

Healthcare Resource Utilization, Antiseizure Medication Claims, and Treatment Persistence in Patients With Lennox-Gastaut Syndrome Receiving Fenfluramine in the United States

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Background

- Lennox-Gastaut syndrome (LGS) is a rare, severe, developmental, and epileptic encephalopathy characterized by treatment-resistant seizures that begin in childhood and persist into adulthood.
- Fenfluramine was approved for the management of seizures associated with LGS in patients ≥ 2 years of age in the United States in 2022.¹
- Fenfluramine differs from other treatments for developmental and epileptic encephalopathies due to its multimodal mechanism of action, which involves both serotonergic and sigma-1 receptor pathways.²
- Real-world evidence on fenfluramine use in patients with LGS remains limited with respect to treatment persistence and patient characteristics.

Objective

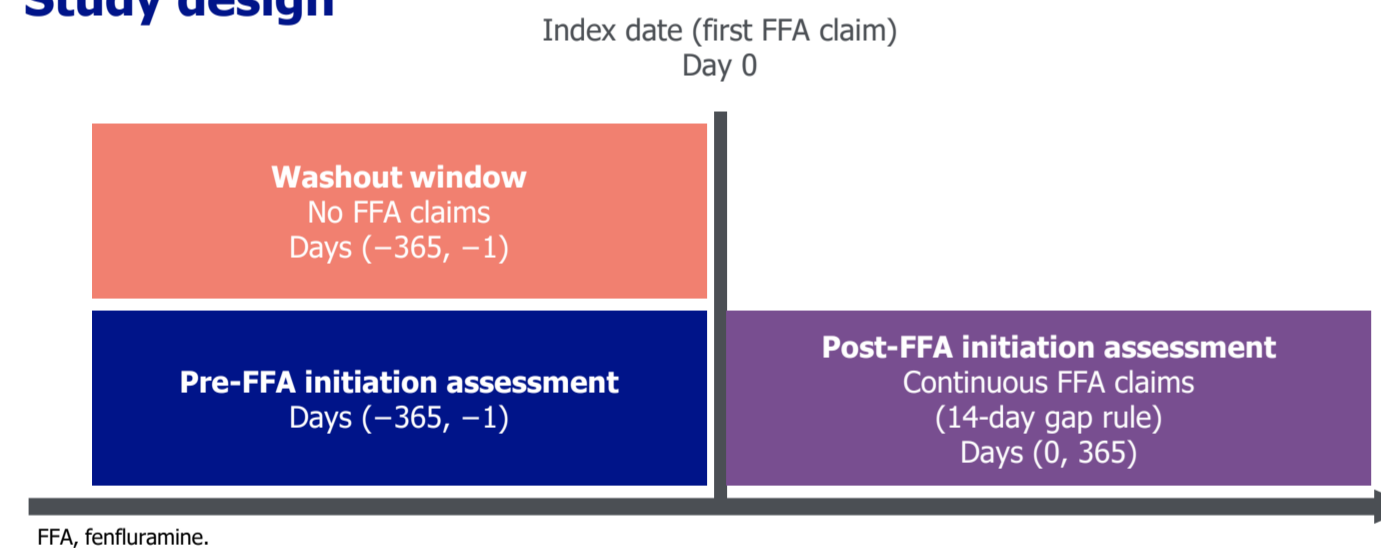
- To assess healthcare resource utilization (HCRU), antiseizure medication (ASM) treatment claims, and treatment persistence in patients with LGS receiving fenfluramine.

Methods

- In this retrospective study, patients with LGS claims (International Classification of Disease, 10th Revision, G40.81) were identified from the Komodo US healthcare claims database.

HCRU ANALYSIS

Study design



- The patient selection period was January 1, 2022, to December 31, 2024.
- Eligible patients had ≥ 1 fenfluramine prescription claim (earliest claim: initiation date) and ≥ 2 LGS claims (≥ 1 month apart), 12 months of claims data pre- and post-fenfluramine initiation, and received fenfluramine for ≥ 12 months with no gaps of >14 days.
- Differences in HCRU, number of unique ASM claims, and average ASM claims (excluding fenfluramine) pre- vs post-fenfluramine initiation were assessed using paired t-tests.
- Interrupted time series (ITS) analyses using a generalized estimating equation were conducted to control for time trends.
- Propensity score-matched cohort difference-in-difference (DiD) regression analyses were used to assess robustness vs a matched control group (patients with ≥ 1 LGS claim and no fenfluramine claims).

