CareSource Rxinnovations

PHARMACY POLICY STATEMENT
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:

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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
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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

Effective date: 07/01/2025
Revised date: 02/05/2025