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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_wp139_nsdp_v01

Request ID: cder_mpl1r_wp139_nsdp_v01

Request Description: In this report we described biologics and biosimilars use and dispensing patterns among all patients in the Sentinel Distributed Database (SDD). This is report 2 of 2. Report 1 described the indication history of patients exposed to biologics and biosimilars for filgrastim, pegfilgrastim, and infliximab; uptake of these drugs over time; and coding patterns of these drugs in claims data in the Sentinel Distributed Database (SDD).

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 7.2.1

Data Source: Data from January 1, 2015 to August 21, 2018 from 17 Data Partners contributing to the SDD were included in this report. This request was distributed to Data Partners on March 15, 2019[1]. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: This study characterized patterns of drug use.

Exposures of Interest: We used non-proprietary and brand names, National Drug Code (NDC) codes, and Healthcare Common Procedure Coding System (HCPCS) codes to define exposures of interest: filgrastim biologic (Neupogen) and biosimilars (Granix, Zarxio, Nivestym), pegfilgrastim biologic (Neulasta) and biosimilar (Fulphila), and infliximab biologic (Remicade) and biosimilars (Inflectra, Renflexis). Please see Appendix B for a list of non-proprietary and brand names of medical products and Appendix C for a list of HCPCS codes used to define exposures.

Cohort Eligibility Criteria: We included patients of all ages. We required patients to have medical and drug coverage as of any qualifying dispensing (index date). Groups assessing the Procedure Table (labeled 'Procedure') excluded patients who ever had that exposure in the Dispensing Table; groups assessing the Dispensing Table (labeled 'Dispensing') excluded patients who ever had that exposure in the Procedure Table; groups labeled 'All' had no exclusions and included exposures in either the Procedure Table or the Dispensing Table.

The two infliximab biosimilars (Inflectra and Renflexis) have a shared procedure code (Q5102). We applied the following definitions for these groups:

(1) *Infliximab Procedure Exclude NDC:* assessed Procedure Table for presence of Q5102, and excluded patients who ever had Inflectra or Renflexis in the Dispensing Table

(2) *Infliximab Procedure:* assessed Procedure Table for presence of Q5102 with no exclusions

(3) *Infliximab Biosimilar All:* assessed Procedure Table for presence of all procedure and NDC codes in both the Procedure Table and Dispensing Table, no exclusions

Limitations: Algorithms to define exposures and outcomes are imperfect and, therefore, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind

Please see Appendix D for the specifications of parameters to be used in the analyses for this request.

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

[1]This request was re-distributed to one data partner to get updated data on March 29, 2019; the request package was not changed in this second distribution.

Table of Contents

List of Terms Found in this Report and their Definitions

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

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

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 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

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

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”

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

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

Evaluation Period - number of days relative to index wherein a member is required to have evidence of a condition

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

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

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

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

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
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 before exposure episode that 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: Number of Patients by Biologic and Biosimilar Group[1] in the in the Sentinel Distributed Database (SDD) between January 1, 2015 and August 31, 2018

Exposures	Patients
Neupogen Dispensing	17,170
Neupogen Procedure	81,056
Neupogen All	105,533
Granix Dispensing	1,205
Granix Procedure	28,160
Granix All	30,033
Zarxio Dispensing	9,031
Zarxio Procedure	31,398
Zarxio All	41,697
Nivestym Dispensing	-
Nivestym Procedure	-
Nivestym All	-
Neulasta Dispensing	7,566
Neulasta Procedure	285,618
Neulasta All	298,382
Fulphila Dispensing	-
Fulphila Procedure	-
Fulphila All	-
Remicade Dispensing	2,640
Remicade Procedure	126,884
Remicade All	135,321
Inflectra Dispensing	87
Inflectra Procedure	189
Inflectra All	1,116
Renflexis Dispensing	*****
Renflexis Procedure	*****
Renflexis All	54
Infliximab Procedure Exclude NDC	4,798
Infliximab Procedure	5,113
Infliximab Biosimilar All	5,479

[1] "All" categories will add up to more than the "Dispensing" plus "Procedure" categories because they include patients who have a history of the exposure in both the procedure and dispensing tables.

