Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

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).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

Overview for Request: cder_mpl1r_wp268

Request ID: cder_mpl1r_wp268_mkscn_v01

Request Description: In this report, we assessed utilization patterns of risankizumab, guselkumab, tildrakizumab, ustekinumab, secukinumab, ixekizumab, and brodalumab in Sentinel's internal test data (Merative™ Marketscan® Research Databases).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 12.2.2

Data Source: We did not distribute this query to Sentinel Data Partners, but rather queried Sentinel's Merative™ Marketscan® Research Databases on December 11, 2023. The study period included data April 23, 2019 to December 31, 2022. Please see Appendix A for a list of dates of available data.

Study Design: We identified individuals with new use of risankizumab among a cohort of individuals of any age who were between 0 and 65+ years of age, and then characterized use and dispensing patterns by examining all episodes of use occurring after the initial exposure. We did the same for the following exposures: guselkumab, tildrakizumab, ustekinumab, secukinumab, ixekizumab, and brodalumab. This is a Type 5 analysis in the Query Request Package (QRP) documentation.

Exposures of Interest: We defined the exposures of interest using outpatient dispensing and administrative procedure claims. Each qualifying dispensing of risankizumab (index) was identified for all individuals and the first qualifying dispensing (index) was assigned after applying a 400-day washout for the exposure. No exposure episode gap or extension were applied, and after adjusting for early and/or late dispensings, all subsequent valid exposure episodes were included (without applying a washout) and described. Exposures episodes were censored at evidence of death or data end. Please see Appendix B for a list of generic and brand names of medical products and Appendix C for a list of Healthcare Common Procedure Coding System (HCPCS) codes used to define exposures in this request.

Metrics of Interest: We defined the following utilization metrics: (1) days supplied per dispensing; (2) cumulative treatment episode duration; and (3) first treatment episode duration. We described each metric using both categories and descriptive statistics. We additionally visualized entry into the query by month and reasons for end of first treatment episodes.

Cohort Eligibility Criteria: We required members to be enrolled in health plans with medical and drug coverage in the 400 days prior to their index date in order to be included in the cohort; a gap in coverage of up to 45 days was allowed and treated as continuous enrollment. The following age groups were included in the cohort: 0-17, 18-64, and 65+ years. We defined incident exposure as no evidence of the exposure of interest in the previous 400 days.

Baseline Characteristics: We assessed the following characteristics on the index date: age, sex, and year. We assessed the following characteristics in the 400 days prior to the index date: combined comorbidity score, 1 health service and drug utilization, risankizumab indications (Crohn's disease, plaque psoriasis, psoriatic arthritis), and evidence of each comparator. We identified indications by presence of a diagnosis or procedure code in any care setting, in any diagnosis position and used International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. Please see Appendix F for a list of codes used to define indications in this request. Evidence of each comparator was assessed using the same NDCs and HCPCS codes as to define exposures. Please see Appendix D for a list of generic and brand names of medical products and Appendix E for a list of HCPCS codes used to define comparators in this request.

Please see Appendices G and H for the specification of parameters used in this request and a design diagram.

Limitations: Algorithms to define exposures, outcomes, inclusion and exclusion criteria, and covariates are imperfect and may be misclassified. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation.

[1] *The Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A Combined Comorbidity Score Predicted Mortality in Elderly Patients Better Than Existing Scores. J Clin Epidemiol. 2011;64(7):749-759; Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and Validation of the Combined Comorbidity Score for ICD-10-CM. Med Care. 2017;55(12):1046-1051)*

Sentinel

Table of Contents

Table of Contents

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

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.
Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.
Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).
Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.
Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.
Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.
Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.
Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.
Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.
Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.
Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.
Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).
Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."
Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.
Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).
Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.
Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

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

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 1a. Characteristics of Risankizumab Users and Guselkumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

	Medical Product				Characteristic Balance	
	Risankizumab Users		Guselkumab Users			
Patient Characteristics[1]	Number/ Mean	Percent/ Standard Deviation[2]	Number/ Mean	Percent/ Standard Deviation[2]	Absolute Difference	Standardized Difference
Unique patients	10,030	N/A	7,369	N/A	N/A	N/A
Demographic Characteristics						
Age (years)	47.5	13.2	47.9	12.4	-0.448	-0.035
Age						
0-17 years	39	0.4%	15	0.2%	0.185	0.034
18-64 years	9,480	94.5%	7,076	96.0%	-1.507	-0.071
≥ 65 years	511	5.1%	278	3.8%	1.322	0.064
Sex						
Female	5,045	50.3%	3,891	52.8%	-2.503	-0.050
Male	4,985	49.7%	3,478	47.2%	2.503	0.050
Year						
2019	1,205	12.0%	760	10.3%	1.700	0.054
2020	2,157	21.5%	1,734	23.5%	-2.026	-0.049
2021	2,695	26.9%	2,333	31.7%	-4.790	-0.105
2022	3,973	39.6%	2,542	34.5%	5.115	0.106
Health Characteristics						
Crohn's disease	198	2.0%	33	0.4%	1.526	0.140
Plaque psoriasis	9,667	96.4%	6,857	93.1%	3.329	0.149
Psoriatic arthritis	1,797	17.9%	2,627	35.6%	-17.733	-0.409
Any riskankizumab indication	9,913	98.8%	7,256	98.5%	0.367	0.032
Medical Product Use						
risankizumab-rzaa	0	0.0%	186	2.5%	NaN	NaN
guselkumab	504	5.0%	0	0.0%	NaN	NaN
tildrakizumab-asmn	57	0.6%	19	0.3%	0.310	0.048
ustekinumab	666	6.6%	611	8.3%	-1.651	-0.063
secukinumab	803	8.0%	808	11.0%	-2.959	-0.101
ixekizumab	852	8.5%	722	9.8%	-1.303	-0.045
brodalumab	56	0.6%	14	0.2%	0.368	0.060
Any Prior Comparator Use	2,660	26.5%	2,015	27.3%	-0.824	-0.019
Health Service Utilization Intensity Metrics						
Mean number of ambulatory encounters	16.0	16.6	17.7	16.9	-1.733	-0.103
Mean number of inpatient hospital encounters	0.1	0.4	0.1	0.4	-0.006	-0.018
Mean number of filled prescriptions	28.0	25.3	31.7	29.5	-3.703	-0.135
Mean number of generics dispensed	9.3	6.4	10.1	7.1	-0.784	-0.116

[1]Characteristics in blue show a standardized difference greater than 0.1.

[2]Value represents standard deviation where no % follows the value.

NaN: Not a number

Table 1b. Characteristics of Risankizumab Users and Tildrakizumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

	Medical Product				Characteristic Balance	
	Risankizumab Users		Tildrakizumab Users			
Patient Characteristics[1]	Number/ Mean	Percent/ Standard Deviation[2]	Number/ Mean	Percent/ Standard Deviation[2]	Absolute Difference	Standardized Difference
Unique patients	10,030	N/A	382	N/A	N/A	N/A
Demographic Characteristics						
Age (years)	47.5	13.2	51.5	15.5	-4.036	-0.280
Age						
0-17 years	39	0.4%	1	0.3%	0.127	0.022
18-64 years	9,480	94.5%	315	82.5%	12.056	0.385
≥ 65 years	511	5.1%	66	17.3%	-12.183	-0.394
Sex						
Female	5,045	50.3%	205	53.7%	-3.366	-0.067
Male	4,985	49.7%	177	46.3%	3.366	0.067
Year						
2019	1,205	12.0%	104	27.2%	-15.211	-0.390
2020	2,157	21.5%	96	25.1%	-3.625	-0.086
2021	2,695	26.9%	88	23.0%	3.833	0.089
2022	3,973	39.6%	94	24.6%	15.004	0.326
Health Characteristics						
Any riskankizumab indication	9,913	98.8%	376	98.4%	0.404	0.035
Crohn's disease	198	2.0%	3	0.8%	1.189	0.102
Plaque psoriasis	9,667	96.4%	374	97.9%	-1.525	-0.092
Psoriatic arthritis	1,797	17.9%	69	18.1%	-0.147	-0.004
Medical Product Use						
Any Prior Comparator Use	2,660	26.5%	95	24.9%	1.651	0.038
brodalumab	56	0.6%	3	0.8%	-0.227	-0.028
guselkumab	504	5.0%	22	5.8%	-0.734	-0.033
ixekizumab	852	8.5%	25	6.5%	1.950	0.074
risankizumab-rzaa	0	0.0%	14	3.7%	NaN	NaN
secukinumab	803	8.0%	29	7.6%	0.414	0.015
tildrakizumab-asmn	57	0.6%	0	0.0%	NaN	NaN
ustekinumab	666	6.6%	29	7.6%	-0.952	-0.037
Health Service Utilization Intensity Metrics						
Mean number of ambulatory encounters	16.0	16.6	19.1	19.5	-3.148	-0.174
Mean number of inpatient hospital encounters	0.1	0.4	0.1	0.4	-0.001	-0.002
Mean number of filled prescriptions	28.0	25.3	28.8	25.4	-0.783	-0.031
Mean number of generics dispensed	9.3	6.4	9.6	6.6	-0.312	-0.048

[1]Characteristics in blue show a standardized difference greater than 0.1.

[2]Value represents standard deviation where no % follows the value.

NaN: Not a number

Table 1c. Characteristics of Risankizumab Users and Ustekinumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

	Medical Product				Characteristic Balance	
	Risankizumab Users		Ustekinumab Users			
Patient Characteristics[1]	Number/ Mean	Percent/ Standard Deviation[2]	Number/ Mean	Percent/ Standard Deviation[2]	Absolute Difference	Standardized Difference
Unique patients	10,030	N/A	10,317	N/A	N/A	N/A
Demographic Characteristics						
Age (years)	47.5	13.2	42.8	15.6	4.663	0.322
Age						
0-17 years	39	0.4%	652	6.3%	-5.931	-0.334
18-64 years	9,480	94.5%	9,206	89.2%	5.285	0.194
≥ 65 years	511	5.1%	459	4.4%	0.646	0.030
Sex						
Female	5,045	50.3%	5,659	54.9%	-4.552	-0.091
Male	4,985	49.7%	4,658	45.1%	4.552	0.091
Year						
2019	1,205	12.0%	2,175	21.1%	-9.068	-0.246
2020	2,157	21.5%	2,693	26.1%	-4.597	-0.108
2021	2,695	26.9%	2,795	27.1%	-0.222	-0.005
2022	3,973	39.6%	2,654	25.7%	13.887	0.299
Health Characteristics						
Any riskankizumab indication	9,913	98.8%	8,701	84.3%	14.497	0.541
Crohn's disease	198	2.0%	5,038	48.8%	-46.858	-1.277
Plaque psoriasis	9,667	96.4%	3,736	36.2%	60.169	1.650
Psoriatic arthritis	1,797	17.9%	1,450	14.1%	3.862	0.106
Medical Product Use						
Any Prior Comparator Use	2,660	26.5%	644	6.2%	20.278	0.570
brodalumab	56	0.6%	5	0.0%	0.510	0.093
guselkumab	504	5.0%	95	0.9%	4.104	0.243
ixekizumab	852	8.5%	221	2.1%	6.352	0.286
risankizumab-rzaa	0	0.0%	48	0.5%	NaN	NaN
secukinumab	803	8.0%	387	3.8%	4.255	0.182
tildrakizumab-asmn	57	0.6%	0	0.0%	NaN	NaN
ustekinumab	666	6.6%	0	0.0%	NaN	NaN
Health Service Utilization Intensity Metrics						
Mean number of ambulatory encounters	16.0	16.6	20.9	16.7	-4.908	-0.295
Mean number of inpatient hospital encounters	0.1	0.4	0.3	0.8	-0.219	-0.354
Mean number of filled prescriptions	28.0	25.3	31.2	27.3	-3.157	-0.120
Mean number of generics dispensed	9.3	6.4	10.3	6.9	-0.987	-0.149

[1]Characteristics in blue show a standardized difference greater than 0.1.

