Disclaimer

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

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the Query Builder analysis.

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

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.

<u>Request Description</u>: In this request, we investigated utilization patterns of Dupixent (dupilumab). The assessed cohorts differed by inclusion requirement: no inclusion requirement; a diagnosis of eosinophilic esophagitis (EoE) using a narrow definition; a diagnosis of EoE using a broad definition; a diagnosis of other health outcomes including atopic dermatitis, asthma, or chronic rhinosinusitis with nasal polyps; a diagnosis of EoE using the narrow definition and a diagnosis of one of the aforementioned other health outcomes; and a diagnosis of EoE using the broad definition and a diagnosis of one of the aforementioned other health outcomes.

<u>Sentinel Routine Querying Module</u>: Cohort Identification and Descriptive Analysis (CIDA) module, version 10.3.3

Data Source: We executed this request on IBM[®] MarketScan[®] Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 147 million members, on July 23, 2021. The study period included data from January 1, 2017 to March 31, 2020. 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.

<u>Notes:</u> Please contact the Sentinel Operations Center (<u>info@sentinelsystem.org</u>) 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 (<u>https://dev.sentinelsystem.org/projects/QB/repos/querybuilder/</u>browse).



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Table 1a: Baseline table (Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication)
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Benign Prostatic Hyperplasia 22 3.3% Breast Cancer 7 1.1% Cataracts 36 5.4% Chronic Kidney Disease 63 9.5% Chronic Obstructive Pulmonary Disease 73 11.0% Colorectal Cancer 8 1.2% Depression 124 18.6% Diabetes 90 13.5% Endometrial Cancer 1 0.2% Glaucoma 23 3.5% Heart Failure 23 3.5% Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hyperlipidemia 163 24.5% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Asthma	310	46.6%
Breast Cancer 7 1.1% Cataracts 36 5.4% Chronic Kidney Disease 63 9.5% Chronic Obstructive Pulmonary Disease 73 11.0% Colorectal Cancer 8 1.2% Depression 124 18.6% Diabetes 90 13.5% Endometrial Cancer 1 0.2% Glaucoma 23 3.5% Heart Failure 23 3.5% Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hypertension 216 32.5% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Atrial Fibrillation	15	2.3%
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Chronic Obstructive Pulmonary Disease 73 11.0% Colorectal Cancer 8 1.2% Depression 124 18.6% Diabetes 90 13.5% Endometrial Cancer 1 0.2% Glaucoma 23 3.5% Heart Failure 23 3.5% Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hypertension 216 32.5% Ischemic Heart Disease 38 5.7% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Cataracts	36	5.4%
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Depression 124 18.6% Diabetes 90 13.5% Endometrial Cancer 1 0.2% Glaucoma 23 3.5% Heart Failure 23 3.5% Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hypertension 216 32.5% Ischemic Heart Disease 38 5.7% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Chronic Obstructive Pulmonary Disease	73	11.0%
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Endometrial Cancer10.2%Glaucoma233.5%Heart Failure233.5%Hip / Pelvic Fracture20.3%Hyperlipidemia16324.5%Hypertension21632.5%Ischemic Heart Disease385.7%Lung Cancer10.2%Osteoporosis142.1%Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:16.212.1	Depression	124	18.6%
Glaucoma 23 3.5% Heart Failure 23 3.5% Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hypertension 216 32.5% Ischemic Heart Disease 38 5.7% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Diabetes	90	13.5%
Heart Failure 23 3.5% Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hypertension 216 32.5% Ischemic Heart Disease 38 5.7% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Endometrial Cancer	1	0.2%
Hip / Pelvic Fracture 2 0.3% Hyperlipidemia 163 24.5% Hypertension 216 32.5% Ischemic Heart Disease 38 5.7% Lung Cancer 1 0.2% Osteoporosis 14 2.1% Prostate Cancer 5 0.8% Rheumatoid Arthritis / Osteoarthritis 88 13.2% Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 16.2 12.1	Glaucoma	23	3.5%
Hyperlipidemia16324.5%Hypertension21632.5%Ischemic Heart Disease385.7%Lung Cancer10.2%Osteoporosis142.1%Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:16.212.1	Heart Failure	23	3.5%
Hypertension21632.5%Ischemic Heart Disease385.7%Lung Cancer10.2%Osteoporosis142.1%Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:Mean number of ambulatory encounters (AV)16.212.1	Hip / Pelvic Fracture	2	0.3%
Ischemic Heart Disease385.7%Lung Cancer10.2%Osteoporosis142.1%Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:Mean number of ambulatory encounters (AV)16.212.1	Hyperlipidemia	163	24.5%
Lung Cancer10.2%Osteoporosis142.1%Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:Mean number of ambulatory encounters (AV)16.212.1	Hypertension	216	32.5%
Osteoporosis142.1%Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:Mean number of ambulatory encounters (AV)16.212.1	Ischemic Heart Disease	38	5.7%
Prostate Cancer50.8%Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:Mean number of ambulatory encounters (AV)16.212.1	Lung Cancer	1	0.2%
Rheumatoid Arthritis / Osteoarthritis8813.2%Stroke / Transient Ischemic Attack60.9%Health Service Utilization Intensity:Image: Colspan="2">Image: Colspan="2"Health Service Utilization Intensity:Image: Colspan="2"Mean number of ambulatory encounters (AV)16.212.1	Osteoporosis	14	2.1%
Stroke / Transient Ischemic Attack 6 0.9% Health Service Utilization Intensity: 7 Mean number of ambulatory encounters (AV) 16.2 12.1	Prostate Cancer	5	0.8%
Health Service Utilization Intensity: Mean number of ambulatory encounters (AV) 16.2 12.1	Rheumatoid Arthritis / Osteoarthritis	88	13.2%
Mean number of ambulatory encounters (AV) 16.2 12.1	Stroke / Transient Ischemic Attack	6	0.9%
	Health Service Utilization Intensity:		
Mean number of emergency room encounters (ED) 0.7 1.5	Mean number of ambulatory encounters (AV)	16.2	12.1
	Mean number of emergency room encounters (ED)	0.7	1.5