Table 2: Descriptive Statistics of the Length of the First Gap between Treatment Episodes, in days, in the Sentinel Distributed Database (SDD) between January 1, 2015 and August 31, 2018

Exposures	Total Gaps[1]	Mean	Standard Deviation	Minimum	Quartile 1	Median	Quartile 3	Maximum
Neupogen Dispensing	9,218	35.95	60.64	0	14.00	22.00	34.00	1,227
Neupogen Procedure	59,931	15.11	53.89	0	0.00	0.00	10.00	1,224
Neupogen All	75,886	19.27	59.12	0	0.00	2.00	20.00	1,227
Granix Dispensing	528	32.00	40.92	0	15.00	22.00	34.00	404
Granix Procedure	18,046	19.22	58.57	0	0.00	1.00	20.00	1,002
Granix All	19,222	19.75	58.46	0	0.00	2.00	20.00	1,121
Zarxio Dispensing	6,441	26.48	32.74	0	14.00	20.00	27.00	749
Zarxio Procedure	24,001	10.86	35.42	0	0.00	0.00	6.00	760
Zarxio All	31,679	14.38	35.84	0	0.00	2.00	20.00	760
Nivestym Dispensing	0	-	-	-	-	-	-	-
Nivestym Procedure	0	-	-	-	-	-	-	-
Nivestym All	0	-	-	-	-	-	-	-
Neulasta Dispensing	5,769	27.40	32.10	0	18.00	22.00	28.00	891
Neulasta Procedure	229,712	28.01	44.62	0	19.00	20.00	27.00	1,224
Neulasta All	240,879	27.99	44.71	0	19.00	20.00	27.00	1,224
Fulphila Dispensing	0	-	-	-	-	-	-	-
Fulphila Procedure	0	-	-	-	-	-	-	-
Fulphila All	0	-	-	-	-	-	-	-
Remicade Dispensing	2,245	47.01	36.08	0	27.00	42.00	55.00	508
Remicade Procedure	117,398	44.18	42.80	0	16.00	42.00	55.00	1,203
Remicade All	125,253	44.36	43.26	0	17.00	42.00	55.00	1,203
Inflectra Dispensing	57	41.81	25.98	1	27.00	45.00	55.00	188
Inflectra Procedure	91	27.78	19.21	10	13.00	14.00	48.00	83
Inflectra All	812	44.30	30.73	1	27.00	45.00	55.00	378
Renflexis Dispensing	0	-	-	-	-	-	-	-
Renflexis Procedure	*****	18.60	10.31	8	13.00	13.00	27.00	32
Renflexis All	*****	18.60	10.31	8	13.00	13.00	27.00	32

Table 2: Descriptive Statistics of the Length of the First Gap between Treatment Episodes, in days, in the Sentinel Distributed Database (SDD) between January 1, 2015 and August 31, 2018

Exposures	Total Gaps[1]	Mean	Standard Deviation	Minimum	Quartile 1	Median	Quartile 3	Maximum
Infliximab Procedure Exclude NDC	3,568	46.24	28.37	0	29.00	48.00	55.00	622
Infliximab Procedure	3,774	46.12	27.84	0	30.00	48.00	55.00	622
Infliximab Biosimilar All	4,129	45.81	28.90	0	27.00	48.00	55.00	622

[1]Includes only the first gap; patients with only one index date are not included. This represents the number of patients with two or more episodes.

Table 3: Descriptive Statistics of the Length of All Gaps between Treatment Episodes, in days, in the Sentinel Distributed Database (SDD) between January 1, 2015 and August 31, 2018

Exposures	Total Gaps[1]	Mean	Standard Deviation	Minimum	Quartile 1	Median	Quartile 3	Maximum
Neupogen Dispensing	36,949	32.67	47.25	0	15.00	23.00	33.00	1,227
Neupogen Procedure	509,450	10.73	38.98	0	0.00	2.00	8.00	1,224
Neupogen All	608,378	13.01	42.02	0	0.00	3.00	13.00	1,227
Granix Dispensing	1,556	29.83	36.82	0	14.00	22.00	32.00	555
Granix Procedure	140,777	11.17	38.91	0	0.00	1.00	10.00	1,048
Granix All	147,669	11.58	39.35	0	0.00	1.00	11.00	1,121
Zarxio Dispensing	22,519	25.29	30.28	0	13.00	20.00	27.00	749
Zarxio Procedure	206,603	8.33	26.80	0	0.00	1.00	6.00	825
Zarxio All	241,958	10.11	27.91	0	0.00	2.00	12.00	825
Nivestym Dispensing	0	-	-	-	-	-	-	-
Nivestym Procedure	0	-	-	-	-	-	-	-
Nivestym All	0	-	-	-	-	-	-	-
Neulasta Dispensing	19,609	27.55	34.99	0	18.00	21.00	27.00	1,059
Neulasta Procedure	915,823	29.24	49.69	0	19.00	20.00	27.00	1,224
Neulasta All	966,890	29.31	49.94	0	19.00	20.00	27.00	1,224
Fulphila Dispensing	0	-	-	-	-	-	-	-
Fulphila Procedure	0	-	-	-	-	-	-	-
Fulphila All	0	-	-	-	-	-	-	-
Remicade Dispensing	16,806	50.02	30.67	0	37.00	48.00	56.00	893
Remicade Procedure	1,302,459	50.20	28.74	0	41.00	51.00	55.00	1,203
Remicade All	1,401,359	49.83	29.28	0	41.00	50.00	55.00	1,203
Inflectra Dispensing	141	43.02	21.85	1	28.00	41.00	55.00	188
Inflectra Procedure	145	31.34	18.08	10	13.00	27.00	48.00	83
Inflectra All	2,814	45.85	23.24	0	34.00	47.00	55.00	378
Renflexis Dispensing	0	-	-	-	-	-	-	-
Renflexis Procedure	*****	18.60	10.31	8	13.00	13.00	27.00	32
Renflexis All	*****	18.60	10.31	8	13.00	13.00	27.00	32