[2]Value represents standard deviation where no % follows the value.

NaN: Not a number

Table 1d. Characteristics of Risankizumab Users and Secukinumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

	Medical Product				Characteristic Balance	
	Risankizumab Users		Secukinumab Users			
Patient Characteristics[1]	Number/ Mean	Percent/ Standard Deviation[2]	Number/ Mean	Percent/ Standard Deviation[2]	Absolute Difference	Standardized Difference
Unique patients	10,030	N/A	7,577	N/A	N/A	N/A
Demographic Characteristics						
Age (years)	47.5	13.2	49.1	12.3	-1.581	-0.124
Age						
0-17 years	39	0.4%	65	0.9%	-0.469	-0.060
18-64 years	9,480	94.5%	7,122	94.0%	0.521	0.022
≥ 65 years	511	5.1%	390	5.1%	-0.052	-0.002
Sex						
Female	5,045	50.3%	4,445	58.7%	-8.365	-0.169
Male	4,985	49.7%	3,132	41.3%	8.365	0.169
Year						
2019	1,205	12.0%	2,103	27.8%	-15.741	-0.402
2020	2,157	21.5%	2,416	31.9%	-10.380	-0.236
2021	2,695	26.9%	1,619	21.4%	5.502	0.129
2022	3,973	39.6%	1,439	19.0%	20.619	0.465
Health Characteristics						
Any riskankizumab indication	9,913	98.8%	6,381	84.2%	14.618	0.544
Crohn's disease	198	2.0%	34	0.4%	1.525	0.140
Plaque psoriasis	9,667	96.4%	5,284	69.7%	26.643	0.760
Psoriatic arthritis	1,797	17.9%	4,211	55.6%	-37.660	-0.849
Medical Product Use						
Any Prior Comparator Use	2,660	26.5%	921	12.2%	14.365	0.370
brodalumab	56	0.6%	8	0.1%	0.453	0.079
guselkumab	504	5.0%	193	2.5%	2.478	0.130
ixekizumab	852	8.5%	322	4.2%	4.245	0.174
risankizumab-rzaa	0	0.0%	107	1.4%	NaN	NaN
secukinumab	803	8.0%	0	0.0%	NaN	NaN
tildrakizumab-asmn	57	0.6%	9	0.1%	0.450	0.077
ustekinumab	666	6.6%	442	5.8%	0.807	0.033
Health Service Utilization Intensity Metrics						
Mean number of ambulatory encounters	16.0	16.6	21.1	17.6	-5.100	-0.298
Mean number of inpatient hospital encounters	0.1	0.4	0.1	0.4	-0.012	-0.032
Mean number of filled prescriptions	28.0	25.3	38.2	31.7	-10.162	-0.354
Mean number of generics dispensed	9.3	6.4	11.7	7.4	-2.327	-0.336

[1]Characteristics in blue show a standardized difference greater than 0.1.

[2]Value represents standard deviation where no % follows the value.

NaN: Not a number

Table 1e. Characteristics of Risankizumab Users and Ixekizumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

	Medical Product				Characteristic Balance	
	Risankizumab Users		Ixekizumab Users			
Patient Characteristics[1]	Number/ Mean	Percent/ Standard Deviation[2]	Number/ Mean	Percent/ Standard Deviation[2]	Absolute Difference	Standardized Difference
Unique patients	10,030	N/A	7,619	N/A	N/A	N/A
Demographic Characteristics						
Age (years)	47.5	13.2	48.1	12.4	-0.642	-0.050
Age						
0-17 years	39	0.4%	134	1.8%	-1.370	-0.133
18-64 years	9,480	94.5%	7,225	94.8%	-0.312	-0.014
≥ 65 years	511	5.1%	260	3.4%	1.682	0.083
Sex						
Female	5,045	50.3%	4,085	53.6%	-3.317	-0.066
Male	4,985	49.7%	3,534	46.4%	3.317	0.066
Year						
2019	1,205	12.0%	1,118	14.7%	-2.660	-0.078
2020	2,157	21.5%	1,642	21.6%	-0.046	-0.001
2021	2,695	26.9%	2,800	36.8%	-9.881	-0.213
2022	3,973	39.6%	2,059	27.0%	12.587	0.269
Health Characteristics						
Any riskankizumab indication	9,913	98.8%	7,029	92.3%	6.577	0.323
Crohn's disease	198	2.0%	24	0.3%	1.659	0.156
Plaque psoriasis	9,667	96.4%	6,354	83.4%	12.984	0.441
Psoriatic arthritis	1,797	17.9%	3,464	45.5%	-27.549	-0.620
Medical Product Use						
Any Prior Comparator Use	2,660	26.5%	2,214	29.1%	-2.538	-0.057
brodalumab	56	0.6%	21	0.3%	0.283	0.044
guselkumab	504	5.0%	302	4.0%	1.061	0.051
ixekizumab	852	8.5%	0	0.0%	NaN	NaN
risankizumab-rzaa	0	0.0%	262	3.4%	NaN	NaN
secukinumab	803	8.0%	1,521	20.0%	-11.957	-0.350
tildrakizumab-asmn	57	0.6%	16	0.2%	0.358	0.058
ustekinumab	666	6.6%	454	6.0%	0.681	0.028
Health Service Utilization Intensity Metrics						
Mean number of ambulatory encounters	16.0	16.6	18.6	17.0	-2.651	-0.158
Mean number of inpatient hospital encounters	0.1	0.4	0.1	0.4	-0.002	-0.005
Mean number of filled prescriptions	28.0	25.3	34.5	30.5	-6.471	-0.231
Mean number of generics dispensed	9.3	6.4	10.6	7.1	-1.232	-0.182

[1]Characteristics in blue show a standardized difference greater than 0.1.

[2]Value represents standard deviation where no % follows the value.

NaN: Not a number

Table 1f. Characteristics of Risankizumab Users and Brodalumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

	Medical Product				Characteristic Balance	
	Risankizumab Users		Brodalumab Users			
Patient Characteristics[1]	Number/ Mean	Percent/ Standard Deviation[2]	Number/ Mean	Percent/ Standard Deviation[2]	Absolute Difference	Standardized Difference
Unique patients	10,030	N/A	123	N/A	N/A	N/A
Demographic Characteristics						
Age (years)	47.5	13.2	49.1	11.9	-1.628	-0.130
Age						
0-17 years	39	0.4%	0	0.0%	NaN	NaN
18-64 years	9,480	94.5%	119	96.7%	-2.232	-0.109
≥ 65 years	511	5.1%	4	3.3%	1.843	0.092
Sex						
Female	5,045	50.3%	51	41.5%	8.836	0.178
Male	4,985	49.7%	72	58.5%	-8.836	-0.178
Year						
2019	1,205	12.0%	56	45.5%	-33.514	-0.797
2020	2,157	21.5%	32	26.0%	-4.511	-0.106
2021	2,695	26.9%	20	16.3%	10.609	0.260
2022	3,973	39.6%	15	12.2%	27.416	0.659
Health Characteristics						
Any riskankizumab indication	9,913	98.8%	121	98.4%	0.460	0.039
Crohn's disease	198	2.0%	0	0.0%	NaN	NaN
Plaque psoriasis	9,667	96.4%	121	98.4%	-1.993	-0.125
Psoriatic arthritis	1,797	17.9%	54	43.9%	-25.986	-0.586
Medical Product Use						
Any Prior Comparator Use	2,660	26.5%	79	64.2%	-37.707	-0.818
brodalumab	56	0.6%	0	0.0%	NaN	NaN
guselkumab	504	5.0%	24	19.5%	-14.487	-0.453
ixekizumab	852	8.5%	34	27.6%	-19.148	-0.514
risankizumab-rzaa	0	0.0%	17	13.8%	NaN	NaN
secukinumab	803	8.0%	32	26.0%	-18.010	-0.494
tildrakizumab-asmn	57	0.6%	2	1.6%	-1.058	-0.102
ustekinumab	666	6.6%	3	2.4%	4.201	0.203
Health Service Utilization Intensity Metrics						
Mean number of ambulatory encounters	16.0	16.6	23.6	26.4	-7.633	-0.346
Mean number of inpatient hospital encounters	0.1	0.4	0.1	0.6	-0.069	-0.142
Mean number of filled prescriptions	28.0	25.3	39.5	31.1	-11.480	-0.405
Mean number of generics dispensed	9.3	6.4	12.0	7.5	-2.719	-0.390

[1]Characteristics in blue show a standardized difference greater than 0.1.

[2]Value represents standard deviation where no % follows the value.

NaN: Not a number

Table 2. Characteristic Profile of Risankizumab-rzaa and Potential Comparator Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

Medical Product	Guselkumab Users		Risankizumab Users		Tildrakizumab Users		Ustekinumab Users		Secukinumab Users		Ixekizumab Users		Brodalumab Users	
Characteristic Category	Number of Patients	% of Patients	Number of Patients	% of Patients	Number of Patients	% of Patients	Number of Patients	% of Patients	Number of Patients	% of Patients	Number of Patients	% of Patients	Number of Patients	% of Patients
Crohn's disease only	2	0.0%	139	1.4%	0	0.0%	4,610	44.7%	17	0.2%	7	0.1%	0	0.0%
Plaque psoriasis only	4,614	62.6%	7,930	79.1%	304	79.6%	2,306	22.4%	2,148	28.3%	3,552	46.6%	67	54.5%
Psoriatic arthritis only	392	5.3%	104	1.0%	2	0.5%	320	3.1%	1,078	14.2%	666	8.7%	0	0.0%
Crohn's disease and Plaque psoriasis	13	0.2%	47	0.5%	3	0.8%	335	3.2%	5	0.1%	6	0.1%	0	0.0%
Crohn's disease and Psoriatic arthritis	5	0.1%	3	0.0%	0	0.0%	35	0.3%	2	0.0%	2	0.0%	0	0.0%
Plaque psoriasis and Psoriatic arthritis	2,217	30.1%	1,681	16.8%	67	17.5%	1,037	10.1%	3,121	41.2%	2,787	36.6%	54	43.9%
All Characteristics Present	13	0.2%	9	0.1%	0	0.0%	58	0.6%	10	0.1%	9	0.1%	0	0.0%
No Characteristics Present	113	1.5%	117	1.2%	6	1.6%	1,616	15.7%	1,196	15.8%	590	7.7%	2	1.6%

Table 3a. Categorical Summary of Days Supplied per Dispensing for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

