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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 Query Builder analysis.

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Overview

Query Builder Report: This report details the results of an analysis generated by the Sentinel Query Builder application. Query Builder enables FDA to visualize, draft, and create standardized medical product utilization queries examining dispensing patterns and cohort characteristics using a set of pre-defined parameters. This is a Type 5 (Medical Product Utilization) analysis as described in the Query Request Package (QRP) documentation.

Request Description: In this request, we investigated utilization patterns of drugs with approved REMS (Risk Evaluation and Mitigation Strategies) that employ ETASU (Elements to Assure Safe Use). This is report 1 of 2. Products assessed in this report include: collagenase clostridium histolyticum, isotretinoin, mycophenolate, lenalidomide, mifepristone, clozapine, phentermine/topiramate, eculizumab, natalizumab, and pomalidomide. Report 2 assessed 10 additional products.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 10.1.1

Data Source: We executed this request on IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 144 million members on May 5, 2021. The study period included data from January 1, 2010 to September 30, 2019. Please see Appendix A for data availability dates.

Limitations: Algorithms used to define exposures and inclusion and exclusion criteria are imperfect; thus it is possible that there may be misclassification. Therefore, data should be interpreted with these limitations in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel Query Builder, please refer to the documentation (<https://dev.sentinelssystem.org/projects/QB/repos/querybuilder/browse>).

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Table 1a: Baseline table (Collagenase clostridium histolyticum)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	108,363	
Demographics		
Mean Age (Years)	66.9	17.5
Age (Years): 00-01	74	0.1%
Age (Years): 02-04	91	0.1%
Age (Years): 05-09	158	0.1%
Age (Years): 10-14	337	0.3%
Age (Years): 15-18	575	0.5%
Age (Years): 19-21	530	0.5%
Age (Years): 22-44	8,359	7.7%
Age (Years): 45-64	42,894	39.6%
Age (Years): 65-74	16,539	15.3%
Age (Years): 75+	38,806	35.8%
Sex (Female)	52,432	48.4%
Sex (Male)	55,931	51.6%
Year (2010)	7,170	6.6%
Year (2011)	16,346	15.1%
Year (2012)	16,961	15.7%
Year (2013)	14,125	13.0%
Year (2014)	13,327	12.3%
Year (2015)	10,666	9.8%
Year (2016)	10,185	9.4%
Year (2017)	8,367	7.7%
Year (2018)	6,551	6.0%
Year (2019)	4,665	4.3%
Recorded history of:		
Prior combined comorbidity score ³	2.6	3.1
Acquired Hypothyroidism	13,825	12.8%
Acute Myocardial Infarction	3,002	2.8%
Alzheimer's Disease	5,346	4.9%
Alzheimer's Disease, Related Disorders, or Senile Dementia	15,043	13.9%
Anemia	29,504	27.2%
Asthma	6,460	6.0%
Atrial Fibrillation	17,929	16.5%
Benign Prostatic Hyperplasia	6,881	6.3%
Breast Cancer	3,112	2.9%
Cataracts	11,648	10.7%
Chronic Kidney Disease	29,682	27.4%
Chronic Obstructive Pulmonary Disease	16,995	15.7%
Colorectal Cancer	1,558	1.4%
Depression	15,341	14.2%
Diabetes	43,834	40.5%
Endometrial Cancer	320	0.3%
Glaucoma	7,407	6.8%
Heart Failure	20,995	19.4%
Hip / Pelvic Fracture	4,238	3.9%
Hyperlipidemia	39,910	36.8%
Hypertension	65,725	60.7%
Ischemic Heart Disease	27,008	24.9%
Lung Cancer	1,258	1.2%
Osteoporosis	5,329	4.9%

Table 1a: Baseline table (Collagenase clostridium histolyticum)		
Characteristic¹	N/Mean	%/Std Dev²
Prostate Cancer	2,520	2.3%
Rheumatoid Arthritis / Osteoarthritis	29,759	27.5%
Stroke / Transient Ischemic Attack	9,467	8.7%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	14.4	15.5
Mean number of emergency room encounters (ED)	0.8	1.5
Mean number of inpatient hospital encounters (IP)	0.6	1.0
Mean number of non-acute institutional encounters (IS)	0.0	0.1
Mean number of other ambulatory encounters (OA)	10.7	16.7
Mean number of filled prescriptions	26.5	21.3
Mean number of generics	11.6	6.4
Mean number of unique drug classes	10.6	5.7
¹ All metrics based on total number of unique patients ² Value represents standard deviation where no % follows the value ³ 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. <i>J Clin Epidemiol.</i> 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. <i>Med Care.</i> 2017;55(12):1046-1051).		

Table 1b: Baseline table (Clozapine)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	3,561	
Demographics		
Mean Age (Years)	38.6	19.4
Age (Years): 00-01	-	-
Age (Years): 02-04	-	-
Age (Years): 05-09	8	0.2%
Age (Years): 10-14	89	2.5%
Age (Years): 15-18	325	9.1%
Age (Years): 19-21	428	12.0%
Age (Years): 22-44	1,428	40.1%
Age (Years): 45-64	879	24.7%
Age (Years): 65-74	212	6.0%
Age (Years): 75+	192	5.4%
Sex (Female)	1,523	42.8%
Sex (Male)	2,038	57.2%
Year (2010)	230	6.5%
Year (2011)	535	15.0%
Year (2012)	548	15.4%
Year (2013)	440	12.4%
Year (2014)	405	11.4%
Year (2015)	313	8.8%
Year (2016)	315	8.8%
Year (2017)	281	7.9%
Year (2018)	292	8.2%
Year (2019)	202	5.7%
Recorded history of:		
Prior combined comorbidity score ³	1.6	1.5
Acquired Hypothyroidism	476	13.4%
Acute Myocardial Infarction	5	0.1%
Alzheimer's Disease	83	2.3%
Alzheimer's Disease, Related Disorders, or Senile Dementia	346	9.7%
Anemia	325	9.1%
Asthma	273	7.7%
Atrial Fibrillation	65	1.8%
Benign Prostatic Hyperplasia	88	2.5%
Breast Cancer	17	0.5%
Cataracts	123	3.5%
Chronic Kidney Disease	236	6.6%
Chronic Obstructive Pulmonary Disease	165	4.6%
Colorectal Cancer	7	0.2%
Depression	1,779	50.0%
Diabetes	431	12.1%
Endometrial Cancer	1	0.0%
Glaucoma	79	2.2%
Heart Failure	66	1.9%
Hip / Pelvic Fracture	12	0.3%
Hyperlipidemia	760	21.3%
Hypertension	886	24.9%
Ischemic Heart Disease	137	3.8%
Lung Cancer	7	0.2%
Osteoporosis	41	1.2%

Table 1b: Baseline table (Clozapine)		
Characteristic¹	N/Mean	%/Std Dev²
Prostate Cancer	19	0.5%
Rheumatoid Arthritis / Osteoarthritis	285	8.0%
Stroke / Transient Ischemic Attack	81	2.3%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	14.0	14.1
Mean number of emergency room encounters (ED)	1.1	2.1
Mean number of inpatient hospital encounters (IP)	1.0	1.3
Mean number of non-acute institutional encounters (IS)	0.0	0.3
Mean number of other ambulatory encounters (OA)	6.1	12.4
Mean number of filled prescriptions	23.9	19.2
Mean number of generics	9.4	5.7
Mean number of unique drug classes	8.6	5.1
¹ All metrics based on total number of unique patients ² Value represents standard deviation where no % follows the value ³ 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. <i>J Clin Epidemiol.</i> 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. <i>Med Care.</i> 2017;55(12):1046-1051).		

Table 1c: Baseline table (Eculizumab)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	631	
Demographics		
Mean Age (Years)	41.9	19.2
Age (Years): 00-01	1	0.2%
Age (Years): 02-04	10	1.6%
Age (Years): 05-09	15	2.4%
Age (Years): 10-14	25	4.0%
Age (Years): 15-18	35	5.5%
Age (Years): 19-21	36	5.7%
Age (Years): 22-44	216	34.2%
Age (Years): 45-64	232	36.8%
Age (Years): 65-74	44	7.0%
Age (Years): 75+	17	2.7%
Sex (Female)	376	59.6%
Sex (Male)	255	40.4%
Year (2010)	19	3.0%
Year (2011)	42	6.7%
Year (2012)	71	11.3%
Year (2013)	56	8.9%
Year (2014)	61	9.7%
Year (2015)	55	8.7%
Year (2016)	80	12.7%
Year (2017)	53	8.4%
Year (2018)	120	19.0%
Year (2019)	74	11.7%
Recorded history of:		
Prior combined comorbidity score ³	3.3	3.0
Acquired Hypothyroidism	76	12.0%
Acute Myocardial Infarction	15	2.4%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	3	0.5%
Anemia	494	78.3%
Asthma	48	7.6%
Atrial Fibrillation	31	4.9%
Benign Prostatic Hyperplasia	19	3.0%
Breast Cancer	10	1.6%
Cataracts	34	5.4%
Chronic Kidney Disease	330	52.3%
Chronic Obstructive Pulmonary Disease	39	6.2%
Colorectal Cancer	8	1.3%
Depression	75	11.9%
Diabetes	94	14.9%
Endometrial Cancer	1	0.2%
Glaucoma	23	3.6%
Heart Failure	67	10.6%
Hip / Pelvic Fracture	1	0.2%
Hyperlipidemia	136	21.6%
Hypertension	329	52.1%
Ischemic Heart Disease	70	11.1%
Lung Cancer	3	0.5%
Osteoporosis	12	1.9%

Table 1c: Baseline table (Eculizumab)		
Characteristic¹	N/Mean	%/Std Dev²
Prostate Cancer	5	0.8%
Rheumatoid Arthritis / Osteoarthritis	90	14.3%
Stroke / Transient Ischemic Attack	36	5.7%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	21.7	21.5
Mean number of emergency room encounters (ED)	0.8	1.4
Mean number of inpatient hospital encounters (IP)	1.1	1.4
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	7.0	13.7
Mean number of filled prescriptions	19.0	17.8
Mean number of generics	9.3	7.2
Mean number of unique drug classes	8.5	6.5
¹ All metrics based on total number of unique patients ² Value represents standard deviation where no % follows the value ³ 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. <i>J Clin Epidemiol.</i> 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. <i>Med Care.</i> 2017;55(12):1046-1051).		