Table 1a: Baseline table (Du	

N/Mean	%/Std Dev ²
0.2	0.6
0.0	0.0
3.3	7.3
22.9	17.4
11.2	6.6
10.1	5.8
	0.2 0.0 3.3 22.9 11.2



Table 1b: Baseline table (Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication and Other Labeled Indication)

Characteristic ¹	N/Mean	%/Std Dev ²
Number of unique patients	602	
Demographics		
Mean Age (Years)	43.3	17.3
Age (Years): 00-05	-	-
Age (Years): 06-11	6	1.0%
Age (Years): 12-16	50	8.3%
Age (Years): 17+	546	90.7%
Sex (Female)	348	57.8%
Sex (Male)	254	42.2%
Year (2017)	51	8.5%
Year (2018)	119	19.8%
Year (2019)	309	51.3%
Year (2020)	123	20.4%
Recorded history of:		
Prior combined comorbidity score ³	1.3	1.6
Acquired Hypothyroidism	69	11.5%
Acute Myocardial Infarction	8	1.3%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	2	0.3%
Anemia	80	13.3%
Asthma	310	51.5%
Atrial Fibrillation	12	2.0%
Benign Prostatic Hyperplasia	18	3.0%
Breast Cancer	7	1.2%
Cataracts	33	5.5%
Chronic Kidney Disease	58	9.6%
Chronic Obstructive Pulmonary Disease	71	11.8%
Colorectal Cancer	7	1.2%
Depression	114	18.9%
Diabetes	80	13.3%
Endometrial Cancer	1	0.2%
Glaucoma	23	3.8%
Heart Failure	22	3.7%
Hip / Pelvic Fracture	2	0.3%
Hyperlipidemia	138	22.9%
Hypertension	194	32.2%
Ischemic Heart Disease	33	5.5%
Lung Cancer	1	0.2%
Osteoporosis	12	2.0%
Prostate Cancer	4	0.7%
Rheumatoid Arthritis / Osteoarthritis	81	13.5%
Stroke / Transient Ischemic Attack	6	1.0%
Health Service Utilization Intensity:	16.0	12.2
Mean number of ambulatory encounters (AV)	16.6	12.3
Mean number of emergency room encounters (ED)	0.7	1.5



Table 1b: Baseline table (Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication and Other Labeled Indication)

Characteristic ¹	N/Mean	%/Std Dev ²
Mean number of inpatient hospital encounters (IP)	0.2	0.6
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	3.4	7.7
Mean number of filled prescriptions	23.2	17.7
Mean number of generics	11.4	6.7
Mean number of unique drug classes	10.3	5.9



Table 1c: Baseline table (Dupixent; Narrow Eosinop	philic Esophagitis (EpE) Indication)

Characteristic ¹	N/Mean	%/Std Dev ²
Number of unique patients	87	
Demographics		
Mean Age (Years)	31.4	17.2
Age (Years): 00-05	-	-
Age (Years): 06-11	3	3.4%
Age (Years): 12-16	27	31.0%
Age (Years): 17+	57	65.5%
Sex (Female)	37	42.5%
Sex (Male)	50	57.5%
Year (2017)	2	2.3%
Year (2018)	14	16.1%
Year (2019)	50	57.5%
Year (2020)	21	24.1%
Recorded history of:		
Prior combined comorbidity score ³	0.9	1.0
Acquired Hypothyroidism	7	8.0%
Acute Myocardial Infarction	0	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	0	0.0%
Anemia	5	5.7%
Asthma	59	67.8%
Atrial Fibrillation	0	0.0%
Benign Prostatic Hyperplasia	0	0.0%
Breast Cancer	0	0.0%
Cataracts	2	2.3%
Chronic Kidney Disease	1	1.1%
Chronic Obstructive Pulmonary Disease	4	4.6%
Colorectal Cancer	1	1.1%
Depression	8	9.2%
Diabetes	0	0.0%
Endometrial Cancer	0	0.0%
Glaucoma	0	0.0%
Heart Failure	0	0.0%
Hip / Pelvic Fracture	1	1.1%
Hyperlipidemia	4	4.6%
Hypertension	11	12.6%
Ischemic Heart Disease	1	1.1%
Lung Cancer	0	0.0%
Osteoporosis	1	1.1%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	5	5.7%
Stroke / Transient Ischemic Attack	0	0.0%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	14.0	10.5
Mean number of emergency room encounters (ED)	0.5	1.1



Characteristic ¹	N/Mean	%/Std Dev ²
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)	2.0	3.0
Mean number of filled prescriptions	18.6	13.7
Mean number of generics	8.9	4.8
Mean number of unique drug classes	8.1	4.3



 Table 1d: Baseline table (Dupixent; Narrow Eosinophilic Esophagitis (EoE) Indication and

 Other Labeled Indication)

Characteristic ¹	N/Mean	%/Std Dev ²
Number of unique patients	82	
Demographics		
Mean Age (Years)	31.3	17.5
Age (Years): 00-05	-	-
Age (Years): 06-11	3	3.7%
Age (Years): 12-16	27	32.9%
Age (Years): 17+	52	63.4%
Sex (Female)	35	42.7%
Sex (Male)	47	57.3%
Year (2017)	2	2.4%
Year (2018)	14	17.1%
Year (2019)	46	56.1%
Year (2020)	20	24.4%
Recorded history of:		
Prior combined comorbidity score ³	1.0	1.0
Acquired Hypothyroidism	7	8.5%
Acute Myocardial Infarction	0	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	0	0.0%
Anemia	5	6.1%
Asthma	59	72.0%
Atrial Fibrillation	0	0.0%
Benign Prostatic Hyperplasia	0	0.0%
Breast Cancer	0	0.0%
Cataracts	2	2.4%
Chronic Kidney Disease	1	1.2%
Chronic Obstructive Pulmonary Disease	4	4.9%
Colorectal Cancer	1	1.2%
Depression	7	8.5%
Diabetes	0	0.0%
Endometrial Cancer	0	0.0%
Glaucoma	0	0.0%
Heart Failure	0	0.0%
Hip / Pelvic Fracture	1	1.2%
Hyperlipidemia	4	4.9%
Hypertension	10	12.2%
Ischemic Heart Disease	1	1.2%
Lung Cancer	0	0.0%
Osteoporosis	1	1.2%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	5	6.1%
Stroke / Transient Ischemic Attack	0	0.0%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	13.9	10.5
Mean number of emergency room encounters (ED)	0.5	1.1