PERSISTENCY ANALYSIS

- The patient selection period was January 1, 2022, to June 30, 2024.
- Eligible patients had ≥ 1 fenfluramine claim (earliest claim: initiation date), ≥ 1 LGS claim, and ≥ 3 months of pre- and ≥ 6 months of post-fenfluramine initiation claims data.
- Treatment persistence (no gaps in fenfluramine claims >90 days in the first 12 months post initiation) was evaluated using Kaplan-Meier analysis.

COMPARISON OF PATIENTS WITH AND WITHOUT FENFLURAMINE CLAIMS

- The patient selection period was January 1, 2022, to December 31, 2023.
- Eligible patients had claims data for 12 months pre- and post-index date.
- Two-sample t-tests and chi-square tests were used to compare demographic and clinical characteristics for patients with fenfluramine claims (regardless of persistence) vs those with ≥ 1 LGS claim and no fenfluramine claims.

Overview

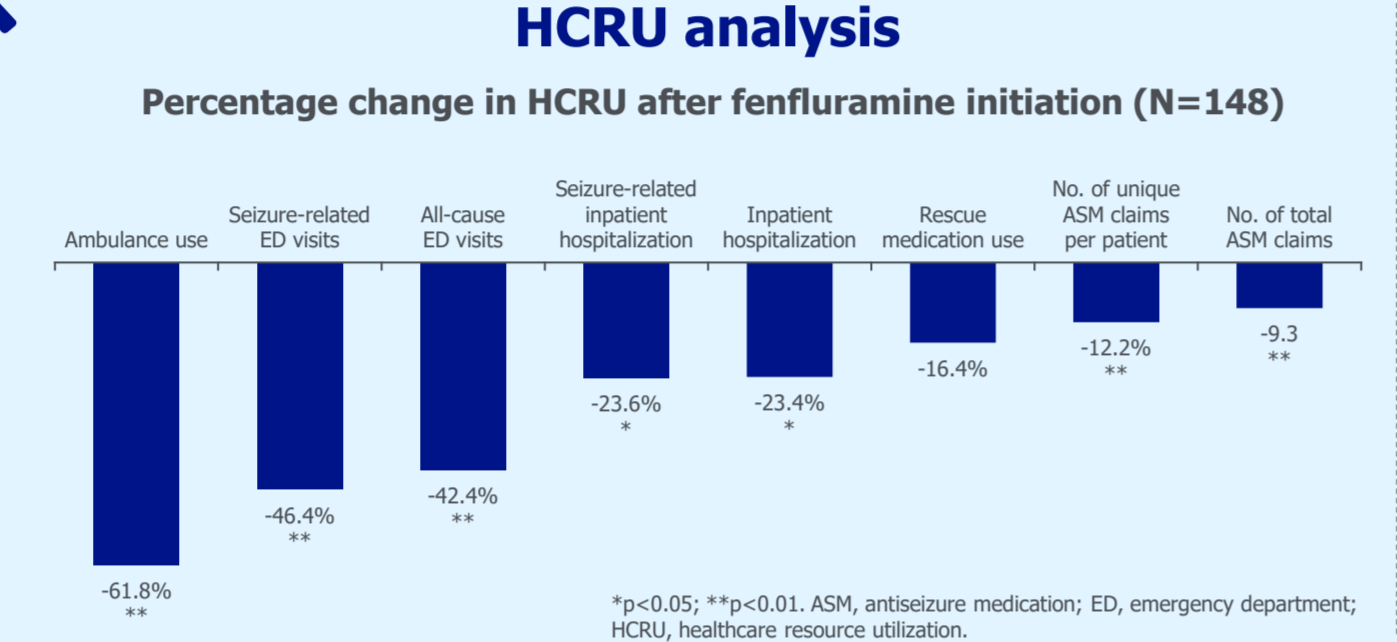
QUESTIONS

- What are the real-world changes in healthcare resource utilization (HCRU) and antiseizure medication (ASM) use among patients with Lennox-Gastaut syndrome (LGS) before and after initiating fenfluramine?
- What is the 12-month treatment persistence with fenfluramine in patients with LGS?
- How do characteristics differ between patients with and without fenfluramine claims?