Table 1d: Baseline table (Isotretinoin)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	267,161	
Demographics		
Mean Age (Years)	21.9	9.5
Age (Years): 00-01	18	0.0%
Age (Years): 02-04	104	0.0%
Age (Years): 05-09	104	0.0%
Age (Years): 10-14	31,841	11.9%
Age (Years): 15-18	119,409	44.7%
Age (Years): 19-21	35,769	13.4%
Age (Years): 22-44	68,512	25.6%
Age (Years): 45-64	10,960	4.1%
Age (Years): 65-74	366	0.1%
Age (Years): 75+	78	0.0%
Sex (Female)	127,202	47.6%
Sex (Male)	139,959	52.4%
Year (2010)	14,952	5.6%
Year (2011)	29,323	11.0%
Year (2012)	34,627	13.0%
Year (2013)	29,462	11.0%
Year (2014)	29,787	11.1%
Year (2015)	25,578	9.6%
Year (2016)	28,011	10.5%
Year (2017)	27,149	10.2%
Year (2018)	27,604	10.3%
Year (2019)	20,668	7.7%
Recorded history of:		
Prior combined comorbidity score ³	0.1	0.5
Acquired Hypothyroidism	4,297	1.6%
Acute Myocardial Infarction	19	0.0%
Alzheimer's Disease	3	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	71	0.0%
Anemia	4,171	1.6%
Asthma	8,474	3.2%
Atrial Fibrillation	153	0.1%
Benign Prostatic Hyperplasia	370	0.1%
Breast Cancer	264	0.1%
Cataracts	610	0.2%
Chronic Kidney Disease	1,429	0.5%
Chronic Obstructive Pulmonary Disease	1,767	0.7%
Colorectal Cancer	63	0.0%
Depression	14,378	5.4%
Diabetes	2,499	0.9%
Endometrial Cancer	10	0.0%
Glaucoma	1,085	0.4%
Heart Failure	118	0.0%
Hip / Pelvic Fracture	186	0.1%
Hyperlipidemia	7,966	3.0%
Hypertension	5,314	2.0%
Ischemic Heart Disease	426	0.2%
Lung Cancer	26	0.0%
Osteoporosis	243	0.1%

Table 1d: Baseline table (Isotretinoin)		
Characteristic¹	N/Mean	%/Std Dev²
Prostate Cancer	75	0.0%
Rheumatoid Arthritis / Osteoarthritis	3,053	1.1%
Stroke / Transient Ischemic Attack	181	0.1%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	6.0	6.0
Mean number of emergency room encounters (ED)	0.1	0.4
Mean number of inpatient hospital encounters (IP)	0.0	0.2
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	1.0	1.9
Mean number of filled prescriptions	7.4	6.7
Mean number of generics	4.5	2.9
Mean number of unique drug classes	4.2	2.6
¹ All metrics based on total number of unique patients ² Value represents standard deviation where no % follows the value ³ 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. <i>J Clin Epidemiol.</i> 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. <i>Med Care.</i> 2017;55(12):1046-1051).		

Table 1e: Baseline table (Lenalidomide)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	15,721	
Demographics		
Mean Age (Years)	65.2	11.9
Age (Years): 00-01	-	-
Age (Years): 02-04	-	-
Age (Years): 05-09	3	0.0%
Age (Years): 10-14	8	0.1%
Age (Years): 15-18	9	0.1%
Age (Years): 19-21	3	0.0%
Age (Years): 22-44	613	3.9%
Age (Years): 45-64	8,047	51.2%
Age (Years): 65-74	3,464	22.0%
Age (Years): 75+	3,574	22.7%
Sex (Female)	6,852	43.6%
Sex (Male)	8,869	56.4%
Year (2010)	1,201	7.6%
Year (2011)	2,407	15.3%
Year (2012)	2,340	14.9%
Year (2013)	1,960	12.5%
Year (2014)	1,734	11.0%
Year (2015)	1,380	8.8%
Year (2016)	1,557	9.9%
Year (2017)	1,272	8.1%
Year (2018)	1,040	6.6%
Year (2019)	830	5.3%
Recorded history of:		
Prior combined comorbidity score ³	3.8	3.1
Acquired Hypothyroidism	1,822	11.6%
Acute Myocardial Infarction	196	1.2%
Alzheimer's Disease	48	0.3%
Alzheimer's Disease, Related Disorders, or Senile Dementia	237	1.5%
Anemia	9,284	59.1%
Asthma	924	5.9%
Atrial Fibrillation	1,419	9.0%
Benign Prostatic Hyperplasia	1,201	7.6%
Breast Cancer	518	3.3%
Cataracts	1,796	11.4%
Chronic Kidney Disease	4,619	29.4%
Chronic Obstructive Pulmonary Disease	1,710	10.9%
Colorectal Cancer	206	1.3%
Depression	1,388	8.8%
Diabetes	3,377	21.5%
Endometrial Cancer	37	0.2%
Glaucoma	1,119	7.1%
Heart Failure	1,542	9.8%
Hip / Pelvic Fracture	449	2.9%
Hyperlipidemia	5,353	34.0%
Hypertension	8,476	53.9%
Ischemic Heart Disease	2,406	15.3%
Lung Cancer	226	1.4%
Osteoporosis	1,098	7.0%

Table 1e: Baseline table (Lenalidomide)

Characteristic ¹	N/Mean	%/Std Dev ²
Prostate Cancer	685	4.4%
Rheumatoid Arthritis / Osteoarthritis	4,422	28.1%
Stroke / Transient Ischemic Attack	406	2.6%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	23.1	15.1
Mean number of emergency room encounters (ED)	0.6	1.5
Mean number of inpatient hospital encounters (IP)	0.6	1.0
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	5.2	8.0
Mean number of filled prescriptions	22.2	14.8
Mean number of generics	11.4	5.7
Mean number of unique drug classes	10.4	5.0

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³The 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).

Table 1f: Baseline table (Mifepristone)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	28,075	
Demographics		
Mean Age (Years)	29.2	7.2
Age (Years): 00-01	-	-
Age (Years): 02-04	2	0.0%
Age (Years): 05-09	-	-
Age (Years): 10-14	43	0.2%
Age (Years): 15-18	1,237	4.4%
Age (Years): 19-21	3,287	11.7%
Age (Years): 22-44	23,125	82.4%
Age (Years): 45-64	354	1.3%
Age (Years): 65-74	23	0.1%
Age (Years): 75+	4	0.0%
Sex (Female)	27,980	99.7%
Sex (Male)	95	0.3%
Year (2010)	1,558	5.5%
Year (2011)	3,121	11.1%
Year (2012)	3,420	12.2%
Year (2013)	3,106	11.1%
Year (2014)	3,239	11.5%
Year (2015)	2,597	9.3%
Year (2016)	2,791	9.9%
Year (2017)	2,810	10.0%
Year (2018)	3,018	10.7%
Year (2019)	2,415	8.6%
Recorded history of:		
Prior combined comorbidity score ³	0.2	0.6
Acquired Hypothyroidism	838	3.0%
Acute Myocardial Infarction	5	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	7	0.0%
Anemia	1,048	3.7%
Asthma	938	3.3%
Atrial Fibrillation	21	0.1%
Benign Prostatic Hyperplasia	4	0.0%
Breast Cancer	50	0.2%
Cataracts	46	0.2%
Chronic Kidney Disease	248	0.9%
Chronic Obstructive Pulmonary Disease	270	1.0%
Colorectal Cancer	4	0.0%
Depression	2,322	8.3%
Diabetes	508	1.8%
Endometrial Cancer	3	0.0%
Glaucoma	140	0.5%
Heart Failure	26	0.1%
Hip / Pelvic Fracture	5	0.0%
Hyperlipidemia	776	2.8%
Hypertension	791	2.8%
Ischemic Heart Disease	68	0.2%
Lung Cancer	3	0.0%
Osteoporosis	33	0.1%

Table 1f: Baseline table (Mifepristone)

Characteristic ¹	N/Mean	%/Std Dev ²
Prostate Cancer	4	0.0%
Rheumatoid Arthritis / Osteoarthritis	333	1.2%
Stroke / Transient Ischemic Attack	30	0.1%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	5.2	5.9
Mean number of emergency room encounters (ED)	0.3	0.7
Mean number of inpatient hospital encounters (IP)	0.0	0.2
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	1.0	1.9
Mean number of filled prescriptions	5.1	6.6
Mean number of generics	3.3	3.2
Mean number of unique drug classes	3.2	2.9

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³The 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).

Table 1g: Baseline table (Mycophenolate)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	65,711	
Demographics		
Mean Age (Years)	49.4	16.2
Age (Years): 00-01	143	0.2%
Age (Years): 02-04	281	0.4%
Age (Years): 05-09	638	1.0%
Age (Years): 10-14	1,111	1.7%
Age (Years): 15-18	1,507	2.3%
Age (Years): 19-21	1,238	1.9%
Age (Years): 22-44	17,309	26.3%
Age (Years): 45-64	35,141	53.5%
Age (Years): 65-74	6,087	9.3%
Age (Years): 75+	2,256	3.4%
Sex (Female)	36,292	55.2%
Sex (Male)	29,419	44.8%
Year (2010)	4,910	7.5%
Year (2011)	9,265	14.1%
Year (2012)	9,526	14.5%
Year (2013)	7,449	11.3%
Year (2014)	7,397	11.3%
Year (2015)	5,661	8.6%
Year (2016)	6,033	9.2%
Year (2017)	5,703	8.7%
Year (2018)	5,541	8.4%
Year (2019)	4,226	6.4%
Recorded history of:		
Prior combined comorbidity score ³	2.5	2.7
Acquired Hypothyroidism	7,473	11.4%
Acute Myocardial Infarction	881	1.3%
Alzheimer's Disease	59	0.1%
Alzheimer's Disease, Related Disorders, or Senile Dementia	509	0.8%
Anemia	25,557	38.9%
Asthma	4,841	7.4%
Atrial Fibrillation	3,948	6.0%
Benign Prostatic Hyperplasia	1,880	2.9%
Breast Cancer	774	1.2%
Cataracts	5,161	7.9%
Chronic Kidney Disease	30,047	45.7%
Chronic Obstructive Pulmonary Disease	6,490	9.9%
Colorectal Cancer	278	0.4%
Depression	7,028	10.7%
Diabetes	16,389	24.9%
Endometrial Cancer	77	0.1%
Glaucoma	3,340	5.1%
Heart Failure	6,680	10.2%
Hip / Pelvic Fracture	194	0.3%
Hyperlipidemia	19,139	29.1%
Hypertension	35,388	53.9%
Ischemic Heart Disease	8,673	13.2%
Lung Cancer	305	0.5%
Osteoporosis	2,961	4.5%

Table 1g: Baseline table (Mycophenolate)

Characteristic ¹	N/Mean	%/Std Dev ²
Prostate Cancer	597	0.9%
Rheumatoid Arthritis / Osteoarthritis	10,712	16.3%
Stroke / Transient Ischemic Attack	2,118	3.2%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	21.6	26.6
Mean number of emergency room encounters (ED)	0.6	1.4
Mean number of inpatient hospital encounters (IP)	0.7	1.2
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	5.4	10.3
Mean number of filled prescriptions	23.9	16.8
Mean number of generics	11.5	6.4
Mean number of unique drug classes	10.6	5.7

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³The 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).