Table 3: Descriptive Statistics of the Length of All Gaps between Treatment Episodes, in days, in the Sentinel Distributed Database (SDD) between January 1, 2015 and August 31, 2018

Exposures	Total Gaps[1]	Mean	Standard Deviation	Minimum	Quartile 1	Median	Quartile 3	Maximum
Infliximab Procedure Exclude NDC[2]	11,673	47.74	21.39	0	39.00	48.00	55.00	622
Infliximab Procedure[2]	11,932	47.62	21.30	0	39.00	48.00	55.00	622
Infliximab Biosimilar All[2]	14,452	47.42	21.69	0	38.00	48.00	55.00	622

[1]Includes all gaps; patients with only one index date and the final 'gap' (time to censor) are not included.

[2]Groups are similar due to the high proportion of patients with only the Procedure code and no history of an NDC in the Dispensing table for Inflectra or Renflexis. Please see the Overview details on these groups.

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (March 15, 2019)

DP ID	Start Date[1]	End Date[1]
DP01	1/1/2008	6/30/2018
DP02	1/1/2012	6/30/2017
DP03	1/1/2010	3/31/2018
DP04	1/1/2006	5/31/2018
DP05	1/1/2004	8/31/2018
DP06	1/1/2000	6/30/2018
DP07	1/1/2000	3/31/2018
DP08	1/1/2000	4/30/2018
DP09	1/1/2000	3/31/2016
DP10	6/1/2007	4/30/2018
DP11	1/1/2000	7/31/2017
DP12	1/1/2000	3/31/2018
DP13	1/1/2005	9/30/2017
DP14	1/1/2000	12/31/2017
DP15	1/1/2000	6/30/2018
DP16	1/1/2008	9/30/2017
DP17	1/1/2000	12/31/2017

[1]The 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 Non-Proprietary and Brand Drug Names Used to Define Exposures in this Request

Non-Proprietary Name	Brand Name
Filgrastim	
filgrastim	Neupogen
tbo-filgrastim	Granix
filgrastim-sndz	Zarxio
filgrastim-aafi	Nivestym
Pegfilgrastim	
pegfilgrastim	Neulasta
pegfilgrastim-jmdb	Fulphila
Infliximab	
infliximab	Remicade
infliximab-dyyb	Inflectra
infliximab-abda	Renflexis

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

Code	Description	Code Category	Code Type
	Filgrastim: Neupogen		
J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram	Procedure	HCPCS
	Filgrastim: Granix		
J1446	Injection, tbo-filgrastim, 5 mcg	Procedure	HCPCS
J1447	Injection, tbo-filgrastim, 1 mcg	Procedure	HCPCS
	Filgrastim: Zarxio		
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	Procedure	HCPCS
	Filgrastim: Nivestym		
Q5110	Injection, filgrastim-aafi, biosimilar, 1 mcg	Procedure	HCPCS
	Pegfilgrastim: Neulasta		
J2505	Injection, pegfilgrastim, 6 mg	Procedure	HCPCS
	Pegfilgrastim: Fulphila		
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, 0.5 mg	Procedure	HCPCS
	Infliximab: Remicade		
J1745	Injection, infliximab, excludes biosimilar, 10 mg	Procedure	HCPCS
	Infliximab: Inflectra/Renflexis		
Q5102	Injection, infliximab, biosimilar, 10 mg	Procedure	HCPCS
	Infliximab: Inflectra		
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	Procedure	HCPCS
	Infliximab: Renflexis		
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	Procedure	HCPCS

Appendix D: Specifications Defining Parameters in this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool to examine the use of biologics and their biosimilars among all patients, examining gaps between episodes in the Sentinel Distributed Database (SDD).