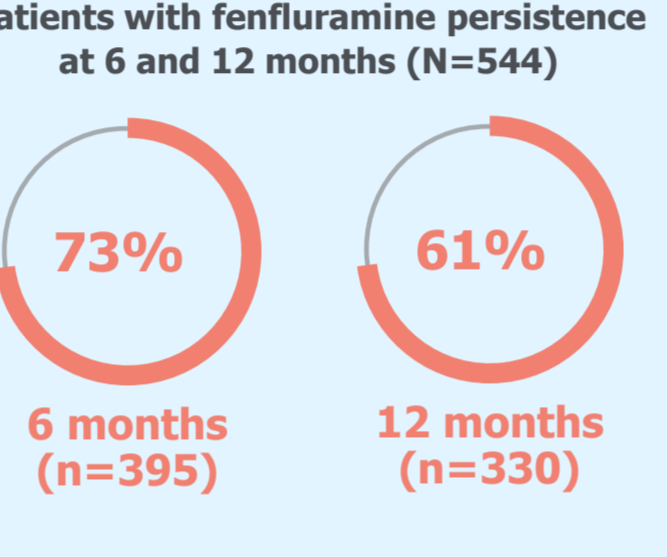
INVESTIGATION

- Retrospective study of patients with LGS claims (International Classification of Disease, 10th Revision, G40.81) using the Komodo US healthcare claims database.
- HCRU analyses:** Patients with ≥ 1 fenfluramine claim, ≥ 2 LGS claims, 12 months of data pre- and post-fenfluramine initiation, and 12 months of persistent fenfluramine use.
- Persistence analyses:** Patients with ≥ 1 fenfluramine claim, ≥ 1 LGS claim, and ≥ 3 months of pre- and ≥ 6 months of post-fenfluramine initiation claims data.
- Comparisons of patient characteristics:** Patients with fenfluramine claims vs those with no claims.

RESULTS



Persistency analysis



Comparison of patients with and without fenfluramine claims

Demographics and clinical characteristics during baseline period

| Patient characteristics | FFA claims | |
|--------------------------------------|--------------------------|--------------------------|
| | Yes (n=373) ^a | No (n=2361) ^b |
| Mean age at index, years | 16 | 38** |
| Mean HCRU severity score | 128.3 | 57.1** |
| Mean pre-index HCRU claims, n | | |
| ED visits | 1.6 | 1.1** |
| Status epilepticus | 12.7 | 4.3** |
| Unique ASMs | 5.8 | 3.7** |
| Rescue medications | 3.3 | 1.0** |

| Patients with comorbidities, % | FFA claims | |
|---------------------------------|-------------|-------------|
| | Yes (n=373) | No (n=2361) |
| Behavioral disorders | 38 | 29** |
| Respiratory/CV complications | 69 | 51** |
| Developmental impairments | 76 | 38** |
| Gastrointestinal disorders | 53 | 41** |
| Mobility dysfunction | 36 | 22** |
| Sleep disturbances ^a | 28 | 16** |

**p<0.01. ^aIncluding sleep apnea. ASM, antiseizure medication; CV, cardiovascular; ED, emergency department; FFA, fenfluramine; HCRU, healthcare resource utilization.

CONCLUSIONS

- Among patients with LGS who remained on treatment for 12 months, fenfluramine was associated with lower HCRU and reduced ASM burden.
- Treatment persistence was high among patients with LGS receiving fenfluramine, with rates of 73% and 61% at 6 and 12 months, respectively.
- Patients who received fenfluramine were younger, had a higher incidence of comorbidities, and had a greater HCRU burden than those without fenfluramine claims, indicating more severe disease.