		Number of Dispensings by Days Supplied					
		0-1 Days		2-27 Days		28-30 Days	
	Total Number of Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings
Risankizumab Users	46,419	133	0.3%	2,739	5.9%	12,633	27.2%
Guselkumab Users	43,090	596	1.4%	2,379	5.5%	10,123	23.5%
Tildrakizumab Users	1,505	875	58.1%	27	1.8%	189	12.6%
Ustekinumab Users	69,235	9,724	14.0%	3,158	4.6%	13,946	20.1%
Secukinumab Users	68,285	75	0.1%	3,616	5.3%	58,706	86.0%
Ixekizumab Users	70,677	85	0.1%	3,939	5.6%	61,881	87.6%
Brodalumab Users	1,142	2	0.2%	126	11.0%	987	86.4%

Table 3a. Categorical Summary of Days Supplied per Dispensing for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

		Number of Dispensings by Days Supplied					
		31-83 Days		84-90 Days		91+ Days	
	Total Number of Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings
Risankizumab Users	46,419	4,422	9.5%	25,984	56.0%	508	1.1%
Guselkumab Users	43,090	29,073	67.5%	156	0.4%	763	1.8%
Tildrakizumab Users	1,505	55	3.7%	349	23.2%	10	0.7%
Ustekinumab Users	69,235	31,711	45.8%	9,710	14.0%	986	1.4%
Secukinumab Users	68,285	2,711	4.0%	3,057	4.5%	120	0.2%
Ixekizumab Users	70,677	2,433	3.4%	2,251	3.2%	88	0.1%
Brodalumab Users	1,142	17	1.5%	9	0.8%	1	0.1%

Table 3b. Continuous Summary of Days Supplied per Dispensing for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

		Distribution of Days Supplied by Dispensing						
	Total Number of Dispensings	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
Risankizumab Users	46,419	1	28	84	84	382	62.6	29.5
Guselkumab Users	43,090	1	30	56	56	364	45.8	18.6
Tildrakizumab Users	1,505	1	1	1	63	336	27.1	36.8
Ustekinumab Users	69,235	1	28	56	56	420	44.8	27.8
Secukinumab Users	68,285	1	28	28	28	378	31.1	14.7
Ixekizumab Users	70,677	1	28	28	28	420	30.2	12.7
Brodalumab Users	1,142	1	28	28	28	168	27.4	8.5

Table 4a. Categorical Summary of Patients' Cumulative Treatment Episode Durations for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

		Number of Patients by Cumulative Treatment Episode Duration											
		0-1 Days		2-27 Days		28-30 Days		31-83 Days		84-90 Days		91-182 Days	
	Total Number of Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Risankizumab Users	10,030	18	0.2%	517	5.2%	509	5.1%	1,176	11.7%	268	2.7%	1,842	18.4%
Guselkumab Users	7,369	52	0.7%	333	4.5%	361	4.9%	900	12.2%	396	5.4%	1,493	20.3%
Tildrakizumab Users	382	58	15.2%	162	42.4%	12	3.1%	21	5.5%	14	3.7%	36	9.4%
Ustekinumab Users	10,317	646	6.3%	731	7.1%	232	2.2%	1,046	10.1%	242	2.3%	1,814	17.6%
Secukinumab Users	7,577	4	0.1%	230	3.0%	430	5.7%	853	11.3%	387	5.1%	1,567	20.7%
Ixekizumab Users	7,619	3	0.0%	266	3.5%	507	6.7%	928	12.2%	396	5.2%	1,482	19.5%
Brodalumab Users	123	1	0.8%	6	4.9%	4	3.3%	27	22.0%	2	1.6%	27	22.0%

Table 4a. Categorical Summary of Patients' Cumulative Treatment Episode Durations for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

		Number of Patients by Cumulative Treatment Episode Duration									
		183-364 Days		365-729 Days		730-1094 Days		1095-1459 Days		1460+ Days	
	Total Number of Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Risankizumab Users	10,030	2,845	28.4%	2,087	20.8%	676	6.7%	92	0.9%	0	0.0%
Guselkumab Users	7,369	1,969	26.7%	1,409	19.1%	399	5.4%	57	0.8%	0	0.0%
Tildrakizumab Users	382	43	11.3%	31	8.1%	3	0.8%	2	0.5%	0	0.0%
Ustekinumab Users	10,317	2,345	22.7%	2,221	21.5%	858	8.3%	182	1.8%	0	0.0%
Secukinumab Users	7,577	2,089	27.6%	1,477	19.5%	454	6.0%	86	1.1%	0	0.0%
Ixekizumab Users	7,619	1,949	25.6%	1,604	21.1%	417	5.5%	67	0.9%	0	0.0%
Brodalumab Users	123	23	18.7%	29	23.6%	4	3.3%	0	0.0%	0	0.0%

Table 4b. Continuous Summary of Patients' Cumulative Treatment Episode Durations for Utilization of Risankizumab-rzaa and Potential Comparators in the Sentinel Test Database from April 23, 2019 to December 31, 2022

		Distribution of Cumulative Treatment Episode Duration, days						
	Total Number of Patients	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
Risankizumab Users	10,030	1	93	209	412	1,319	289.6	255.6
Guselkumab Users	7,369	1	84	196	369	1,345	267.8	242.6
Tildrakizumab Users	382	1	2	8	146	1,185	106.7	186.3
Ustekinumab Users	10,317	1	77	208	449	1,342	300.2	286.5
Secukinumab Users	7,577	1	90	201	392	1,316	280.6	250.7
Ixekizumab Users	7,619	1	84	196	393	1,343	276.8	248.2
Brodalumab Users	123	1	70	178	409	1,024	254.0	238.6

Table 5a. Categorical Summary of First Treatment Episodes for Utilization of Risankizumab-rzaa and Potential Comparators in the Sentinel Test Database from April 23, 2019 to December 31, 2022

		Number of Patients by First Treatment Episode Duration					
		0-1 Days		2-27 Days		28-30 Days	
	Total Number of	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Risankizumab Users	10,030	50	0.5%	575	5.7%	4,557	45.4%
Guselkumab Users	7,369	156	2.1%	348	4.7%	3,024	41.0%
Tildrakizumab Users	382	229	59.9%	8	2.1%	78	20.4%
Ustekinumab Users	10,317	5,198	50.4%	194	1.9%	1,772	17.2%
Secukinumab Users	7,577	8	0.1%	339	4.5%	3,229	42.6%
Ixekizumab Users	7,619	8	0.1%	381	5.0%	3,673	48.2%
Brodalumab Users	123	1	0.8%	41	33.3%	28	22.8%

Table 5a. Categorical Summary of First Treatment Episodes for Utilization of Risankizumab-rzaa and Potential Comparators in the Sentinel Test Database from April 23, 2019 to December 31, 2022

		Number of Patients by First Treatment Episode Duration					
		31-83 Days		84-90 Days		91+ Days	
	Total Number of	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Risankizumab Users	10,030	1,312	13.1%	392	3.9%	3,144	31.3%
Guselkumab Users	7,369	1,873	25.4%	383	5.2%	1,585	21.5%
Tildrakizumab Users	382	17	4.5%	28	7.3%	22	5.8%
Ustekinumab Users	10,317	1,262	12.2%	310	3.0%	1,581	15.3%
Secukinumab Users	7,577	1,568	20.7%	585	7.7%	1,848	24.4%
Ixekizumab Users	7,619	1,761	23.1%	419	5.5%	1,377	18.1%
Brodalumab Users	123	23	18.7%	1	0.8%	29	23.6%

Table 5b. Continuous Summary of First Treatment Episodes for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 and December 31, 2022

		Distribution of First Treatment Episode Duration, days						
	Total Number of Patients	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
Risankizumab Users	10,030	1	28	30	112	1,319	99.0	133.2
Guselkumab Users	7,369	1	28	32	84	1,333	83.9	118.3
Tildrakizumab Users	382	1	1	1	28	1,152	31.8	87.2
Ustekinumab Users	10,317	1	1	1	56	1,342	51.9	109.5
Secukinumab Users	7,577	1	28	35	86	1,285	88.3	119.5
Ixekizumab Users	7,619	1	28	28	79	1,343	71.7	99.1
Brodalumab Users	123	1	14	28	81	640	70.9	107.9

Table 6. Summary of Reasons First Treatment Episodes Ended for Utilization of Risankizumab-rzaa and Potential Comparators in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

		Censoring Reason[1]									
		End of Exposure Episode[2]		Occurrence of User-Defined Censoring Criteria[3]		Evidence of Death[4]		Disenrollment[5]		End of Data[6]	
	Total Number of Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Risankizumab Users	10,030	9,815	97.9%	217	2.2%	0	0.0%	2,361	23.5%	1,798	17.9%
Guselkumab Users	7,369	7,194	97.6%	177	2.4%	0	0.0%	1,182	16.0%	854	11.6%
Tildrakizumab Users	382	373	97.6%	9	2.4%	0	0.0%	14	3.7%	4	1.0%
Ustekinumab Users	10,317	10,220	99.1%	98	0.9%	0	0.0%	879	8.5%	488	4.7%
Secukinumab Users	7,577	7,424	98.0%	160	2.1%	0	0.0%	951	12.6%	466	6.2%
Ixekizumab Users	7,619	7,450	97.8%	177	2.3%	0	0.0%	817	10.7%	492	6.5%
Brodalumab Users	123	115	93.5%	9	7.3%	0	0.0%	13	10.6%	8	6.5%

[1]A patient's episode may be censored due to more than one reason if they occur on the same date. Therefore, the sum of the reasons for censoring may be greater than the total number of patients.

[2]Represents episodes censored due to end of the exposure episode. In as-treated analyses, exposure episodes are defined using days supplied as recorded in outpatient pharmacy dispensing records, and episodes end after days supplied are exhausted or a pre-determined maximum episode duration is met. In point exposure analyses, exposure episodes end when a pre-determined maximum episode duration is met.

[3]Represents episodes censored due to occurrence of additional user-defined criteria using drug, procedure, diagnosis, and/or laboratory codes.

[4]Represents episodes censored due to evidence of death. Death data source and completeness varies by Data Partner.

[5]Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that date. Therefore, a patient may have dual reasons for censoring as "disenrollment" and "end of data" on the same day - this can be interpreted as right-censoring in most cases.

[6]Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the Sentinel Common Data Model have at least 80% of the record count relative to the prior month.

