

Demographics and Clinical Factors Associated With Persistence on Cannabidiol (CBD) in US Patients With Lennox-Gastaut Syndrome (LGS), Dravet Syndrome (DS), Tuberous Sclerosis Complex (TSC), or Other Refractory Epilepsies

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Objective

- To evaluate baseline demographic and clinical factors associated with persistence on CBD among patients with LGS, DS, TSC, or other refractory epilepsies

Conclusions

- Clinical and demographic factors were associated with persistence on CBD. Persistence on CBD was higher among patients with TSC, LGS, and DS, as well as those using clobazam at baseline and those enrolled in the Northeast US, and lower among patients with anxiety; these findings remained robust post-Bonferroni correction
- Associations with age at CBD initiation, ethnicity, and polypharmacy were observed before Bonferroni correction for multiple comparisons but did not remain statistically significant after correction
- Overall, results suggest that persistence on CBD may be more strongly influenced by factors such as diagnosis, comorbidities, concomitant clobazam use, and region of enrollment
- These insights may support clinicians in recognizing factors associated with higher persistence and support treatment continuity

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Support and Acknowledgments: This study was sponsored by Jazz Pharmaceuticals, Inc. Writing and editorial assistance was provided to the authors by Marjan Shah, PhD on behalf of Syneca Health, and funded by Jazz Pharmaceuticals, Inc., in accordance with Good Publication Practice (GPP) 2022 guidelines.

Disclosures: All authors met the ICMJE authorship criteria and had full access to relevant data and information. Neither honoraria nor payments were made for authorship. **LB, ASillah, TS, MF, MM, and SS** are employees of Jazz Pharmaceuticals, Inc., and hold stock and/or stock options in the company. **VO** is an employee of Jazz Pharmaceuticals, UK Ltd., and holds stock and/or options in the company. **TB, ASachdev, and AG** have consulted for, conducted studies funded by, or received honoraria for services provided to Jazz Pharmaceuticals, Inc. **MK** has served as a speaker for US Pharma.

Epidiolex[®] is approved in the US for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients ≥1 year of age.

Introduction

- Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), and tuberous sclerosis complex (TSC) are severe developmental and epileptic encephalopathies with an onset in infancy or early childhood and are often resistant to antiseizure medications (ASMs)¹⁻³
- A plant-derived, highly purified pharmaceutical formulation of cannabidiol (CBD; Epidiolex[®], 100 mg/mL oral solution) is approved for the treatment of seizures associated with LGS, DS, or TSC.⁴ The efficacy of CBD in these indications has been well established in randomized clinical trials⁵⁻⁹
- Previous real-world studies have reported relatively high long-term persistence on CBD treatment^{10,11}; however, factors influencing persistence remain unclear

Methods

- This retrospective cohort study used the US Optum[®] Market Clarity claims database and integrated clinical data from >70 million patients and >150 US payers. Study details and design are shown in **Figures 1 and 2**
- A summary of factors analyzed in this study is shown in **Figure 3**
- This study included patients with Epidiolex[®] prescription records (pharmacy claims and written prescriptions) and results do not apply to other CBD-containing products

Figure 1. Study details

	Study population	Patients with LGS, DS, TSC, or other refractory epilepsies who initiated CBD treatment during the indexing period
	Study period	May 15, 2017–June 30, 2024
	Indexing period	May 15, 2018–June 30, 2024
	Inclusion criteria	• ≥1 EHR or medical claim with ICD-10-CM diagnosis code ^a for LGS, DS ^b , TSC or other refractory epilepsies during the indexing period • ≥1 record of CBD prescribed or dispensed
	Exclusion criteria	• Invalid demographic data • Evidence of prior CBD use during the 12-month lookback period
	Outcome	Persistence on CBD based on time to discontinuation (>60-day supply gap)
	Statistical analyses	• Time to event analysis: Multivariable Cox proportional hazard model was used to identify factors associated with discontinuation. HRs (95% CIs), reflective of the relative risk of discontinuation, were used to assess persistence • Bonferroni correction was applied as a sensitivity analysis to account for multiple comparisons (63 in total)

^aExpert algorithms were used to identify epilepsy types using ICD-10-CM diagnosis codes. Codes included: G40.B1* (LGS); G40.B3 (DS); O85.1 (TSC); Other refractory epilepsies: G40* (Epilepsy and recurrent seizures); F44.5, G40*, P90, O85.1, R56* (Epilepsy, seizures, LGS, or TSC); R56.0* (Fetile seizures); F70, F71, F72, F73, F77, F79, F80*, F81*, F82*, F84*, F88, F89, R41.83 (Intellectual disability/developmental delay); G40.D1*, G40.D11, G40.D21*, G40.D31*, G40.D41*, G40.B03, G40.B04, G40.B13, G40.B14, G40.B22, G40.B23, G40.B24, G40.B1*, G40.A1*, G40.B1* (Intractable/refractory epilepsy); F44.5, G40.D0*, G40.D20*, G40.D30*, G40.D40*, G40.D50*, G40.B01, G40.B11, G40.B12, G40.B21, G40.B22, G40.B3, G40.D0*, G40.A0*, G40.B0*, P90, R56* (Seizure or non-intractable/non-refractory epilepsy). Codes for abnormal brain imaging (G11*, G04*, G05*, G10, G11*, G12*, G20, G21*, G22*, G23*, G24*, G25*, G26*, G27*, G28*, G29*, G30*, G31*, G32*, G33*, G34*, G35*, G36*, G37*, G38*, G39*, G40.4*, G40.5, G40.6, G40.8, G40.9, G41.1, G41.2, G42, G43.1, G43.2, G43.3, G43.4, G43.5, G43.6, G43.7, G43.8, G43.9, G44.0, G44.1, G44.2, G44.3, G44.4, G44.5, G44.6, G44.7, G44.8, G44.9, G45.0, G45.1, G45.2, G45.3, G45.4, G45.5, G45.6, G45.7, G45.8, G45.9, G46.0, G46.1, G46.2, G46.3, G46.4, G46.5, G46.6, G46.7, G46.8, G46.9, G47.0, G47.1, G47.2, G47.3, G47.4, G47.5, G47.6, G47.7, G47.8, G47.9, G48.0, G48.1, G48.2, G48.3, G48.4, G48.5, G48.6, G48.7, G48.8, G48.9, G49.0, G49.1, G49.2, G49.3, G49.4, G49.5, G49.6, G49.7, G49.8, G49.9, G50.0, G50.1, G50.2, G50.3, G50.4, G50.5, G50.6, G50.7, G50.8, G50.9, G51.0, G51.1, G51.2, G51.3, G51.4, G51.5, G51.6, G51.7, G51.8, G51.9, G52.0, G52.1, G52.2, G52.3, G52.4, G52.5, G52.6, G52.7, G52.8, G52.9, G53.0, G53.1, G53.2, G53.3, G53.4, G53.5, G53.6, G53.7, G53.8, 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