Table 1h: Baseline table (Natalizumab)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	8,326	
Demographics		
Mean Age (Years)	43.3	11.4
Age (Years): 00-01	-	-
Age (Years): 02-04	-	-
Age (Years): 05-09	5	0.1%
Age (Years): 10-14	5	0.1%
Age (Years): 15-18	80	1.0%
Age (Years): 19-21	130	1.6%
Age (Years): 22-44	4,390	52.7%
Age (Years): 45-64	3,575	42.9%
Age (Years): 65-74	122	1.5%
Age (Years): 75+	19	0.2%
Sex (Female)	6,250	75.1%
Sex (Male)	2,076	24.9%
Year (2010)	571	6.9%
Year (2011)	1,441	17.3%
Year (2012)	1,671	20.1%
Year (2013)	977	11.7%
Year (2014)	954	11.5%
Year (2015)	646	7.8%
Year (2016)	755	9.1%
Year (2017)	515	6.2%
Year (2018)	465	5.6%
Year (2019)	331	4.0%
Recorded history of:		
Prior combined comorbidity score ³	0.4	1.0
Acquired Hypothyroidism	610	7.3%
Acute Myocardial Infarction	9	0.1%
Alzheimer's Disease	7	0.1%
Alzheimer's Disease, Related Disorders, or Senile Dementia	63	0.8%
Anemia	742	8.9%
Asthma	340	4.1%
Atrial Fibrillation	53	0.6%
Benign Prostatic Hyperplasia	89	1.1%
Breast Cancer	50	0.6%
Cataracts	211	2.5%
Chronic Kidney Disease	187	2.2%
Chronic Obstructive Pulmonary Disease	188	2.3%
Colorectal Cancer	15	0.2%
Depression	1,495	18.0%
Diabetes	542	6.5%
Endometrial Cancer	6	0.1%
Glaucoma	250	3.0%
Heart Failure	46	0.6%
Hip / Pelvic Fracture	12	0.1%
Hyperlipidemia	1,105	13.3%
Hypertension	1,404	16.9%
Ischemic Heart Disease	149	1.8%
Lung Cancer	4	0.0%
Osteoporosis	152	1.8%

Table 1h: Baseline table (Natalizumab)		
Characteristic¹	N/Mean	%/Std Dev²
Prostate Cancer	17	0.2%
Rheumatoid Arthritis / Osteoarthritis	1,024	12.3%
Stroke / Transient Ischemic Attack	208	2.5%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	12.9	9.0
Mean number of emergency room encounters (ED)	0.4	0.9
Mean number of inpatient hospital encounters (IP)	0.2	0.5
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	2.7	5.2
Mean number of filled prescriptions	14.1	13.8
Mean number of generics	6.3	5.0
Mean number of unique drug classes	5.9	4.5
¹ All metrics based on total number of unique patients ² Value represents standard deviation where no % follows the value ³ 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. <i>J Clin Epidemiol.</i> 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. <i>Med Care.</i> 2017;55(12):1046-1051).		

Table 1i: Baseline table (Phentermine/topiramate)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	24,871	
Demographics		
Mean Age (Years)	46.8	10.7
Age (Years): 00-01	-	-
Age (Years): 02-04	-	-
Age (Years): 05-09	-	-
Age (Years): 10-14	4	0.0%
Age (Years): 15-18	69	0.3%
Age (Years): 19-21	189	0.8%
Age (Years): 22-44	10,365	41.7%
Age (Years): 45-64	13,609	54.7%
Age (Years): 65-74	585	2.4%
Age (Years): 75+	50	0.2%
Sex (Female)	20,262	81.5%
Sex (Male)	4,609	18.5%
Year (2010)	-	-
Year (2011)	-	-
Year (2012)	775	3.1%
Year (2013)	4,654	18.7%
Year (2014)	6,791	27.3%
Year (2015)	5,165	20.8%
Year (2016)	2,412	9.7%
Year (2017)	2,179	8.8%
Year (2018)	1,832	7.4%
Year (2019)	1,063	4.3%
Recorded history of:		
Prior combined comorbidity score ³	0.1	0.9
Acquired Hypothyroidism	4,902	19.7%
Acute Myocardial Infarction	11	0.0%
Alzheimer's Disease	2	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	13	0.1%
Anemia	1,918	7.7%
Asthma	1,538	6.2%
Atrial Fibrillation	111	0.4%
Benign Prostatic Hyperplasia	254	1.0%
Breast Cancer	324	1.3%
Cataracts	683	2.7%
Chronic Kidney Disease	906	3.6%
Chronic Obstructive Pulmonary Disease	724	2.9%
Colorectal Cancer	46	0.2%
Depression	3,375	13.6%
Diabetes	4,112	16.5%
Endometrial Cancer	38	0.2%
Glaucoma	549	2.2%
Heart Failure	110	0.4%
Hip / Pelvic Fracture	4	0.0%
Hyperlipidemia	8,040	32.3%
Hypertension	8,366	33.6%
Ischemic Heart Disease	525	2.1%
Lung Cancer	17	0.1%
Osteoporosis	216	0.9%

Table 1i: Baseline table (Phentermine/topiramate)

Characteristic ¹	N/Mean	%/Std Dev ²
Prostate Cancer	46	0.2%
Rheumatoid Arthritis / Osteoarthritis	3,283	13.2%
Stroke / Transient Ischemic Attack	102	0.4%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	8.3	8.0
Mean number of emergency room encounters (ED)	0.1	0.5
Mean number of inpatient hospital encounters (IP)	0.0	0.2
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	1.5	2.4
Mean number of filled prescriptions	14.5	12.3
Mean number of generics	7.3	4.6
Mean number of unique drug classes	6.9	4.2

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³The 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).

Table 1j: Baseline table (Pomalidomide)		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	2,582	
Demographics		
Mean Age (Years)	64.3	10.9
Age (Years): 00-01	-	-
Age (Years): 02-04	-	-
Age (Years): 05-09	-	-
Age (Years): 10-14	1	0.0%
Age (Years): 15-18	2	0.1%
Age (Years): 19-21	-	-
Age (Years): 22-44	84	3.3%
Age (Years): 45-64	1,441	55.8%
Age (Years): 65-74	586	22.7%
Age (Years): 75+	468	18.1%
Sex (Female)	1,100	42.6%
Sex (Male)	1,482	57.4%
Year (2010)	-	-
Year (2011)	-	-
Year (2012)	-	-
Year (2013)	543	21.0%
Year (2014)	450	17.4%
Year (2015)	319	12.4%
Year (2016)	351	13.6%
Year (2017)	328	12.7%
Year (2018)	325	12.6%
Year (2019)	266	10.3%
Recorded history of:		
Prior combined comorbidity score ³	4.4	3.4
Acquired Hypothyroidism	289	11.2%
Acute Myocardial Infarction	34	1.3%
Alzheimer's Disease	8	0.3%
Alzheimer's Disease, Related Disorders, or Senile Dementia	35	1.4%
Anemia	1,520	58.9%
Asthma	137	5.3%
Atrial Fibrillation	282	10.9%
Benign Prostatic Hyperplasia	152	5.9%
Breast Cancer	64	2.5%
Cataracts	389	15.1%
Chronic Kidney Disease	845	32.7%
Chronic Obstructive Pulmonary Disease	284	11.0%
Colorectal Cancer	23	0.9%
Depression	267	10.3%
Diabetes	529	20.5%
Endometrial Cancer	11	0.4%
Glaucoma	194	7.5%
Heart Failure	300	11.6%
Hip / Pelvic Fracture	74	2.9%
Hyperlipidemia	743	28.8%
Hypertension	1,267	49.1%
Ischemic Heart Disease	330	12.8%
Lung Cancer	30	1.2%
Osteoporosis	139	5.4%

Table 1j: Baseline table (Pomalidomide)

Characteristic ¹	N/Mean	%/Std Dev ²
Prostate Cancer	91	3.5%
Rheumatoid Arthritis / Osteoarthritis	560	21.7%
Stroke / Transient Ischemic Attack	64	2.5%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	30.6	18.2
Mean number of emergency room encounters (ED)	0.6	1.9
Mean number of inpatient hospital encounters (IP)	0.6	1.0
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	6.3	9.8
Mean number of filled prescriptions	29.3	16.1
Mean number of generics	12.8	5.9
Mean number of unique drug classes	11.4	5.1

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³The 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).

Table 2a: Descriptive statistics of cumulative exposure duration, all episodes, in days								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	108,363	28.59	35.44	1	10	20	30	1,340
Clozapine	3,561	434.26	556.49	1	54	199	603	3,358
Eculizumab	631	108.95	317.11	1	5	16	53	2,982
Isotretinoin	267,161	150.59	87.32	1	90	150	180	2,400
Lenalidomide	15,721	279.78	354.34	1	56	140	360	3,017
Mifepristone	28,075	3.43	38.56	1	1	1	1	2,385
Mycophenolate	65,711	382.03	492.27	1	60	180	509	3,357
Natalizumab	8,326	78.00	227.35	1	5	14	35	3,035
Phentermine/topiramate	24,871	149.09	198.04	1	30	76	180	2,432
Pomalidomide	2,582	207.49	254.69	1	56	112	252	2,160

Table 2b: Descriptive statistics of cumulative exposure duration, all episodes, in days, by sex								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	108,363	28.59	35.44	1	10	20	30	1,340
Female	52,432	28.24	35.45	1	10	20	30	1,340
Male	55,931	28.92	35.42	1	10	20	30	1,088
Clozapine	3,561	434.26	556.49	1	54	199	603	3,358
Female	1,523	427.81	562.55	1	54	178	599	3,358
Male	2,038	439.08	552.00	1	53	217	606	3,079
Eculizumab	631	108.95	317.11	1	5	16	53	2,982
Female	376	109.58	296.98	1	6	18	57	2,982
Male	255	108.02	345.26	1	4	13	49	2,784
Isotretinoin	267,161	150.59	87.32	1	90	150	180	2,400
Female	127,202	152.83	88.92	1	90	150	180	2,400
Male	139,959	148.55	85.79	1	90	150	180	2,253
Lenalidomide	15,721	279.78	354.34	1	56	140	360	3,017
Female	6,852	280.94	359.51	1	56	140	364	2,968
Male	8,869	278.88	350.30	1	56	140	357	3,017
Mifepristone	28,075	3.43	38.56	1	1	1	1	2,385
Female	27,980	2.83	34.63	1	1	1	1	2,385
Male	95	178.42	236.35	1	30	77	295	1,156
Mycophenolate	65,711	382.03	492.27	1	60	180	509	3,357
Female	36,292	364.23	469.95	1	60	180	480	3,357
Male	29,419	403.97	517.64	1	60	194	540	3,332
Natalizumab	8,326	78.00	227.35	1	5	14	35	3,035
Female	6,250	78.46	229.96	1	5	14	36	3,035
Male	2,076	76.61	219.38	1	5	13	34	2,248
Phentermine/topiramate	24,871	149.09	198.04	1	30	76	180	2,432
Female	20,262	144.93	192.87	1	30	74	171	2,432
Male	4,609	167.36	218.42	1	33	90	210	2,160
Pomalidomide	2,582	207.49	254.69	1	56	112	252	2,160
Female	1,100	216.06	273.55	1	56	112	266	2,160
Male	1,482	201.12	239.62	1	56	112	252	1,826

