Health Care Resource Utilization Before and After Initiation of Cannabidiol Among Medicaid Patients With Dravet Syndrome, Lennox-Gastaut Syndrome, Tuberous Sclerosis Complex, and Other Refractory Epilepsies

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Background

- The plant-derived, highly purified pharmaceutical formulation of cannabidiol (CBD) oral solution (EPIDIOLEX®) is approved in the United States (US) for the treatment of seizures associated with Lennox-Gastaut Syndrome (LGS), Dravet syndrome (DS), and tuberous sclerosis complex (TSC) in individuals aged ≥1 year.[1]
- The potential beneficial effects of CBD in caregiver-reported seizure and nonseizure outcomes have been reported in the real-world setting.[2,3]
- However, the association between CBD and health care resource utilization (HCRU) remains unclear.

Objective

- To assess changes in HCRU before and after CBD initiation among Medicaid patients with DS, LGS, TSC, and other refractory epilepsies.

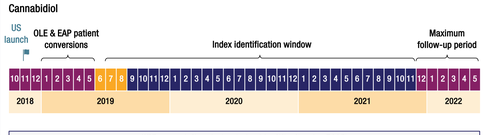
Methods

- This was a retrospective pre-post study of Medicaid patients using the US MarketScan® administrative claims database (**Figure 1**).
- HCRU included epilepsy-related (primary diagnosis) and all-cause visits to the physician's office, hospital outpatient, and emergency department (ED), and home health, inpatient admissions, and intensive care unit admissions.
- The number of events for each type of HCRU per patient per month was assessed in the 6 months pre- and post-CBD initiation.
- Segmented regression-based interrupted time series (ITS) analyses were applied to investigate trends in HCRU use (detailed description of ITS analysis available via QR code).[4–7]
- Regression coefficients from the ITS analyses were used to compute the annualized changes in HCRU after CBD initiation.
- This study was conducted with Epidiolex®, and results do not apply to other CBD-containing products.

Results

- Of 1663 patients included in the analyses, 973 had LGS, 70 had DS, 72 had TSC, and 568 had other refractory epilepsies.
  - Patient characteristics are shown in **Table 1**.
  - The study population was primarily pediatric; however, about 33% were ≥19 years.

Figure 1. Study design and sample selection



[a]Baseline defined as the period 180 days before CBD initiation.
CBD, cannabidiol; DS, Dravet syndrome; EAP, expanded access program; LGS, Lennox-Gastaut syndrome; OLE, open-label extension; TSC, tuberous sclerosis complex.

Table 1. Patient characteristics

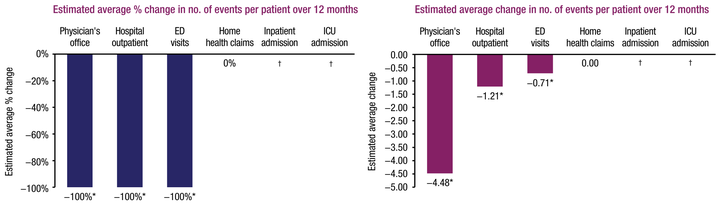
Characteristic	All[a] (n=1663)	LGS (n=973)	DS (n=70)	TSC (n=72)	Other refractory epilepsy (n=568)
Age, mean (SD)	15.5 (11.0)	14.9 (10.2)	12.1 (8.3)	12.9 (9.5)	17.3 (12.5)
Female gender, n (%)	727 (44)	403 (41)	35 (50)	27 (38)	270 (48)
Comorbidities, n (%)					
CCI[b]					
0	49 (3)	0	2 (3)	1 (1)	46 (8)
1–2	722 (43)	381 (39)	50 (71)	48 (67)	255 (45)
3–4	702 (42)	460 (47)	15 (21)	17 (24)	215 (38)
5+	190 (11)	132 (14)	3 (4)	6 (8)	52 (9)
Asthma	168 (10)	113 (12)	5 (7)	2 (3)	48 (8)
Diabetes	15 (1)	8 (1)	2 (3)	1 (1)	5 (1)
Cancer	17 (1)	6 (1)	0 (0)	4 (6)	8 (1)
Anxiety	177 (11)	92 (9)	8 (11)	6 (8)	72 (13)
Attention deficit hyperactivity disorder	41 (2)	20 (2)	2 (3)	4 (6)	16 (3)
Autism spectrum disorder	356 (21)	237 (24)	25 (36)	29 (40)	76 (13)
Bipolar disorder	24 (1)	13 (1)	2 (3)	1 (1)	8 (1)
Depression	101 (6)	42 (4)	4 (6)	1 (1)	54 (10)
Intellectual disorder(s)	1184 (71)	829 (85)	63 (90)	57 (79)	254 (45)
Learning disabilities	175 (11)	109 (11)	8 (11)	2 (3)	57 (10)
Schizophrenia	13 (1)	7 (1)	0	0	6 (1)