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Test Database from April 23, 2019 to December 31, 2022

	Guselkumab Users		Risankizumab Users		Tildrakizumab Users		Ustekinumab Users	
	Remaining	Excluded	Remaining	Excluded	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements								
Enrolled at any point during the query period	42,449,617	N/A	42,449,617	N/A	42,449,617	N/A	42,449,617	N/A
Had required coverage type (medical and/or drug coverage)	40,677,875	1,771,742	40,677,875	1,771,742	40,677,875	1,771,742	40,677,875	1,771,742
Enrolled during specified age range	40,677,835	40	40,677,835	40	40,677,835	40	40,677,835	40
Had requestable medical charts	40,677,835	0	40,677,835	0	40,677,835	0	40,677,835	0
Met demographic requirements (sex, race, and Hispanic origin)	40,677,835	0	40,677,835	0	40,677,835	0	40,677,835	0
Members with a valid index event								
Had any cohort-defining claim during the query period	13,203	40,664,632	15,592	40,662,243	638	40,677,197	27,408	40,650,427
Claim recorded during specified age range	13,203	0	15,592	0	638	0	27,408	0
Episode defining index claim recorded during the query period	11,864	1,339	15,592	0	594	44	20,182	7,226
Members with required pre-index history								
Had sufficient pre-index continuous enrollment	7,369	4,495	10,030	5,562	382	212	10,317	9,865
Met inclusion and exclusion criteria	7,369	0	10,030	0	382	0	10,317	0
Had sufficient post-index continuous enrollment	7,369	0	10,030	0	382	0	10,317	0
Final cohort								
Number of members	7,369	N/A	10,030	N/A	382	N/A	10,317	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Test Database from April 23, 2019 to December 31, 2022

	Secukinumab Users		Ixekizumab Users		Brodalumab Users	
	Remaining	Excluded	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements						
Enrolled at any point during the query period	42,449,617	N/A	42,449,617	N/A	42,449,617	N/A
Had required coverage type (medical and/or drug coverage)	40,677,875	1,771,742	40,677,875	1,771,742	40,677,875	1,771,742
Enrolled during specified age range	40,677,835	40	40,677,835	40	40,677,835	40
Had requestable medical charts	40,677,835	0	40,677,835	0	40,677,835	0
Met demographic requirements (sex, race, and Hispanic origin)	40,677,835	0	40,677,835	0	40,677,835	0
Members with a valid index event						
Had any cohort-defining claim during the query period	17,996	40,659,839	14,252	40,663,583	277	40,677,558
Claim recorded during specified age range	17,996	0	14,252	0	277	0
Episode defining index claim recorded during the query period	13,037	4,959	12,188	2,064	189	88
Members with required pre-index history						
Had sufficient pre-index continuous enrollment	7,577	5,460	7,619	4,569	123	66
Met inclusion and exclusion criteria	7,577	0	7,619	0	123	0
Had sufficient post-index continuous enrollment	7,577	0	7,619	0	123	0
Final cohort						
Number of members	7,577	N/A	7,619	N/A	123	N/A

Figure 1a. Patient Entry into Study by Month for Risankizumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

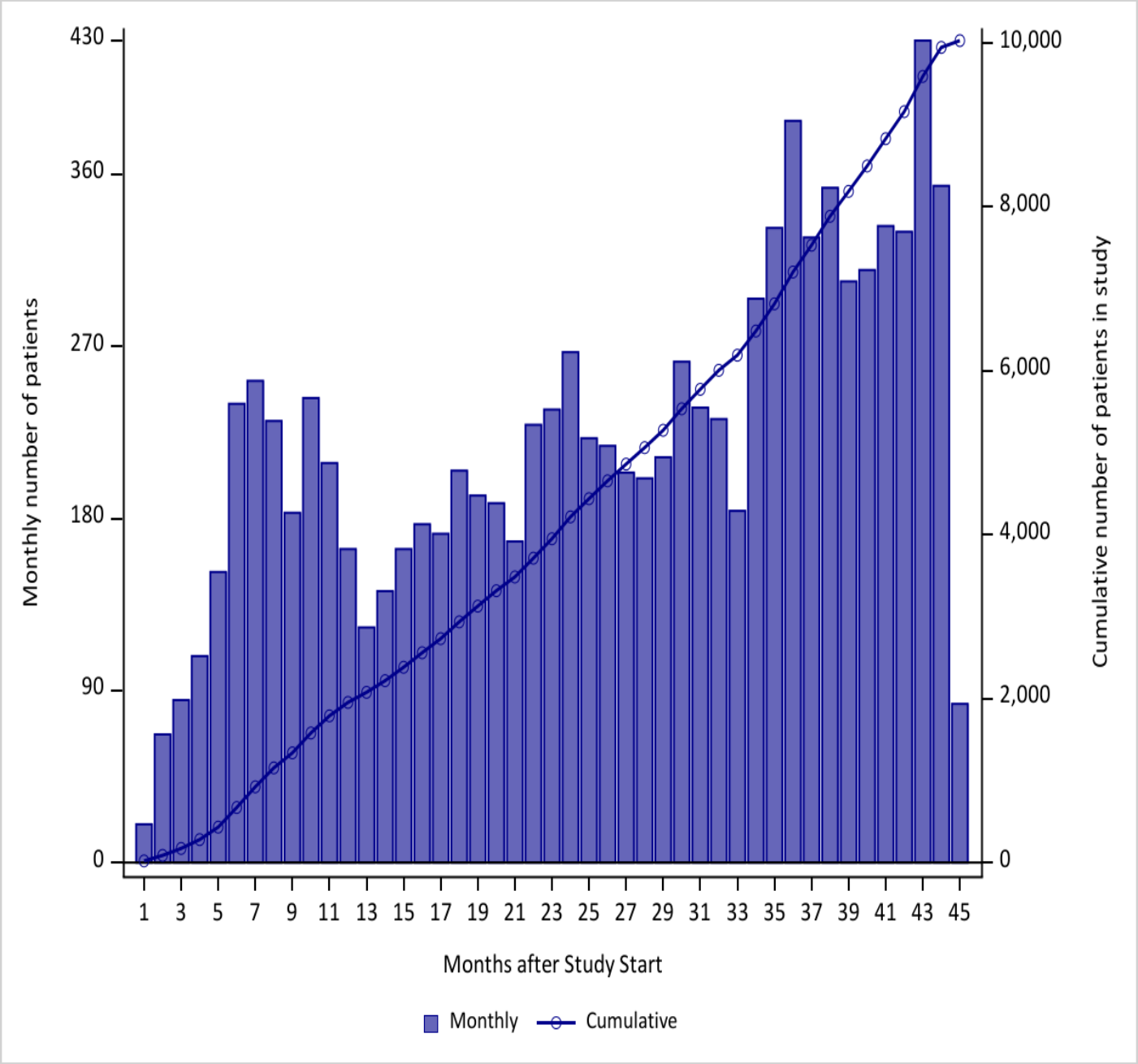


Figure 1b. Patient Entry into Study by Month for Guselkumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

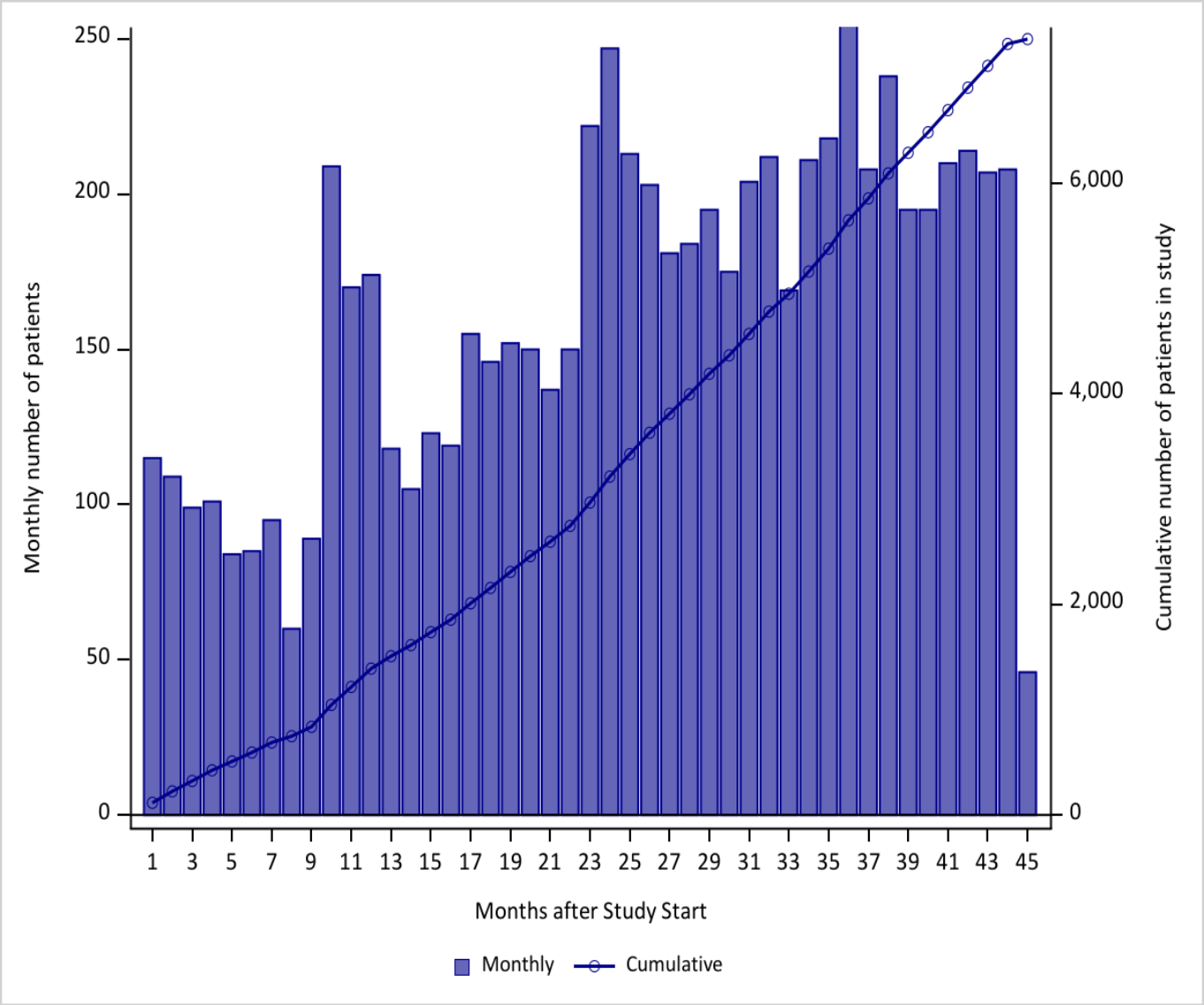


Figure 1c. Patient Entry into Study by Month for Tildrakizumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