Results

HCRU ANALYSIS

Demographics and clinical characteristics

| | PATIENTS WITH LGS (N=148) |
|--|---------------------------|
| Male, n (%) | 76 (51) |
| Age at index date, n (%) | |
| <18 years | 81 (55) |
| ≥ 18 years | 67 (45) |
| Comorbidities, n (%)^{a,b} | |
| Developmental complications | 118 (80) |
| Respiratory/cardiovascular complications | 104 (70) |
| Gastrointestinal issues | 81 (55) |
| Behavioral/psychiatric disorders | 53 (36) |
| Mobility issues/wheelchair use | 52 (35) |
| Sleep disturbances, including sleep apnea | 45 (30) |
| Payer type, n (%) | |
| Commercial | 84 (57) |
| Medicaid | 41 (28) |
| Medicare | 10 (7) |
| Unknown | 13 (9) |
| Prescribing physician, n (%) | |
| Epileptologist | 35 (24) |
| Pediatric neurologist | 35 (24) |
| Pediatric neurologist/epileptologist | 29 (20) |
| Neurologist | 12 (8) |
| Adult neurologist/epileptologist | 11 (7) |
| Pediatrician | 10 (7) |
| Nurse practitioner or physician's assistant | 1 (1) |
| Unknown | 15 (10) |
| Specialty physician type, n (%)^a | |
| Epileptologist at COE ^c | 109 (74) |
| Epileptologist outside of COE ^c | 22 (15) |
| Pediatric neurologist | 14 (9) |
| Neurologist | 3 (2) |
| Other, non-prescription treatments, n (%)^d | |
| Yes | 81 (55) |
| No | 67 (45) |

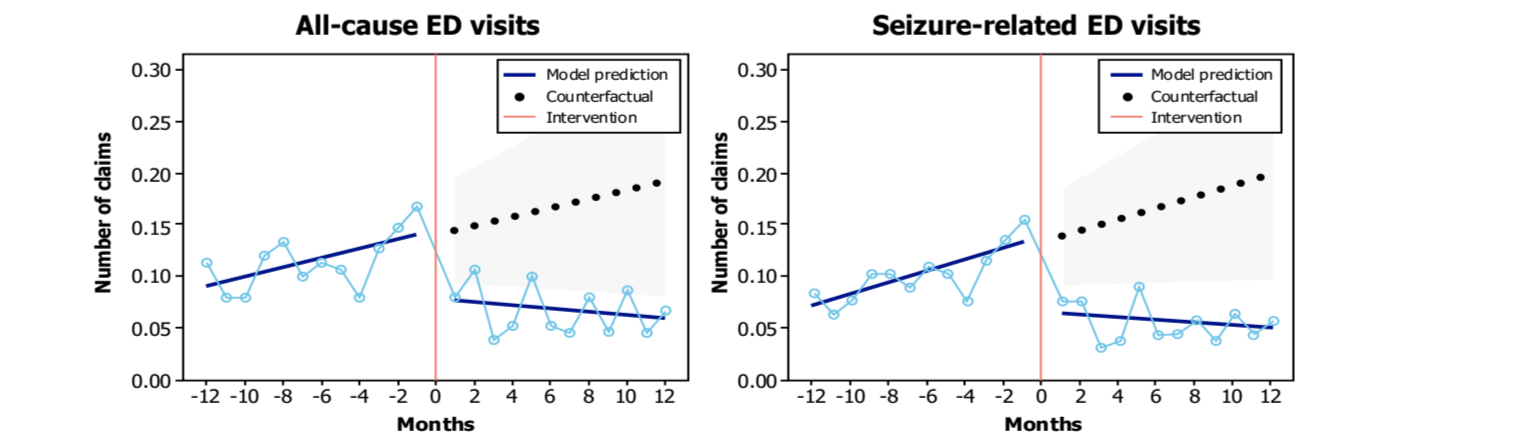
^aPre-fenfluramine initiation; ^bPatients may have >1 comorbidity; ^cLevel 4 National Association of Epilepsy Centers; ^dIncludes vagal nerve stimulation, deep brain stimulation, neurostimulation, and epilepsy surgery. COE, Centers of Excellence; LGS, Lennox-Gastaut syndrome.

HCRU and ASM claims in 12 months pre- and post-fenfluramine initiation (N=148)

| | PRE-FFA INITIATION, MEAN | POST-FFA INITIATION, MEAN | % CHANGE | p-VALUE |
|--|--------------------------|---------------------------|----------|---------|
| Ambulance use ^a | 0.5 | 0.2 | -61.8 | <0.01 |
| Seizure-related ED visits ^a | 1.3 | 0.7 | -46.4 | <0.01 |
| All-cause ED visits ^a | 1.4 | 0.8 | -42.4 | <0.01 |
| Seizure-related inpatient hospitalization ^a | 4.0 | 3.0 | -23.6 | 0.04 |
| Inpatient hospitalization ^a | 4.0 | 3.1 | -23.4 | 0.04 |
| Rescue medication use ^b | 3.3 | 2.8 | -16.4 | 0.08 |
| No. of unique ASM claims/patient ^{b,c} | 3.4 | 3.0 | -12.2 | <0.01 |
| No. of total ASM claims ^{b,c} | 31.9 | 28.9 | -9.3 | <0.01 |

