICD-10-CM	Diagnosis
M05.31	Rheumatoid heart disease with rheumatoid arthritis of shoulder	ICD-10-CM	Diagnosis
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder	ICD-10-CM	Diagnosis
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder	ICD-10-CM	Diagnosis
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder	ICD-10-CM	Diagnosis
M05.32	Rheumatoid heart disease with rheumatoid arthritis of elbow	ICD-10-CM	Diagnosis
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow	ICD-10-CM	Diagnosis
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow	ICD-10-CM	Diagnosis
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow	ICD-10-CM	Diagnosis
M05.33	Rheumatoid heart disease with rheumatoid arthritis of wrist	ICD-10-CM	Diagnosis
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist	ICD-10-CM	Diagnosis
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist	ICD-10-CM	Diagnosis
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist	ICD-10-CM	Diagnosis
M05.34	Rheumatoid heart disease with rheumatoid arthritis of hand	ICD-10-CM	Diagnosis
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand	ICD-10-CM	Diagnosis
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand	ICD-10-CM	Diagnosis
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand	ICD-10-CM	Diagnosis
M05.35	Rheumatoid heart disease with rheumatoid arthritis of hip	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip	ICD-10-CM	Diagnosis
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip	ICD-10-CM	Diagnosis
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip	ICD-10-CM	Diagnosis
M05.36	Rheumatoid heart disease with rheumatoid arthritis of knee	ICD-10-CM	Diagnosis
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee	ICD-10-CM	Diagnosis
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee	ICD-10-CM	Diagnosis
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee	ICD-10-CM	Diagnosis
M05.37	Rheumatoid heart disease with rheumatoid arthritis of ankle and foot	ICD-10-CM	Diagnosis
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot	ICD-10-CM	Diagnosis
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot	ICD-10-CM	Diagnosis
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot	ICD-10-CM	Diagnosis
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites	ICD-10-CM	Diagnosis
M05.4	Rheumatoid myopathy with rheumatoid arthritis	ICD-10-CM	Diagnosis
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site	ICD-10-CM	Diagnosis
M05.41	Rheumatoid myopathy with rheumatoid arthritis of shoulder	ICD-10-CM	Diagnosis
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder	ICD-10-CM	Diagnosis
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder	ICD-10-CM	Diagnosis
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder	ICD-10-CM	Diagnosis
M05.42	Rheumatoid myopathy with rheumatoid arthritis of elbow	ICD-10-CM	Diagnosis
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow	ICD-10-CM	Diagnosis
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow	ICD-10-CM	Diagnosis
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow	ICD-10-CM	Diagnosis
M05.43	Rheumatoid myopathy with rheumatoid arthritis of wrist	ICD-10-CM	Diagnosis
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist	ICD-10-CM	Diagnosis
M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist	ICD-10-CM	Diagnosis
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist	ICD-10-CM	Diagnosis
M05.44	Rheumatoid myopathy with rheumatoid arthritis of hand	ICD-10-CM	Diagnosis
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand	ICD-10-CM	Diagnosis
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand	ICD-10-CM	Diagnosis
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand	ICD-10-CM	Diagnosis
M05.45	Rheumatoid myopathy with rheumatoid arthritis of hip	ICD-10-CM	Diagnosis
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip	ICD-10-CM	Diagnosis
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip	ICD-10-CM	Diagnosis
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip	ICD-10-CM	Diagnosis
M05.46	Rheumatoid myopathy with rheumatoid arthritis of knee	ICD-10-CM	Diagnosis
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee	ICD-10-CM	Diagnosis
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee	ICD-10-CM	Diagnosis
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee	ICD-10-CM	Diagnosis
M05.47	Rheumatoid myopathy with rheumatoid arthritis of ankle and foot	ICD-10-CM	Diagnosis
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot	ICD-10-CM	Diagnosis
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot	ICD-10-CM	Diagnosis
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot	ICD-10-CM	Diagnosis
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites	ICD-10-CM	Diagnosis
M05.5	Rheumatoid polyneuropathy with rheumatoid arthritis	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site	ICD-10-CM	Diagnosis
M05.51	Rheumatoid polyneuropathy with rheumatoid arthritis of shoulder	ICD-10-CM	Diagnosis
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder	ICD-10-CM	Diagnosis
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder	ICD-10-CM	Diagnosis
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder	ICD-10-CM	Diagnosis