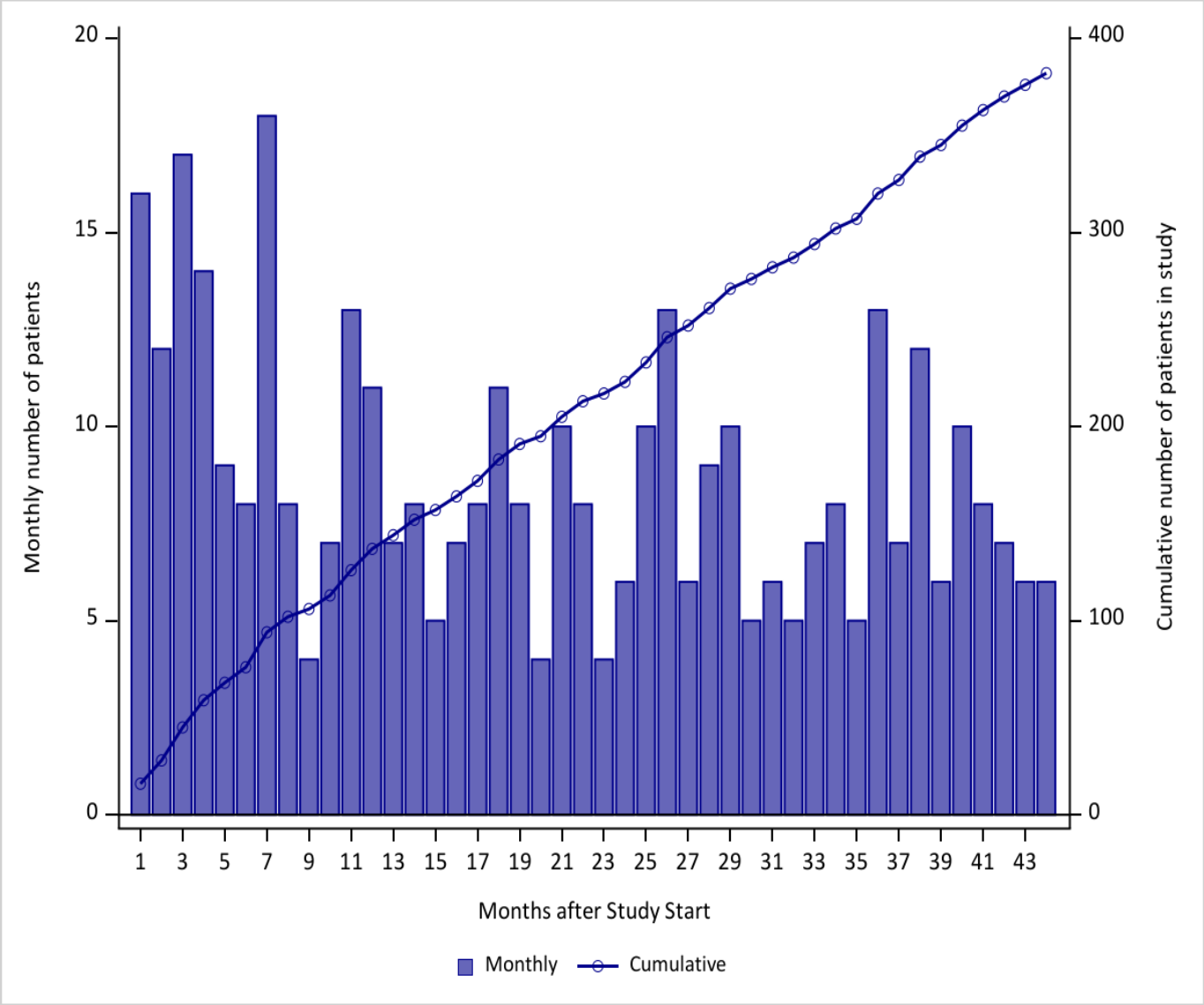


Figure 1d. Patient Entry into Study by Month for Ustekinumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

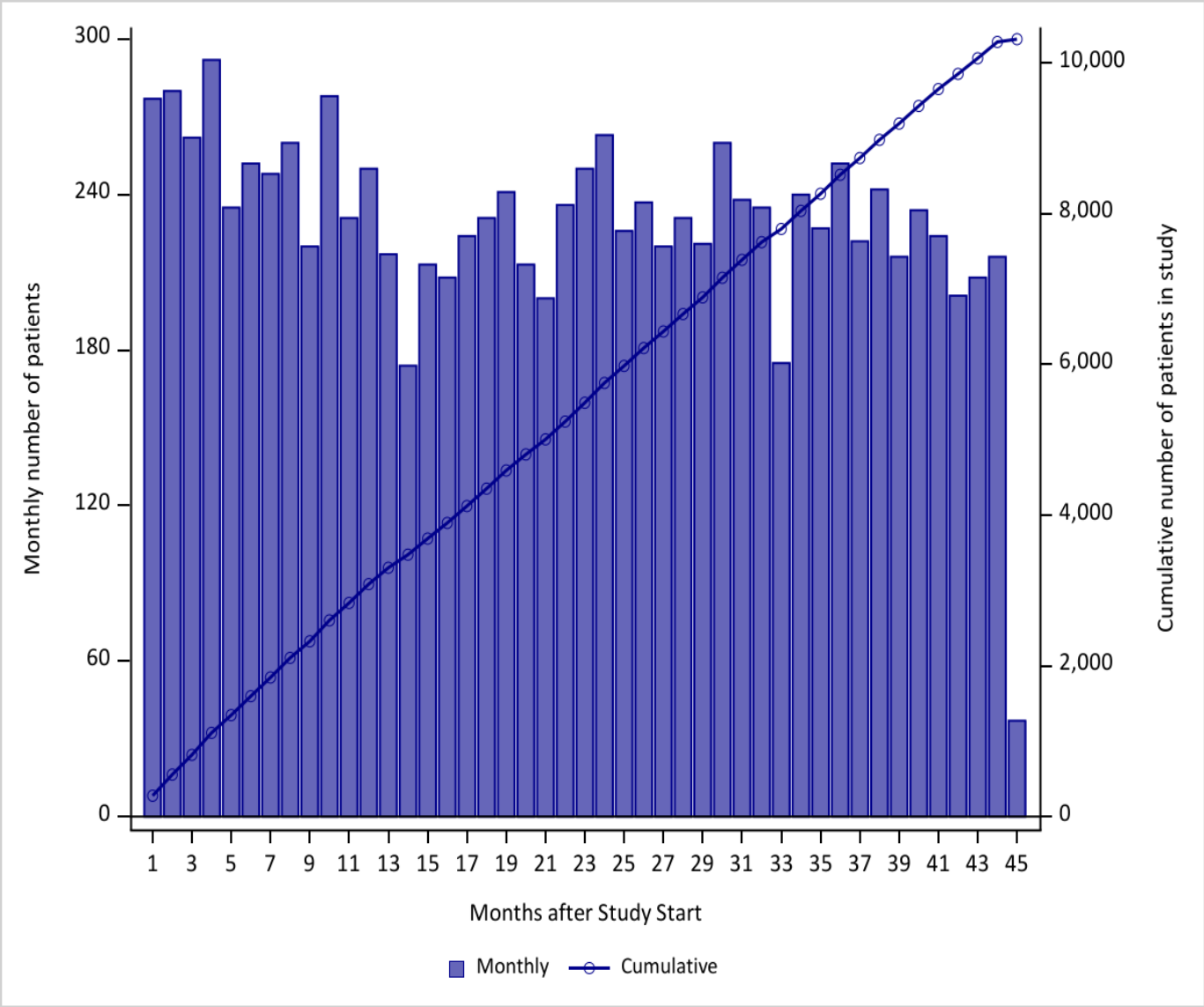


Figure 1e. Patient Entry into Study by Month for Secukinumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

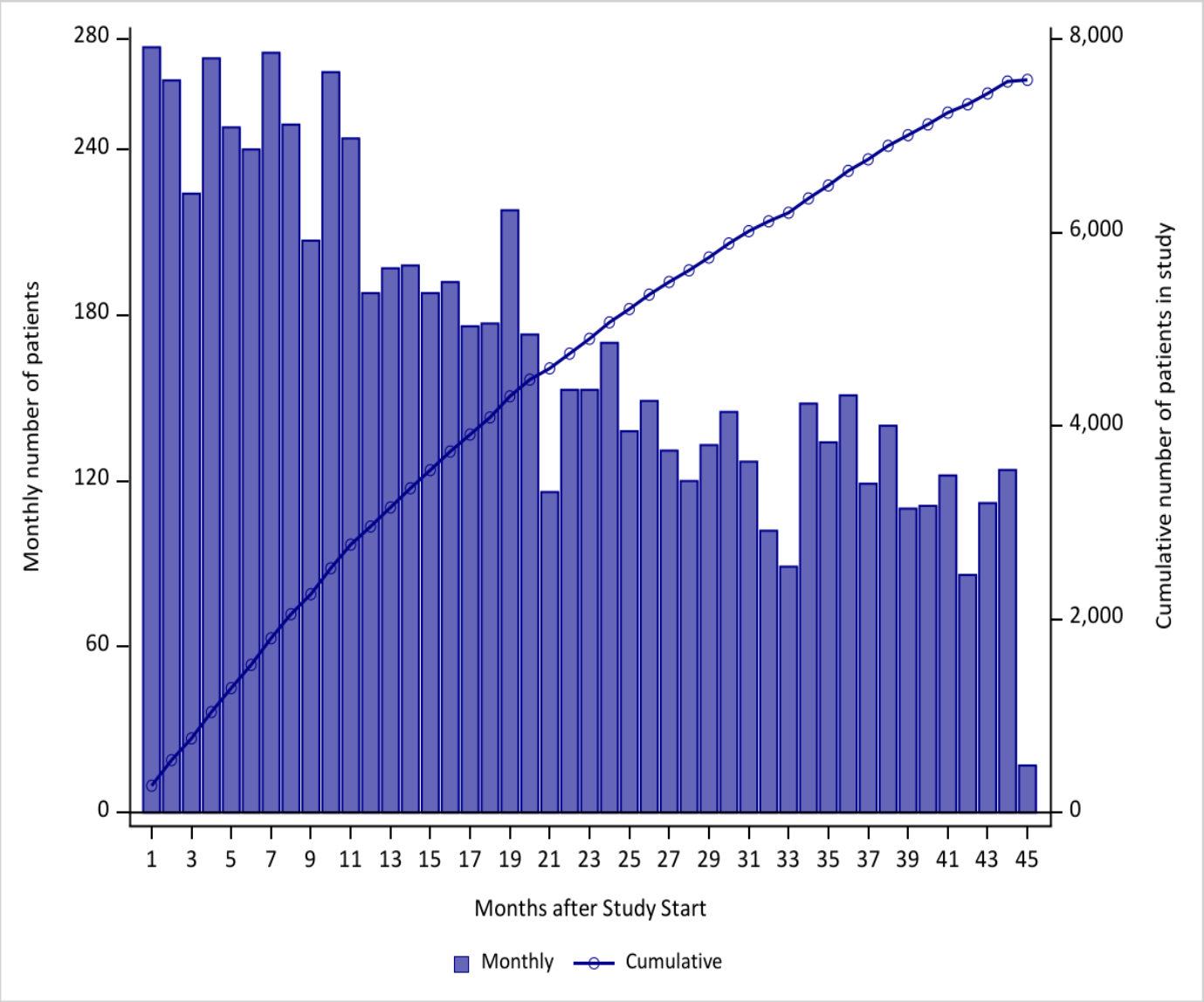


Figure 1f. Patient Entry into Study by Month for Ixekizumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

