

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Fintepla (fenfluramine)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Fintepla is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older. It exhibits agonist activity at serotonin 5-HT₂ receptors. Fintepla has a black box warning for valvular heart disease and pulmonary arterial hypertension. Dravet syndrome is a developmental epileptic encephalopathy that usually presents in the first year of life with recurrent seizures which are often prolonged and triggered by fever. With time, other types of seizures may occur, as well as intellectual disability, neurological abnormalities, behavioral issues, and other comorbidities. Complete seizure control is rarely achievable. In 80-85% of cases, variants in the SCN1A gene are present.

Lennox-Gastaut syndrome is a severe developmental epileptic encephalopathy characterized by several seizure types, including drop seizures, as well as cognitive impairment. Seizures usually begin before 8 years of age and persist into adulthood.

Fintepla (fenfluramine) will be considered for coverage when the following criteria are met:

Dravet Syndrome

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of seizures associated with Dravet Syndrome; AND
4. Chart notes must document the member's seizure frequency on current treatment; AND
5. Chart notes must show that an echocardiogram has been or will be done before starting treatment; AND
6. The member has tried and failed or has contraindication to valproic acid.
7. **Dosage allowed/Quantity limit:** See package insert for titration schedule. QL: 360 mL per 30 days
 - a) Without Diacomit (stiripentol): Up to 0.35 mg/kg twice daily, up to 26 mg/day.
 - b) Concomitant Diacomit (stiripentol) and clobazam: Up to 0.2 mg/kg twice daily, up to 17 mg/day.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must document a reduction in convulsive seizure frequency since starting Fintepla.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Lennox-Gastaut Syndrome (LGS)

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of seizures associated with Lennox-Gastaut syndrome; AND
4. Chart notes must document the member's seizure frequency on current treatment; AND
5. Chart notes must show that an echocardiogram has been or will be done before starting treatment; AND
6. Chart notes must show trial and failure of at least 2 of the following: valproate, lamotrigine, topiramate, rufinamide, clobazam, felbamate.
7. **Dosage allowed/Quantity limit:** See package insert for titration schedule. QL: 360 mL per 30 days
 - a) Without Diacomit (stiripentol): Up to 0.35 mg/kg twice daily, up to 26 mg/day.
 - b) Concomitant Diacomit (stiripentol) and clobazam: Up to 0.2 mg/kg twice daily, up to 17 mg/day.

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes must document a reduction in frequency of drop seizures since starting Fintepla.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Fintepla (fenfluramine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/28/2020	New policy for Fintepla created.
04/15/2022	Transferred to new template. Created criteria for LGS. DS: Added new reference. Removed trial of Diacomit or topiramate.
02/05/2025	Updated references. Removed weight documentation. Added "up to" in the dosing info. Corrected "electrocardiogram" to "echocardiogram." DS: Changed step requirement from VPA and clobazam to just VPA (Wirrell 2022). LGS: In renewal, changed "convulsive seizure frequency" to "frequency of drop seizures" to match endpoint wording.

References:

1. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc; 2023.
2. Lagae L, Sullivan J, Knupp K, et al. Fenfluramine hydrochloride for the treatment of seizures in Dravet syndrome: a randomised, double-blind, placebo-controlled trial. *Lancet*. 2019;394(10216):2243-2254. doi:10.1016/S0140-6736(19)32500-0
3. Nabbout R, Mistry A, Zuberi S, et al. Fenfluramine for Treatment-Resistant Seizures in Patients With Dravet Syndrome Receiving Stiripentol-Inclusive Regimens: A Randomized Clinical Trial [published online ahead of print, 2019 Dec 2]. *JAMA Neurol*. 2019;77(3):300-308. doi:10.1001/jamaneurol.2019.4113
4. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. *Pediatric Neurology*. 2017;68:18-34. doi:10.1016/j.pediatrneurol.2017.01.025
5. Cross JH, Caraballo RH, Nabbout R, Vigevano F, Guerrini R, Lagae L. Dravet syndrome: Treatment options and management of prolonged seizures. *Epilepsia*. 2019;60 Suppl 3:S39-S48. doi:10.1111/epi.16334

6. Devi N, Madaan P, Asrar MM, Sahu JK, Bansal D. Comparative short-term efficacy and safety of add-on anti-seizure medications in Dravet syndrome: An indirect treatment comparison. *Seizure*. 2021;91:316-324. doi:10.1016/j.seizure.2021.06.020
7. Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63(7):1761-1777. doi:10.1111/epi.17274
8. Knupp KG, Scheffer IE, Ceulemans B, et al. Efficacy and Safety of Fenfluramine for the Treatment of Seizures Associated With Lennox-Gastaut Syndrome: A Randomized Clinical Trial. *JAMA Neurol*. 2022;79(6):554-564. doi:10.1001/jamaneurol.2022.0829
9. Brigo F, Jones K, Eltze C, Matricardi S. Anti-seizure medications for Lennox-Gastaut syndrome. *Cochrane Database Syst Rev*. 2021;4(4):CD003277. Published 2021 Apr 7. doi:10.1002/14651858.CD003277.pub4
10. Cross JH, Auvin S, Falip M, Striano P, Arzimanoglou A. Expert Opinion on the Management of Lennox-Gastaut Syndrome: Treatment Algorithms and Practical Considerations. *Front Neurol*. 2017;8:505. Published 2017 Sep 29. doi:10.3389/fneur.2017.00505
11. Strzelczyk A, Schubert-Bast S. Expanding the Treatment Landscape for Lennox-Gastaut Syndrome: Current and Future Strategies. *CNS Drugs*. 2021;35(1):61-83. doi:10.1007/s40263-020-00784-8
12. Wirrell EC, Lagae L, Scheffer IE, Cross JH, Specchio N, Strzelczyk A. Practical considerations for the use of fenfluramine to manage patients with Dravet syndrome or Lennox-Gastaut syndrome in clinical practice. *Epilepsia Open*. 2024;9(5):1643-1657. doi:10.1002/epi4.12998

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