M05.52	Rheumatoid polyneuropathy with rheumatoid arthritis of elbow	ICD-10-CM	Diagnosis
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow	ICD-10-CM	Diagnosis
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow	ICD-10-CM	Diagnosis
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow	ICD-10-CM	Diagnosis
M05.53	Rheumatoid polyneuropathy with rheumatoid arthritis of wrist	ICD-10-CM	Diagnosis
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist	ICD-10-CM	Diagnosis
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist	ICD-10-CM	Diagnosis
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist	ICD-10-CM	Diagnosis
M05.54	Rheumatoid polyneuropathy with rheumatoid arthritis of hand	ICD-10-CM	Diagnosis
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand	ICD-10-CM	Diagnosis
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand	ICD-10-CM	Diagnosis
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand	ICD-10-CM	Diagnosis
M05.55	Rheumatoid polyneuropathy with rheumatoid arthritis of hip	ICD-10-CM	Diagnosis
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip	ICD-10-CM	Diagnosis
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip	ICD-10-CM	Diagnosis
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip	ICD-10-CM	Diagnosis
M05.56	Rheumatoid polyneuropathy with rheumatoid arthritis of knee	ICD-10-CM	Diagnosis
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee	ICD-10-CM	Diagnosis
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee	ICD-10-CM	Diagnosis
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee	ICD-10-CM	Diagnosis
M05.57	Rheumatoid polyneuropathy with rheumatoid arthritis of ankle and foot	ICD-10-CM	Diagnosis
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot	ICD-10-CM	Diagnosis
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot	ICD-10-CM	Diagnosis
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and	ICD-10-CM	Diagnosis
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites	ICD-10-CM	Diagnosis
M05.6	Rheumatoid arthritis with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.61	Rheumatoid arthritis of shoulder with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.62	Rheumatoid arthritis of elbow with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.63	Rheumatoid arthritis of wrist with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.64	Rheumatoid arthritis of hand with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.65	Rheumatoid arthritis of hip with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.66	Rheumatoid arthritis of knee with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.67	Rheumatoid arthritis of ankle and foot with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems	ICD-10-CM	Diagnosis
M05.7	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement	ICD-10-CM	Diagnosis
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement	ICD-10-CM	Diagnosis
M05.71	Rheumatoid arthritis with rheumatoid factor of shoulder without organ or systems involvement	ICD-10-CM	Diagnosis
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement	ICD-10-CM	Diagnosis
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement	ICD-10-CM	Diagnosis
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
M05.72	Rheumatoid arthritis with rheumatoid factor of elbow without organ or systems involvement	ICD-10-CM	Diagnosis
M05.721	Rheumatoid arthritis with rheumatoid factor of right elbow without organ or systems involvement	ICD-10-CM	Diagnosis
M05.722	Rheumatoid arthritis with rheumatoid factor of left elbow without organ or systems involvement	ICD-10-CM	Diagnosis
M05.729	Rheumatoid arthritis with rheumatoid factor of unspecified elbow without organ or systems involvement	ICD-10-CM	Diagnosis
M05.73	Rheumatoid arthritis with rheumatoid factor of wrist without organ or systems involvement	ICD-10-CM	Diagnosis
M05.731	Rheumatoid arthritis with rheumatoid factor of right wrist without organ or systems involvement	ICD-10-CM	Diagnosis
M05.732	Rheumatoid arthritis with rheumatoid factor of left wrist without organ or systems involvement	ICD-10-CM	Diagnosis
M05.739	Rheumatoid arthritis with rheumatoid factor of unspecified wrist without organ or systems involvement	ICD-10-CM	Diagnosis
M05.74	Rheumatoid arthritis with rheumatoid factor of hand without organ or systems involvement	ICD-10-CM	Diagnosis
M05.741	Rheumatoid arthritis with rheumatoid factor of right hand without organ or systems involvement	ICD-10-CM	Diagnosis
M05.742	Rheumatoid arthritis with rheumatoid factor of left hand without organ or systems involvement	ICD-10-CM	Diagnosis
M05.749	Rheumatoid arthritis with rheumatoid factor of unspecified hand without organ or systems involvement	ICD-10-CM	Diagnosis
M05.75	Rheumatoid arthritis with rheumatoid factor of hip without organ or systems involvement	ICD-10-CM	Diagnosis
M05.751	Rheumatoid arthritis with rheumatoid factor of right hip without organ or systems involvement	ICD-10-CM	Diagnosis
M05.752	Rheumatoid arthritis with rheumatoid factor of left hip without organ or systems involvement	ICD-10-CM	Diagnosis
M05.759	Rheumatoid arthritis with rheumatoid factor of unspecified hip without organ or systems involvement	ICD-10-CM	Diagnosis