Table 2c: Descriptive statistics of cumulative exposure duration, all episodes, in days, by age group (years)								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	108,363	28.59	35.44	1	10	20	30	1,340
00-01	74	17.42	9.43	1	10	15	30	33
02-04	91	20.27	14.10	5	10	15	30	95
05-09	158	22.00	13.41	5	10	15	30	60
10-14	337	24.12	24.61	1	10	15	30	285
15-18	575	25.51	24.32	1	14	20	30	243
19-21	530	25.57	24.02	1	10	20	30	213
22-44	8,359	29.45	37.26	1	14	22	30	1,340
45-64	42,894	31.01	38.42	1	10	27	30	1,081
65-74	16,539	28.49	36.26	1	10	20	30	1,088
75+	38,806	25.96	31.28	1	10	15	30	1,154
Clozapine	3,561	434.26	556.49	1	54	199	603	3,358
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	8	1012.38	1245.92	12	29	344	2,236	2,870
10-14	89	678.62	753.94	5	150	332	915	3,049
15-18	325	590.06	618.85	1	134	372	846	3,079
19-21	428	419.32	517.77	3	63	205	574	2,771
22-44	1,428	424.60	551.70	1	55	200	564	3,358
45-64	879	403.13	539.44	1	36	155	582	3,301
65-74	212	388.00	486.07	1	30	178	517	2,115
75+	192	332.02	479.40	1	29	110	414	2,639
Ecuzumab	631	108.95	317.11	1	5	16	53	2,982
00-01	1	1.00	-	1	1	1	1	1
02-04	10	36.80	43.79	1	1	12	71	124
05-09	15	94.27	285.64	1	3	11	60	1,123
10-14	25	157.80	458.50	1	1	8	49	1,938
15-18	35	84.17	257.18	1	1	7	42	1,148
19-21	36	75.86	190.31	1	4	20	48	1,043
22-44	216	140.64	412.83	1	6	18	53	2,982
45-64	232	102.35	258.94	1	5	22	69	1,767
65-74	44	43.93	96.53	1	7	13	39	602
75+	17	75.53	173.03	1	4	9	70	714
Isotretinoin	267,161	150.59	87.32	1	90	150	180	2,400
00-01	18	76.39	42.97	15	40	89	100	168
02-04	104	139.40	117.65	7	81	120	180	1,020
05-09	104	138.83	148.70	4	51	105	180	1,295
10-14	31,841	169.79	99.84	1	120	150	210	2,253

Table 2c: Descriptive statistics of cumulative exposure duration, all episodes, in days, by age group (years)								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
15-18	119,409	155.27	83.33	1	120	150	180	1,320
19-21	35,769	143.39	79.62	1	90	150	180	1,397
22-44	68,512	140.42	84.54	1	90	150	180	1,657
45-64	10,960	132.50	108.43	1	60	120	180	1,676
65-74	366	119.99	187.04	9	30	90	150	2,400
75+	78	112.29	127.90	7	30	60	150	824
Lenalidomide	15,721	279.78	354.34	1	56	140	360	3,017
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	3	220.67	142.50	112	112	168	382	382
10-14	8	339.00	261.95	21	112	326	526	763
15-18	9	122.44	128.04	15	35	84	123	404
19-21	3	112.00	122.05	28	28	56	252	252
22-44	613	268.92	339.76	3	63	126	336	2,303
45-64	8,047	303.86	371.51	1	71	154	393	3,017
65-74	3,464	294.51	369.94	1	56	146	386	2,765
75+	3,574	213.58	288.03	1	42	105	259	2,966
Mifepristone	28,075	3.43	38.56	1	1	1	1	2,385
00-01	0	-	-	-	-	-	-	-
02-04	2	1.00	0.00	1	1	1	1	1
05-09	0	-	-	-	-	-	-	-
10-14	43	1.05	0.21	1	1	1	1	2
15-18	1,237	1.41	11.06	1	1	1	1	390
19-21	3,287	1.59	20.17	1	1	1	1	1,111
22-44	23,125	1.71	17.57	1	1	1	1	1,320
45-64	354	134.01	274.63	1	1	15	137	2,385
65-74	23	89.48	93.29	1	21	60	150	368
75+	4	21.25	13.79	1	13	27	30	30
Mycophenolate	65,711	382.03	492.27	1	60	180	509	3,357
00-01	143	251.71	373.42	1	30	90	334	2,471
02-04	281	378.87	500.49	1	60	186	490	2,803
05-09	638	430.48	515.65	1	87	230	570	3,234
10-14	1,111	456.57	525.97	1	90	270	626	3,357
15-18	1,507	409.27	490.69	1	90	214	553	2,870
19-21	1,238	330.38	393.19	1	60	180	450	2,295
22-44	17,309	367.85	480.00	1	60	180	472	3,323
45-64	35,141	400.43	507.57	1	60	195	540	3,296
65-74	6,087	323.27	455.50	1	30	121	425	3,332

Table 2c: Descriptive statistics of cumulative exposure duration, all episodes, in days, by age group (years)								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
75+	2,256	331.02	443.10	1	43	150	442	2,989
Natalizumab	8,326	78.00	227.35	1	5	14	35	3,035
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	5	1.40	0.55	1	1	1	2	2
10-14	5	13.80	18.14	1	1	11	11	45
15-18	80	77.13	245.43	1	6	16	45	1,989
19-21	130	72.10	182.83	1	4	11	29	1,134
22-44	4,390	78.78	231.67	1	5	14	35	2,681
45-64	3,575	78.79	226.44	1	5	14	37	3,035
65-74	122	49.73	134.24	1	3	9	20	952
75+	19	12.53	32.66	1	1	1	6	139
Phentermine/topiramate	24,871	149.09	198.04	1	30	76	180	2,432
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	0	-	-	-	-	-	-	-
10-14	4	78.00	62.80	14	37	67	119	164
15-18	69	173.88	220.06	4	30	90	210	1,099
19-21	189	141.67	157.38	14	44	88	180	970
22-44	10,365	134.21	172.83	1	30	74	150	2,303
45-64	13,609	159.88	214.57	1	30	90	180	2,432
65-74	585	154.68	194.77	1	30	77	187	1,506
75+	50	228.76	315.94	14	44	104	330	1,950
Pomalidomide	2,582	207.49	254.69	1	56	112	252	2,160
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	0	-	-	-	-	-	-	-
10-14	1	507.00	-	507	507	507	507	507
15-18	2	87.00	4.24	84	84	87	90	90
19-21	0	-	-	-	-	-	-	-
22-44	84	265.00	317.60	4	60	140	333	1,617
45-64	1,441	205.87	256.85	1	56	112	252	2,160
65-74	586	217.16	261.45	2	56	121	280	1,783
75+	468	189.90	224.11	1	43	112	225	1,853

Table 3a: Descriptive statistics of first exposure episode duration, in days

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	108,363	18.23	15.93	1	7	15	30	484
Clozapine	3,561	158.01	344.85	1	13	30	125	3,358
Eculizumab	631	14.69	78.23	1	1	1	1	1,106
Isotretinoin	267,161	55.30	54.48	1	30	30	60	1,530
Lenalidomide	15,721	56.74	87.03	1	21	28	56	2,989
Mifepristone	28,075	2.21	22.79	1	1	1	1	1,973
Mycophenolate	65,711	107.78	209.86	1	30	30	90	3,357
Natalizumab	8,326	9.94	45.41	1	1	1	1	1,450
Phentermine/topiramate	24,871	46.98	60.36	1	30	30	44	1,962
Pomalidomide	2,582	62.27	93.71	1	28	28	56	1,783

Table 3b: Descriptive statistics of first exposure episode duration, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	108,363	18.23	15.93	1	7	15	30	484
Female	52,432	18.30	15.77	1	7	15	30	484
Male	55,931	18.17	16.07	1	7	15	30	450
Clozapine	3,561	158.01	344.85	1	13	30	125	3,358
Female	1,523	148.67	342.68	1	12	30	114	3,358
Male	2,038	164.99	346.38	1	14	30	140	3,079
Eculizumab	631	14.69	78.23	1	1	1	1	1,106
Female	376	15.60	86.00	1	1	1	1	1,106
Male	255	13.34	65.27	1	1	1	1	546
Isotretinoin	267,161	55.30	54.48	1	30	30	60	1,530
Female	127,202	55.15	54.70	1	30	30	60	1,530
Male	139,959	55.44	54.29	1	30	30	60	1,380
Lenalidomide	15,721	56.74	87.03	1	21	28	56	2,989
Female	6,852	56.32	85.92	1	21	28	56	1,967
Male	8,869	57.06	87.88	1	21	28	56	2,989
Mifepristone	28,075	2.21	22.79	1	1	1	1	1,973
Female	27,980	1.87	19.94	1	1	1	1	1,973
Male	95	101.06	163.90	1	30	30	104	1,156
Mycophenolate	65,711	107.78	209.86	1	30	30	90	3,357
Female	36,292	103.07	200.93	1	30	30	90	3,357
Male	29,419	113.60	220.25	1	30	30	91	3,323
Natalizumab	8,326	9.94	45.41	1	1	1	1	1,450
Female	6,250	9.61	40.87	1	1	1	1	1,134
Male	2,076	10.92	56.93	1	1	1	1	1,450
Phentermine_topiramate	24,871	46.98	60.36	1	30	30	44	1,962
Female	20,262	46.26	59.72	1	30	30	44	1,962
Male	4,609	50.17	63.02	1	30	30	56	1,230
Pomalidomide	2,582	62.27	93.71	1	28	28	56	1,783
Female	1,100	59.83	81.72	1	28	28	56	980
Male	1,482	64.09	101.69	1	28	28	61	1,783

Table 3c: Descriptive statistics of first exposure episode duration, in days, by age group (years)								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	108,363	18.23	15.93	1	7	15	30	484
00-01	74	16.85	9.46	1	10	15	30	30
02-04	91	18.93	10.37	5	10	15	30	45
05-09	158	18.93	10.73	2	10	15	30	60
10-14	337	19.04	11.79	1	10	15	30	90
15-18	575	20.68	15.93	1	10	15	30	210
19-21	530	19.77	12.80	1	10	15	30	95
22-44	8,359	20.99	15.91	1	10	15	30	360
45-64	42,894	19.85	16.11	1	10	15	30	484
65-74	16,539	18.07	16.42	1	7	15	30	376
75+	38,806	15.85	15.28	1	5	10	25	450
Clozapine	3,561	158.01	344.85	1	13	30	125	3,358
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	8	61.88	61.96	7	17	36	102	180
10-14	89	221.24	447.68	2	12	36	171	2,566
15-18	325	253.51	462.23	1	14	56	283	3,079
19-21	428	191.36	383.51	3	14	39	158	2,771
22-44	1,428	155.77	334.77	1	14	30	131	3,358
45-64	879	129.49	304.04	1	14	30	92	2,558
65-74	212	117.36	260.91	1	7	28	91	1,764
75+	192	88.83	254.28	1	7	21	57	2,639
Ecuzumab	631	14.69	78.23	1	1	1	1	1,106
00-01	1	1.00	-	1	1	1	1	1
02-04	10	1.00	0.00	1	1	1	1	1
05-09	15	74.67	285.31	1	1	1	1	1,106
10-14	25	3.72	11.20	1	1	1	1	56
15-18	35	1.17	1.01	1	1	1	1	7
19-21	36	1.92	3.92	1	1	1	1	21
22-44	216	18.23	80.60	1	1	1	1	707
45-64	232	12.91	55.69	1	1	1	1	546
65-74	44	6.18	26.31	1	1	1	1	168
75+	17	42.94	172.93	1	1	1	1	714
Isotretinoin	267,161	55.30	54.48	1	30	30	60	1,530
00-01	18	31.22	30.52	14	15	18	30	112
02-04	104	69.50	75.83	7	15	30	90	380
05-09	104	52.35	68.97	4	15	30	59	325
10-14	31,841	56.38	56.91	1	30	30	60	1,530