Table 1d: Baseline table (Dupixent; Narrow Eosinophilic Esophagitis (EoE) Indication and Other Labeled Indication)

Characteristic ¹	N/Mean	%/Std Dev ²
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)	2.1	3.1
Mean number of filled prescriptions	18.4	13.6
Mean number of generics	8.9	4.8
Mean number of unique drug classes	8.1	4.2



Table 1e: Baseline table (Dupixent; Other Labeled Indication)		
Characteristic ¹	N/Mean	%/Std Dev ²
Number of unique patients	12,787	
Demographics		
Mean Age (Years)	40.6	16.8
Age (Years): 00-05	8	0.1%
Age (Years): 06-11	114	0.9%
Age (Years): 12-16	922	7.2%
Age (Years): 17+	11,743	91.8%
Sex (Female)	7,056	55.2%
Sex (Male)	5,731	44.8%
Year (2017)	1,851	14.5%
Year (2018)	2,843	22.2%
Year (2019)	6,225	48.7%
Year (2020)	1,868	14.6%
Recorded history of:		
Prior combined comorbidity score3	0.5	1.1
Acquired Hypothyroidism	833	6.5%
Acute Myocardial Infarction	29	0.2%
Alzheimer's Disease	2	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	11	0.1%
Anemia	637	5.0%
Asthma	4,082	31.9%
Atrial Fibrillation	145	1.1%
Benign Prostatic Hyperplasia	202	1.6%
Breast Cancer	93	0.7%
Cataracts	474	3.7%
Chronic Kidney Disease	519	4.1%
Chronic Obstructive Pulmonary Disease	711	5.6%
Colorectal Cancer	23	0.2%
Depression	1,342	10.5%
Diabetes	896	7.0%
Endometrial Cancer	5	0.0%
Glaucoma	338	2.6%
Heart Failure	117	0.9%
Hip / Pelvic Fracture	14	0.1%
Hyperlipidemia	2,089	16.3%
Hypertension	2,483	19.4%
Ischemic Heart Disease	326	2.5%
Lung Cancer	12	0.1%
Osteoporosis	151	1.2%
Prostate Cancer	54	0.4%
Rheumatoid Arthritis / Osteoarthritis	988	7.7%
Stroke / Transient Ischemic Attack	63	0.5%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	10.2	9.6
Mean number of emergency room encounters (ED)	0.2	0.7



Table 1e: Baseline table (Dupixent; Other Labeled Indicatio	on)	
Characteristic ¹	N/Mean	%/Std Dev ²
Mean number of inpatient hospital encounters (IP)	0.0	0.3
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	1.5	3.4
Mean number of filled prescriptions	15.0	13.3
Mean number of generics	7.6	5.2
Mean number of unique drug classes	6.8	4.6



Table 2a: Descriptive statistics of cumulative exposure duration, all epis	odes, in days							
Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	16,481	241.90	227.12	1	70	174	342	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	196.35	188.24	2	61	140	267	1,063
Dupixent; Broad EoE Indication and Other Labeled Indication	602	195.19	187.48	2	58	138	268	1,049
Dupixent; Narrow EoE Indication	87	180.59	159.29	6	56	135	278	749
Dupixent; Narrow EoE Indication and Other Labeled Indication	82	184.15	161.82	6	60	141	278	749
Dupixent; Other Labeled Indication	12,787	240.70	225.82	1	70	174	336	1,090



Table 2b: Descriptive statistics of cumulative exposure duration,	all episodes, i	n days, b	y sex					
Exposures 1	otal Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	16,481	241.90	227.12	1	70	174	342	1,090
Female	9,112	234.87	221.77	1	67	168	335	1,087
Male	7,369	250.58	233.29	1	72	181	351	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	196.35	188.24	2	61	140	267	1,063
Female	384	190.93	185.87	5	56	135	269	981
Male	281	203.75	191.52	2	69	141	265	1,063
Dupixent; Broad EoE Indication and Other Labeled Indication	602	195.19	187.48	2	58	138	268	1,049
Female	348	191.78	188.89	5	56	134	269	981
Male	254	199.87	185.80	2	64	141	268	1,049
Dupixent; Narrow EoE Indication	87	180.59	159.29	6	56	135	278	749
Female	37	194.03	192.60	6	56	105	298	749
Male	50	170.64	130.54	6	63	137	263	515
Dupixent; Narrow EoE Indication and Other Labeled Indication	n 82	184.15	161.82	6	60	141	278	749
Female	35	195.37	195.67	6	56	105	338	749
Male	47	175.79	132.83	6	63	153	271	515
Dupixent; Other Labeled Indication	12,787	240.70	225.82	1	70	174	336	1,090
Female	7,056	235.27	220.33	1	70	170	330	1,087
Male	5,731	247.40	232.24	1	73	176	343	1,090