p<0.05 is considered significant. The index date is the date of the first FFA prescription claim. ^aPaired t-tests performed to assess the difference in the average number of claims pre- and post-index; ^bPaired t-tests performed to assess the difference in the average number of claims per patient pre- and post-index; ^cASM excluding FFA, ASM, antiseizure medication; ED, emergency department; FFA, fenfluramine; HCRU, healthcare resource utilization.

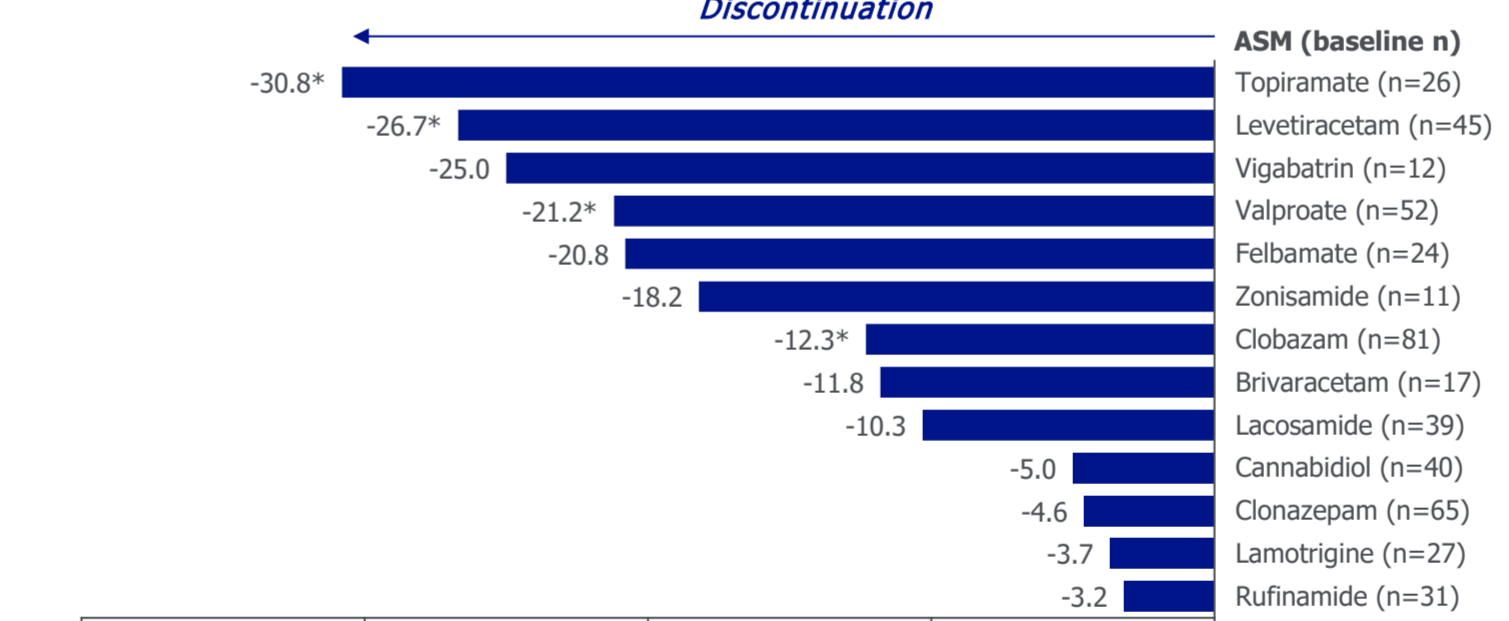
Interrupted time series analysis (N=148)



A generalized estimating equation was used: $y_i(t) = \beta_1 * \text{time from start} + \beta_2 * \text{treatment variable} (0/1) + \beta_3 * \text{time since treatment} + \epsilon$. CI, confidence interval; ED, emergency department; FFA, fenfluramine.

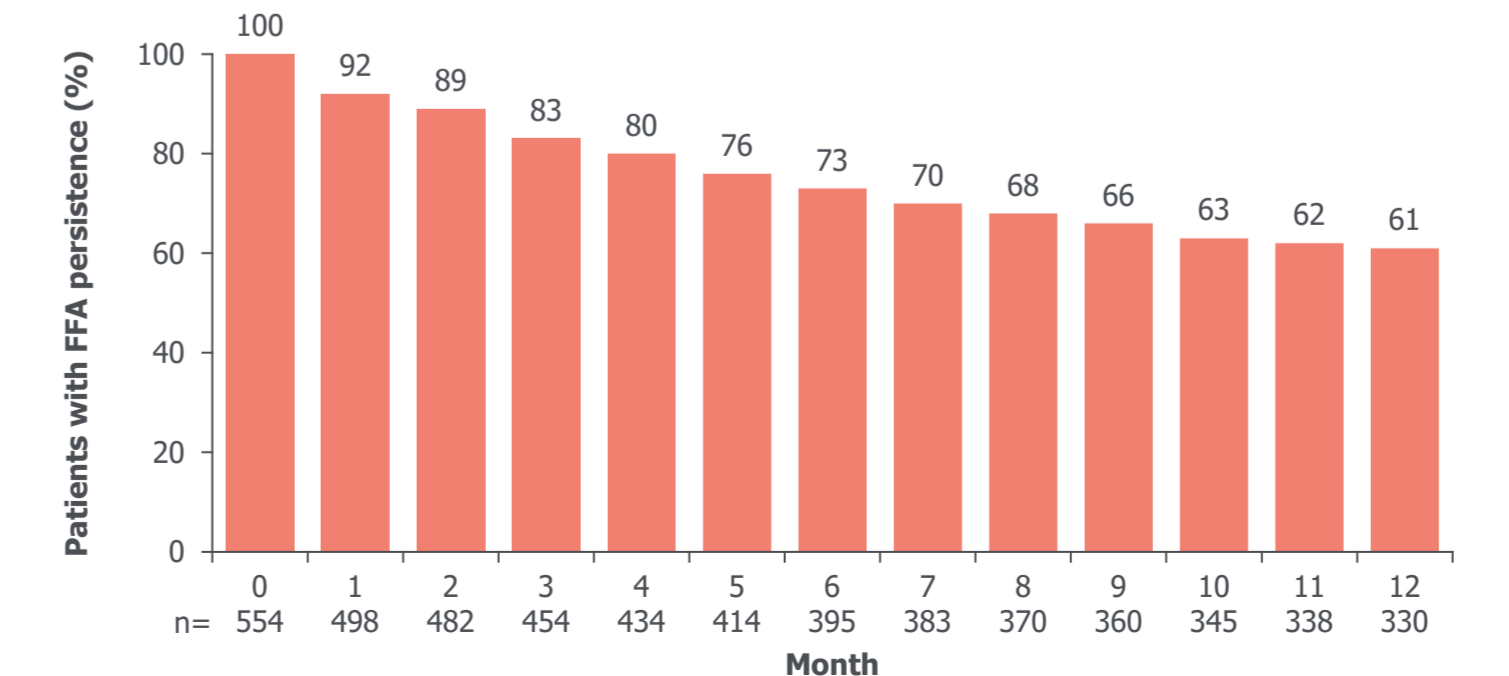
- ITS analyses showed immediate reductions in claims at fenfluramine initiation and continued improvement over 12 months for all-cause and seizure-related emergency department (ED) visits and ambulance use.
- DiD regression analyses confirmed these reductions were significant when compared with matched controls.

Change in concomitant ASM prescriptions from pre- to post-fenfluramine initiation



