Pharmacy Policy Bulletin: J-0277 Fintepla (fenfluramine) – Commercial and Healthcare Reform	
Number: J-0277	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)**: **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0277-007	**Original Date:** 08/05/2020
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Fintepla (fenfluramine)
FDA-Approved Indication(s):	• Treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older.

Background:	• Fenfluramine and its metabolite, norfenfluramine, increase extracellular levels of serotonin through interaction with serotonin transporter proteins and exhibit agonist activity at serotonin 5HT-2 receptors. The mechanisms by which fenfluramine exerts its therapeutic effects in the treatment of seizures associated with Dravet syndrome are unknown. • Dravet syndrome (DS) is a rare, drug-resistant epilepsy that typically appears in the first year of life in an otherwise healthy infant. It usually presents as a prolonged seizure that affects one side of the body and fever. DS is rare, affecting 1 in every 15,700 individuals (about 2,000 to 8,000 patients in the United States), but is associated with a 15-20% mortality rate. • A 2022 international consensus on diagnosis and management of Dravet syndrome recommends valproate as first line therapy; fenfluramine, stiripentol, or clobazam as second line therapy; pharmaceutical grade cannabidiol as third line; and topiramate or ketogenic diet as fourth line. The following drugs should be avoided in Dravet syndrome: carbamazepine, oxcarbazepine, lamotrigine, and phenytoin. • LGS is a severe condition characterized by recurrent seizures that begin early in life. Affected individuals have multiple types of seizures, a particular pattern of brain activity (called slow spike-and-wave) measured by an electroencephalogram (EEG), and impaired mental abilities. • Multiple treatment modalities exist for LGS. While not FDA-approved, valproic acid is most often used first line. The American Academy of Neurology (AAN) guidelines currently recommend using rufinamide or clobazam as adjunctive therapies for LGS. The National Organization for Rare Disease (NORD) additionally recommends topiramate, lamotrigine, felbamate, rufinamide, clobazam and

	cannabidiol as adjunctive therapies. Due to serious side effects, felbamate is typically not used first or second line.
	• Prescribing Considerations:
	  ○ Fintepla has a black box warning for valvular heart disease and pulmonary arterial hypertension and has Risk Evaluation and Mitigation Strategies (REMS) requiring prescribers, patients, and pharmacies to enroll. Cardiac monitoring with echocardiogram is required prior to starting treatment, every 6 months during treatment, and every 3 to 6 months after treatment with Fintepla concludes.
	  ○ Fintepla must be used within 3 months of first opening the bottle.

Approval Criteria

I. Initial Authorization

A. Dravet Syndrome

When a benefit, coverage of Fintepla may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 2 years of age or older.
2. The member has a diagnosis of Dravet syndrome. (ICD-10: G40.83)
3. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following agents **(a., b., or c.)**:
  a. clobazam
  b. topiramate
  c. valproic acid or divalproex sodium

B. Lennox-Gastaut Syndrome

When a benefit, coverage of Fintepla may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member is 2 years of age or older.
2. The member has a diagnosis of Lennox-Gastaut syndrome. (ICD-10: G40.81)
3. The member has experienced therapeutic failure, contraindication, or intolerance to two (2) of the following agents **(a. through d.):**
  a. valproic acid or divalproex sodium
  b. lamotrigine
  c. topiramate
  d. clobazam

II. Reauthorization

When a benefit, reauthorization of Fintepla may be approved when the following criterion is met **(A.)**:

A. The prescriber attests that the member has experienced a reduction in seizure frequency from baseline.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc.; April 2025.
2. Dravet Syndrome Foundation. What is Dravet Syndrome? Available at: https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed: May 2, 2025.
3. Wirrell E, Hood V, Knupp K, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63:1761–1777.
4. Kanner A, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy. *Neurology*. 2018;91:82-90.
5. U.S. National Library of Medicine. Lennox-Gastaut Syndrome. Available at: https://medlineplus.gov/genetics/condition/lennox-gastaut-syndrome/. Accessed May 2, 2025.
6. NORD. Lennox-Gastaut Syndrome. Available at: https://rarediseases.org/rare-diseases/lennox-gastaut-syndrome/. Accessed May 2, 2025.