M05.76	Rheumatoid arthritis with rheumatoid factor of knee without organ or systems involvement	ICD-10-CM	Diagnosis
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement	ICD-10-CM	Diagnosis
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement	ICD-10-CM	Diagnosis
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement	ICD-10-CM	Diagnosis
M05.77	Rheumatoid arthritis with rheumatoid factor of ankle and foot without organ or systems involvement	ICD-10-CM	Diagnosis
M05.771	Rheumatoid arthritis with rheumatoid factor of right ankle and foot without organ or systems involvement	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
M05.772	Rheumatoid arthritis with rheumatoid factor of left ankle and foot without organ or systems involvement	ICD-10-CM	Diagnosis
M05.779	Rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot without organ or systems involvement	ICD-10-CM	Diagnosis
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement	ICD-10-CM	Diagnosis
M05.8	Other rheumatoid arthritis with rheumatoid factor	ICD-10-CM	Diagnosis
M05.80	Other rheumatoid arthritis with rheumatoid factor of unspecified site	ICD-10-CM	Diagnosis
M05.81	Other rheumatoid arthritis with rheumatoid factor of shoulder	ICD-10-CM	Diagnosis
M05.811	Other rheumatoid arthritis with rheumatoid factor of right shoulder	ICD-10-CM	Diagnosis
M05.812	Other rheumatoid arthritis with rheumatoid factor of left shoulder	ICD-10-CM	Diagnosis
M05.819	Other rheumatoid arthritis with rheumatoid factor of unspecified shoulder	ICD-10-CM	Diagnosis
M05.82	Other rheumatoid arthritis with rheumatoid factor of elbow	ICD-10-CM	Diagnosis
M05.821	Other rheumatoid arthritis with rheumatoid factor of right elbow	ICD-10-CM	Diagnosis
M05.822	Other rheumatoid arthritis with rheumatoid factor of left elbow	ICD-10-CM	Diagnosis
M05.829	Other rheumatoid arthritis with rheumatoid factor of unspecified elbow	ICD-10-CM	Diagnosis
M05.83	Other rheumatoid arthritis with rheumatoid factor of wrist	ICD-10-CM	Diagnosis
M05.831	Other rheumatoid arthritis with rheumatoid factor of right wrist	ICD-10-CM	Diagnosis
M05.832	Other rheumatoid arthritis with rheumatoid factor of left wrist	ICD-10-CM	Diagnosis
M05.839	Other rheumatoid arthritis with rheumatoid factor of unspecified wrist	ICD-10-CM	Diagnosis
M05.84	Other rheumatoid arthritis with rheumatoid factor of hand	ICD-10-CM	Diagnosis
M05.841	Other rheumatoid arthritis with rheumatoid factor of right hand	ICD-10-CM	Diagnosis
M05.842	Other rheumatoid arthritis with rheumatoid factor of left hand	ICD-10-CM	Diagnosis
M05.849	Other rheumatoid arthritis with rheumatoid factor of unspecified hand	ICD-10-CM	Diagnosis
M05.85	Other rheumatoid arthritis with rheumatoid factor of hip	ICD-10-CM	Diagnosis
M05.851	Other rheumatoid arthritis with rheumatoid factor of right hip	ICD-10-CM	Diagnosis
M05.852	Other rheumatoid arthritis with rheumatoid factor of left hip	ICD-10-CM	Diagnosis
M05.859	Other rheumatoid arthritis with rheumatoid factor of unspecified hip	ICD-10-CM	Diagnosis
M05.86	Other rheumatoid arthritis with rheumatoid factor of knee	ICD-10-CM	Diagnosis
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee	ICD-10-CM	Diagnosis
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee	ICD-10-CM	Diagnosis
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee	ICD-10-CM	Diagnosis
M05.87	Other rheumatoid arthritis with rheumatoid factor of ankle and foot	ICD-10-CM	Diagnosis
M05.871	Other rheumatoid arthritis with rheumatoid factor of right ankle and foot	ICD-10-CM	Diagnosis
M05.872	Other rheumatoid arthritis with rheumatoid factor of left ankle and foot	ICD-10-CM	Diagnosis
M05.879	Other rheumatoid arthritis with rheumatoid factor of unspecified ankle and foot	ICD-10-CM	Diagnosis
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites	ICD-10-CM	Diagnosis
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified	ICD-10-CM	Diagnosis
M06.0	Rheumatoid arthritis without rheumatoid factor	ICD-10-CM	Diagnosis
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site	ICD-10-CM	Diagnosis
M06.01	Rheumatoid arthritis without rheumatoid factor, shoulder	ICD-10-CM	Diagnosis
M06.011	Rheumatoid arthritis without rheumatoid factor, right shoulder	ICD-10-CM	Diagnosis
M06.012	Rheumatoid arthritis without rheumatoid factor, left shoulder	ICD-10-CM	Diagnosis
M06.019	Rheumatoid arthritis without rheumatoid factor, unspecified shoulder	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
M06.02	Rheumatoid arthritis without rheumatoid factor, elbow	ICD-10-CM	Diagnosis
M06.021	Rheumatoid arthritis without rheumatoid factor, right elbow	ICD-10-CM	Diagnosis
M06.022	Rheumatoid arthritis without rheumatoid factor, left elbow	ICD-10-CM	Diagnosis
M06.029	Rheumatoid arthritis without rheumatoid factor, unspecified elbow	ICD-10-CM	Diagnosis
M06.03	Rheumatoid arthritis without rheumatoid factor, wrist	ICD-10-CM	Diagnosis
M06.031	Rheumatoid arthritis without rheumatoid factor, right wrist	ICD-10-CM	Diagnosis
M06.032	Rheumatoid arthritis without rheumatoid factor, left wrist	ICD-10-CM	Diagnosis
M06.039	Rheumatoid arthritis without rheumatoid factor, unspecified wrist	ICD-10-CM	Diagnosis
M06.04	Rheumatoid arthritis without rheumatoid factor, hand	ICD-10-CM	Diagnosis
M06.041	Rheumatoid arthritis without rheumatoid factor, right hand	ICD-10-CM	Diagnosis
M06.042	Rheumatoid arthritis without rheumatoid factor, left hand	ICD-10-CM	Diagnosis
M06.049	Rheumatoid arthritis without rheumatoid factor, unspecified hand	ICD-10-CM	Diagnosis
M06.05	Rheumatoid arthritis without rheumatoid factor, hip	ICD-10-CM	Diagnosis
M06.051	Rheumatoid arthritis without rheumatoid factor, right hip	ICD-10-CM	Diagnosis
M06.052	Rheumatoid arthritis without rheumatoid factor, left hip	ICD-10-CM	Diagnosis
M06.059	Rheumatoid arthritis without rheumatoid factor, unspecified hip	ICD-10-CM	Diagnosis
M06.06	Rheumatoid arthritis without rheumatoid factor, knee	ICD-10-CM	Diagnosis
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee	ICD-10-CM	Diagnosis
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee	ICD-10-CM	Diagnosis
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee	ICD-10-CM	Diagnosis
M06.07	Rheumatoid arthritis without rheumatoid factor, ankle and foot	ICD-10-CM	Diagnosis
M06.071	Rheumatoid arthritis without rheumatoid factor, right ankle and foot	ICD-10-CM	Diagnosis
M06.072	Rheumatoid arthritis without rheumatoid factor, left ankle and foot	ICD-10-CM	Diagnosis
M06.079	Rheumatoid arthritis without rheumatoid factor, unspecified ankle and foot	ICD-10-CM	Diagnosis
M06.08	Rheumatoid arthritis without rheumatoid factor, vertebrae	ICD-10-CM	Diagnosis
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites	ICD-10-CM	Diagnosis
M06.1	Adult-onset Still's disease	ICD-10-CM	Diagnosis
M06.2	Rheumatoid bursitis	ICD-10-CM	Diagnosis
M06.20	Rheumatoid bursitis, unspecified site	ICD-10-CM	Diagnosis
M06.21	Rheumatoid bursitis, shoulder	ICD-10-CM	Diagnosis
M06.211	Rheumatoid bursitis, right shoulder	ICD-10-CM	Diagnosis
M06.212	Rheumatoid bursitis, left shoulder	ICD-10-CM	Diagnosis
M06.219	Rheumatoid bursitis, unspecified shoulder	ICD-10-CM	Diagnosis
M06.22	Rheumatoid bursitis, elbow	ICD-10-CM	Diagnosis
M06.221	Rheumatoid bursitis, right elbow	ICD-10-CM	Diagnosis
M06.222	Rheumatoid bursitis, left elbow	ICD-10-CM	Diagnosis
M06.229	Rheumatoid bursitis, unspecified elbow	ICD-10-CM	Diagnosis
M06.23	Rheumatoid bursitis, wrist	ICD-10-CM	Diagnosis
M06.231	Rheumatoid bursitis, right wrist	ICD-10-CM	Diagnosis
M06.232	Rheumatoid bursitis, left wrist	ICD-10-CM	Diagnosis
M06.239	Rheumatoid bursitis, unspecified wrist	ICD-10-CM	Diagnosis
M06.24	Rheumatoid bursitis, hand	ICD-10-CM	Diagnosis
M06.241	Rheumatoid bursitis, right hand	ICD-10-CM	Diagnosis
M06.242	Rheumatoid bursitis, left hand	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
M06.249	Rheumatoid bursitis, unspecified hand	ICD-10-CM	Diagnosis
M06.25	Rheumatoid bursitis, hip	ICD-10-CM	Diagnosis
M06.251	Rheumatoid bursitis, right hip	ICD-10-CM	Diagnosis
M06.252	Rheumatoid bursitis, left hip	ICD-10-CM	Diagnosis
M06.259	Rheumatoid bursitis, unspecified hip	ICD-10-CM	Diagnosis
M06.26	Rheumatoid bursitis, knee	ICD-10-CM	Diagnosis
M06.261	Rheumatoid bursitis, right knee	ICD-10-CM	Diagnosis
M06.262	Rheumatoid bursitis, left knee	ICD-10-CM	Diagnosis
M06.269	Rheumatoid bursitis, unspecified knee	ICD-10-CM	Diagnosis
M06.27	Rheumatoid bursitis, ankle and foot	ICD-10-CM	Diagnosis
M06.271	Rheumatoid bursitis, right ankle and foot	ICD-10-CM	Diagnosis
M06.272	Rheumatoid bursitis, left ankle and foot	ICD-10-CM	Diagnosis
M06.279	Rheumatoid bursitis, unspecified ankle and foot	ICD-10-CM	Diagnosis
M06.28	Rheumatoid bursitis, vertebrae	ICD-10-CM	Diagnosis
M06.29	Rheumatoid bursitis, multiple sites	ICD-10-CM	Diagnosis
M06.3	Rheumatoid nodule	ICD-10-CM	Diagnosis
M06.30	Rheumatoid nodule, unspecified site	ICD-10-CM	Diagnosis
M06.31	Rheumatoid nodule, shoulder	ICD-10-CM	Diagnosis
M06.311	Rheumatoid nodule, right shoulder	ICD-10-CM	Diagnosis
M06.312	Rheumatoid nodule, left shoulder	ICD-10-CM	Diagnosis
M06.319	Rheumatoid nodule, unspecified shoulder	ICD-10-CM	Diagnosis
M06.32	Rheumatoid nodule, elbow	ICD-10-CM	Diagnosis
M06.321	Rheumatoid nodule, right elbow	ICD-10-CM	Diagnosis
M06.322	Rheumatoid nodule, left elbow	ICD-10-CM	Diagnosis
M06.329	Rheumatoid nodule, unspecified elbow	ICD-10-CM	Diagnosis
M06.33	Rheumatoid nodule, wrist	ICD-10-CM	Diagnosis
M06.331	Rheumatoid nodule, right wrist	ICD-10-CM	Diagnosis
M06.332	Rheumatoid nodule, left wrist	ICD-10-CM	Diagnosis
M06.339	Rheumatoid nodule, unspecified wrist	ICD-10-CM	Diagnosis
M06.34	Rheumatoid nodule, hand	ICD-10-CM	Diagnosis
M06.341	Rheumatoid nodule, right hand	ICD-10-CM	Diagnosis
M06.342	Rheumatoid nodule, left hand	ICD-10-CM	Diagnosis
M06.349	Rheumatoid nodule, unspecified hand	ICD-10-CM	Diagnosis
M06.35	Rheumatoid nodule, hip	ICD-10-CM	Diagnosis
M06.351	Rheumatoid nodule, right hip	ICD-10-CM	Diagnosis
M06.352	Rheumatoid nodule, left hip	ICD-10-CM	Diagnosis
M06.359	Rheumatoid nodule, unspecified hip	ICD-10-CM	Diagnosis
M06.36	Rheumatoid nodule, knee	ICD-10-CM	Diagnosis
M06.361	Rheumatoid nodule, right knee	ICD-10-CM	Diagnosis
M06.362	Rheumatoid nodule, left knee	ICD-10-CM	Diagnosis
M06.369	Rheumatoid nodule, unspecified knee	ICD-10-CM	Diagnosis
M06.37	Rheumatoid nodule, ankle and foot	ICD-10-CM	Diagnosis
M06.371	Rheumatoid nodule, right ankle and foot	ICD-10-CM	Diagnosis
M06.372	Rheumatoid nodule, left ankle and foot	ICD-10-CM	Diagnosis

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Code	Description	Code Type	Code Category
M06.379	Rheumatoid nodule, unspecified ankle and foot	ICD-10-CM	Diagnosis
M06.38	Rheumatoid nodule, vertebrae	ICD-10-CM	Diagnosis
M06.39	Rheumatoid nodule, multiple sites	ICD-10-CM	Diagnosis
M06.8	Other specified rheumatoid arthritis	ICD-10-CM	Diagnosis
M06.80	Other specified rheumatoid arthritis, unspecified site	ICD-10-CM	Diagnosis
M06.81	Other specified rheumatoid arthritis, shoulder	ICD-10-CM	Diagnosis
M06.811	Other specified rheumatoid arthritis, right shoulder	ICD-10-CM	Diagnosis
M06.812	Other specified rheumatoid arthritis, left shoulder	ICD-10-CM	Diagnosis
M06.819	Other specified rheumatoid arthritis, unspecified shoulder	ICD-10-CM	Diagnosis
M06.82	Other specified rheumatoid arthritis, elbow	ICD-10-CM	Diagnosis
M06.821	Other specified rheumatoid arthritis, right elbow	ICD-10-CM	Diagnosis
M06.822	Other specified rheumatoid arthritis, left elbow	ICD-10-CM	Diagnosis
M06.829	Other specified rheumatoid arthritis, unspecified elbow	ICD-10-CM	Diagnosis
M06.83	Other specified rheumatoid arthritis, wrist	ICD-10-CM	Diagnosis
M06.831	Other specified rheumatoid arthritis, right wrist	ICD-10-CM	Diagnosis
M06.832	Other specified rheumatoid arthritis, left wrist	ICD-10-CM	Diagnosis
M06.839	Other specified rheumatoid arthritis, unspecified wrist	ICD-10-CM	Diagnosis
M06.84	Other specified rheumatoid arthritis, hand	ICD-10-CM	Diagnosis
M06.841	Other specified rheumatoid arthritis, right hand	ICD-10-CM	Diagnosis
M06.842	Other specified rheumatoid arthritis, left hand	ICD-10-CM	Diagnosis
M06.849	Other specified rheumatoid arthritis, unspecified hand	ICD-10-CM	Diagnosis
M06.85	Other specified rheumatoid arthritis, hip	ICD-10-CM	Diagnosis
M06.851	Other specified rheumatoid arthritis, right hip	ICD-10-CM	Diagnosis
M06.852	Other specified rheumatoid arthritis, left hip	ICD-10-CM	Diagnosis
M06.859	Other specified rheumatoid arthritis, unspecified hip	ICD-10-CM	Diagnosis
M06.86	Other specified rheumatoid arthritis, knee	ICD-10-CM	Diagnosis
M06.861	Other specified rheumatoid arthritis, right knee	ICD-10-CM	Diagnosis
M06.862	Other specified rheumatoid arthritis, left knee	ICD-10-CM	Diagnosis
M06.869	Other specified rheumatoid arthritis, unspecified knee	ICD-10-CM	Diagnosis
M06.87	Other specified rheumatoid arthritis, ankle and foot	ICD-10-CM	Diagnosis
M06.871	Other specified rheumatoid arthritis, right ankle and foot	ICD-10-CM	Diagnosis
M06.872	Other specified rheumatoid arthritis, left ankle and foot	ICD-10-CM	Diagnosis
M06.879	Other specified rheumatoid arthritis, unspecified ankle and foot	ICD-10-CM	Diagnosis
M06.88	Other specified rheumatoid arthritis, vertebrae	ICD-10-CM	Diagnosis
M06.89	Other specified rheumatoid arthritis, multiple sites	ICD-10-CM	Diagnosis
M06.9	Rheumatoid arthritis, unspecified	ICD-10-CM	Diagnosis
M08.0	Unspecified juvenile rheumatoid arthritis	ICD-10-CM	Diagnosis
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site	ICD-10-CM	Diagnosis
M08.01	Unspecified juvenile rheumatoid arthritis, shoulder	ICD-10-CM	Diagnosis
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder	ICD-10-CM	Diagnosis
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder	ICD-10-CM	Diagnosis
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder	ICD-10-CM	Diagnosis
M08.02	Unspecified juvenile rheumatoid arthritis of elbow	ICD-10-CM	Diagnosis
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow	ICD-10-CM	Diagnosis
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow	ICD-10-CM	Diagnosis
M08.03	Unspecified juvenile rheumatoid arthritis, wrist	ICD-10-CM	Diagnosis
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist	ICD-10-CM	Diagnosis
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist	ICD-10-CM	Diagnosis
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist	ICD-10-CM	Diagnosis
M08.04	Unspecified juvenile rheumatoid arthritis, hand	ICD-10-CM	Diagnosis
M08.041	Unspecified juvenile rheumatoid arthritis, right hand	ICD-10-CM	Diagnosis
M08.042	Unspecified juvenile rheumatoid arthritis, left hand	ICD-10-CM	Diagnosis
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand	ICD-10-CM	Diagnosis
M08.05	Unspecified juvenile rheumatoid arthritis, hip	ICD-10-CM	Diagnosis
M08.051	Unspecified juvenile rheumatoid arthritis, right hip	ICD-10-CM	Diagnosis
M08.052	Unspecified juvenile rheumatoid arthritis, left hip	ICD-10-CM	Diagnosis
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip	ICD-10-CM	Diagnosis
M08.06	Unspecified juvenile rheumatoid arthritis, knee	ICD-10-CM	Diagnosis
M08.061	Unspecified juvenile rheumatoid arthritis, right knee	ICD-10-CM	Diagnosis
M08.062	Unspecified juvenile rheumatoid arthritis, left knee	ICD-10-CM	Diagnosis
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee	ICD-10-CM	Diagnosis
M08.07	Unspecified juvenile rheumatoid arthritis, ankle and foot	ICD-10-CM	Diagnosis
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot	ICD-10-CM	Diagnosis
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot	ICD-10-CM	Diagnosis
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot	ICD-10-CM	Diagnosis
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae	ICD-10-CM	Diagnosis
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites	ICD-10-CM	Diagnosis
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site	ICD-10-CM	Diagnosis
M08.21	Juvenile rheumatoid arthritis with systemic onset, shoulder	ICD-10-CM	Diagnosis
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder	ICD-10-CM	Diagnosis
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder	ICD-10-CM	Diagnosis
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder	ICD-10-CM	Diagnosis
M08.22	Juvenile rheumatoid arthritis with systemic onset, elbow	ICD-10-CM	Diagnosis
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow	ICD-10-CM	Diagnosis
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow	ICD-10-CM	Diagnosis
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow	ICD-10-CM	Diagnosis
M08.23	Juvenile rheumatoid arthritis with systemic onset, wrist	ICD-10-CM	Diagnosis
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist	ICD-10-CM	Diagnosis
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist	ICD-10-CM	Diagnosis
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist	ICD-10-CM	Diagnosis
M08.24	Juvenile rheumatoid arthritis with systemic onset, hand	ICD-10-CM	Diagnosis
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand	ICD-10-CM	Diagnosis
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand	ICD-10-CM	Diagnosis
M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand	ICD-10-CM	Diagnosis
M08.25	Juvenile rheumatoid arthritis with systemic onset, hip	ICD-10-CM	Diagnosis
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip	ICD-10-CM	Diagnosis
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip	ICD-10-CM	Diagnosis
M08.26	Juvenile rheumatoid arthritis with systemic onset, knee	ICD-10-CM	Diagnosis
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee	ICD-10-CM	Diagnosis
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee	ICD-10-CM	Diagnosis
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee	ICD-10-CM	Diagnosis
M08.27	Juvenile rheumatoid arthritis with systemic onset, ankle and foot	ICD-10-CM	Diagnosis
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot	ICD-10-CM	Diagnosis
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot	ICD-10-CM	Diagnosis
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot	ICD-10-CM	Diagnosis
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae	ICD-10-CM	Diagnosis
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites	ICD-10-CM	Diagnosis
M08.4	Pauciarticular juvenile rheumatoid arthritis	ICD-10-CM	Diagnosis
M08.40	Pauciarticular juvenile rheumatoid arthritis, unspecified site	ICD-10-CM	Diagnosis
M08.41	Pauciarticular juvenile rheumatoid arthritis, shoulder	ICD-10-CM	Diagnosis
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder	ICD-10-CM	Diagnosis
M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder	ICD-10-CM	Diagnosis
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder	ICD-10-CM	Diagnosis
M08.42	Pauciarticular juvenile rheumatoid arthritis, elbow	ICD-10-CM	Diagnosis
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow	ICD-10-CM	Diagnosis
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow	ICD-10-CM	Diagnosis
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow	ICD-10-CM	Diagnosis
M08.43	Pauciarticular juvenile rheumatoid arthritis, wrist	ICD-10-CM	Diagnosis
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist	ICD-10-CM	Diagnosis
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist	ICD-10-CM	Diagnosis
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist	ICD-10-CM	Diagnosis
M08.44	Pauciarticular juvenile rheumatoid arthritis, hand	ICD-10-CM	Diagnosis
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand	ICD-10-CM	Diagnosis
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand	ICD-10-CM	Diagnosis
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand	ICD-10-CM	Diagnosis
M08.45	Pauciarticular juvenile rheumatoid arthritis, hip	ICD-10-CM	Diagnosis
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip	ICD-10-CM	Diagnosis
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip	ICD-10-CM	Diagnosis
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip	ICD-10-CM	Diagnosis
M08.46	Pauciarticular juvenile rheumatoid arthritis, knee	ICD-10-CM	Diagnosis
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee	ICD-10-CM	Diagnosis
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee	ICD-10-CM	Diagnosis
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee	ICD-10-CM	Diagnosis
M08.47	Pauciarticular juvenile rheumatoid arthritis, ankle and foot	ICD-10-CM	Diagnosis
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot	ICD-10-CM	Diagnosis
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot	ICD-10-CM	Diagnosis
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot	ICD-10-CM	Diagnosis
M08.48	Pauciarticular juvenile rheumatoid arthritis, vertebrae	ICD-10-CM	Diagnosis

Appendix E. 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) Diagnosis Codes Used to Define Exclusion Criteria

Code	Description	Code Type	Code Category
Psoriatic Arthritis			
696.0	Psoriatic arthritis (PsA) Psoriatic arthropathy	ICD-10-CM	Diagnosis
L40.50	Arthropathic psoriasis, unspecified	ICD-10-CM	Diagnosis
L40.51	Distal interphalangeal psoriatic arthropathy	ICD-10-CM	Diagnosis
L40.52	Psoriatic arthritis mutilans	ICD-10-CM	Diagnosis
L40.53	Psoriatic spondylitis	ICD-10-CM	Diagnosis
L40.54	Psoriatic juvenile arthropathy	ICD-10-CM	Diagnosis
L40.59	Other psoriatic arthropathy	ICD-10-CM	Diagnosis
Psoriasis			
696.1	Other psoriasis	ICD-10-CM	Diagnosis
L40.0	Psoriasis vulgaris	ICD-10-CM	Diagnosis
L40.1	Generalized pustular psoriasis	ICD-10-CM	Diagnosis
L40.8	Other psoriasis	ICD-10-CM	Diagnosis
L40.9	Psoriasis, unspecified	ICD-10-CM	Diagnosis
Ankylosing Spondylitis			
720.0	Ankylosing spondylitis	ICD-10-CM	Diagnosis
M08.1	Juvenile ankylosing spondylitis	ICD-10-CM	Diagnosis
M45.0	Ankylosing spondylitis of multiple sites in spine	ICD-10-CM	Diagnosis
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region	ICD-10-CM	Diagnosis
M45.2	Ankylosing spondylitis of cervical region	ICD-10-CM	Diagnosis
M45.3	Ankylosing spondylitis of cervicothoracic region	ICD-10-CM	Diagnosis
M45.4	Ankylosing spondylitis of thoracic region	ICD-10-CM	Diagnosis
M45.5	Ankylosing spondylitis of thoracolumbar region	ICD-10-CM	Diagnosis
M45.6	Ankylosing spondylitis lumbar region	ICD-10-CM	Diagnosis
M45.7	Ankylosing spondylitis of lumbosacral region	ICD-10-CM	Diagnosis
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region	ICD-10-CM	Diagnosis
M45.9	Ankylosing spondylitis of unspecified sites in spine	ICD-10-CM	Diagnosis
Hidradenitis suppurativa			
705.83	Hidradenitis	ICD-10-CM	Diagnosis
L73.2	Hidradenitis	ICD-10-CM	Diagnosis