PERSISTENCY ANALYSIS

Fenfluramine persistence across the first year (N=544)^a



COMPARISON OF PATIENTS WITH AND WITHOUT FENFLURAMINE CLAIMS

Demographics and clinical characteristics during baseline period

| | FFA CLAIMS | | p-VALUE |
|---|--------------------------|--------------------------|---------|
| | YES (n=373) ^a | NO (n=2361) ^b | |
| Mean age at index, c years | 16 | 38 | <0.01 |
| Sex, n (%) | | | |
| Male | 184 (49) | 1297 (55) | 0.05 |
| Physician specialty, n (%) | | | |
| Epileptologists at COE ^d | 256 (69) | 1071 (45) | <0.01 |
| Epileptologist outside of COE ^d | 65 (17) | 516 (22) | 0.06 |
| Neurologist | 10 (3) | 376 (16) | <0.01 |
| Pediatric neurologist | 42 (11) | 236 (10) | 0.51 |
| Other | 0 | 162 (7) | <0.01 |
| Comorbidities, n (%) | | | |
| Behavioral disorders | 140 (38) | 675 (29) | <0.01 |
| Respiratory/cardiovascular complications | 259 (69) | 1207 (51) | <0.01 |
| Developmental impairments | 284 (76) | 889 (38) | <0.01 |
| Gastrointestinal disorders | 197 (53) | 973 (41) | <0.01 |
| Mobility dysfunction | 134 (36) | 522 (22) | <0.01 |
| Sleep disturbances, including sleep apnea | 105 (28) | 388 (16) | <0.01 |
| Comorbidity index, mean | | | |
| Charlson Comorbidity Index ^e | 1.5 | 2.0 | <0.01 |
| Germaine Smith Index ^e | 2.3 | 2.8 | <0.01 |
| Average ADI rank^f | 47.7 | 45.2 | 0.03 |
| HCRU severity score, g mean | 128.3 | 57.1 | <0.01 |
| Mean pre-index^h HCRU claims | | | |
| ED visits | 1.6 | 1.1 | <0.01 |
| Length of inpatient stay | 3.8 | 2.3 | 0.02 |
| GTC seizures | 1.2 | 0.5 | 0.06 |
| Status epilepticus | 12.7 | 4.3 | <0.01 |
| No. of unique ASMs | 5.8 | 3.7 | <0.01 |
| No. of rescue medications | 3.3 | 1.0 | <0.01 |

^aPatients with FFA claims: ≥ 12 months of claims data pre- and post-first FFA claim; ^bPatients without any FFA claims: ≥ 12 months of claims data pre- and post-LGS diagnosis, and no FFA claims; ^cFor patients with FFA claims, the index date was date of first FFA claim. For patients without FFA claims, the index date was January 1, 2022 (which aligns closely with index dates in patients with FFA claims); ^dLevel 4 National Association of Epilepsy Centers; ^eData are not age adjusted; ^fHigher ADI rank indicative of greater socioeconomic disadvantage (100 is most disadvantaged); ^gUnvalidated weighted composite score of HCRU elements (ED visit, 10 points/visit; inpatient admissions, 5 points/day of stay; any status epilepticus claim, 5 points/claim; any GTC seizure claim, 4 points/claim; rescue medication, 4 points/claim; ASM, 2 points/distinct ASM molecule [if a patient had an ED visit for status epilepticus, points were counted for both the ED visit and the status epilepticus claim]); ^hADI, Area Deprivation Index; ASM, antiseizure medication; COE, Centers of Excellence; ED, emergency department; FFA, fenfluramine; GTC, generalized tonic-clonic; HCRU, healthcare resource utilization; LGS, Lennox-Gastaut syndrome.

Conclusions

- Among patients with LGS who remained on treatment for 12 months, fenfluramine was associated with lower HCRU and reduced ASM burden, suggesting a clinically meaningful reduction in disease burden.
- Fenfluramine use was associated with reductions in ED visits (all-cause and seizure-related), inpatient hospitalizations (all-cause and seizure-related), and ambulance use.
- The results for ED visits and ambulance use remained robust, following more rigorous analytical approaches.
- Mean total ASM claims and number of unique concomitant ASMs per patient decreased following fenfluramine initiation.
- Treatment persistence was high among patients with LGS receiving fenfluramine, with rates of 73% and 61% at 6 and 12 months, respectively.
- Patients who received fenfluramine were younger, had a higher comorbidity burden, and had a higher HCRU burden (including claims for status epilepticus, concomitant ASMs, and rescue medications) than those without fenfluramine claims, indicating more severe disease.
- While claims data limit the direct measurement of seizure and non-seizure outcomes, these findings reflect sustained treatment in $>60\%$ of patients at 12 months and support the real-world utility of fenfluramine in LGS.

References

- FINTEPLA® (fenfluramine) oral solution. US Prescribing Information. UCB Inc. 2023. www.ucb.com/sites/default/files/2023-10/FinTEPLA_Oral_soln_2023.pdf. Accessed March 2026.
- Martin P, et al. *Epilepsy Behav* 2020;105:106999.

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