Table 2c: Descriptive statistics of cumulative exposure durat	ion, all episod	es, in da	ys, by age group (year	5)				
Exposures	Total Patients	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	16,481	241.90	227.12	1	70	174	342	1,090
00-05	9	81.56	74.79	15	28	48	108	230
06-11	131	176.42	163.52	4	48	139	246	820
12-16	1,070	188.01	142.03	1	72	167	279	873
17+	15,271	246.33	231.85	1	70	175	351	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	196.35	188.24	2	61	140	267	1,063
00-05	0	-	-	-	-	-	-	-
06-11	6	152.00	103.65	33	62	150	246	271
12-16	50	156.28	110.15	5	64	136	216	405
17+	609	200.07	193.57	2	58	140	278	1,063
Dupixent; Broad EoE Indication and Other Labeled Indication	602	195.19	187.48	2	58	138	268	1,049
00-05	0	-	-	-	-	-	-	-
06-11	6	152.00	103.65	33	62	150	246	271
12-16	50	156.28	110.15	5	64	136	216	405
17+	546	199.23	193.38	2	58	138	278	1,049
Dupixent; Narrow EoE Indication	87	180.59	159.29	6	56	135	278	749
00-05	0	-	-	-	-	-	-	-
06-11	3	129.67	125.13	33	33	85	271	271
12-16	27	167.19	123.05	8	63	139	244	405
17+	57	189.61	176.26	6	56	135	278	749
Dupixent; Narrow EoE Indication and Other Labeled Indicatio	n 82	184.15	161.82	6	60	141	278	749
00-05	0	-	-	-	-	-	-	-
06-11	3	129.67	125.13	33	33	85	271	271
12-16	27	167.19	123.05	8	63	139	244	405
17+	52	196.10	181.06	6	58	147	280	749
Dupixent; Other Labeled Indication	12,787	240.70	225.82	1	70	174	336	1,090
00-05	8	86.38	78.45	15	24	59	140	230
06-11	114	182.52	162.51	4	48	148	253	820
12-16	922	190.96	139.60	1	82	174	280	873
17+	11,743	245.28	231.25	1	70	174	348	1,090



Table 3a: Descriptive statistics of first exposure episode dura	ation, in days							
Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	16,481	173.93	192.77	1	37	109	237	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	145.86	159.39	2	34	89	194	1,049
Dupixent; Broad EoE Indication and Other Labeled Indication	602	145.06	159.20	2	30	90	196	1,049
Dupixent; Narrow EoE Indication	87	126.44	130.44	6	28	85	183	748
Dupixent; Narrow EoE Indication and Other Labeled Indication	82	126.70	132.42	6	28	85	183	748
Dupixent; Other Labeled Indication	12,787	173.34	192.71	1	37	109	235	1,090



Table 3b: Descriptive statistics of first exposure episode duration	, in days, by se	x						
Exposures	Fotal Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	16,481	173.93	192.77	1	37	109	237	1,090
Female	9,112	171.50	189.75	1	37	105	236	1,087
Male	7,369	176.94	196.41	1	40	112	238	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	145.86	159.39	2	34	89	194	1,049
Female	384	144.08	161.82	5	28	88	189	981
Male	281	148.31	156.26	2	42	90	199	1,049
Dupixent; Broad EoE Indication and Other Labeled Indication	602	145.06	159.20	2	30	90	196	1,049
Female	348	145.07	165.09	5	28	91	189	981
Male	254	145.03	151.08	2	41	89	202	1,049
Dupixent; Narrow EoE Indication	87	126.44	130.44	6	28	85	183	748
Female	37	138.97	161.58	6	28	75	183	748
Male	50	117.16	102.35	6	30	86	176	418
Dupixent; Narrow EoE Indication and Other Labeled Indication	82	126.70	132.42	6	28	85	183	748
Female	35	137.17	163.18	6	28	75	183	748
Male	47	118.89	105.12	6	30	86	183	418
Dupixent; Other Labeled Indication	12,787	173.34	192.71	1	37	109	235	1,090
Female	7,056	172.40	190.18	1	37	108	237	1,087
Male	5,731	174.49	195.80	1	36	111	233	1,090



Table 3c: Descriptive statistics of first exposure episode du	ration, in days, l	oy age grou	up (years)					
Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	16,481	173.93	192.77	1	37	109	237	1,090
00-05	9	70.33	55.63	15	28	48	96	174
06-11	131	115.69	112.91	4	28	70	181	499
12-16	1,070	145.61	126.96	1	42	112	222	841
17+	15,271	176.48	196.89	1	37	109	238	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	145.86	159.39	2	34	89	194	1,049
00-05	0	-	-	-	-	-	-	-
06-11	6	139.67	95.72	28	62	131	215	271
12-16	50	119.92	96.87	5	48	93	182	405
17+	609	148.06	163.87	2	33	88	196	1,049
Dupixent; EoE Indication and Other Labeled Indication	602	145.06	159.20	2	30	90	196	1,049
00-05	0	-	-	-	-	-	-	-
06-11	6	139.67	95.72	28	62	131	215	271
12-16	50	119.92	96.87	5	48	93	182	405
17+	546	147.42	164.18	2	30	89	197	1,049
Dupixent; Narrow EoE Indication	87	126.44	130.44	6	28	85	183	748
00-05	0	-	-	-	-	-	-	-
06-11	3	128.00	127.08	28	28	85	271	271
12-16	27	124.52	114.31	8	28	88	183	405
17+	57	127.26	139.58	6	28	77	182	748
Dupixent; Narrow EoE Indication and Other Labeled Indication	on 82	126.70	132.42	6	28	85	183	748
00-05	0	-	-	-	-	-	-	-
06-11	3	128.00	127.08	28	28	85	271	271
12-16	27	124.52	114.31	8	28	88	183	405
17+	52	127.75	143.35	6	28	76	183	748
Dupixent; Other Labeled Indication	12,787	173.34	192.71	1	37	109	235	1,090
00-05	8	73.75	58.45	15	24	59	118	174
06-11	114	120.13	112.10	4	28	80	195	499
12-16	922	146.64	125.81	1	42	114	224	752
17+	11,743	176.02	197.43	1	36	109	238	1,090



Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	26,532	150.26	173.85	1	28	85	197	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	1,017	128.39	147.28	1	28	83	168	1,049
Dupixent; Broad EoE Indication and Other Labeled Indication	918	128.00	147.73	1	28	83	168	1,049
Dupixent; Narrow EoE Indication	130	120.85	123.21	1	28	84	176	748
Dupixent; Narrow EoE Indication and Other Labeled Indication	125	120.80	124.29	1	28	84	176	748
Dupixent; Other Labeled Indication	20,695	148.73	173.33	1	28	85	196	1,090



Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	26,532	150.26	173.85	1	28	85	197	1,090
Female	14,423	148.38	171.28	1	28	84	196	1,087
Male	12,109	152.49	176.85	1	28	86	198	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	1,017	128.39	147.28	1	28	83	168	1,049
Female	579	126.63	146.13	1	28	82	160	981
Male	438	130.72	148.91	2	28	83	181	1,049
Dupixent; Broad EoE Indication and Other Labeled Indication	918	128.00	147.73	1	28	83	168	1,049
Female	519	128.60	149.87	1	28	83	167	981
Male	399	127.23	145.09	2	28	81	177	1,049
Dupixent; Narrow EoE Indication	130	120.85	123.21	1	28	84	176	748
Female	57	125.95	144.34	1	28	75	180	748
Male	73	116.88	104.69	5	30	86	175	473
Dupixent; Narrow EoE Indication and Other Labeled Indication	ı 125	120.80	124.29	1	28	84	176	748
Female	55	124.33	144.66	1	28	75	180	748
Male	70	118.03	106.61	5	30	86	176	473
Dupixent; Other Labeled Indication	20,695	148.73	173.33	1	28	85	196	1,090
Female	11,254	147.51	170.97	1	28	84	196	1,087
Male	9,441	150.18	176.09	1	28	86	196	1,090



Table 4c: Descriptive statistics of all exposure episode duration	ions, in days, b	y age grou	ıp (years)					
Exposures	Total Episodes	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	26,532	150.26	173.85	1	28	85	197	1,090
00-05	14	52.43	50.62	5	20	28	70	174
06-11	193	119.75	127.53	3	30	71	168	786
12-16	1,554	129.46	120.37	1	30	92	191	841
17+	24,771	151.86	176.90	1	28	85	197	1,090
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	1,017	128.39	147.28	1	28	83	168	1,049
00-05	0	-	-	-	-	-	-	-
06-11	9	101.33	95.47	5	28	62	177	271
12-16	77	101.48	87.83	5	28	84	148	405
17+	931	130.88	151.37	1	28	83	170	1,049
Dupixent; Broad EoE Indication and Other Labeled Indication	918 ·	128.00	147.73	1	28	83	168	1,049
00-05	0	-	-	-	-	-	-	-
06-11	9	101.33	95.47	5	28	62	177	271
12-16	77	101.48	87.83	5	28	84	148	405
17+	832	130.75	152.35	1	28	83	171	1,049
Dupixent; Narrow EoE Indication	130	120.85	123.21	1	28	84	176	748
00-05	0	-	-	-	-	-	-	-
06-11	4	97.25	120.62	5	17	57	178	271
12-16	43	104.98	99.26	8	28	71	160	405
17+	83	130.22	134.37	1	30	84	183	748
Dupixent; Narrow EoE Indication and Other Labeled Indicatio	n 125	120.80	124.29	1	28	84	176	748
00-05	0	-	-	-	-	-	-	-
06-11	4	97.25	120.62	5	17	57	178	271
12-16	43	104.98	99.26	8	28	71	160	405
17+	78	130.73	136.63	1	28	84	183	748
Dupixent; Other Labeled Indication	20,695	148.73	173.33	1	28	85	196	1,090
00-05	13	53.15	52.61	5	20	28	70	174
06-11	163	127.65	131.86	3	30	84	189	786
12-16	1,353	130.13	119.01	1	30	97	193	752
17+	19,166	150.28	176.79	1	28	84	196	1,090



Table 5a: Descriptive statistics of days supplied per dispensing									
Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum	
Dupixent; Any Indication	138,043	27.81	12.21	1	28	28	28	350	
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	4,554	27.57	12.17	1	28	28	28	182	
Dupixent; Broad EoE Indication and Other Labeled Indication	4,152	27.25	11.42	1	28	28	28	182	
Dupixent; Narrow EoE Indication	574	26.28	9.83	1	28	28	28	84	
Dupixent; Narrow EoE Indication and Other Labeled Indication	550	26.34	9.93	1	28	28	28	84	
Dupixent; Other Labeled Indication	106,496	27.83	12.17	1	28	28	28	285	



Table 5b: Descriptive statistics of days supplied per dispension	g, by sex							
Exposures	otal Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	138,043	27.81	12.21	1	28	28	28	350
Female	74,451	27.68	12.15	1	28	28	28	350
Male	63,592	27.97	12.28	1	28	28	28	308
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	4,554	27.57	12.17	1	28	28	28	182
Female	2,587	27.27	11.38	1	28	28	28	84
Male	1,967	27.97	13.14	1	28	28	28	182
Dupixent; Broad EoE Indication and Other Labeled Indication	on 4,152	27.25	11.42	1	28	28	28	182
Female	2,369	27.14	11.10	1	28	28	28	84
Male	1,783	27.39	11.85	1	28	28	28	182
Dupixent; Narrow EoE Indication	574	26.28	9.83	1	28	28	28	84
Female	265	25.82	6.93	1	28	28	28	84
Male	309	26.68	11.76	1	28	28	28	84
Dupixent; Narrow EoE Indication and Other Labeled Indicat	ion 550	26.34	9.93	1	28	28	28	84
Female	252	25.82	7.01	1	28	28	28	84
Male	298	26.78	11.85	1	28	28	28	84
Dupixent; Other Labeled Indication	106,496	27.83	12.17	1	28	28	28	285
Female	57,760	27.67	11.99	1	28	28	28	285
Male	48,736	28.01	12.38	1	28	28	28	265