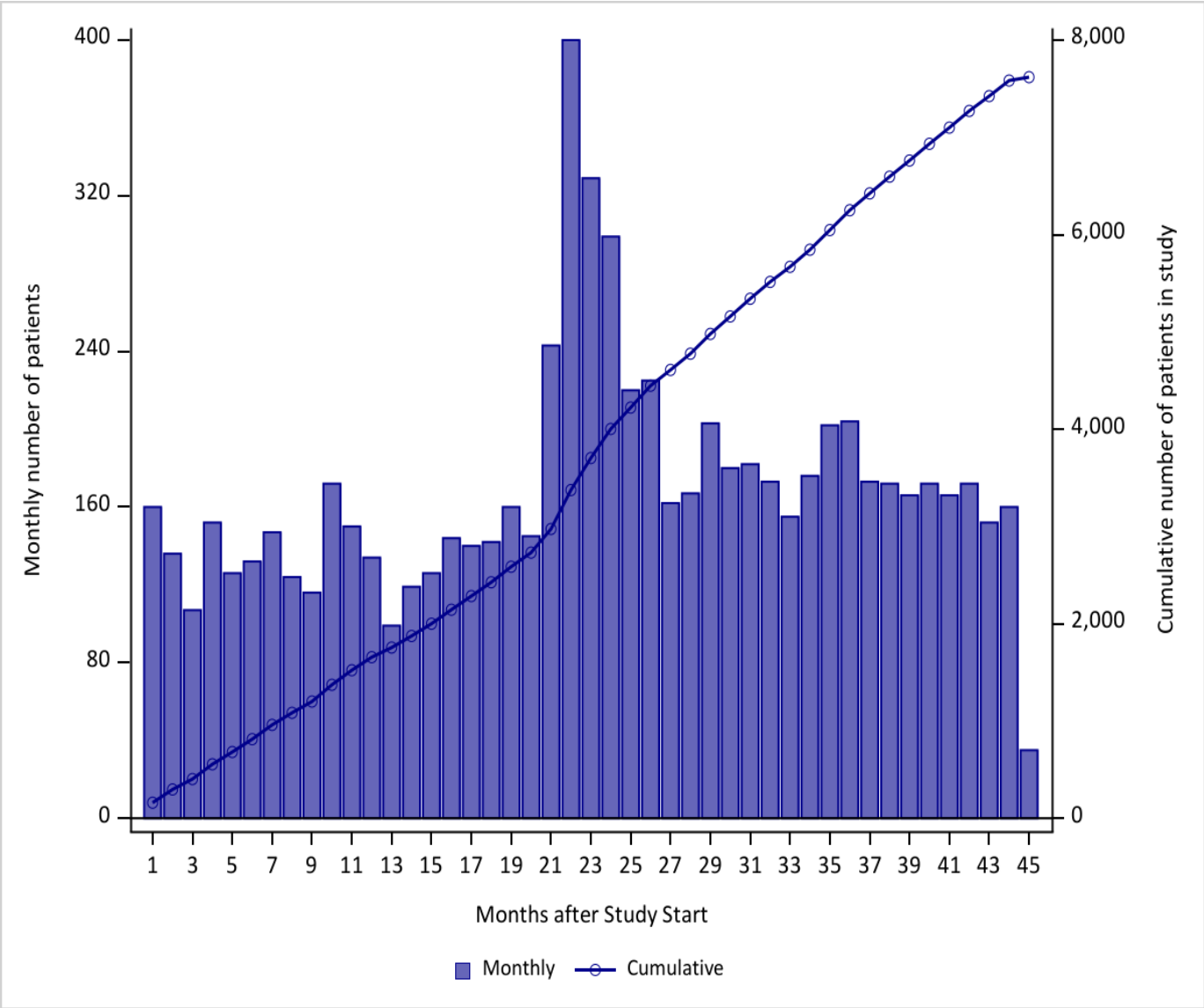


Figure 1g. Patient Entry into Study by Month for Brodalumab Users in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022

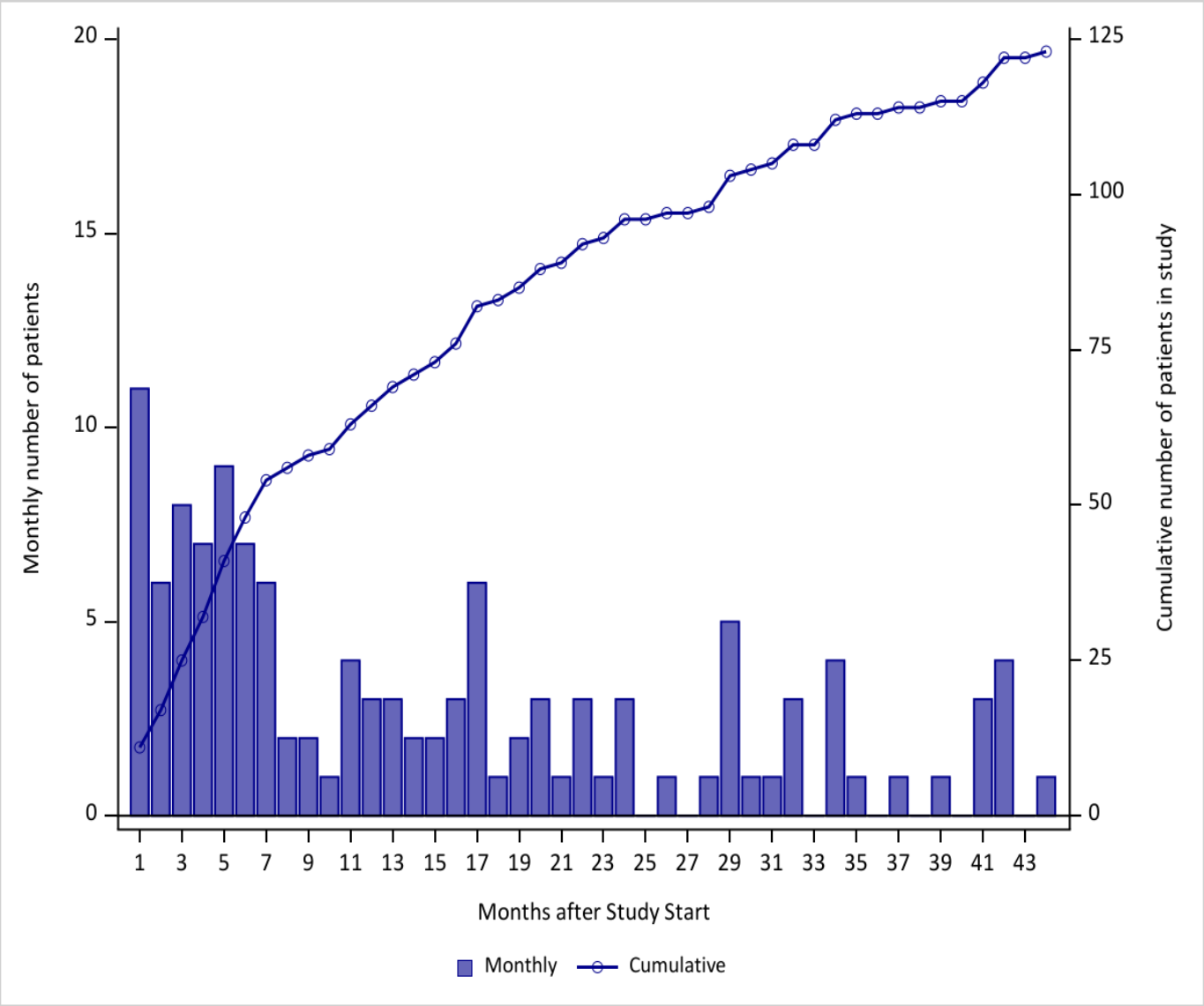
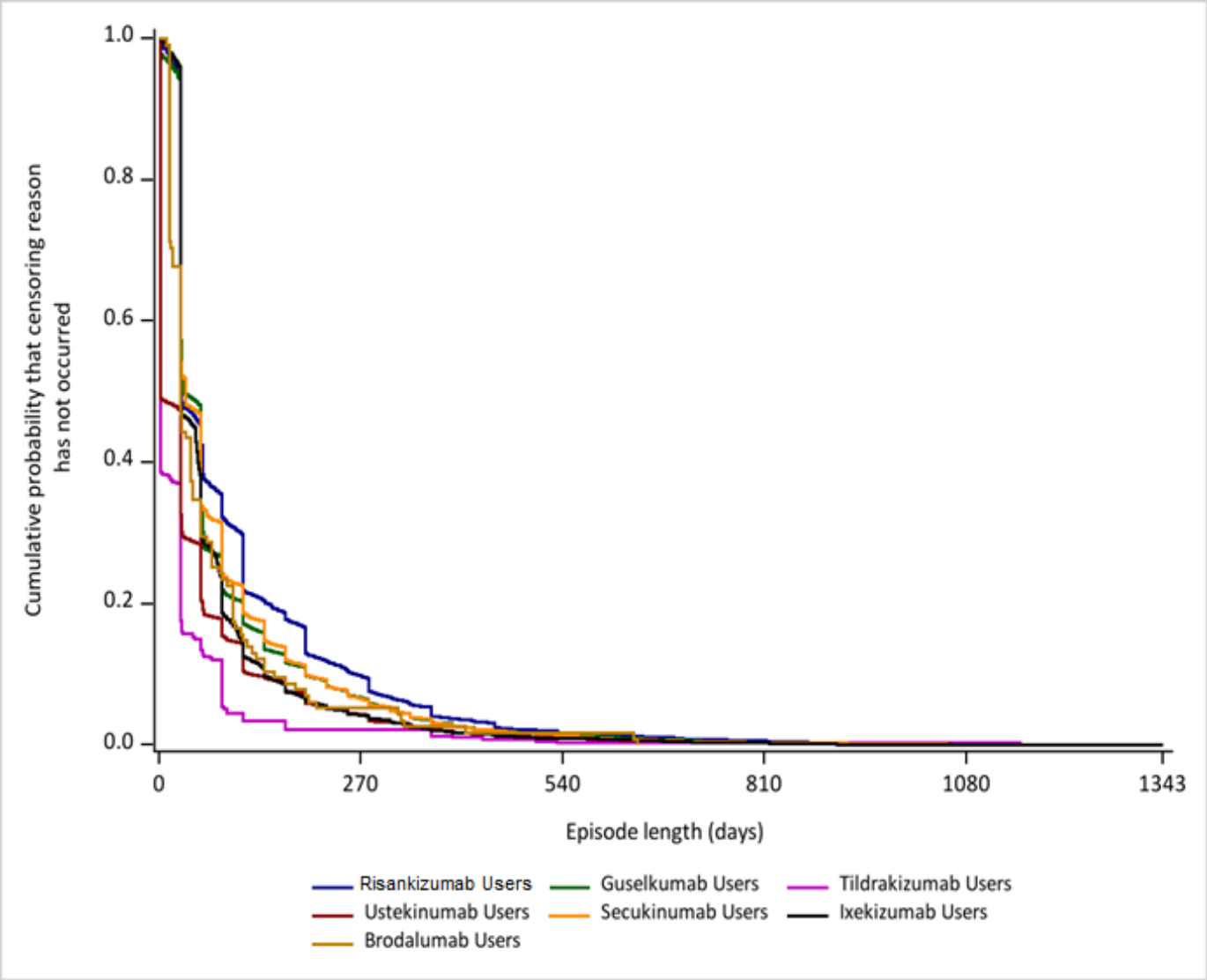


Figure 2. End of First Treatment Episode due to End of Exposure Episode in the Merative™ Marketscan® Research Databases from April 23, 2019 to December 31, 2022



Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (December 11, 2023)

Masked DP ID	DP Start Date	DP End Date[1]
DP01	01/01/2010	12/31/2022

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

Appendix B. List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
Risankizumab	
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
Brodalumab	
brodalumab	Siliq
Guselkumab	
guselkumab	Tremfya
Ixekizumab	
ixekizumab	Taltz Autoinjector
ixekizumab	Taltz Autoinjector (2 Pack)
ixekizumab	Taltz Autoinjector (3 Pack)
ixekizumab	Taltz Syringe
ixekizumab	Taltz Syringe (2 Pack)
ixekizumab	Taltz Syringe (3 Pack)
Ixekizumab	Taltz
Ixekizumab	Taltz
Secukinumab	
SECUKINUMAB	Cosentyx
SECUKINUMAB	Cosentyx (2 Syringes)
SECUKINUMAB	Cosentyx Pen
SECUKINUMAB	Cosentyx Pen (2 Pens)
secukinumab	Cosentyx
secukinumab	Cosentyx UnoReady Pen