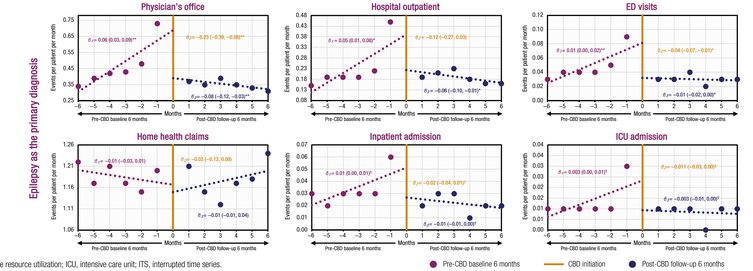
[a]The categories for LGS, DS, and TSC are not mutually exclusive. [b]CCI includes myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, chronic obstructive pulmonary disease, dementia, paraplegia and hemiplegia, diabetes, diabetes with complications, renal disease, mild liver disease, moderate/severe liver disease, peptic ulcers, rheumatic disease, human immunodeficiency virus/acquired immunodeficiency syndrome, cancer, and metastatic solid tumor.
CCI, Charlson Comorbidity Index; DS, Dravet syndrome; LGS, Lennox-Gastaut syndrome; SD, standard deviation; TSC, tuberous sclerosis complex.

ITS analysis[4,5]

View via QR code

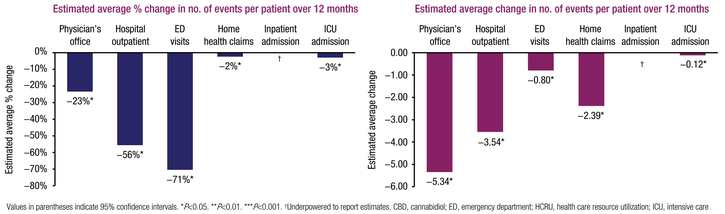
Figure 2. ITS analysis of epilepsy-related HCRU

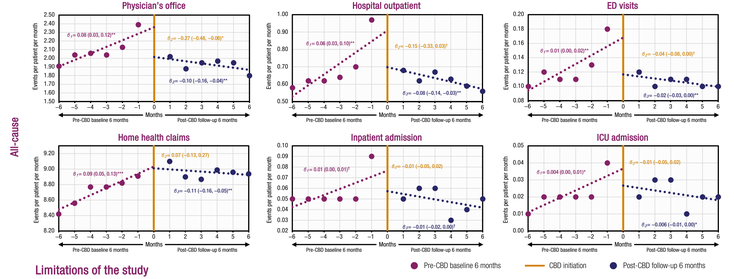




100% means back to baseline level and not zero events. Values in parentheses indicate 95% confidence intervals. *P<0.05. **P<0.01. †Underpowered to report estimates. CBD, cannabidiol; ED, emergency department; HCRU, health care resource utilization; ICU, intensive care unit; ITS, interrupted time series.

Figure 3. ITS analysis of all-cause HCRU





Values in parentheses indicate 95% confidence intervals. *P<0.05. **P<0.01. ***P<0.001. †Underpowered to report estimates. CBD, cannabidiol; ED, emergency department; HCRU, health care resource utilization; ICU, intensive care unit; ITS, interrupted time series.

- Epilepsy-related HCRU is defined as HCRU with epilepsy as the first diagnosis.
- Based on ITS analysis of change in epilepsy-related HCRU, there were increasing trends pre-CBD initiation for all categories, except home health claims (**Figure 2**). There were decreasing/flat trends for all categories, post-CBD initiation.
- Changes in all-cause HCRU show increasing trends pre-CBD and decreasing trends post-CBD initiation for all categories (**Figure 3**).

Limitations of the study

- Due to the pre-post study design, the effects on HCRU may not be solely attributable to CBD.
- Although real-world HCRU studies have often used 6-month baseline and follow-up periods, 6 months may not be sufficient to estimate long-term HCRU for this population.

Conclusions

- Among Medicaid patients, post-CBD initiation was associated with significantly lower epilepsy-related physician's office, hospital outpatient, and ED visits, as well as lower all-cause HCRU, except for inpatient admissions (underpowered).
- Progressively decreasing trends of HCRU were associated with CBD use.
- The progressively increasing HCRU before CBD initiation and progressively decreasing HCRU after CBD initiation provide support for the real-world effectiveness of CBD.
- The substantial reduction in all-cause HRCU suggests the potential benefits of CBD in nonseizure outcomes; however, further studies to quantify the association between HCRU reduction and quality of life and other humanistic outcomes among CBD users are needed.

References: **1.** EPIDIOLEX® [prescribing information]. Jazz Pharmaceuticals, Inc. 2023. **2.** Dixon-Salazar T, et al. Presented at the AES Annual Meeting; December 3–7, 2021; Chicago, IL, USA. Abstract 3.3. **3.** Berg AT, et al. Presented at the AES Annual Meeting; December 3–7, 2021; Chicago, IL, USA. Abstract 3.304. **4.** Kontopantelis E, et al. *BMJ.* 2015;350:h2750. **5.** Wagner AK, et al. *J Clin Pharm Ther.* 2002;27(4):299-309. **6.** Jandoc R, et al. *J Clin Epidemiol.* 2015;68:950-956. **7.** Hawton K, et al. *BMJ.* 2013;346:f403.

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