Table 5c: Descriptive statistics of days supplied per dispensing	ı, by age group (yea	rs)						
Exposures	Total Dispensings	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	138,043	27.81	12.21	1	28	28	28	350
00-05	31	22.03	8.64	1	14	28	28	28
06-11	826	26.59	11.24	1	28	28	28	84
12-16	7,206	26.79	12.96	1	28	28	28	299
17+	129,980	27.88	12.17	1	28	28	28	350
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	4,554	27.57	12.17	1	28	28	28	182
00-05	0	-	-	-	-	-	-	-
06-11	36	23.64	8.23	1	24	28	28	28
12-16	293	25.46	11.55	2	28	28	28	182
17+	4,225	27.75	12.22	1	28	28	28	154
Dupixent; Broad EoE Indication and Other Labeled Indication	4,152	27.25	11.42	1	28	28	28	182
00-05	0	-	-	-	-	-	-	-
06-11	36	23.64	8.23	1	24	28	28	28
12-16	293	25.46	11.55	2	28	28	28	182
17+	3,823	27.42	11.43	1	28	28	28	84
Dupixent; Narrow EoE Indication	574	26.28	9.83	1	28	28	28	84
00-05	0	-	-	-	-	-	-	-
06-11	16	24.31	8.65	1	28	28	28	28
12-16	173	24.84	7.30	6	28	28	28	56
17+	385	27.01	10.76	1	28	28	28	84
Dupixent; Narrow EoE Indication and Other Labeled Indication	550	26.34	9.93	1	28	28	28	84
00-05	0	-	-	-	-	-	-	-
06-11	16	24.31	8.65	1	28	28	28	28
12-16	173	24.84	7.30	6	28	28	28	56
17+	361	27.15	10.95	1	28	28	28	84
Dupixent; Other Labeled Indication	106,496	27.83	12.17	1	28	28	28	285
00-05	28	22.86	7.88	5	14	28	28	28
06-11	740	26.68	11.46	1	28	28	28	84
12-16	6,328	26.69	12.23	1	28	28	28	224
17+	99,400	27.91	12.17	1	28	28	28	285



Table 6a: Descriptive statistics of the length of all gaps between treatment episodes, in days								
Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	10,051	48.88	67.88	7	20	27	47	856
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	352	46.36	67.82	15	19	29	47	755
Dupixent; Broad EoE Indication and Other Labeled Indication	316	47.25	70.79	15	19	28	47	755
Dupixent; Narrow EoE Indication	43	39.60	34.74	15	19	29	49	225
Dupixent; Narrow EoE Indication and Other Labeled Indication	43	39.60	34.74	15	19	29	49	225
Dupixent; Other Labeled Indication	7,908	47.96	67.24	15	20	27	46	856



Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	10,051	48.88	67.88	7	20	27	47	856
Female	5,311	50.24	70.40	12	20	28	49	856
Male	4,740	47.35	64.90	7	19	27	46	777
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	352	46.36	67.82	15	19	29	47	755
Female	195	47.52	75.22	15	20	29	46	755
Male	157	44.92	57.54	15	19	28	48	506
Dupixent; Broad EoE Indication and Other Labeled Indication	316	47.25	70.79	15	19	28	47	755
Female	171	48.81	79.23	15	20	29	47	755
Male	145	45.41	59.53	15	19	28	47	506
Dupixent; Narrow EoE Indication	43	39.60	34.74	15	19	29	49	225
Female	20	44.85	45.46	17	21	31	55	225
Male	23	35.04	21.73	15	18	26	47	99
Dupixent; Narrow EoE Indication and Other Labeled Indication	43	39.60	34.74	15	19	29	49	225
Female	20	44.85	45.46	17	21	31	55	225
Male	23	35.04	21.73	15	18	26	47	99
Dupixent; Other Labeled Indication	7,908	47.96	67.24	15	20	27	46	856
Female	4,198	49.17	69.88	15	20	27	47	856
Male	3,710	46.58	64.11	15	20	27	45	777



Table 6c: Descriptive statistics of the length of all gaps between	treatment epi	sodes, in	days, by age group (year	s)				
Exposures	Total Gaps	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Dupixent; Any Indication	10,051	48.88	67.88	7	20	27	47	856
00-05	5	28.40	7.92	18	24	28	34	38
06-11	62	35.50	36.30	15	18	24	37	224
12-16	484	38.71	45.52	15	19	26	41	504
17+	9,500	49.49	68.94	7	20	27	48	856
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	352	46.36	67.82	15	19	29	47	755
00-05	0	-	-	-	-	-	-	-
06-11	3	38.33	33.50	18	18	20	77	77
12-16	27	34.85	19.96	15	18	28	47	91
17+	322	47.40	70.55	15	19	29	47	755
Dupixent; Broad EoE Indication and Other Labeled Indication	316	47.25	70.79	15	19	28	47	755
00-05	0	-	-	-	-	-	-	-
06-11	3	38.33	33.50	18	18	20	77	77
12-16	27	34.85	19.96	15	18	28	47	91
17+	286	48.51	74.01	15	19	28	47	755
Dupixent; Narrow EoE Indication	43	39.60	34.74	15	19	29	49	225
00-05	0	-	-	-	-	-	-	-
06-11	1	18.00	-	18	18	18	18	18
12-16	16	36.38	16.24	15	20	36	48	63
17+	26	42.42	42.84	15	21	27	57	225
Dupixent; Narrow EoE Indication and Other Labeled Indication	43	39.60	34.74	15	19	29	49	225
00-05	0	-	-	-	-	-	-	-
06-11	1	18.00	-	18	18	18	18	18
12-16	16	36.38	16.24	15	20	36	48	63
17+	26	42.42	42.84	15	21	27	57	225
Dupixent; Other Labeled Indication	7,908	47.96	67.24	15	20	27	46	856
00-05	5	28.40	7.92	18	24	28	34	38
06-11	49	29.61	17.13	15	18	24	33	95
12-16	431	38.48	46.56	15	19	26	40	504
17+	7,423	48.64	68.42	15	20	27	47	856