Appendix B. List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
Tildrakizumab	
tildrakizumab-asmn	Ilumya
Ustekinumab	
ustekinumab	Stelara

Appendix C. List of Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Exposures in this Request

Code	Description	Code Category	Code Type
	Risankizumab		
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	Procedure	HCPCS
	Tildrakizumab		
J3245	Injection, tildrakizumab, 1 mg	Procedure	HCPCS
	Ustekinumab		
C9261	Injection, ustekinumab, 1 mg	Procedure	HCPCS
C9487	Ustekinumab, for intravenous injection, 1 mg	Procedure	HCPCS
J3357	Ustekinumab, for subcutaneous injection, 1 mg	Procedure	HCPCS
J3358	Ustekinumab, for intravenous injection, 1 mg	Procedure	HCPCS
Q9989	Ustekinumab, for intravenous injection, 1 mg	Procedure	HCPCS

Appendix D. List of Generic and Brand Names of Medical Products Used to Define Exposure Censoring Criteria in this Request

Generic Name	Brand Name
Risankizumab	
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
risankizumab-rzaa	Skyrizi
Brodalumab	
brodalumab	Siliq
Guselkumab	
guselkumab	Tremfya
Ixekizumab	
ixekizumab	Taltz Autoinjector
ixekizumab	Taltz Autoinjector (2 Pack)
ixekizumab	Taltz Autoinjector (3 Pack)
ixekizumab	Taltz Syringe
ixekizumab	Taltz Syringe (2 Pack)
ixekizumab	Taltz Syringe (3 Pack)
Ixekizumab	Taltz
Ixekizumab	Taltz
Secukinumab	
SECUKINUMAB	Cosentyx
SECUKINUMAB	Cosentyx (2 Syringes)
SECUKINUMAB	Cosentyx Pen
SECUKINUMAB	Cosentyx Pen (2 Pens)
secukinumab	Cosentyx

Appendix D. List of Generic and Brand Names of Medical Products Used to Define Exposure Censoring Criteria in this Request

Generic Name	Brand Name
secukinumab	Cosentyx UnoReady Pen
Tildrakizumab	
tildrakizumab-asmn	Ilumya
Ustekinumab	
ustekinumab	Stelara

Appendix E. List of Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Exposure Censoring Criteria in this Request

Code	Description	Code Category	Code Type
	Risankizumab		
00074105001	risankizumab-rzaa	Procedure	NDC
00074105070	risankizumab-rzaa	Procedure	NDC
00074106501	risankizumab-rzaa	Procedure	NDC
00074106502	risankizumab-rzaa	Procedure	NDC
00074106601	risankizumab-rzaa	Procedure	NDC
00074106901	risankizumab-rzaa	Procedure	NDC
00074107001	risankizumab-rzaa	Procedure	NDC
00074107002	risankizumab-rzaa	Procedure	NDC
00074204201	risankizumab-rzaa	Procedure	NDC
00074204202	risankizumab-rzaa	Procedure	NDC
00074204271	risankizumab-rzaa	Procedure	NDC
00074210001	risankizumab-rzaa	Procedure	NDC
00074210070	risankizumab-rzaa	Procedure	NDC
00074501501	risankizumab-rzaa	Procedure	NDC
00074501502	risankizumab-rzaa	Procedure	NDC
00074703402	risankizumab-rzaa	Procedure	NDC
00074703604	risankizumab-rzaa	Procedure	NDC
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	Procedure	HCPCS
	Tildrakizumab		
47335017701	tildrakizumab-asmn	Procedure	NDC
47335017710	tildrakizumab-asmn	Procedure	NDC
47335017795	tildrakizumab-asmn	Procedure	NDC
47335017796	tildrakizumab-asmn	Procedure	NDC
J3245	Injection, tildrakizumab, 1 mg	Procedure	HCPCS
	Ustekinumab		
57894005416	ustekinumab	Procedure	NDC
57894005427	ustekinumab	Procedure	NDC
57894006002	ustekinumab	Procedure	NDC
57894006003	ustekinumab	Procedure	NDC
57894006004	ustekinumab	Procedure	NDC
57894006103	ustekinumab	Procedure	NDC
57894006104	ustekinumab	Procedure	NDC
C9261	Injection, ustekinumab, 1 mg	Procedure	HCPCS
C9487	Ustekinumab, for intravenous injection, 1 mg	Procedure	HCPCS
J3357	Ustekinumab, for subcutaneous injection, 1 mg	Procedure	HCPCS
J3358	Ustekinumab, for intravenous injection, 1 mg	Procedure	HCPCS
Q9989	Ustekinumab, for intravenous injection, 1 mg	Procedure	HCPCS

Appendix F. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
	Ankylosing Spondylitis		
M08.1	Juvenile ankylosing spondylitis	Diagnosis	ICD-10-CM
M45.0	Ankylosing spondylitis of multiple sites in spine	Diagnosis	ICD-10-CM
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region	Diagnosis	ICD-10-CM
M45.2	Ankylosing spondylitis of cervical region	Diagnosis	ICD-10-CM
M45.3	Ankylosing spondylitis of cervicothoracic region	Diagnosis	ICD-10-CM
M45.4	Ankylosing spondylitis of thoracic region	Diagnosis	ICD-10-CM
M45.5	Ankylosing spondylitis of thoracolumbar region	Diagnosis	ICD-10-CM
M45.6	Ankylosing spondylitis lumbar region	Diagnosis	ICD-10-CM
M45.7	Ankylosing spondylitis of lumbosacral region	Diagnosis	ICD-10-CM
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region	Diagnosis	ICD-10-CM
M45.9	Ankylosing spondylitis of unspecified sites in spine	Diagnosis	ICD-10-CM
	Crohn's Disease		
K50.0	Crohn's disease of small intestine	Diagnosis	ICD-10-CM
K50.00	Crohn's disease of small intestine without complications	Diagnosis	ICD-10-CM
K50.01	Crohn's disease of small intestine with complications	Diagnosis	ICD-10-CM
K50.011	Crohn's disease of small intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.012	Crohn's disease of small intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.013	Crohn's disease of small intestine with fistula	Diagnosis	ICD-10-CM
K50.014	Crohn's disease of small intestine with abscess	Diagnosis	ICD-10-CM
K50.018	Crohn's disease of small intestine with other complication	Diagnosis	ICD-10-CM
K50.019	Crohn's disease of small intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.1	Crohn's disease of large intestine	Diagnosis	ICD-10-CM
K50.10	Crohn's disease of large intestine without complications	Diagnosis	ICD-10-CM
K50.11	Crohn's disease of large intestine with complications	Diagnosis	ICD-10-CM
K50.111	Crohn's disease of large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.112	Crohn's disease of large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.113	Crohn's disease of large intestine with fistula	Diagnosis	ICD-10-CM
K50.114	Crohn's disease of large intestine with abscess	Diagnosis	ICD-10-CM
K50.118	Crohn's disease of large intestine with other complication	Diagnosis	ICD-10-CM
K50.119	Crohn's disease of large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.8	Crohn's disease of both small and large intestine	Diagnosis	ICD-10-CM
K50.80	Crohn's disease of both small and large intestine without complications	Diagnosis	ICD-10-CM
K50.81	Crohn's disease of both small and large intestine with complications	Diagnosis	ICD-10-CM
K50.811	Crohn's disease of both small and large intestine with rectal bleeding	Diagnosis	ICD-10-CM
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction	Diagnosis	ICD-10-CM
K50.813	Crohn's disease of both small and large intestine with fistula	Diagnosis	ICD-10-CM
K50.814	Crohn's disease of both small and large intestine with abscess	Diagnosis	ICD-10-CM
K50.818	Crohn's disease of both small and large intestine with other complication	Diagnosis	ICD-10-CM
K50.819	Crohn's disease of both small and large intestine with unspecified complications	Diagnosis	ICD-10-CM
K50.9	Crohn's disease, unspecified	Diagnosis	ICD-10-CM
K50.90	Crohn's disease, unspecified, without complications	Diagnosis	ICD-10-CM
K50.91	Crohn's disease, unspecified, with complications	Diagnosis	ICD-10-CM
K50.911	Crohn's disease, unspecified, with rectal bleeding	Diagnosis	ICD-10-CM

Appendix F. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
K50.912	Crohn's disease, unspecified, with intestinal obstruction	Diagnosis	ICD-10-CM
K50.913	Crohn's disease, unspecified, with fistula	Diagnosis	ICD-10-CM
K50.914	Crohn's disease, unspecified, with abscess	Diagnosis	ICD-10-CM
K50.918	Crohn's disease, unspecified, with other complication	Diagnosis	ICD-10-CM
K50.919	Crohn's disease, unspecified, with unspecified complications	Diagnosis	ICD-10-CM
	Enthesitis-related Arthritis		
M08.80	Other juvenile arthritis, unspecified site	Diagnosis	ICD-10-CM
M46.0	Spinal enthesopathy	Diagnosis	ICD-10-CM
M46.00	Spinal enthesopathy, site unspecified	Diagnosis	ICD-10-CM
M46.01	Spinal enthesopathy, occipito-atlanto-axial region	Diagnosis	ICD-10-CM
M46.02	Spinal enthesopathy, cervical region	Diagnosis	ICD-10-CM
M46.03	Spinal enthesopathy, cervicothoracic region	Diagnosis	ICD-10-CM
M46.04	Spinal enthesopathy, thoracic region	Diagnosis	ICD-10-CM
M46.05	Spinal enthesopathy, thoracolumbar region	Diagnosis	ICD-10-CM
M46.06	Spinal enthesopathy, lumbar region	Diagnosis	ICD-10-CM
M46.07	Spinal enthesopathy, lumbosacral region	Diagnosis	ICD-10-CM
M46.08	Spinal enthesopathy, sacral and sacrococcygeal region	Diagnosis	ICD-10-CM
M46.09	Spinal enthesopathy, multiple sites in spine	Diagnosis	ICD-10-CM
M76	Enthesopathies, lower limb, excluding foot	Diagnosis	ICD-10-CM
M76.8	Other specified enthesopathies of lower limb, excluding foot	Diagnosis	ICD-10-CM
M76.89	Other specified enthesopathies of lower limb, excluding foot	Diagnosis	ICD-10-CM
M76.891	Other specified enthesopathies of right lower limb, excluding foot	Diagnosis	ICD-10-CM
M76.892	Other specified enthesopathies of left lower limb, excluding foot	Diagnosis	ICD-10-CM
M76.899	Other specified enthesopathies of unspecified lower limb, excluding foot	Diagnosis	ICD-10-CM
M76.9	Unspecified enthesopathy, lower limb, excluding foot	Diagnosis	ICD-10-CM
M77	Other enthesopathies	Diagnosis	ICD-10-CM
M77.5	Other enthesopathy of foot and ankle	Diagnosis	ICD-10-CM
M77.50	Other enthesopathy of unspecified foot and ankle	Diagnosis	ICD-10-CM
M77.51	Other enthesopathy of right foot and ankle	Diagnosis	ICD-10-CM
M77.52	Other enthesopathy of left foot and ankle	Diagnosis	ICD-10-CM
M77.8	Other enthesopathies, not elsewhere classified	Diagnosis	ICD-10-CM
M77.9	Enthesopathy, unspecified	Diagnosis	ICD-10-CM
	Non-radiographic Axial Spondyloarthritis		
M45.A	Non-radiographic axial spondyloarthritis	Diagnosis	ICD-10-CM
M45.A0	Non-radiographic axial spondyloarthritis of unspecified sites in spine	Diagnosis	ICD-10-CM
M45.A1	Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region	Diagnosis	ICD-10-CM
M45.A2	Non-radiographic axial spondyloarthritis of cervical region	Diagnosis	ICD-10-CM
M45.A3	Non-radiographic axial spondyloarthritis of cervicothoracic region	Diagnosis	ICD-10-CM
M45.A4	Non-radiographic axial spondyloarthritis of thoracic region	Diagnosis	ICD-10-CM
M45.A5	Non-radiographic axial spondyloarthritis of thoracolumbar region	Diagnosis	ICD-10-CM
M45.A6	Non-radiographic axial spondyloarthritis of lumbar region	Diagnosis	ICD-10-CM
M45.A7	Non-radiographic axial spondyloarthritis of lumbosacral region	Diagnosis	ICD-10-CM
M45.A8	Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region	Diagnosis	ICD-10-CM
M45.AB	Non-radiographic axial spondyloarthritis of multiple sites in spine	Diagnosis	ICD-10-CM
	Plaque Psoriasis		

Appendix F. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
L40.0	Psoriasis vulgaris	Diagnosis	ICD-10-CM
L40.1	Generalized pustular psoriasis	Diagnosis	ICD-10-CM
L40.2	Acrodermatitis continua	Diagnosis	ICD-10-CM
L40.3	Pustulosis palmaris et plantaris	Diagnosis	ICD-10-CM
L40.4	Guttate psoriasis	Diagnosis	ICD-10-CM
L40.8	Other psoriasis	Diagnosis	ICD-10-CM
L40.9	Psoriasis, unspecified	Diagnosis	ICD-10-CM
	Psoriatic Arthritis		
L40.50	Arthropathic psoriasis, unspecified	Diagnosis	ICD-10-CM
L40.51	Distal interphalangeal psoriatic arthropathy	Diagnosis	ICD-10-CM
L40.52	Psoriatic arthritis mutilans	Diagnosis	ICD-10-CM
L40.53	Psoriatic spondylitis	Diagnosis	ICD-10-CM
L40.54	Psoriatic juvenile arthropathy	Diagnosis	ICD-10-CM
L40.59	Other psoriatic arthropathy	Diagnosis	ICD-10-CM
	Ulcerative Colitis		
K51.0	Ulcerative (chronic) pancolitis	Diagnosis	ICD-10-CM
K51.00	Ulcerative (chronic) pancolitis without complications	Diagnosis	ICD-10-CM
K51.01	Ulcerative (chronic) pancolitis with complications	Diagnosis	ICD-10-CM
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.013	Ulcerative (chronic) pancolitis with fistula	Diagnosis	ICD-10-CM
K51.014	Ulcerative (chronic) pancolitis with abscess	Diagnosis	ICD-10-CM
K51.018	Ulcerative (chronic) pancolitis with other complication	Diagnosis	ICD-10-CM
K51.019	Ulcerative (chronic) pancolitis with unspecified complications	Diagnosis	ICD-10-CM
K51.2	Ulcerative (chronic) proctitis	Diagnosis	ICD-10-CM
K51.20	Ulcerative (chronic) proctitis without complications	Diagnosis	ICD-10-CM
K51.21	Ulcerative (chronic) proctitis with complications	Diagnosis	ICD-10-CM
K51.211	Ulcerative (chronic) proctitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.213	Ulcerative (chronic) proctitis with fistula	Diagnosis	ICD-10-CM
K51.214	Ulcerative (chronic) proctitis with abscess	Diagnosis	ICD-10-CM
K51.218	Ulcerative (chronic) proctitis with other complication	Diagnosis	ICD-10-CM
K51.219	Ulcerative (chronic) proctitis with unspecified complications	Diagnosis	ICD-10-CM
K51.3	Ulcerative (chronic) rectosigmoiditis	Diagnosis	ICD-10-CM
K51.30	Ulcerative (chronic) rectosigmoiditis without complications	Diagnosis	ICD-10-CM
K51.31	Ulcerative (chronic) rectosigmoiditis with complications	Diagnosis	ICD-10-CM
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding	Diagnosis	ICD-10-CM
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula	Diagnosis	ICD-10-CM
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess	Diagnosis	ICD-10-CM
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication	Diagnosis	ICD-10-CM
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications	Diagnosis	ICD-10-CM
K51.5	Left sided colitis	Diagnosis	ICD-10-CM
K51.50	Left sided colitis without complications	Diagnosis	ICD-10-CM
K51.51	Left sided colitis with complications	Diagnosis	ICD-10-CM
K51.511	Left sided colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.512	Left sided colitis with intestinal obstruction	Diagnosis	ICD-10-CM

Appendix F. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Covariates in this Request

Code	Description	Code Category	Code Type
K51.513	Left sided colitis with fistula	Diagnosis	ICD-10-CM
K51.514	Left sided colitis with abscess	Diagnosis	ICD-10-CM
K51.518	Left sided colitis with other complication	Diagnosis	ICD-10-CM
K51.519	Left sided colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.8	Other ulcerative colitis	Diagnosis	ICD-10-CM
K51.80	Other ulcerative colitis without complications	Diagnosis	ICD-10-CM
K51.81	Other ulcerative colitis with complications	Diagnosis	ICD-10-CM
K51.811	Other ulcerative colitis with rectal bleeding	Diagnosis	ICD-10-CM
K51.812	Other ulcerative colitis with intestinal obstruction	Diagnosis	ICD-10-CM
K51.813	Other ulcerative colitis with fistula	Diagnosis	ICD-10-CM
K51.814	Other ulcerative colitis with abscess	Diagnosis	ICD-10-CM
K51.818	Other ulcerative colitis with other complication	Diagnosis	ICD-10-CM
K51.819	Other ulcerative colitis with unspecified complications	Diagnosis	ICD-10-CM
K51.9	Ulcerative colitis, unspecified	Diagnosis	ICD-10-CM
K51.90	Ulcerative colitis, unspecified, without complications	Diagnosis	ICD-10-CM
K51.91	Ulcerative colitis, unspecified, with complications	Diagnosis	ICD-10-CM
K51.911	Ulcerative colitis, unspecified with rectal bleeding	Diagnosis	ICD-10-CM
K51.912	Ulcerative colitis, unspecified with intestinal obstruction	Diagnosis	ICD-10-CM
K51.913	Ulcerative colitis, unspecified with fistula	Diagnosis	ICD-10-CM
K51.914	Ulcerative colitis, unspecified with abscess	Diagnosis	ICD-10-CM
K51.918	Ulcerative colitis, unspecified with other complication	Diagnosis	ICD-10-CM
K51.919	Ulcerative colitis, unspecified with unspecified complications	Diagnosis	ICD-10-CM

Appendix G. Specifications Defining Parameters for this Request (Exposure)

The Division of Pharmacovigilance within the Center for Drug Evaluation and Research has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool version 12.2.2 to describe the use of risankizumab, guselkumab, tildrakizumab, ustekinumab, secukinumab, ixekizumab, and brodalumab in the Sentinel Merative™ Marketscan® Research Databases.

Query period: 01/01/2010 - 12/31/2022 (Dates included in Sentinel Merative™ Marketscan® Research Databases ETL 23)
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 400
Post-index requirement: 0
Enrollment gap: 45
Stratifications: Age group, Sex, Calendar year, covar1, covar2, covar3
Censor output categorization: [1, 27], [28, 55], [56, 83], [84, 139], [140, 195], [196+] (AKA <4 weeks, 4 to <8 weeks, 8 to <12 weeks, 12 to <20 weeks, 20 to <28 weeks, 28+ weeks)
Restrictions: M/F Sex
Distribution of index-defining codes: Distribution of index-defining codes and encounters
Profile Output Generation Indicator: Yes, return an aggregated dataset of patients/episodes that contain unique covariate combinations
Envelope macro: No reclassification on inpatient Adate
Freeze data: No

	Exposure											
Scenario	Index Exposure	Age Groups	Cohort definition	Incident exposure washout period	Exclude evidence of days supply if exposure washout includes dispensings	Treatment episode gap	Treatment episode extension	Care setting	Principal diagnosis position	Create Baseline Table?	Forced supply to attach to dispensings	Censor treatment episode at evidence of:
1	risankizumab-rzaa	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date

Appendix G. Specifications Defining Parameters for this Request (Exposure)												
2	guselkumab	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date
3	tildrakizumab-asmn	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date
4	ustekinumab	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date
5	secukinumab	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date
6	ixekizumab	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date

Appendix G. Specifications Defining Parameters for this Request (Exposure)												
7	brodalumab	0-17, 18-64, 65+	Include all valid exposure episodes during query period (only the first valid exposure episode's incidence is assessed using washout criteria)	400	Washout lookback period should search for only evidence of a dispensing date	0	0	N/A	N/A	Yes	1 for procedure codes; N/A for NDCs	*Death; *DP end date; *Query end date
ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360. NDC codes are checked against First Data Bank's FDB MedKnowledge®.												

Appendix G. Specifications Defining Parameters for this Request (Inclusion/Exclusion Criteria)

The Division of Pharmacovigilance within the Center for Drug Evaluation and Research has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool version 12.2.2 to describe the use of risankizumab, guselkumab, tildrakizumab, ustekinumab, secukinumab, ixekizumab, and brodalumab in the Sentinel Merative™ Marketscan® Research Databases.

Query period: 01/01/2010 - 12/31/2022
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 400
Post-index requirement: 0
Enrollment gap: 45
Stratifications: Age group, Sex, Calendar year, covar1, covar2, covar3
Censor output categorization: (1, 27], (28, 55], (56, 83], (84, 139], (140, 195], (196+] (AKA <4 weeks, 4 to <8 weeks, 8 to <12 weeks, 12 to <20 weeks, 20 to <28 weeks, 28+ weeks)
Restrictions: M/F Sex
Distribution of index-defining codes: Distribution of index-defining codes and encounters
Profile Output Generation Indicator: Yes, return an aggregated dataset of patients/episodes that contain unique covariate combinations
Envelope macro: No reclassification on inpatient Adate
Freeze data: No

Inclusion/Exclusion Criteria

Scenario	Inclusion/ Exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start	Evaluation period end	Exclude evidence of days supply if inclusion/exclusion evaluation period includes dispensings	Number of instances the criteria should be found in evaluation period	Minimum Days Supplied	Forced supply to attach to dispensings
1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

ICD-9, ICD-10, HCPCS, and CPT codes are provided by Optum360.
NDC codes are checked against First Data Bank's FDB MedKnowledge®.

Appendix H. Diagram Detailing the Design of this Request