Appendix F. Specifications Used to Define Exposures in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.0, to evaluate dispensing patterns among patients with exposure to ustekinumab or Comparator Drugs in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2014 - April 30, 2019	Enrollment Gap: 45 days
Coverage Requirement: Medical & Drug Coverage	Age Groups: 0-5, 6-11, 12-17, 18-39, 40-54, 55-64, 65+ years
Pre-index Enrollment Requirement: 183 days	Stratifications: None
Post-index Enrollment Requirement: 0 days	Freeze Data: No

Exposure

Cohort	Index Exposure	Cohort Definition	Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	Censor Treatment Episode at Evidence of:
1	Ustekinumab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	1 day	Death; DP end date; Query end date; Disenrollment Use of comparator drug;
2	Ustekinumab Px codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	NA	Death; DP end date; Query end date; Disenrollment Use of comparator drug;

Appendix F. Specifications Used to Define Exposures in this Request

Cohort	Index Exposure	Cohort Definition	Exposure							Censor Treatment Episode at Evidence of:
			Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	
3	Ustekinumab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	56 days (8 weeks)	56 days (8 weeks)	Any	56 days (8 weeks)	NA	Death; DP end date; Query end date; Disenrollment Use of comparator drug;
4	Ustekinumab NDC codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	56 days (8 weeks)	56 days (8 weeks)	Any	NA	NA	Death; DP end date; Query end date; Disenrollment Use of comparator drug;
5	Infliximab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	1 day	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;

Appendix F. Specifications Used to Define Exposures in this Request

Cohort	Index Exposure	Cohort Definition	Exposure							Censor Treatment Episode at Evidence of:
			Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	
6	Infliximab Px codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
7	Infliximab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	56 days (8 weeks)	56 days (8 weeks)	Any	56 days (8 weeks)	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
8	Infliximab NDC codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	56 days (8 weeks)	56 days (8 weeks)	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;

Appendix F. Specifications Used to Define Exposures in this Request

Cohort	Index Exposure	Cohort Definition	Exposure							Censor Treatment Episode at Evidence of:
			Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	
9	Adalimumab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	1 day	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
10	Adalimumab Px codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
11	Adalimumab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	14 days (2 weeks)	14 days (2 weeks)	Any	14 days (2 weeks)	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;

Appendix F. Specifications Used to Define Exposures in this Request

Cohort	Index Exposure	Cohort Definition	Exposure							Censor Treatment Episode at Evidence of:
			Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	
12	Adalimumab NDC codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	14 days (2 weeks)	14 days (2 weeks)	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
13	Certolizumab pegol NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	1 day	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
14	Certolizumab pegol Px codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;