Table 7: Counts of reason for censoring, all episodes and first	episode									
	Total		Disenroll	Disenrollment		Evidence of death		DP/Query end date		end
	N	%	N	%	Ν	%	N	%	N	%
Exposures										
Dupixent; Any Indication	26,532	100.0	11,624	43.8	0	0.0	8,819	33.2	26,532	100.0
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	1,017	100.0	466	45.8	0	0.0	378	37.2	1,017	100.0
Dupixent; Broad EoE Indication and Other Labeled Indication	918	100.0	425	46.3	0	0.0	343	37.4	918	100.0
Dupixent; Narrow EoE Indication	130	100.0	63	48.5	0	0.0	50	38.5	130	100.0
Dupixent; Narrow EoE Indication and Other Labeled Indication	125	100.0	60	48.0	0	0.0	48	38.4	125	100.0
Dupixent; Other Labeled Indication	20,695	100.0	8,948	43.2	0	0.0	7,051	34.1	20,695	100.0
Patients' First Episode										
Dupixent; Any Indication	16,481	100.0	7,811	47.4	0	0.0	5,783	35.1	16,481	100.0
Dupixent; Broad Eosinophilic Esophagitis (EoE) Indication	665	100.0	309	46.5	0	0.0	246	37.0	665	100.0
Dupixent; Broad EoE Indication and Other Labeled Indication	602	100.0	281	46.7	0	0.0	224	37.2	602	100.0
Dupixent; Narrow EoE Indication	87	100.0	40	46.0	0	0.0	30	34.5	87	100.0
Dupixent; Narrow EoE Indication and Other Labeled Indication	82	100.0	37	45.1	0	0.0	28	34.1	82	100.0
Dupixent; Other Labeled Indication	12,787	100.0	5,946	46.5	0	0.0	4,582	35.8	12,787	100.0



Appendix A. Dates of Available Data for Each Data Partner (DP) up to Request End Date (03/31/2020) as of Query Distribution Date						
Data Partner (Masked)	Start Date	End Date				
DP01	01/01/2010	03/31/2020				

Appendix B. Specifications Defining Parameters in this Query

Global Values

Enroliment Criteria: Medical and Drug Coverage

Enrol^Iment Gap (Days): 45

Age Groups (Years): 0 0 05, 06-11, 12-16, 17+

Baseline Characteristics Table: Yes

Baseline Evaluation Window (Day): -183,-1

#	Cohert Name	index Exposure	Pre-Index Enrollment Perioel (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	Dupixent; Any Indication	Dupixent ^[1]		0	14	0					
2	Dupixent; Narrow Eosinophilic Esophagitis (EoE)	Dup ⁱ xent ^[2]	183	0	14	0	Inclusion	Êe≣ narrow	Narrow Eosinophilic Esophagitis (EoE) Indication ³	-183	30
	Indication										
3	Dupixent; Other Labeled	Dup ⁱ xent ^{4]}	183	0	14	0	Inclusion	Labeled ind	Other Labeled Indication ⁵	-183	30
	Indication										
4	Dupixent; Narrow EoE Indication and Other Labeled Indication	Dupixent	183	0	14	0	Incluston	EoE narrow AND labeled ind	Other Labeled Indication ⁷ and Narrow EoE Indication ⁸	-183	30
											-
5	Dupixent; Broad Eosinophilic Esophagitis	Dup ⁱ xent ^[9]	183	0	14	0	Inclusion	≊e E bread	Broad Eosinophilic Esophagitis (EoE) Indication ¹⁰	-183	30
	(EoE) Indication										
6	Dupixent; Broad EoE Indication and Other Labeled Indication	Dupixent ^[11]	183	0	14	0	Inclusion	≅eE bread AND labeled ind	Other Labeled Indication ¹² and Broad EoE	- 183	30
	multation										

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 Appendix D

[2] See Appendix D

[3] See Appendix C

[4] See Appendix DD

[5] See Appendix C

[6] See Appendix D

[7] See Appendix C-

[8] See Appendix C

[9] See Appendix D

[10] See Appendix C-

[11] See Appendix D

[12] See Appendix C-

[13] See Appendix C

Baseline Characteristics Table

Acquired Hypothyroidism Acute Myocardial Infarction Alzheimer's Disease Aizheimer's Disease, Related Disorders, or Senile Dementia Anemia Asthma Atrial Fibrillation Benign Prostatic Hyperplasia Breast Cancer Cataracts Chronic Kidney Disease Chronic Obstructive Pulmonary Disease Colorectal Cancer Depression Diabetes Endometrial Cancer Glaucoma Heart Failure Hip / Pelvic Fracture Hyperlipi demia

Hypertension Ischemic Heart Disease Lung Cancer Osteoporosis Prostate Cancer Rheumatoid Arthritis / Osteoarthritis Stroke / Transient Ischemic Attack

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 Caresetting/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. guery_builder_wp701 Appendix C. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Inclusion Criteria in this Request