Table 3c: Descriptive statistics of first exposure episode duration, in days, by age group (years)									
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max	
15-18	119,409	56.75	56.13	1	30	30	60	1,220	
19-21	35,769	54.16	52.79	1	30	30	60	1,389	
22-44	68,512	53.95	52.41	1	30	30	60	986	
45-64	10,960	48.94	45.92	1	30	30	60	722	
65-74	366	41.79	32.84	7	30	30	30	300	
75+	78	47.92	56.03	7	30	30	30	450	
Lenalidomide	15,721	56.74	87.03	1	21	28	56	2,989	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	3	134.33	190.27	21	21	28	354	354	
10-14	8	46.38	43.30	21	21	28	56	140	
15-18	9	34.00	33.85	14	21	28	28	123	
19-21	3	56.00	48.50	28	28	28	112	112	
22-44	613	47.32	51.39	3	21	28	56	725	
45-64	8,047	56.02	82.36	1	21	28	56	2,989	
65-74	3,464	61.79	105.84	1	21	28	56	1,967	
75+	3,574	55.08	81.62	1	28	28	56	1,385	
Mifepristone	28,075	2.21	22.79	1	1	1	1	1,973	
00-01	0	-	-	-	-	-	-	-	
02-04	2	1.00	0.00	1	1	1	1	1	
05-09	0	-	-	-	-	-	-	-	
10-14	43	1.00	0.00	1	1	1	1	1	
15-18	1,237	1.05	1.68	1	1	1	1	60	
19-21	3,287	1.44	19.78	1	1	1	1	1,111	
22-44	23,125	1.30	7.50	1	1	1	1	411	
45-64	354	69.38	170.09	1	1	14	60	1,973	
65-74	23	54.13	66.88	1	21	30	60	240	
75+	4	21.25	13.79	1	13	27	30	30	
Mycophenolate	65,711	107.78	209.86	1	30	30	90	3,357	
00-01	143	59.67	92.34	1	30	30	60	649	
02-04	281	66.74	90.56	1	30	30	60	727	
05-09	638	123.04	239.82	1	30	30	105	2,170	
10-14	1,111	138.49	267.08	1	30	30	120	3,357	
15-18	1,507	122.01	226.27	1	30	30	119	2,650	
19-21	1,238	91.89	160.33	1	30	30	90	1,855	
22-44	17,309	97.25	192.52	1	30	30	90	3,323	
45-64	35,141	112.75	214.58	1	30	30	90	3,254	
65-74	6,087	105.59	226.89	1	15	30	90	2,987	

Table 3c: Descriptive statistics of first exposure episode duration, in days, by age group (years)									
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max	
75+	2,256	105.10	197.09	1	30	30	90	2,306	
Natalizumab	8,326	9.94	45.41	1	1	1	1	1,450	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	5	1.00	0.00	1	1	1	1	1	
10-14	5	1.00	0.00	1	1	1	1	1	
15-18	80	7.03	28.57	1	1	1	1	224	
19-21	130	18.51	107.17	1	1	1	1	1,134	
22-44	4,390	9.67	43.59	1	1	1	1	1,450	
45-64	3,575	10.19	44.96	1	1	1	1	944	
65-74	122	6.54	18.47	1	1	1	1	140	
75+	19	2.42	6.19	1	1	1	1	28	
Phentermine_topiramate	24,871	46.98	60.36	1	30	30	44	1,962	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	4	29.50	12.26	14	22	30	37	44	
15-18	69	47.68	85.37	4	30	30	44	704	
19-21	189	47.26	49.68	9	30	30	45	420	
22-44	10,365	44.75	50.55	1	30	30	44	1,230	
45-64	13,609	48.59	66.93	1	30	30	44	1,962	
65-74	585	49.01	58.26	1	30	30	46	734	
75+	50	49.00	53.59	14	30	30	44	300	
Pomalidomide	2,582	62.27	93.71	1	28	28	56	1,783	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	1	28.00	-	28	28	28	28	28	
15-18	2	42.00	19.80	28	28	42	56	56	
19-21	0	-	-	-	-	-	-	-	
22-44	84	64.51	64.51	4	28	28	84	364	
45-64	1,441	59.34	77.33	1	28	28	56	812	
65-74	586	69.96	131.13	2	28	28	56	1,783	
75+	468	61.43	87.80	1	28	28	56	924	

Table 4a: Descriptive statistics of all exposure episode durations, in days

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	183,660	16.87	17.21	1	5	14	28	1,020
Clozapine	16,918	91.41	227.35	1	14	30	60	3,358
Eculizumab	15,367	4.47	46.75	1	1	1	1	2,016
Isotretinoin	873,654	46.05	40.98	1	30	30	60	1,530
Lenalidomide	81,612	53.89	84.40	1	21	28	56	2,989
Mifepristone	30,750	3.13	26.82	1	1	1	1	1,973
Mycophenolate	334,342	75.08	154.71	1	30	30	84	3,357
Natalizumab	130,447	4.98	28.79	1	1	1	1	1,876
Phentermine/topiramate	82,809	44.78	50.16	1	30	30	44	1,962
Pomalidomide	9,877	54.24	77.15	1	28	28	56	1,783

Table 4b: Descriptive statistics of all exposure episode durations, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	183,660	16.87	17.21	1	5	14	28	1,020
Female	87,547	16.91	17.43	1	6	14	30	1,020
Male	96,113	16.83	17.01	1	5	14	28	660
Clozapine	16,918	91.41	227.35	1	14	30	60	3,358
Female	7,319	89.02	229.26	1	14	28	60	3,358
Male	9,599	93.22	225.88	1	14	30	60	3,079
Eculizumab	15,367	4.47	46.75	1	1	1	1	2,016
Female	8,788	4.69	46.01	1	1	1	1	1,714
Male	6,579	4.19	47.73	1	1	1	1	2,016
Isotretinoin	873,654	46.05	40.98	1	30	30	60	1,530
Female	423,301	45.92	41.09	1	30	30	60	1,530
Male	450,353	46.17	40.87	1	30	30	60	1,380
Lenalidomide	81,612	53.89	84.40	1	21	28	56	2,989
Female	35,719	53.89	83.05	1	21	28	56	2,240
Male	45,893	53.89	85.45	1	21	28	56	2,989
Mifepristone	30,750	3.13	26.82	1	1	1	1	1,973
Female	30,551	2.59	23.95	1	1	1	1	1,973
Male	199	85.18	127.92	1	30	30	85	1,156
Mycophenolate	334,342	75.08	154.71	1	30	30	84	3,357
Female	177,056	74.66	147.80	1	30	30	87	3,357
Male	157,286	75.56	162.14	1	2	30	80	3,323
Natalizumab	130,447	4.98	28.79	1	1	1	1	1,876
Female	99,285	4.94	27.43	1	1	1	1	1,876
Male	31,162	5.10	32.75	1	1	1	1	1,598
Phentermine/topiramate	82,809	44.78	50.16	1	30	30	44	1,962
Female	66,547	44.13	49.29	1	30	30	43	1,962
Male	16,262	47.43	53.51	1	30	30	60	1,262
Pomalidomide	9,877	54.24	77.15	1	28	28	56	1,783
Female	4,251	55.91	77.91	1	28	28	56	1,540
Male	5,626	52.98	76.56	1	21	28	56	1,783

Table 4c: Descriptive statistics of all exposure episode durations, in days, by age group (years)								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	183,660	16.87	17.21	1	5	14	28	1,020
00-01	78	16.53	9.35	1	10	14	30	30
02-04	97	19.02	10.35	5	10	15	30	45
05-09	190	18.29	10.74	2	10	15	30	60
10-14	415	19.58	14.11	1	10	15	30	150
15-18	725	20.23	15.86	1	10	15	30	210
19-21	715	18.95	14.78	1	10	15	30	150
22-44	11,818	20.83	19.78	1	10	15	30	1,020
45-64	69,844	19.04	18.05	1	7	15	30	690
65-74	28,154	16.74	17.55	1	5	14	30	630
75+	71,624	14.07	15.33	1	5	10	18	465
Clozapine	16,918	91.41	227.35	1	14	30	60	3,358
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	83	97.58	244.94	3	14	30	70	1,536
10-14	399	151.37	378.71	2	14	30	98	3,014
15-18	1,582	121.22	289.70	1	14	30	77	3,079
19-21	1,902	94.36	234.92	1	14	28	60	2,771
22-44	6,528	92.88	229.45	1	14	30	60	3,358
45-64	4,284	82.71	202.24	1	14	30	60	2,558
65-74	1,126	73.05	157.45	1	14	28	60	1,764
75+	1,014	62.87	153.00	1	7	28	50	2,639
Eculizumab	15,367	4.47	46.75	1	1	1	1	2,016
00-01	1	1.00	-	1	1	1	1	1
02-04	368	1.00	0.00	1	1	1	1	1
05-09	248	5.70	70.26	1	1	1	1	1,106
10-14	231	17.08	135.67	1	1	1	1	1,714
15-18	776	3.80	47.48	1	1	1	1	1,127
19-21	910	3.00	35.80	1	1	1	1	1,038
22-44	5,517	5.51	56.94	1	1	1	1	2,016
45-64	5,727	4.15	34.10	1	1	1	1	1,082
65-74	1,086	1.78	10.04	1	1	1	1	253
75+	503	2.55	31.88	1	1	1	1	714
Isotretinoin	873,654	46.05	40.98	1	30	30	60	1,530
00-01	59	23.31	20.73	1	14	15	28	112
02-04	325	44.61	58.11	1	15	15	30	380
05-09	380	37.99	47.40	2	15	30	30	325
10-14	117,443	46.03	41.70	1	30	30	60	1,530

Table 4c: Descriptive statistics of all exposure episode durations, in days, by age group (years)									
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max	
15-18	396,524	46.76	41.99	1	30	30	60	1,220	
19-21	112,303	45.67	40.04	1	30	30	60	1,389	
22-44	211,128	45.57	39.90	1	30	30	58	986	
45-64	34,251	42.40	35.46	1	30	30	30	722	
65-74	1,035	42.43	35.53	2	30	30	30	480	
75+	206	42.52	44.11	7	30	30	30	450	
Lenalidomide	81,612	53.89	84.40	1	21	28	56	2,989	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	13	50.92	91.57	21	21	21	28	354	
10-14	66	41.09	44.17	21	21	28	28	308	
15-18	30	36.73	26.45	12	28	28	28	123	
19-21	7	48.00	31.16	28	28	28	56	112	
22-44	3,642	45.26	63.24	1	21	28	49	1,645	
45-64	45,585	53.64	83.53	1	21	28	56	2,989	
65-74	17,761	57.44	93.45	1	21	28	56	2,253	
75+	14,508	52.61	80.01	1	21	28	56	2,434	
Mifepristone	30,750	3.13	26.82	1	1	1	1	1,973	
00-01	0	-	-	-	-	-	-	-	
02-04	2	1.00	0.00	1	1	1	1	1	
05-09	0	-	-	-	-	-	-	-	
10-14	45	1.00	0.00	1	1	1	1	1	
15-18	1,362	1.28	5.98	1	1	1	1	150	
19-21	3,647	1.43	18.82	1	1	1	1	1,111	
22-44	25,025	1.58	10.23	1	1	1	1	420	
45-64	628	75.54	152.35	1	1	30	60	1,973	
65-74	37	55.62	59.61	1	30	30	60	240	
75+	4	21.25	13.79	1	13	27	30	30	
Mycophenolate	334,342	75.08	154.71	1	30	30	84	3,357	
00-01	750	47.99	105.78	1	30	30	30	2,226	
02-04	1,788	59.54	137.42	1	30	30	40	2,640	
05-09	3,683	74.57	161.38	1	30	30	60	3,144	
10-14	5,847	86.75	175.68	1	30	30	73	3,357	
15-18	7,519	82.03	164.20	1	30	30	64	2,650	
19-21	5,955	68.68	122.41	1	30	30	60	1,887	
22-44	84,175	75.64	145.98	1	30	30	88	3,323	
45-64	171,925	81.85	163.04	1	30	30	90	3,270	
65-74	41,037	47.95	135.01	1	1	1	30	2,987	

Table 4c: Descriptive statistics of all exposure episode durations, in days, by age group (years)									
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max	
75+	11,663	64.03	143.05	1	1	30	60	2,306	
Natalizumab	130,447	4.98	28.79	1	1	1	1	1,876	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	7	1.00	0.00	1	1	1	1	1	
10-14	69	1.00	0.00	1	1	1	1	1	
15-18	1,725	3.58	13.34	1	1	1	1	224	
19-21	1,598	5.87	37.35	1	1	1	1	1,134	
22-44	67,836	5.10	28.43	1	1	1	1	1,598	
45-64	57,913	4.86	29.47	1	1	1	1	1,876	
65-74	1,197	5.07	19.71	1	1	1	1	224	
75+	102	2.33	8.96	1	1	1	1	84	
Phentermine/topiramate	82,809	44.78	50.16	1	30	30	44	1,962	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	10	31.20	8.39	14	30	30	30	44	
15-18	307	39.08	46.68	1	30	30	30	704	
19-21	625	42.84	40.28	1	30	30	30	420	
22-44	32,827	42.38	43.00	1	30	30	30	1,410	
45-64	46,972	46.32	54.57	1	30	30	44	1,962	
65-74	1,862	48.60	50.79	1	30	30	60	734	
75+	206	55.52	68.70	7	30	30	60	600	
Pomalidomide	9,877	54.24	77.15	1	28	28	56	1,783	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	15	33.80	23.85	3	21	21	49	84	
15-18	4	43.50	14.64	28	31	45	56	56	
19-21	0	-	-	-	-	-	-	-	
22-44	400	55.65	70.48	1	21	28	56	672	
45-64	5,505	53.89	76.32	1	28	28	56	1,540	
65-74	2,189	58.13	86.23	1	28	28	56	1,783	
75+	1,764	50.38	69.04	1	21	28	56	1,014	

Table 5a: Descriptive statistics of days supplied per dispensing

Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	207,940	14.90	11.86	1	5	10	28	454
Clozapine	87,058	17.76	13.15	1	7	14	28	367
Eculizumab	17,824	3.88	7.88	1	1	1	1	84
Isotretinoin	1,313,057	30.64	7.15	1	30	30	30	750
Lenalidomide	170,193	25.84	5.07	1	21	28	28	308
Mifepristone	32,315	2.98	7.34	1	1	1	1	90
Mycophenolate	705,327	35.60	25.48	1	30	30	30	999
Natalizumab	143,962	4.52	9.21	1	1	1	1	252
Phentermine/topiramate	126,507	29.31	7.53	1	30	30	30	365
Pomalidomide	20,036	26.74	4.75	1	28	28	28	112

Table 5b: Descriptive statistics of days supplied per dispensing, by sex								
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	207,940	14.90	11.86	1	5	10	28	454
Female	100,381	14.75	11.38	1	5	10	25	454
Male	107,559	15.04	12.29	1	5	14	28	450
Clozapine	87,058	17.76	13.15	1	7	14	28	367
Female	37,468	17.39	13.28	1	7	14	28	367
Male	49,590	18.04	13.04	1	7	14	28	120
Eculizumab	17,824	3.88	7.88	1	1	1	1	84
Female	10,249	4.04	8.28	1	1	1	1	84
Male	7,575	3.65	7.30	1	1	1	1	30
Isotretinoin	1,313,057	30.64	7.15	1	30	30	30	750
Female	633,804	30.67	7.15	1	30	30	30	300
Male	679,253	30.61	7.16	1	30	30	30	750
Lenalidomide	170,193	25.84	5.07	1	21	28	28	308
Female	74,404	25.87	5.20	1	21	28	28	308
Male	95,789	25.82	4.97	1	21	28	28	219
Mifepristone	32,315	2.98	7.34	1	1	1	1	90
Female	31,715	2.50	6.46	1	1	1	1	90
Male	600	28.25	6.73	1	30	30	30	90
Mycophenolate	705,327	35.60	25.48	1	30	30	30	999
Female	363,684	36.36	25.04	1	30	30	30	999
Male	341,643	34.80	25.93	1	30	30	30	540
Natalizumab	143,962	4.52	9.21	1	1	1	1	252
Female	109,386	4.50	9.17	1	1	1	1	252
Male	34,576	4.61	9.34	1	1	1	1	90
Phentermine/topiramate	126,507	29.31	7.53	1	30	30	30	365
Female	100,386	29.25	7.56	1	30	30	30	365
Male	26,121	29.53	7.41	1	30	30	30	180
Pomalidomide	20,036	26.74	4.75	1	28	28	28	112
Female	8,839	26.89	4.59	1	28	28	28	106
Male	11,197	26.62	4.87	1	28	28	28	112

Table 5c: Descriptive statistics of days supplied per dispensing, by age group (years)								
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	207,940	14.90	11.86	1	5	10	28	454
00-01	81	15.91	9.26	1	10	14	30	30
02-04	106	17.41	9.53	1	10	15	30	30
05-09	207	16.79	9.15	2	10	15	30	40
10-14	448	18.14	10.48	1	10	15	30	90
15-18	794	18.47	9.76	1	10	15	30	90
19-21	810	16.73	10.84	1	7	15	30	90
22-44	13,266	18.56	11.27	1	10	15	30	105
45-64	77,730	17.12	12.25	1	7	15	30	454
65-74	32,091	14.69	12.23	1	5	10	28	180
75+	82,407	12.23	10.84	1	5	7	15	450
Clozapine	87,058	17.76	13.15	1	7	14	28	367
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	434	18.66	14.54	1	7	14	28	84
10-14	3,158	19.13	13.12	1	7	14	28	86
15-18	10,702	17.92	13.67	1	7	14	28	134
19-21	10,656	16.84	12.82	1	7	14	28	120
22-44	33,403	18.15	13.24	1	7	14	28	367
45-64	19,021	18.63	13.66	1	7	14	28	120
65-74	5,252	15.66	11.32	1	7	14	28	90
75+	4,432	14.38	10.51	1	7	8	28	62
Eculizumab	17,824	3.88	7.88	1	1	1	1	84
00-01	1	1.00	-	1	1	1	1	1
02-04	368	1.00	0.00	1	1	1	1	1
05-09	361	4.07	7.50	1	1	1	1	30
10-14	382	10.33	11.61	1	1	1	28	28
15-18	898	3.28	6.02	1	1	1	1	28
19-21	1,014	2.70	5.47	1	1	1	1	28
22-44	6,553	4.65	8.73	1	1	1	1	84
45-64	6,565	3.64	7.85	1	1	1	1	84
65-74	1,151	1.71	3.97	1	1	1	1	28
75+	531	2.42	5.86	1	1	1	1	28
Isotretinoin	1,313,057	30.64	7.15	1	30	30	30	750
00-01	69	19.93	9.01	1	15	15	28	60
02-04	584	24.83	11.82	1	15	28	30	90
05-09	546	26.44	13.49	2	15	30	30	120
10-14	176,171	30.69	7.25	1	30	30	30	300

Table 5c: Descriptive statistics of days supplied per dispensing, by age group (years)									
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max	
15-18	602,503	30.77	7.30	1	30	30	30	750	
19-21	167,474	30.62	7.01	1	30	30	30	286	
22-44	315,655	30.48	7.04	1	30	30	30	330	
45-64	48,277	30.08	5.80	1	30	30	30	120	
65-74	1,479	29.69	5.33	1	30	30	30	120	
75+	299	29.29	4.95	4	30	30	30	60	
Lenalidomide	170,193	25.84	5.07	1	21	28	28	308	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	24	27.58	9.45	18	21	28	28	56	
10-14	102	26.59	5.67	8	28	28	28	56	
15-18	42	26.24	4.91	12	28	28	28	42	
19-21	12	28.00	0.00	28	28	28	28	28	
22-44	6,482	25.43	5.20	1	21	28	28	142	
45-64	95,127	25.70	5.11	1	21	28	28	280	
65-74	39,196	26.03	5.17	1	21	28	28	308	
75+	29,208	26.13	4.74	1	24	28	28	168	
Mifepristone	32,315	2.98	7.34	1	1	1	1	90	
00-01	0	-	-	-	-	-	-	-	
02-04	2	1.00	0.00	1	1	1	1	1	
05-09	0	-	-	-	-	-	-	-	
10-14	45	1.00	0.00	1	1	1	1	1	
15-18	1,371	1.27	2.81	1	1	1	1	30	
19-21	3,695	1.41	3.56	1	1	1	1	60	
22-44	25,343	1.56	4.03	1	1	1	1	90	
45-64	1,781	26.64	9.36	1	30	30	30	90	
65-74	74	27.81	10.86	1	30	30	30	90	
75+	4	21.25	13.79	1	13	27	30	30	
Mycophenolate	705,327	35.60	25.48	1	30	30	30	999	
00-01	1,141	31.58	18.07	1	30	30	30	253	
02-04	3,244	32.83	15.26	1	30	30	30	301	
05-09	8,422	32.62	16.02	1	30	30	30	180	
10-14	14,596	34.77	19.99	1	30	30	30	200	
15-18	17,654	34.95	20.91	1	30	30	30	365	
19-21	11,657	35.10	21.91	1	30	30	30	240	
22-44	173,738	36.66	23.53	1	30	30	30	540	
45-64	382,289	36.82	25.95	1	30	30	30	900	
65-74	70,017	28.12	29.19	1	1	30	30	999	

Table 5c: Descriptive statistics of days supplied per dispensing, by age group (years)									
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max	
75+	22,569	33.10	27.77	1	20	30	30	210	
Natalizumab	143,962	4.52	9.21	1	1	1	1	252	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	7	1.00	0.00	1	1	1	1	1	
10-14	69	1.00	0.00	1	1	1	1	1	
15-18	1,822	3.40	7.68	1	1	1	1	30	
19-21	1,823	5.17	9.72	1	1	1	1	29	
22-44	74,944	4.63	9.36	1	1	1	1	252	
45-64	63,892	4.42	9.06	1	1	1	1	90	
65-74	1,301	4.67	9.24	1	1	1	1	28	
75+	104	2.29	5.76	1	1	1	1	28	
Phentermine/topiramate	126,507	29.31	7.53	1	30	30	30	365	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	11	28.36	8.24	14	30	30	30	44	
15-18	420	28.57	5.42	1	30	30	30	44	
19-21	924	28.98	8.59	1	30	30	30	90	
22-44	47,621	29.21	7.52	1	30	30	30	300	
45-64	74,059	29.38	7.52	1	30	30	30	365	
65-74	3,092	29.26	7.35	1	30	30	30	90	
75+	380	30.10	9.37	5	30	30	30	90	
Pomalidomide	20,036	26.74	4.75	1	28	28	28	112	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	21	24.14	5.94	3	21	28	28	28	
15-18	7	24.86	8.32	6	28	28	28	28	
19-21	0	-	-	-	-	-	-	-	
22-44	834	26.69	4.07	1	28	28	28	56	
45-64	11,119	26.68	4.48	1	28	28	28	106	
65-74	4,687	27.15	5.50	1	28	28	28	112	
75+	3,368	26.39	4.61	1	28	28	28	91	