Appendix F. Specifications Used to Define Exposures in this Request

Cohort	Index Exposure	Cohort Definition	Exposure							Censor Treatment Episode at Evidence of:
			Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	
15	Certolizumab pegol NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	28 days (4 weeks)	28 days (4 weeks)	Any	28 days (4 weeks)	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
16	Certolizumab pegol NDC codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	28 days (4 weeks)	28 days (4 weeks)	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
17	Vedolizumab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	1 day	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;

Appendix F. Specifications Used to Define Exposures in this Request

Cohort	Index Exposure	Cohort Definition	Exposure							Censor Treatment Episode at Evidence of:
			Incident Exposure Washout Period (days)	Exposure Episode Length (ITT)	Treatment Episode Gap	Exposure Episode Extension	Care Setting	Forced Supply to Attach to Procedures	Forced Supply to Attach to NDCs	
18	Vedolizumab Px codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	NA	NA	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
19	Vedolizumab NDC or PX codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	56 days (8 weeks)	56 days (8 weeks)	Any	56 days (8 weeks)	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;
20	Vedolizumab NDC codes	*Include all valid exposure episodes during query period; --only the first valid exposure episode's incidence is assessed using washout criteria	0	NA	56 days (8 weeks)	56 days (8 weeks)	Any	NA	NA	Death; DP end date; Query end date; Disenrollment; Other drug in comparator group; Use of Stelara;

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.
NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

Appendix G. Specifications Used to Define Inclusions in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.0, to evaluate dispensing patterns among patients with exposure to ustekinumab or Comparator Drugs in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2014 - April 30, 2019		Enrollment Gap: 45 days				
Coverage Requirement: Medical & Drug Coverage		Age Groups: 0-5, 6-11, 12-17, 18-39, 40-54, 55-64, 65+ years				
Pre-index Enrollment Requirement: 183 days		Stratifications: None				
Post-index Enrollment Requirement: 0 days		Freeze Data: No				
Inclusion Criteria						
Cohort	Inclusion/ Exclusion Group	Criteria	Care Setting	Evaluation Period		Number of Instances the Criteria Should be Found in Evaluation Period
				Start	End	
1	Crohn's Disease	Inclusion	Any care setting	-183	0	1
2	Crohn's Disease	Inclusion	Any care setting	-183	0	1
3	Crohn's Disease	Inclusion	Any care setting	-183	0	1
4	Crohn's Disease	Inclusion	Any care setting	-183	0	1
5	Crohn's Disease	Inclusion	Any care setting	-183	0	1
6	Crohn's Disease	Inclusion	Any care setting	-183	0	1
7	Crohn's Disease	Inclusion	Any care setting	-183	0	1
8	Crohn's Disease	Inclusion	Any care setting	-183	0	1
9	Crohn's Disease	Inclusion	Any care setting	-183	0	1
10	Crohn's Disease	Inclusion	Any care setting	-183	0	1
11	Crohn's Disease	Inclusion	Any care setting	-183	0	1
12	Crohn's Disease	Inclusion	Any care setting	-183	0	1
13	Crohn's Disease	Inclusion	Any care setting	-183	0	1
14	Crohn's Disease	Inclusion	Any care setting	-183	0	1
15	Crohn's Disease	Inclusion	Any care setting	-183	0	1
16	Crohn's Disease	Inclusion	Any care setting	-183	0	1
17	Crohn's Disease	Inclusion	Any care setting	-183	0	1
18	Crohn's Disease	Inclusion	Any care setting	-183	0	1
19	Crohn's Disease	Inclusion	Any care setting	-183	0	1
20	Crohn's Disease	Inclusion	Any care setting	-183	0	1
ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.						
NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."						

Appendix H. Specifications Used to Define Exclusions in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.0.0, to evaluate dispensing patterns among patients with exposure to ustekinumab or Comparator Drugs in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2014 - April 30, 2019		Enrollment Gap: 45 days					
Coverage Requirement: Medical & Drug Coverage		Age Groups: 0-5, 6-11, 12-17, 18-39, 40-54, 55-64, 65+ years					
Pre-index Enrollment Requirement: 183 days		Stratifications: None					
Post-index Enrollment Requirement: 0 days		Freeze Data: No					
Exclusion Criteria							
Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
1	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Ustekinumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
2	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Ustekinumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

Appendix H. Specifications Used to Define Exclusions in this Request

Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
3	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Ustekinumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
4	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Ustekinumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
5	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Infliximab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

Appendix H. Specifications Used to Define Exclusions in this Request

Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
6	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Infliximab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
7	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Infliximab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
8	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Infliximab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

Appendix H. Specifications Used to Define Exclusions in this Request

Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
9	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Adalimumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
10	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Adalimumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
11	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Adalimumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

Appendix H. Specifications Used to Define Exclusions in this Request

Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
12	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Adalimumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
13	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Certolizumab pegol NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
14	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Certolizumab pegol NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

Appendix H. Specifications Used to Define Exclusions in this Request

Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
15	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Certolizumab pegol NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
16	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Certolizumab pegol NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
17	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Vedolizumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

Appendix H. Specifications Used to Define Exclusions in this Request

Cohort	Inclusion/ Exclusion group	Criteria	Care setting	Evaluation period start	Evaluation period end	Exclude evidence of days supply if exposure washout includes dispensings	Number of instances the criteria should be found in evaluation period
18	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Vedolizumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
19	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Vedolizumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1
20	Plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ankylosing spondylitis Juvenile rheumatoid arthritis Hidradenitis suppurativa	Exclusion	Any care setting	-183	0	N/A	1
	Vedolizumab NDC or PX codes	Exclusion	Any care setting	-183	-1	Lookback period should search for only evidence of a dispensing date	1

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.
NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."