Code	Code Category	Code Type	Description
		Narrow I	Eosinophilic Esophagitis (EoE) Indication
K200	Diagnosis	ICD-10-CM	Eosinophilic esophagitis
		Broad Ed	osinophilic Esophagitis (EoE) Indication
K5281	Diagnosis	ICD-10-CM	Eosinophilic gastritis or gastroenteritis
K200	Diagnosis	ICD-10-CM	Eosinophilic esophagitis
K522	Diagnosis	ICD-10-CM	Allergic and dietetic gastroenteritis and colitis
K20	Diagnosis	ICD-10-CM	Esophagitis
K208	Diagnosis	ICD-10-CM	Other esophagitis
К209	Diagnosis	ICD-10-CM	Esophagitis, unspecified
К290	Diagnosis	ICD-10-CM	Acute gastritis
K2900	Diagnosis	ICD-10-CM	Acute gastritis without bleeding
K2901	Diagnosis	ICD-10-CM	Acute gastritis with bleeding
K293	Diagnosis	ICD-10-CM	Chronic superficial gastritis
K2930	Diagnosis	ICD-10-CM	Chronic superficial gastritis without bleeding
K2931	Diagnosis	ICD-10-CM	Chronic superficial gastritis with bleeding
K294	Diagnosis	ICD-10-CM	Chronic atrophic gastritis
K2940	Diagnosis	ICD-10-CM	Chronic atrophic gastritis without bleeding
K2941	Diagnosis	ICD-10-CM	Chronic atrophic gastritis with bleeding
K295	Diagnosis	ICD-10-CM	Unspecified chronic gastritis
K2950	Diagnosis	ICD-10-CM	Unspecified chronic gastritis without bleeding
K2951	Diagnosis	ICD-10-CM	Unspecified chronic gastritis with bleeding
K296	Diagnosis	ICD-10-CM	Other gastritis
K2960	Diagnosis	ICD-10-CM	Other gastritis without bleeding
K2961	Diagnosis	ICD-10-CM	Other gastritis with bleeding
K297	Diagnosis	ICD-10-CM	Gastritis, unspecified
K2970	Diagnosis	ICD-10-CM	Gastritis, unspecified, without bleeding
K2971	Diagnosis	ICD-10-CM	Gastritis, unspecified, with bleeding
K528	Diagnosis	ICD-10-CM	Other specified noninfective gastroenteritis and colitis
K5289	Diagnosis	ICD-10-CM	Other specified noninfective gastroenteritis and colitis
К529	Diagnosis	ICD-10-CM	Noninfective gastroenteritis and colitis, unspecified
K2081	Diagnosis	ICD-10-CM	Other esophagitis with bleeding
K2080	Diagnosis	ICD-10-CM	Other esophagitis without bleeding
K5221	Diagnosis	ICD-10-CM	Food protein-induced enterocolitis syndrome
K5222	Diagnosis	ICD-10-CM	Food protein-induced enteropathy
K5229	Diagnosis	ICD-10-CM	Other allergic and dietetic gastroenteritis and colitis
		C	Other Labeled Indication
L20	Diagnosis	ICD-10-CM	Atopic dermatitis
L200	Diagnosis	ICD-10-CM	Besnier's prurigo
L208	Diagnosis	ICD-10-CM	Other atopic dermatitis
L2081	Diagnosis	ICD-10-CM	Atopic neurodermatitis
L2082	Diagnosis	ICD-10-CM	Flexural eczema
L2083	Diagnosis	ICD-10-CM	Infantile (acute) (chronic) eczema

Code	Code Category	Code Type	Description
L2084	Diagnosis	ICD-10-CM	Intrinsic (allergic) eczema
L2089	Diagnosis	ICD-10-CM	Other atopic dermatitis
L209	Diagnosis	ICD-10-CM	Atopic dermatitis, unspecified
J45	Diagnosis	ICD-10-CM	Asthma
J452	Diagnosis	ICD-10-CM	Mild intermittent asthma
J4520	Diagnosis	ICD-10-CM	Mild intermittent asthma, uncomplicated
J4521	Diagnosis	ICD-10-CM	Mild intermittent asthma with (acute) exacerbation
J4522	Diagnosis	ICD-10-CM	Mild intermittent asthma with status asthmaticus
J453	Diagnosis	ICD-10-CM	Mild persistent asthma
J4530	Diagnosis	ICD-10-CM	Mild persistent asthma, uncomplicated
J4531	Diagnosis	ICD-10-CM	Mild persistent asthma with (acute) exacerbation
J4532	Diagnosis	ICD-10-CM	Mild persistent asthma with status asthmaticus
J454	Diagnosis	ICD-10-CM	Moderate persistent asthma
J4540	Diagnosis	ICD-10-CM	Moderate persistent asthma, uncomplicated
J4541	Diagnosis	ICD-10-CM	Moderate persistent asthma with (acute) exacerbation
J4542	Diagnosis	ICD-10-CM	Moderate persistent asthma with status asthmaticus
J455	Diagnosis	ICD-10-CM	Severe persistent asthma
J4550	Diagnosis	ICD-10-CM	Severe persistent asthma, uncomplicated
J4551	Diagnosis	ICD-10-CM	Severe persistent asthma with (acute) exacerbation
J4552	Diagnosis	ICD-10-CM	Severe persistent asthma with status asthmaticus
J459	Diagnosis	ICD-10-CM	Other and unspecified asthma
J4590	Diagnosis	ICD-10-CM	Unspecified asthma
J45901	Diagnosis	ICD-10-CM	Unspecified asthma with (acute) exacerbation
J45902	Diagnosis	ICD-10-CM	Unspecified asthma with status asthmaticus
J45909	Diagnosis	ICD-10-CM	Unspecified asthma, uncomplicated
J4599	Diagnosis	ICD-10-CM	Other asthma
J31	Diagnosis	ICD-10-CM	Chronic rhinitis, nasopharyngitis and pharyngitis
J310	Diagnosis	ICD-10-CM	Chronic rhinitis
J311	Diagnosis	ICD-10-CM	Chronic nasopharyngitis
J312	Diagnosis	ICD-10-CM	Chronic pharyngitis
J33	Diagnosis	ICD-10-CM	Nasal polyp
J330	Diagnosis	ICD-10-CM	Polyp of nasal cavity
J331	Diagnosis	ICD-10-CM	Polypoid sinus degeneration
J338	Diagnosis	ICD-10-CM	Other polyp of sinus
J339	Diagnosis	ICD-10-CM	Nasal polyp, unspecified
J45998	Diagnosis	ICD-10-CM	Other asthma
J32	Diagnosis	ICD-10-CM	Chronic sinusitis
J320	Diagnosis	ICD-10-CM	Chronic maxillary sinusitis
J321	Diagnosis	ICD-10-CM	Chronic frontal sinusitis
J322	Diagnosis	ICD-10-CM	Chronic ethmoidal sinusitis
J323	Diagnosis	ICD-10-CM	Chronic sphenoidal sinusitis
J324	Diagnosis	ICD-10-CM	Chronic pansinusitis

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

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

Code	Code Category	Code Type	Description
J328	Diagnosis	ICD-10-CM	Other chronic sinusitis
J329	Diagnosis	ICD-10-CM	Chronic sinusitis, unspecified

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

Generic Name	Brand Name	
Dupixent		
dupilumab	Dupixent	