Table 6a: Descriptive statistics of the length of all gaps between treatment episodes, in days

Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	75,297	107.17	253.98	1	7	22	70	3,118
Clozapine	13,357	20.73	92.72	1	2	4	11	2,200
Eculizumab	14,736	14.90	34.38	1	13	13	13	2,532
Isotretinoin	606,493	28.23	120.06	1	3	5	11	3,071
Lenalidomide	65,891	28.69	100.94	1	3	7	14	2,395
Mifepristone	2,675	384.21	412.27	1	120	252	503	3,054
Mycophenolate	268,631	39.74	101.96	1	5	19	33	3,106
Natalizumab	122,121	32.48	42.82	1	27	27	30	2,100
Phentermine/topiramate	57,938	31.05	91.51	1	3	9	22	2,140
Pomalidomide	7,295	24.70	79.02	1	3	7	14	1,471

Table 6b: Descriptive statistics of the length of all gaps between treatment episodes, in days, by sex								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	75,297	107.17	253.98	1	7	22	70	3,118
Female	35,115	103.45	248.53	1	7	19	65	2,967
Male	40,182	110.43	258.60	1	8	26	74	3,118
Clozapine	13,357	20.73	92.72	1	2	4	11	2,200
Female	5,796	19.45	88.94	1	2	4	10	2,066
Male	7,561	21.71	95.51	1	2	4	11	2,200
Eculizumab	14,736	14.90	34.38	1	13	13	13	2,532
Female	8,412	15.08	35.85	1	13	13	13	2,532
Male	6,324	14.67	32.32	1	13	13	13	1,236
Isotretinoin	606,493	28.23	120.06	1	3	5	11	3,071
Female	296,099	28.35	130.99	1	2	5	9	2,982
Male	310,394	28.12	108.60	1	3	6	13	3,071
Lenalidomide	65,891	28.69	100.94	1	3	7	14	2,395
Female	28,867	28.66	101.43	1	3	7	14	2,395
Male	37,024	28.72	100.56	1	3	7	14	2,343
Mifepristone	2,675	384.21	412.27	1	120	252	503	3,054
Female	2,571	398.96	413.61	1	136	266	523	3,054
Male	104	19.48	65.39	1	2	5	15	626
Mycophenolate	268,631	39.74	101.96	1	5	19	33	3,106
Female	140,764	41.90	108.39	1	5	18	34	3,106
Male	127,867	37.36	94.32	1	5	21	32	2,741
Natalizumab	122,121	32.48	42.82	1	27	27	30	2,100
Female	93,035	32.56	42.92	1	27	27	30	2,100
Male	29,086	32.24	42.51	1	27	27	30	1,932
Phentermine/topiramate	57,938	31.05	91.51	1	3	9	22	2,140
Female	46,285	31.61	91.95	1	4	9	23	2,140
Male	11,653	28.84	89.72	1	3	8	19	2,133
Pomalidomide	7,295	24.70	79.02	1	3	7	14	1,471
Female	3,151	24.26	76.75	1	3	7	14	1,263
Male	4,144	25.04	80.71	1	3	7	15	1,471

Table 6c: Descriptive statistics of the length of all gaps between treatment episodes, in days, by age group (years)								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Collagenase clostridium histolyticum	75,297	107.17	253.98	1	7	22	70	3,118
00-01	4	61.25	119.83	1	1	2	122	241
02-04	6	159.83	255.93	3	3	52	188	662
05-09	32	134.84	302.67	2	12	21	63	1,163
10-14	78	136.88	425.96	1	4	15	64	3,118
15-18	150	90.97	217.68	1	8	20	71	1,536
19-21	185	88.49	248.34	1	3	8	46	2,275
22-44	3,459	121.25	281.79	1	9	28	83	2,919
45-64	26,950	125.69	277.01	1	10	32	87	2,967
65-74	11,615	127.73	286.10	1	7	23	87	2,902
75+	32,818	83.29	213.39	1	6	16	50	2,877
Clozapine	13,357	20.73	92.72	1	2	4	11	2,200
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	75	5.60	16.22	1	1	2	5	136
10-14	310	20.22	111.26	1	2	4	7	1,767
15-18	1,257	18.67	83.00	1	2	4	9	1,548
19-21	1,474	23.06	113.91	1	2	4	9	2,200
22-44	5,100	21.65	96.13	1	2	4	11	2,066
45-64	3,405	22.73	96.58	1	2	5	13	1,862
65-74	914	16.42	57.67	1	2	4	11	855
75+	822	12.06	37.91	1	2	4	8	715
Ecuzumab	14,736	14.90	34.38	1	13	13	13	2,532
00-01	0	-	-	-	-	-	-	-
02-04	358	16.85	64.74	1	13	13	13	1,236
05-09	233	17.97	59.49	1	13	13	13	920
10-14	206	17.38	38.45	1	11	13	15	495
15-18	741	13.53	14.89	1	13	13	13	391
19-21	874	15.13	36.23	1	13	13	13	1,041
22-44	5,301	15.55	45.22	1	13	13	13	2,532
45-64	5,495	14.20	20.79	1	13	13	13	1,098
65-74	1,042	15.18	15.64	2	13	13	13	405
75+	486	12.82	3.21	5	13	13	13	55
Isotretinoin	606,493	28.23	120.06	1	3	5	11	3,071
00-01	41	15.80	9.12	1	12	13	18	41
02-04	221	27.08	69.80	1	9	14	21	783
05-09	276	34.68	96.81	1	7	14	26	890
10-14	85,602	36.63	140.48	1	3	5	12	3,058

Table 6c: Descriptive statistics of the length of all gaps between treatment episodes, in days, by age group (years)									
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max	
15-18	277,115	26.55	116.46	1	3	5	11	3,071	
19-21	76,534	25.55	111.88	1	3	5	11	2,664	
22-44	142,616	24.44	112.47	1	3	5	10	2,995	
45-64	23,291	48.23	145.73	1	3	7	25	2,797	
65-74	669	61.56	134.67	1	4	11	54	1,481	
75+	128	63.09	118.26	1	4	11	47	729	
Lenalidomide	65,891	28.69	100.94	1	3	7	14	2,395	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	10	8.00	4.06	4	6	7	9	18	
10-14	58	13.31	40.67	1	3	6	11	312	
15-18	21	11.90	19.39	1	4	6	7	85	
19-21	4	5.25	1.71	3	4	6	7	7	
22-44	3,029	29.74	93.75	1	4	7	16	1,679	
45-64	37,538	29.82	104.82	1	3	7	14	2,395	
65-74	14,297	28.50	100.81	1	4	7	14	2,343	
75+	10,934	24.92	89.02	1	4	7	15	2,097	
Mifepristone	2,675	384.21	412.27	1	120	252	503	3,054	
00-01	0	-	-	-	-	-	-	-	
02-04	0	-	-	-	-	-	-	-	
05-09	0	-	-	-	-	-	-	-	
10-14	2	438.00	284.26	237	237	438	639	639	
15-18	125	650.87	624.79	1	200	385	975	2,699	
19-21	360	480.05	414.01	1	173	342	645	2,143	
22-44	1,900	401.95	392.24	1	155	282	514	3,054	
45-64	274	30.30	112.48	1	2	6	17	1,299	
65-74	14	48.86	110.31	1	5	11	28	420	
75+	0	-	-	-	-	-	-	-	
Mycophenolate	268,631	39.74	101.96	1	5	19	33	3,106	
00-01	607	44.63	127.11	1	15	25	34	2,208	
02-04	1,507	34.56	83.21	1	9	19	30	973	
05-09	3,045	31.32	99.39	1	4	12	27	2,069	
10-14	4,736	37.15	106.35	1	4	11	29	2,494	
15-18	6,012	45.51	123.93	1	4	13	36	2,349	
19-21	4,717	46.87	107.53	1	5	15	39	2,037	
22-44	66,866	41.88	112.97	1	5	14	34	3,094	
45-64	136,784	38.42	99.96	1	5	17	33	3,106	
65-74	34,950	40.75	86.93	1	17	27	34	2,574	

Table 6c: Descriptive statistics of the length of all gaps between treatment episodes, in days, by age group (years)								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
75+	9,407	37.15	77.42	1	8	26	33	1,583
Natalizumab	122,121	32.48	42.82	1	27	27	30	2,100
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	2	28.00	1.41	27	27	28	29	29
10-14	64	28.03	3.66	26	27	27	28	48
15-18	1,645	31.73	33.86	1	27	27	31	1,036
19-21	1,468	34.17	46.99	1	27	27	31	949
22-44	63,446	32.36	42.52	1	27	27	30	2,100
45-64	54,338	32.55	43.30	1	27	27	30	1,932
65-74	1,075	35.33	44.06	1	27	27	30	734
75+	83	34.36	43.57	4	27	27	31	419
Phentermine/topiramate	57,938	31.05	91.51	1	3	9	22	2,140
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	0	-	-	-	-	-	-	-
10-14	6	39.83	36.97	12	19	22	57	108
15-18	238	28.95	59.90	1	5	12	24	462
19-21	436	34.61	86.26	1	4	11	27	756
22-44	22,462	32.89	95.87	1	4	9	24	2,140
45-64	33,363	29.92	88.88	1	3	8	21	2,133
65-74	1,277	27.40	86.75	1	3	7	18	1,091
75+	156	31.78	93.03	1	3	10	25	1,000
Pomalidomide	7,295	24.70	79.02	1	3	7	14	1,471
00-01	0	-	-	-	-	-	-	-
02-04	0	-	-	-	-	-	-	-
05-09	0	-	-	-	-	-	-	-
10-14	14	8.21	6.73	1	4	7	9	27
15-18	2	5.00	4.24	2	2	5	8	8
19-21	0	-	-	-	-	-	-	-
22-44	316	25.20	65.07	1	4	7	14	538
45-64	4,064	26.80	85.22	1	3	7	14	1,340
65-74	1,603	22.24	75.50	1	3	7	14	1,471
75+	1,296	21.28	65.34	1	4	7	15	1,085