Query Period: 1/1/2015 - most recent
Coverage Requirement: Medical and Drug
Enrollment Gap: 45 days
Age Stratifications: All ages to be included

	Exposure							Inclusion/Exclusion				
Scenario	Exposure	Episode Gap (Days)	Cohort Definition	Exposure Episode Length	Censor due to Data Partner data end date	Censor due to Query End	Censor due to Evidence of Death	Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/ Principal Diagnosis
1	Neupogen_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Neupogen_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
2	Neupogen_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Neupogen_Disp_NDCs	Exclude	Ever	Ever	Any
3	Neupogen	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
4	Zarxio_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Zarxio_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
5	Zarxio_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Zarxio_Disp_NDCs	Exclude	Ever	Ever	Any

Appendix D: Specifications Defining Parameters in this Request

	Exposure							Inclusion/Exclusion				
Scenario	Exposure	Episode Gap (Days)	Cohort Definition	Exposure Episode Length	Censor due to Data Partner data end date	Censor due to Query End	Censor due to Evidence of Death	Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/ Principal Diagnosis
6	Zarxio	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
7	Granix_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Granix_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
8	Granix_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Granix_Disp_NDCs	Exclude	Ever	Ever	Any
9	Granix	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
10	Nivestym_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Nivestym_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
11	Nivestym_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Nivestym_Disp_NDCs	Exclude	Ever	Ever	Any
12	Nivestym	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A

Appendix D: Specifications Defining Parameters in this Request

	Exposure							Inclusion/Exclusion				
Scenario	Exposure	Episode Gap (Days)	Cohort Definition	Exposure Episode Length	Censor due to Data Partner data end date	Censor due to Query End	Censor due to Evidence of Death	Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/ Principal Diagnosis
13	Neulasta_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Neulasta_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
14	Neulasta_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Neulasta_Disp_NDCs	Exclude	Ever	Ever	Any
15	Neulasta	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
16	Fulphila_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Fulphila_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
17	Fulphila_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Fulphila_Disp_NDCs	Exclude	Ever	Ever	Any
18	Fulphila	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
19	Remicade_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Remicade_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any

Appendix D: Specifications Defining Parameters in this Request

	Exposure							Inclusion/Exclusion				
Scenario	Exposure	Episode Gap (Days)	Cohort Definition	Exposure Episode Length	Censor due to Data Partner data end date	Censor due to Query End	Censor due to Evidence of Death	Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/ Principal Diagnosis
20	Remicade_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Remicade_Disp_NDCs	Exclude	Ever	Ever	Any
21	Remicade	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
22	Infliximab_Proc_Q5102_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Inflectra_Disp_NDCs	Exclude	Ever	Ever	Any
								Renflexis_Disp_NDCs	Exclude	Ever	Ever	Any
23	Infliximab_Proc_Q5102_NDCs_noexcl	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
24	Inflectra_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Infliximab_Proc_Q5102_NDCs Inflectra_Proc_HCPCS_NDCs	Exclude	Ever	Ever	Any
25	Inflectra_Proc_HCPCS_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Inflectra_Disp_NDCs Infliximab_Proc_Q5102_NDCs	Exclude	Ever	Ever	Any

Appendix D: Specifications Defining Parameters in this Request

	Exposure							Inclusion/Exclusion				
Scenario	Exposure	Episode Gap (Days)	Cohort Definition	Exposure Episode Length	Censor due to Data Partner data end date	Censor due to Query End	Censor due to Evidence of Death	Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/ Principal Diagnosis
26	Inflectra	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
27	Renflexis_Disp_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Renflexis_Proc_HCPCs_NDCs Infliximab_Proc_Q5102_NDCs	Exclude	Ever	Ever	Any
28	Renflexis_Proc_HCPCs_NDCs	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	Renflexis_Disp_NDCs Infliximab_Proc_Q5102_NDCs	Exclude	Ever	Ever	Any
29	Renflexis	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A
30	Infliximab_Biosimilar	0	Include all valid episodes during the query period	1	Yes	Yes	Yes	None	N/A	N/A	N/A	N/A

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360.

National Drug Codes (NDC) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus".