

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.

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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. This is report 1 of 2. Report 2 specifies alternate age groupings of 0-17 and 18+ years.

Sentinel Routine Querying Module: 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 22, 2021. The study period included data from July 1, 2018 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.

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 (Any Comparator Drugs, Seizure)		
Characteristic ¹	N/Mean	%/Std Dev²
Number of unique patients	1,605	
Demographics ³		
Mean Age	22.3	12.8
Age: 00-05	108	6.7%
Age: 06-10	116	7.2%
Age: 11-17	431	26.9%
Age: 18+	950	59.2%
Sex (Female)	921	57.4%
Sex (Male)	684	42.6%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	0	0.0%
Race (Black or African American)	0	0.0%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (Unknown)	1,605	100.0%
Race (White)	0	0.0%
Hispanic Origin	0	0.0%
Year (2018)	709	44.2%
Year (2019)	750	46.7%
Year (2020)	146	9.1%
Recorded history of:		
Prior combined comorbidity score	0.6	1.2
Acquired Hypothyroidism	47	2.9%
Acute Myocardial Infarction	1	0.1%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	17	1.1%
Anemia	74	4.6%
Asthma	112	7.0%
Atrial Fibrillation	7	0.4%
Benign Prostatic Hyperplasia	8	0.5%
Breast Cancer	4	0.2%
Cataracts	13	0.8%
Chronic Kidney Disease	76	4.7%
Chronic Obstructive Pulmonary Disease	28	1.7%
Colorectal Cancer	0	0.0%
Depression	157	9.8%
Diabetes	37	2.3%
Endometrial Cancer	1	0.1%
Glaucoma	10	0.6%
Heart Failure	10	0.6%
Hip / Pelvic Fracture	0	0.0%
Hyperlipidemia	54	3.4%
Hypertension	79	4.9%
Ischemic Heart Disease	7	0.4%
Lung Cancer	1	0.1%
Osteoporosis	7	0.4%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	30	1.9%
Stroke / Transient Ischemic Attack	23	1.4%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	8.9	12.9
Mean number of emergency room encounters (ED)	0.5	1.0
Mean number of inpatient hospital encounters (IP)	0.2	0.7

Table 1a: Baseline table (Any Comparator Drugs, Seizure)		
Characteristic¹	N/Mean	%/Std Dev²
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	6.1	21.5
Mean number of filled prescriptions	10.3	11.2
Mean number of generics	4.2	3.9
Mean number of unique drug classes	4.1	3.6

¹All metrics based on total number of unique patients
²Value represents standard deviation where no % follows the value
³Data on Race and Hispanic Origin is not populated in IBM® MarketScan® Research Databases.

Table 1b: Baseline table [Any Epidiolex (prescription cannabidiol), Any Indication]		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	1,204	
Demographics³		
Mean Age	17.3	11.2
Age: 00-05	138	11.5%
Age: 06-10	249	20.7%
Age: 11-17	355	29.5%
Age: 18+	462	38.4%
Sex (Female)	559	46.4%
Sex (Male)	645	53.6%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	0	0.0%
Race (Black or African American)	0	0.0%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (Unknown)	1,204	100.0%
Race (White)	0	0.0%
Hispanic Origin	0	0.0%
Year (2018)	134	11.1%
Year (2019)	959	79.7%
Year (2020)	111	9.2%
Recorded history of:		
Prior combined comorbidity score	0.7	1.2
Acquired Hypothyroidism	58	4.8%
Acute Myocardial Infarction	0	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	16	1.3%
Anemia	64	5.3%
Asthma	123	10.2%
Atrial Fibrillation	0	0.0%
Benign Prostatic Hyperplasia	1	0.1%
Breast Cancer	1	0.1%
Cataracts	7	0.6%
Chronic Kidney Disease	51	4.2%
Chronic Obstructive Pulmonary Disease	37	3.1%
Colorectal Cancer	3	0.2%
Depression	66	5.5%
Diabetes	22	1.8%
Endometrial Cancer	0	0.0%
Glaucoma	13	1.1%
Heart Failure	3	0.2%
Hip / Pelvic Fracture	2	0.2%
Hyperlipidemia	41	3.4%
Hypertension	38	3.2%
Ischemic Heart Disease	3	0.2%
Lung Cancer	1	0.1%
Osteoporosis	23	1.9%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	13	1.1%
Stroke / Transient Ischemic Attack	17	1.4%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	13.5	15.2
Mean number of emergency room encounters (ED)	0.6	1.0
Mean number of inpatient hospital encounters (IP)	0.3	0.7

Table 1b: Baseline table [Any Epidiolex (prescription cannabidiol), Any Indication]		
Characteristic¹	N/Mean	%/Std Dev²
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	14.9	33.9
Mean number of filled prescriptions	23.8	16.2
Mean number of generics	6.9	4.3
Mean number of unique drug classes	6.6	4.0

¹All metrics based on total number of unique patients
²Value represents standard deviation where no % follows the value
³Data on Race and Hispanic Origin is not populated in IBM® MarketScan® Research Databases.

Table 1c: Baseline table [Any Epidiolex (prescription cannabidiol), Seizure]		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	624	
Demographics³		
Mean Age	16.0	9.1
Age: 00-05	74	11.9%
Age: 06-10	137	22.0%
Age: 11-17	182	29.2%
Age: 18+	231	37.0%
Sex (Female)	268	42.9%
Sex (Male)	356	57.1%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	0	0.0%
Race (Black or African American)	0	0.0%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (Unknown)	624	100.0%
Race (White)	0	0.0%
Hispanic Origin	0	0.0%
Year (2018)	79	12.7%
Year (2019)	500	80.1%
Year (2020)	45	7.2%
Recorded history of:		
Prior combined comorbidity score	0.8	1.2
Acquired Hypothyroidism	35	5.6%
Acute Myocardial Infarction	0	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	7	1.1%
Anemia	35	5.6%
Asthma	83	13.3%
Atrial Fibrillation	0	0.0%
Benign Prostatic Hyperplasia	1	0.2%
Breast Cancer	0	0.0%
Cataracts	4	0.6%
Chronic Kidney Disease	30	4.8%
Chronic Obstructive Pulmonary Disease	28	4.5%
Colorectal Cancer	1	0.2%
Depression	9	1.4%
Diabetes	10	1.6%
Endometrial Cancer	0	0.0%
Glaucoma	9	1.4%
Heart Failure	2	0.3%
Hip / Pelvic Fracture	2	0.3%
Hyperlipidemia	16	2.6%
Hypertension	16	2.6%
Ischemic Heart Disease	0	0.0%
Lung Cancer	0	0.0%
Osteoporosis	15	2.4%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	5	0.8%
Stroke / Transient Ischemic Attack	6	1.0%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	14.5	16.3
Mean number of emergency room encounters (ED)	0.5	1.0
Mean number of inpatient hospital encounters (IP)	0.4	0.8

Table 1c: Baseline table [Any Epidiolex (prescription cannabidiol), Seizure]		
Characteristic¹	N/Mean	%/Std Dev²
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	17.3	36.1
Mean number of filled prescriptions	25.9	17.0
Mean number of generics	7.4	4.5
Mean number of unique drug classes	7.1	4.1

¹All metrics based on total number of unique patients
²Value represents standard deviation where no % follows the value
³Data on Race and Hispanic Origin is not populated in IBM® MarketScan® Research Databases.

Table 1d: Baseline table [Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure]

Characteristic ¹	N/Mean	%/Std Dev ²
Number of unique patients	1,466	
Demographics³		
Mean Age	23.1	12.9
Age: 00-05	90	6.1%
Age: 06-10	82	5.6%
Age: 11-17	384	26.2%
Age: 18+	910	62.1%
Sex (Female)	859	58.6%
Sex (Male)	607	41.4%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	0	0.0%
Race (Black or African American)	0	0.0%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (Unknown)	1,466	100.0%
Race (White)	0	0.0%
Hispanic Origin	0	0.0%
Year (2018)	678	46.2%
Year (2019)	663	45.2%
Year (2020)	125	8.5%
Recorded history of:		
Prior combined comorbidity score	0.6	1.2
Acquired Hypothyroidism	43	2.9%
Acute Myocardial Infarction	1	0.1%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	17	1.2%
Anemia	68	4.6%
Asthma	94	6.4%
Atrial Fibrillation	7	0.5%
Benign Prostatic Hyperplasia	8	0.5%
Breast Cancer	4	0.3%
Cataracts	13	0.9%
Chronic Kidney Disease	64	4.4%
Chronic Obstructive Pulmonary Disease	23	1.6%
Colorectal Cancer	0	0.0%
Depression	155	10.6%
Diabetes	35	2.4%
Endometrial Cancer	1	0.1%
Glaucoma	9	0.6%
Heart Failure	9	0.6%
Hip / Pelvic Fracture	0	0.0%
Hyperlipidemia	50	3.4%
Hypertension	76	5.2%
Ischemic Heart Disease	7	0.5%
Lung Cancer	1	0.1%
Osteoporosis	5	0.3%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	29	2.0%
Stroke / Transient Ischemic Attack	21	1.4%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	8.3	12.1
Mean number of emergency room encounters (ED)	0.5	1.0
Mean number of inpatient hospital encounters (IP)	0.2	0.7

Table 1d: Baseline table [Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure]

Characteristic ¹	N/Mean	%/Std Dev ²
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	4.8	18.0
Mean number of filled prescriptions	9.5	10.6
Mean number of generics	4.0	3.7
Mean number of unique drug classes	3.9	3.5

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³Data on Race and Hispanic Origin is not populated in IBM® MarketScan® Research Databases.

Table 1e: Baseline table [Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure]

Characteristic ¹	N/Mean	%/Std Dev ²
Number of unique patients	53	
Demographics³		
Mean Age	17.7	9.5
Age: 00-05	6	11.3%
Age: 06-10	10	18.9%
Age: 11-17	13	24.5%
Age: 18+	24	45.3%
Sex (Female)	24	45.3%
Sex (Male)	29	54.7%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	0	0.0%
Race (Black or African American)	0	0.0%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (Unknown)	53	100.0%
Race (White)	0	0.0%
Hispanic Origin	0	0.0%
Year (2018)	4	7.5%
Year (2019)	46	86.8%
Year (2020)	3	5.7%
Recorded history of:		
Prior combined comorbidity score	0.6	0.9
Acquired Hypothyroidism	1	1.9%
Acute Myocardial Infarction	0	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	0	0.0%
Anemia	1	1.9%
Asthma	8	15.1%
Atrial Fibrillation	0	0.0%
Benign Prostatic Hyperplasia	0	0.0%
Breast Cancer	0	0.0%
Cataracts	0	0.0%
Chronic Kidney Disease	2	3.8%
Chronic Obstructive Pulmonary Disease	3	5.7%
Colorectal Cancer	0	0.0%
Depression	1	1.9%
Diabetes	3	5.7%
Endometrial Cancer	0	0.0%
Glaucoma	0	0.0%
Heart Failure	0	0.0%
Hip / Pelvic Fracture	0	0.0%
Hyperlipidemia	2	3.8%
Hypertension	0	0.0%
Ischemic Heart Disease	0	0.0%
Lung Cancer	0	0.0%
Osteoporosis	1	1.9%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	1	1.9%
Stroke / Transient Ischemic Attack	0	0.0%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	12.8	15.9
Mean number of emergency room encounters (ED)	0.2	0.7
Mean number of inpatient hospital encounters (IP)	0.2	0.4

Table 1e: Baseline table [Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure]		
Characteristic¹	N/Mean	%/Std Dev²
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	20.2	44.4
Mean number of filled prescriptions	14.9	13.4
Mean number of generics	4.6	4.1
Mean number of unique drug classes	4.4	3.8

¹All metrics based on total number of unique patients
²Value represents standard deviation where no % follows the value
³Data on Race and Hispanic Origin is not populated in IBM® MarketScan® Research Databases.

Table 1f: Baseline table [Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure]		
Characteristic¹	N/Mean	%/Std Dev²
Number of unique patients	1,126	
Demographics³		
Mean Age	17.1	10.9
Age: 00-05	130	11.5%
Age: 06-10	235	20.9%
Age: 11-17	337	29.9%
Age: 18+	424	37.7%
Sex (Female)	521	46.3%
Sex (Male)	605	53.7%
Race (American Indian or Alaska Native)	0	0.0%
Race (Asian)	0	0.0%
Race (Black or African American)	0	0.0%
Race (Native Hawaiian or Other Pacific Islander)	0	0.0%
Race (Unknown)	1,126	100.0%
Race (White)	0	0.0%
Hispanic Origin	0	0.0%
Year (2018)	129	11.5%
Year (2019)	894	79.4%
Year (2020)	103	9.1%
Recorded history of:		
Prior combined comorbidity score	0.7	1.2
Acquired Hypothyroidism	57	5.1%
Acute Myocardial Infarction	0	0.0%
Alzheimer's Disease	0	0.0%
Alzheimer's Disease, Related Disorders, or Senile Dementia	15	1.3%
Anemia	58	5.2%
Asthma	117	10.4%
Atrial Fibrillation	0	0.0%
Benign Prostatic Hyperplasia	1	0.1%
Breast Cancer	1	0.1%
Cataracts	7	0.6%
Chronic Kidney Disease	47	4.2%
Chronic Obstructive Pulmonary Disease	36	3.2%
Colorectal Cancer	2	0.2%
Depression	56	5.0%
Diabetes	21	1.9%
Endometrial Cancer	0	0.0%
Glaucoma	12	1.1%
Heart Failure	3	0.3%
Hip / Pelvic Fracture	2	0.2%
Hyperlipidemia	38	3.4%
Hypertension	32	2.8%
Ischemic Heart Disease	3	0.3%
Lung Cancer	1	0.1%
Osteoporosis	20	1.8%
Prostate Cancer	0	0.0%
Rheumatoid Arthritis / Osteoarthritis	13	1.2%
Stroke / Transient Ischemic Attack	15	1.3%
Health Service Utilization Intensity:		
Mean number of ambulatory encounters (AV)	13.5	15.1
Mean number of emergency room encounters (ED)	0.6	1.1
Mean number of inpatient hospital encounters (IP)	0.3	0.8

Table 1f: Baseline table [Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure]

Characteristic ¹	N/Mean	%/Std Dev ²
Mean number of non-acute institutional encounters (IS)	0.0	0.0
Mean number of other ambulatory encounters (OA)	15.4	34.5
Mean number of filled prescriptions	24.4	16.3
Mean number of generics	7.1	4.3
Mean number of unique drug classes	6.7	4.0

¹All metrics based on total number of unique patients

²Value represents standard deviation where no % follows the value

³Data on Race and Hispanic Origin is not populated in IBM® MarketScan® Research Databases.

Table 2a: Descriptive statistics of cumulative exposure duration, all episodes, in days								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,605	238.45	178.49	1	75	201	379	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	217.67	143.32	1	82	211	345	512
Any Epidiolex (prescription cannabidiol), Seizure	624	234.75	144.55	1	98	236	362	512
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	243.58	180.66	1	77	210	388	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	212.74	145.44	1	90	175	360	499
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	218.89	144.18	1	83	211	350	512

Table 2b: Descriptive statistics of cumulative exposure duration, all episodes, in days, by sex								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,605	238.45	178.49	1	75	201	379	639
Female	921	237.02	176.42	1	74	210	377	639
Male	684	240.38	181.34	1	75	200	386	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	217.67	143.32	1	82	211	345	512
Female	559	214.46	144.57	1	72	207	344	512
Male	645	220.44	142.28	1	83	214	345	502
Any Epidiolex (prescription cannabidiol), Seizure	624	234.75	144.55	1	98	236	362	512
Female	268	237.02	145.70	1	105	240	371	512
Male	356	233.04	143.86	4	90	232	358	502
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	243.58	180.66	1	77	210	388	639
Female	859	241.34	178.50	1	76	211	385	639
Male	607	246.75	183.77	1	77	203	399	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	212.74	145.44	1	90	175	360	499
Female	24	201.58	139.59	7	75	173	358	421
Male	29	221.97	151.93	1	90	175	362	499
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	218.89	144.18	1	83	211	350	512
Female	521	214.69	146.13	1	71	200	348	512
Male	605	222.51	142.50	1	88	219	350	502

Table 2c: Descriptive statistics of cumulative exposure duration, all episodes, in days, by age group								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,605	238.45	178.49	1	75	201	379	639
00-05	108	259.37	181.96	1	90	250	372	615
06-10	116	239.77	181.36	5	76	210	371	615
11-17	431	249.32	184.85	1	75	216	398	639
18+	950	230.98	174.60	2	73	194	375	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	217.67	143.32	1	82	211	345	512
00-05	138	234.54	152.12	4	90	233	364	512
06-10	249	235.66	144.19	4	105	235	370	502
11-17	355	214.17	140.56	1	83	197	341	502
18+	462	205.62	141.26	2	60	196	334	497
Any Epidiolex (prescription cannabidiol), Seizure	624	234.75	144.55	1	98	236	362	512
00-05	74	235.34	157.31	4	90	233	371	512
06-10	137	252.10	143.58	6	128	251	384	502
11-17	182	227.69	143.43	1	92	204	358	502
18+	231	229.84	141.84	7	90	240	359	490
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	243.58	180.66	1	77	210	388	639
00-05	90	278.13	183.77	1	120	281	407	615
06-10	82	269.26	185.38	13	94	265	421	615
11-17	384	258.70	188.68	1	82	229	420	639
18+	910	231.47	175.53	2	71	194	375	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	212.74	145.44	1	90	175	360	499
00-05	6	141.33	117.53	14	90	106	175	357
06-10	10	207.60	134.63	30	95	181	282	459
11-17	13	205.85	133.10	59	92	169	297	499
18+	24	236.46	162.88	1	60	332	378	421
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	218.89	144.18	1	83	211	350	512
00-05	130	233.40	152.93	4	90	228	364	512
06-10	235	234.51	145.66	4	100	230	373	502
11-17	337	214.09	142.24	1	82	196	349	502
18+	424	209.60	141.57	2	62	208	339	497

Table 3a: Descriptive statistics of first exposure episode duration, in days								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,605	163.46	168.45	1	30	90	249	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	186.82	146.50	1	55	147	321	512
Any Epidiolex (prescription cannabidiol), Seizure	624	201.51	150.20	1	60	174	338	512
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	166.30	171.03	1	30	90	254	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	174.21	143.36	1	60	112	329	499
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	187.81	147.34	1	57	145	324	512

Table 3b: Descriptive statistics of first exposure episode duration, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,605	163.46	168.45	1	30	90	249	639
Female	921	160.40	165.45	1	30	90	242	639
Male	684	167.59	172.44	1	30	90	257	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	186.82	146.50	1	55	147	321	512
Female	559	181.06	146.47	1	44	132	312	512
Male	645	191.82	146.46	1	58	163	324	502
Any Epidiolex (prescription cannabidiol), Seizure	624	201.51	150.20	1	60	174	338	512
Female	268	197.06	151.98	1	60	150	343	512
Male	356	204.85	148.97	4	60	180	336	502
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	166.30	171.03	1	30	90	254	639
Female	859	163.29	167.64	1	30	90	243	639
Male	607	170.56	175.77	1	30	90	261	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	174.21	143.36	1	60	112	329	499
Female	24	156.75	144.53	7	30	93	304	421
Male	29	188.66	143.30	1	64	152	329	499
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	187.81	147.34	1	57	145	324	512
Female	521	181.00	147.79	1	44	128	314	512
Male	605	193.68	146.82	1	60	163	328	502

Table 3c: Descriptive statistics of first exposure episode duration, in days, by age group								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,605	163.46	168.45	1	30	90	249	639
00-05	108	196.06	179.03	1	57	122	308	615
06-10	116	140.53	157.43	2	30	63	220	615
11-17	431	175.58	178.13	1	30	99	278	639
18+	950	157.06	163.31	1	30	90	228	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	186.82	146.50	1	55	147	321	512
00-05	138	210.04	161.23	4	60	160	357	512
06-10	249	194.58	149.11	4	53	168	324	502
11-17	355	188.94	144.18	1	60	153	324	502
18+	462	174.08	141.42	1	41	124	306	497
Any Epidiolex (prescription cannabidiol), Seizure	624	201.51	150.20	1	60	174	338	512
00-05	74	207.62	167.06	4	54	163	357	512
06-10	137	213.94	149.76	6	64	203	329	502
11-17	182	203.18	149.16	1	60	172	350	502
18+	231	190.86	145.81	5	60	149	334	490
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	166.30	171.03	1	30	90	254	639
00-05	90	207.16	183.66	1	60	146	337	615
06-10	82	151.70	166.95	2	30	68	222	615
11-17	384	182.90	182.88	1	30	104	291	639
18+	910	156.57	163.92	1	30	90	228	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	174.21	143.36	1	60	112	329	499
00-05	6	136.33	120.74	14	60	106	175	357
06-10	10	147.80	108.83	14	90	129	219	384
11-17	13	167.23	143.30	28	90	117	197	499
18+	24	198.46	163.19	1	30	177	359	421
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	187.81	147.34	1	57	145	324	512
00-05	130	211.20	161.60	4	65	160	357	512
06-10	235	194.44	149.89	4	53	163	328	502
11-17	337	188.80	145.58	1	60	152	329	502
18+	424	176.18	142.05	2	47	125	307	497

Table 4a: Descriptive statistics of all exposure episode durations, in days								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	3,073	124.54	146.50	1	30	60	170	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,580	165.87	141.53	1	30	117	286	512
Any Epidiolex (prescription cannabidiol), Seizure	839	174.59	145.35	1	40	121	300	512
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	2,832	126.09	148.36	1	30	60	170	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	75	150.33	136.48	1	30	94	268	499
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,482	166.31	142.27	1	30	117	287	512

Table 4b: Descriptive statistics of all exposure episode durations, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	3,073	124.54	146.50	1	30	60	170	639
Female	1,798	121.41	142.47	1	30	60	165	639
Male	1,275	128.96	151.95	1	30	60	180	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,580	165.87	141.53	1	30	117	286	512
Female	744	161.13	141.19	1	30	106	269	512
Male	836	170.08	141.79	1	34	120	298	502
Any Epidiolex (prescription cannabidiol), Seizure	839	174.59	145.35	1	40	121	300	512
Female	370	171.68	146.13	1	30	118	289	512
Male	469	176.90	144.85	1	45	128	308	502
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	2,832	126.09	148.36	1	30	60	170	639
Female	1,688	122.82	144.00	1	30	60	167	639
Male	1,144	130.92	154.51	1	30	60	183	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	75	150.33	136.48	1	30	94	268	499
Female	35	138.23	134.08	7	30	92	261	421
Male	40	160.93	139.38	1	32	105	306	499
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,482	166.31	142.27	1	30	117	287	512
Female	695	160.94	142.21	1	30	105	270	512
Male	787	171.06	142.25	1	40	120	300	502

Table 4c: Descriptive statistics of all exposure episode durations, in days, by age group								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	3,073	124.54	146.50	1	30	60	170	639
00-05	164	170.80	166.49	1	30	92	286	615
06-10	263	105.75	136.86	2	25	30	130	615
11-17	767	140.10	158.90	1	30	65	209	639
18+	1,879	116.78	139.26	1	30	60	151	639
Any Epidiolex (prescription cannabidiol), Any Indication	1,580	165.87	141.53	1	30	117	286	512
00-05	164	197.35	155.13	4	60	143	338	512
06-10	339	173.09	144.06	4	30	120	288	502
11-17	460	165.28	139.74	1	34	120	278	502
18+	617	153.96	136.40	1	30	97	262	497
Any Epidiolex (prescription cannabidiol), Seizure	839	174.59	145.35	1	40	121	300	512
00-05	93	187.26	159.47	4	34	124	336	512
06-10	180	191.88	146.75	6	59	159	308	502
11-17	243	170.53	145.11	1	40	117	295	502
18+	323	164.37	139.96	1	30	107	292	490
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	2,832	126.09	148.36	1	30	60	170	639
00-05	139	180.09	170.45	1	30	106	299	615
06-10	202	109.30	142.24	2	25	30	130	615
11-17	678	146.52	163.63	1	30	68	224	639
18+	1,813	116.18	139.35	1	30	60	149	639
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	75	150.33	136.48	1	30	94	268	499
00-05	7	121.14	117.32	14	30	100	175	357
06-10	13	159.69	104.50	14	90	152	223	384
11-17	20	133.80	124.71	28	56	98	139	499
18+	35	162.14	158.29	1	30	60	336	421
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,482	166.31	142.27	1	30	117	287	512
00-05	154	197.03	156.02	4	60	141	338	512
06-10	318	173.30	144.76	4	30	120	289	502
11-17	439	164.35	140.97	1	30	118	274	502
18+	571	155.64	136.88	1	30	99	267	497

Table 5a: Descriptive statistics of days supplied per dispensing								
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	12,299	33.83	20.93	1	30	30	30	191
Any Epidiolex (prescription cannabidiol), Any Indication	8,912	28.68	6.06	1	30	30	30	90
Any Epidiolex (prescription cannabidiol), Seizure	4,966	28.74	5.93	1	30	30	30	90
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	11,233	34.23	21.21	1	30	30	30	191
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	384	28.57	4.85	1	30	30	30	37
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	8,386	28.67	5.95	1	30	30	30	90

Table 5b: Descriptive statistics of days supplied per dispensing, by sex								
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	12,299	33.83	20.93	1	30	30	30	191
Female	6,709	34.57	21.58	1	30	30	30	191
Male	5,590	32.94	20.08	1	30	30	30	180
Any Epidiolex (prescription cannabidiol), Any Indication	8,912	28.68	6.06	1	30	30	30	90
Female	4,082	28.57	6.20	1	30	30	30	90
Male	4,830	28.77	5.93	1	30	30	30	90
Any Epidiolex (prescription cannabidiol), Seizure	4,966	28.74	5.93	1	30	30	30	90
Female	2,151	28.63	5.60	1	30	30	30	90
Male	2,815	28.83	6.16	1	30	30	30	90
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	11,233	34.23	21.21	1	30	30	30	191
Female	6,258	34.92	21.79	1	30	30	30	191
Male	4,975	33.36	20.42	1	30	30	30	180
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	384	28.57	4.85	1	30	30	30	37
Female	163	28.80	4.81	1	30	30	30	32
Male	221	28.40	4.89	1	30	30	30	37
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	8,386	28.67	5.95	1	30	30	30	90
Female	3,806	28.59	6.19	1	30	30	30	90
Male	4,580	28.74	5.74	1	30	30	30	90

Table 5c: Descriptive statistics of days supplied per dispensing, by age group								
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	12,299	33.83	20.93	1	30	30	30	191
00-05	1,186	30.12	15.01	1	28	30	30	100
06-10	1,029	29.46	15.37	1	27	30	30	90
11-17	3,565	32.62	19.68	1	30	30	30	191
18+	6,519	35.85	22.93	1	30	30	30	180
Any Epidiolex (prescription cannabidiol), Any Indication	8,912	28.68	6.06	1	30	30	30	90
00-05	1,105	28.77	6.97	1	30	30	30	90
06-10	1,979	28.90	6.04	1	30	30	30	90
11-17	2,592	28.60	5.87	1	30	30	30	90
18+	3,236	28.58	5.88	1	30	30	30	90
Any Epidiolex (prescription cannabidiol), Seizure	4,966	28.74	5.93	1	30	30	30	90
00-05	594	28.77	7.44	1	30	30	30	90
06-10	1,165	28.95	5.60	2	30	30	30	90
11-17	1,406	28.67	5.60	1	30	30	30	90
18+	1,801	28.66	5.82	1	30	30	30	90
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	11,233	34.23	21.21	1	30	30	30	191
00-05	1,034	30.53	15.57	1	30	30	30	100
06-10	808	29.68	14.92	1	27	30	30	90
11-17	3,237	32.88	19.73	1	30	30	30	191
18+	6,154	36.15	23.17	1	30	30	30	180
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	384	28.57	4.85	1	30	30	30	37
00-05	29	28.38	4.09	14	30	30	30	30
06-10	70	28.57	5.00	3	30	30	30	32
11-17	92	28.28	5.17	6	30	30	30	30
18+	193	28.74	4.78	1	30	30	30	37
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	8,386	28.67	5.95	1	30	30	30	90
00-05	1,042	28.64	6.67	1	30	30	30	90
06-10	1,858	28.91	6.10	1	30	30	30	90
11-17	2,463	28.58	5.65	1	30	30	30	90
18+	3,023	28.61	5.82	1	30	30	30	90

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
Any Comparator Drugs, Seizure	1,468	56.57	64.67	1	22	34	62	565
Any Epidiolex (prescription cannabidiol), Any Indication	376	43.66	43.83	3	21	30	48	370
Any Epidiolex (prescription cannabidiol), Seizure	215	41.61	40.87	7	21	28	45	362
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,366	56.09	64.79	1	22	34	61	565
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	22	36.41	31.52	11	18	23	41	140
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	356	43.26	43.10	3	21	29	48	370

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
Any Comparator Drugs, Seizure	1,468	56.57	64.67	1	22	34	62	565
Female	877	55.08	59.98	1	22	35	62	477
Male	591	58.77	71.07	3	21	33	60	565
Any Epidiolex (prescription cannabidiol), Any Indication	376	43.66	43.83	3	21	30	48	370
Female	185	42.26	36.18	3	21	30	50	237
Male	191	45.02	50.20	4	21	29	44	370
Any Epidiolex (prescription cannabidiol), Seizure	215	41.61	40.87	7	21	28	45	362
Female	102	40.81	35.71	10	21	27	48	212
Male	113	42.34	45.16	7	22	28	43	362
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,366	56.09	64.79	1	22	34	61	565
Female	829	55.01	59.93	1	22	35	62	477
Male	537	57.77	71.69	3	21	32	58	565
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	22	36.41	31.52	11	18	23	41	140
Female	11	47.82	41.26	14	18	23	80	140
Male	11	25.00	9.89	11	18	22	35	41
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	356	43.26	43.10	3	21	29	48	370
Female	174	42.80	36.89	3	21	30	51	237
Male	182	43.71	48.39	4	20	29	44	370

Table 6c: Descriptive statistics of the length of all gaps between treatment episodes, in days, by age group								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Any Comparator Drugs, Seizure	1,468	56.57	64.67	1	22	34	62	565
00-05	56	51.48	58.20	11	21	26	53	271
06-10	147	51.13	57.42	6	20	29	55	337
11-17	336	56.00	65.42	4	22	32	58	451
18+	929	57.94	65.87	1	23	37	63	565
Any Epidiolex (prescription cannabidiol), Any Indication	376	43.66	43.83	3	21	30	48	370
00-05	26	36.81	20.45	16	22	31	48	89
06-10	90	44.46	40.73	10	22	32	46	238
11-17	105	37.73	26.22	8	21	27	43	149
18+	155	48.36	55.97	3	20	28	53	370
Any Epidiolex (prescription cannabidiol), Seizure	215	41.61	40.87	7	21	28	45	362
00-05	19	31.21	12.92	16	19	28	40	63
06-10	43	43.33	40.81	10	22	31	48	197
11-17	61	35.87	21.37	11	23	28	42	109
18+	92	46.77	52.45	7	20	27	52	362
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,366	56.09	64.79	1	22	34	61	565
00-05	49	51.88	60.52	11	21	26	52	271
06-10	120	49.75	54.80	6	21	30	51	330
11-17	294	54.77	66.68	5	21	31	54	451
18+	903	57.60	65.64	1	23	37	63	565
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	22	36.41	31.52	11	18	23	41	140
00-05	1	36.00	-	36	36	36	36	36
06-10	3	28.00	20.88	14	14	18	52	52
11-17	7	33.43	23.03	11	18	25	43	80
18+	11	40.64	40.42	16	18	21	41	140
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	356	43.26	43.10	3	21	29	48	370
00-05	24	35.50	18.57	16	22	31	44	89
06-10	83	45.86	42.07	10	22	33	48	238
11-17	102	37.04	24.02	8	21	28	43	112
18+	147	47.39	54.87	3	20	28	51	370

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										
Any Comparator Drugs, Seizure	3,073	100.0	1,154	37.6	0	0.0	904	29.4	3,073	100.0
Any Epidiolex (prescription cannabidiol), Any Indication	1,580	100.0	815	51.6	0	0.0	703	44.5	1,580	100.0
Any Epidiolex (prescription cannabidiol), Seizure	839	100.0	441	52.6	0	0.0	390	46.5	839	100.0
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	2,832	100.0	1,060	37.4	0	0.0	822	29.0	2,832	100.0
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	75	100.0	30	40.0	0	0.0	29	38.7	75	100.0
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,482	100.0	769	51.9	0	0.0	660	44.5	1,482	100.0
Patients' First Episode										
Any Comparator Drugs, Seizure	1,605	100.0	689	42.9	0	0.0	528	32.9	1,605	100.0
Any Epidiolex (prescription cannabidiol), Any Indication	1,204	100.0	630	52.3	0	0.0	534	44.4	1,204	100.0
Any Epidiolex (prescription cannabidiol), Seizure	624	100.0	343	55.0	0	0.0	297	47.6	624	100.0
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	1,466	100.0	625	42.6	0	0.0	473	32.3	1,466	100.0
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	53	100.0	22	41.5	0	0.0	21	39.6	53	100.0
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	1,126	100.0	593	52.7	0	0.0	500	44.4	1,126	100.0

Table 8: Cohort Attrition Table	
Attrition Criteria	Members
Any Comparator Drugs, Seizure	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	33,917,731 (100.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	877,644 (2.6%)
Exclusion - Members must have at least one episode defining index claim during the query period	697,625 (2.1%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	697,625 (2.1%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	557,607 (1.6%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	1,605 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,605 (0.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	31,862,773 (93.9%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	31,862,773 (93.9%)
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	31,862,773 (93.9%)
Exclusion - Members must satisfy the age range condition within the query period	31,862,732 (93.9%)
Exclusion - Members must meet chart availability criterion within the query period	31,862,732 (93.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	31,862,732 (93.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	877,644 (2.6%)
Any Epidiolex (prescription cannabidiol), Any Indication	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	33,917,731 (100.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	1,387 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	1,387 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	1,387 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,204 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	1,204 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,204 (0.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	31,862,773 (93.9%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	31,862,773 (93.9%)
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	31,862,773 (93.9%)
Exclusion - Members must satisfy the age range condition within the query period	31,862,732 (93.9%)
Exclusion - Members must meet chart availability criterion within the query period	31,862,732 (93.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	31,862,732 (93.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	1,387 (0.0%)
Any Epidiolex (prescription cannabidiol), Seizure	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	33,917,731 (100.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	1,387 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	1,387 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	1,387 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,204 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	624 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	624 (0.0%)

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	31,862,773 (93.9%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	31,862,773 (93.9%)
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	31,862,773 (93.9%)
Exclusion - Members must satisfy the age range condition within the query period	31,862,732 (93.9%)
Exclusion - Members must meet chart availability criterion within the query period	31,862,732 (93.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	31,862,732 (93.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	1,387 (0.0%)
Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	33,917,731 (100.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	877,644 (2.6%)
Exclusion - Members must have at least one episode defining index claim during the query period	697,625 (2.1%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	697,625 (2.1%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	557,607 (1.6%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	1,466 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	1,466 (0.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	31,862,773 (93.9%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	31,862,773 (93.9%)
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	31,862,773 (93.9%)
Exclusion - Members must satisfy the age range condition within the query period	31,862,732 (93.9%)
Exclusion - Members must meet chart availability criterion within the query period	31,862,732 (93.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	31,862,732 (93.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	877,644 (2.6%)
Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	33,917,731 (100.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	1,387 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	1,387 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	1,387 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	1,204 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	53 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	53 (0.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	31,862,773 (93.9%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	31,862,773 (93.9%)
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	31,862,773 (93.9%)
Exclusion - Members must satisfy the age range condition within the query period	31,862,732 (93.9%)
Exclusion - Members must meet chart availability criterion within the query period	31,862,732 (93.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	31,862,732 (93.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	1,387 (0.0%)
Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	

Table 8: Cohort Attrition Table	Attrition Criteria	Members
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period		33,917,731 (100.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition		1,387 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period		1,387 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria		1,387 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion		1,204 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria		1,126 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion		1,126 (0.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period		31,862,773 (93.9%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period		31,862,773 (93.9%)
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		31,862,773 (93.9%)
Exclusion - Members must satisfy the age range condition within the query period		31,862,732 (93.9%)
Exclusion - Members must meet chart availability criterion within the query period		31,862,732 (93.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition		31,862,732 (93.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period		1,387 (0.0%)



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
 Enrollment Criteria: Medical and Drug Coverage
 Enrollment Gap (Days): 45
 Age Groups (Years): 0 0 05, 06-10, 11-17, 18+
 Query Period: 07/01/2018-03/31/2020
 Baseline Characteristics Table: Yes
 Baseline Evaluation Window (Day): -183,-1

#	Cohort Name	Index Exposure	Pre-Index Enrollment Period (Days)	Washout Period (Days)	Treatment Episode Gap (% of Prior Dispensing's Days Supplied)	Treatment Episode Extension (Days)	Inclusion/Exclusion	Criteria	Criteria Definition	Evaluation Period Start (Day)	Evaluation Period End (Day)
1	Any Epidiolex (prescription cannabidiol), Any Indication	Epidiolex (prescription cannabidiol) [1]	183	0	50%	0	--	--	--	--	--
2	Any Epidiolex (prescription cannabidiol), Seizure	Epidiolex (prescription cannabidiol) [2]	183	0	50%	0	Inclusion	Seizures	Seizures [3]	Ever	Ever
3	Comparator Drugs, No Epidiolex (prescription cannabidiol), Seizure	Comparator drugs [4]	183	0	50%	0	Inclusion Exclusion	Seizures Epidiolex (prescription cannabidiol)	Seizures [5] Epidiolex (prescription cannabidiol) [6]	Ever -183	Ever 183
4	Epidiolex (prescription cannabidiol) and Comparator Drugs, Seizure	Epidiolex (prescription cannabidiol) [7]	183	0	50%	0	Inclusion	Seizures Comparators	Seizures [8] Comparators [9]	Ever -183	Ever 183
5	Epidiolex (prescription cannabidiol), No Comparator Drugs, Seizure	Epidiolex (prescription cannabidiol) [10]	183	0	50%	0	Inclusion Exclusion	Seizures Comparators	Seizures [11] Comparators [12]	Ever -183	Ever 183
6	Any Comparator Drugs, Seizure	Comparator drugs [13]	183	0	50%	0	Inclusion	Seizures	Seizures [14]	Ever	Ever

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 C
- [2] See Appendix C
- [3] See Appendix D
- [4] See Appendix C
- [5] See Appendix D
- [6] See Appendix F
- [7] See Appendix C
- [8] See Appendix D
- [9] See Appendix E
- [10] See Appendix C
- [11] See Appendix D
- [12] See Appendix F
- [13] See Appendix C
- [14] See Appendix D

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	Hypertlipidemia	

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.

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

Generic Name	Brand Name
	Epidiolex (prescription cannabidiol)
Cannabidiol (CBD)	Epidiolex
	Comparator Drugs
Levetiracetam	
Topiramate	
Rufinamide	
Lamotrigine	
Felbamate	
Clobazam	
Clonazepam	

Appendix D. 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
Seizures			
G4081	Diagnosis	ICD-10-CM	Lennox-Gastaut syndrome
G40811	Diagnosis	ICD-10-CM	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40812	Diagnosis	ICD-10-CM	Lennox-Gastaut syndrome, not intractable, without status epilepticus
G40813	Diagnosis	ICD-10-CM	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40814	Diagnosis	ICD-10-CM	Lennox-Gastaut syndrome, intractable, without status epilepticus
Q851	Diagnosis	ICD-10-CM	Tuberous sclerosis
G40B	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy [impulsive petit mal]
G40B0	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy, not intractable
G40B01	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy, not intractable, with status epilepticus
G40B09	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40B1	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy, intractable
G40B11	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy, intractable, with status epilepticus
G40B19	Diagnosis	ICD-10-CM	Juvenile myoclonic epilepsy, intractable, without status epilepticus

Appendix E. List of Generic and Brand Names of Medical Products Used to Define Inclusion Criteria in this Request

Generic Name	Brand Name
	Epidiolex (prescription cannabidiol)
Cannabidiol (CBD)	Epidiolex
	Comparator Drugs
Levetiracetam	
Topiramate	
Rufinamide	
Lamotrigine	
Felbamate	
Clobazam	
Clonazepam	

Appendix F. List of Generic and Brand Names of Medical Products Used to Define Exclusion Criteria in this Request

Generic Name	Brand Name
Epidiolex (prescription cannabidiol)	
Cannabidiol (CBD)	Epidiolex
Comparator Drugs	
Levetiracetam	
Topiramate	
Rufinamide	
Lamotrigine	
Felbamate	
Clobazam	
Clonazepam	