Table 7: Counts of reason for censoring, all episodes and first episode										
	Total		Disenrollment		Evidence of death		DP/Query end date		Episode end	
	N	%	N	%	N	%	N	%	N	%
Exposures										
Collagenase clostridium histolyticum	183,660	100.0	3,792	2.1	228	0.1	690	0.4	183,460	99.9
Clozapine	16,918	100.0	1,856	11.0	7	0.0	532	3.1	16,911	100.0
Eculizumab	15,367	100.0	82	0.5	0	0.0	44	0.3	15,367	100.0
Isotretinoin	873,654	100.0	43,764	5.0	3	0.0	12,068	1.4	873,652	100.0
Lenalidomide	81,612	100.0	4,774	5.8	132	0.2	1,298	1.6	81,489	99.8
Mifepristone	30,750	100.0	131	0.4	0	0.0	52	0.2	30,750	100.0
Mycophenolate	334,342	100.0	30,027	9.0	237	0.1	8,781	2.6	334,125	99.9
Natalizumab	130,447	100.0	615	0.5	0	0.0	151	0.1	130,447	100.0
Phentermine/topiramate	82,809	100.0	3,279	4.0	2	0.0	876	1.1	82,807	100.0
Pomalidomide	9,877	100.0	757	7.7	34	0.3	292	3.0	9,845	99.7
Patients' First Episode										
Collagenase clostridium histolyticum	108,363	100.0	2,290	2.1	150	0.1	394	0.4	108,230	99.9
Clozapine	3,561	100.0	699	19.6	5	0.1	205	5.8	3,556	99.9
Eculizumab	631	100.0	8	1.3	0	0.0	5	0.8	631	100.0
Isotretinoin	267,161	100.0	16,129	6.0	2	0.0	4,041	1.5	267,160	100.0
Lenalidomide	15,721	100.0	1,020	6.5	75	0.5	221	1.4	15,652	99.6
Mifepristone	28,075	100.0	79	0.3	0	0.0	27	0.1	28,075	100.0
Mycophenolate	65,711	100.0	8,223	12.5	114	0.2	2,071	3.2	65,608	99.8
Natalizumab	8,326	100.0	80	1.0	0	0.0	17	0.2	8,326	100.0
Phentermine/topiramate	24,871	100.0	1,097	4.4	1	0.0	203	0.8	24,870	100.0
Pomalidomide	2,582	100.0	231	8.9	18	0.7	80	3.1	2,565	99.3

Table 8: Cohort Attrition Table	
Attrition Criteria	Members
Collagenase clostridium histolyticum	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	125,482 (0.1%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	125,482 (0.1%)
Exclusion - Members must have at least one episode defining index claim during the query period	125,482 (0.1%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	125,482 (0.1%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	108,363 (0.1%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	108,363 (0.1%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	108,363 (0.1%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	108,363 (0.1%)
Clozapine	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	8,425 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	8,425 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	8,425 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	8,425 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	3,561 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	3,561 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	3,561 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	3,561 (0.0%)
Eculizumab	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)

Table 8: Cohort Attrition Table	
Attrition Criteria	Members
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	1,030 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	1,030 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	1,030 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	1,030 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	631 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	631 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	631 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	631 (0.0%)
Isotretinoin	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	369,857 (0.3%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	369,857 (0.3%)
Exclusion - Members must have at least one episode defining index claim during the query period	369,857 (0.3%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	369,857 (0.3%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	267,161 (0.2%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	267,161 (0.2%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	267,161 (0.2%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	267,161 (0.2%)
Lenalidomide	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	22,080 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	22,080 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	22,080 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	22,080 (0.0%)

Table 8: Cohort Attrition Table	
Attrition Criteria	Members
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	15,721 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	15,721 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	15,721 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	15,721 (0.0%)
Mifepristone	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	36,200 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	36,200 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	36,200 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	36,200 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	28,075 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	28,075 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	28,075 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	28,075 (0.0%)
Mycophenolate	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	132,865 (0.1%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	132,865 (0.1%)
Exclusion - Members must have at least one episode defining index claim during the query period	132,865 (0.1%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	132,865 (0.1%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	65,711 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	65,711 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	65,711 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	65,711 (0.0%)
Natalizumab	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)

Table 8: Cohort Attrition Table	
Attrition Criteria	Members
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	17,792 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	17,792 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	17,792 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	17,792 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	8,326 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	8,326 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	8,326 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	8,326 (0.0%)
Phentermine/topiramate	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	29,831 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	29,831 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	29,831 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	29,831 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	24,871 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	24,871 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	24,871 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	24,871 (0.0%)
Pomalidomide	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	144,370,000 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	115,800,000 (80.2%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the age range condition within the query period	115,800,000 (80.2%)
Exclusion - Members must meet chart availability criterion within the query period	115,800,000 (80.2%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	115,800,000 (80.2%)

Table 8: Cohort Attrition Table	
Attrition Criteria	Members
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	3,028 (0.0%)
Exclusion - Members must have at least one cohort episode beginning within the age range condition	3,028 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	3,028 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	3,028 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	2,582 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	2,582 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	2,582 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	2,582 (0.0%)

Appendix A. Dates of Available Data for Each Data Partner (DP) up to Request End Date (09/30/2019) as of Query Distribution Date

Data Partner (Masked)	Start Date	End Date
DP01	01/01/2010	09/30/2019

Appendix B. Specifications Used to Define Parameters in this Query

Global Values

Enrollment Criteria: Medical and Drug Coverage

Enrollment Gap (Days): 45

Age Groups (Years): 00-01, 02-04, 05-09, 10-14, 15-19, 19-21, 22-44, 45-64, 65-74, 75+

Query Period: 01/01/2010-09/30/2019

Baseline Characteristics Table: Yes

Baseline Evaluation Window (Day): -183,0

#	Cohort Name	Index Exposure	Pre-Index Enrollment Period (Days)	Washout Period (Days)	Treatment Episode Gap (Days)	Treatment Episode Extension (Days)	Inclusion/Exclusion	Criteria	Criteria Definition	Evaluation Period Start (Day)	Evaluation Period End (Day)
1	CCH	collagenase clostridium histolyticum ^[1]	183	183	0	0	--	--	--	--	--
2	Isotretinoin	Isotretinoin ^[2]	183	183	0	0	--	--	--	--	--
3	Mycophenolate	Mycophenolate ^[3]	183	183	0	0	--	--	--	--	--
4	Lenalidomide	Lenalidomide ^[4]	183	183	0	0	--	--	--	--	--
5	Mifepristone	Mifepristone ^[5]	183	183	0	0	--	--	--	--	--
6	Clozapine	Clozapine ^[6]	183	183	0	0	--	--	--	--	--
7	Phentermine_topiramate	Phentermine_topiramate ^[7]	183	183	0	0	--	--	--	--	--
8	Eculizumab	Eculizumab ^[8]	183	183	0	0	--	--	--	--	--
9	Natalizumab	Natalizumab ^[9]	183	183	0	0	--	--	--	--	--
10	Pomalidomide	Pomalidomide ^[10]	183	183	0	0	--	--	--	--	--

ICD-9, ICD-10, HCPCS AND CPT are provided by Optum360
NDCs are checked against First Data Bank's MedKnowledge.

Appendix of Generic Names and Chronic Conditions

[1] See Appendices C and D

[2] isotretinoin
isotretinoin, micronized

[3] See Appendices C and D

[4] lenalidomide

[5] See Appendices C and D

[6] See Appendices C and D

[7] phentermine HCl/topiramate

[8] See Appendices C and D

[9] See Appendices C and D

[10] pomalidomide

Baseline Characteristics Table

Acquired Hypothyroidism	Chronic Kidney Disease	Hypertension
Acute Myocardial Infarction	Chronic Obstructive Pulmonary Disease	Ischemic Heart Disease
Alzheimer's Disease	Colorectal Cancer	Lung Cancer
Alzheimer's Disease, Related Disorders, or Senile Dementia	Depression	Osteoporosis
Anemia	Diabetes	Prostate Cancer
Asthma	Endometrial Cancer	Rheumatoid Arthritis / Osteoarthritis
Atrial Fibrillation	Glaucoma	Stroke / Transient Ischemic Attack
Benign Prostatic Hyperplasia	Heart Failure	
Breast Cancer	Hip / Pelvic Fracture	
Cataracts	Hyperlipidemia	

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

Age Groups - Age groups of members included in the cohort. Strata also used for reporting purposes.

Ambulatory Visit (AV) - A care setting value including visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Baseline Characteristics Table - Optional table containing general characteristics of study population, including background rates of 27 chronic conditions from the CMS Chronic Condition Warehouse (see above if table requested). Users define an evaluation period for the presence of baseline characteristics.

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.

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).

Cohort Definition - Cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using the washout period.

Emergency Department (ED) - A care setting value including ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Enrollment Criteria - Type of coverage required during enrollment period. By default, all patients must have medical and drug coverage.

Enrollment Gap - Allowed gap between coverage periods.

Episodes - Treatment episodes: length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Inclusion/Exclusion - Contains the comprehensive set of codes used to define additional cohort inclusion and/or exclusion criteria (e.g., restrict cohort to individuals with evidence of a pre-existing condition 183 days before the index date). Criteria could be defined with complex algorithms (e.g., diagnosis codes and drug codes) defined under Criteria Definition.

Inpatient Hospital Stay (IP) - A care setting value including 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) - A care setting value including hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - A care setting value including 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.

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 Care Setting/PDX parameter.

Query Period - The period of time which patients can contribute index-defining exposure/events. Data prior to the start date may be used to determine enrollment, washout, and other cohort inclusion criteria.

Treatment Episode Extension - The episode extension adds the selected number of days to the end of an episode to count as exposed time.

Treatment Episode Gap - The maximum number of days allowed between two dispensings to consider them part of the same episode.

Washout Period - The period before an exposure episode during which an individual cannot have evidence of incidence-defining criteria.

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

Code	Code Category	Code Type	Description
Collagenase clostridium histolyticum			
J0775	Procedure	HCPCS	INJECTION, COLLAGENASE, CLOSTRIDIUM HISTOLYTICUM, 0.01 MG
C9266	Procedure	HCPCS	INJECTION, COLLAGENASE CLOSTRIDIUM HISTOLYTICUM, 0.1 MG
Mycophenolate			
J7517	Procedure	HCPCS	MYCOPHENOLATE MOFETIL, ORAL, 250 MG
J7518	Procedure	HCPCS	MYCOPHENOLIC ACID, ORAL, 180 MG
K0412	Procedure	HCPCS	MYCOPHENOLATE MOFETIL, ORAL, 250 MG
C9219	Procedure	HCPCS	MYCOPHENOLIC ACID, ORAL, PER 180 MG
Mifepristone			
S0190	Procedure	HCPCS	MIFEPRISTONE, ORAL, 200 MG
Clozapine			
S0136	Procedure	HCPCS	CLOZAPINE, 25 MG
Eculizumab			
J1300	Procedure	HCPCS	INJECTION, ECULIZUMAB, 10 MG
C9236	Procedure	HCPCS	INJECTION, ECULIZUMAB, 10 MG
Natalizumab			
J2323	Procedure	HCPCS	INJECTION, NATALIZUMAB, 1 MG
Q4079	Procedure	HCPCS	INJECTION, NATALIZUMAB, 1 MG
C9126	Procedure	HCPCS	INJECTION, NATALIZUMAB, PER 5 MG

Appendix D. List of Generic Names of Medical Products Used to Define Index Exposures in this Request

Generic Name

Collagenase clostridium histolyticum
collagenase Clostridium histolyticum
Isotretinoin
isotretinoin isotretinoin, micronized
Mycophenolate
mycophenolate mofetil
Lenalidomide
lenalidomide
Mifepristone
mifepristone
Clozapine
clozapine
Phentermine/topiramate
phentermine HCl/topiramate
Eculizumab
eculizumab
Natalizumab
natalizumab
Pomalidomide
pomalidomide