Drug Coverage Policy

Effective Date 5/1/2026
Coverage Policy Number.....IP0042
Policy Title.....Fintepla

Antiseizure Medications – Fintepla

- Fintepla® (fenfluramine oral solution – Zogenix)

INSTRUCTIONS FOR USE

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OVERVIEW

Fintepla, a serotonin 5-hydroxytryptamine subtype 2 (5-HT_2) agonist, is indicated in patients ≥ 2 years of age for the treatment of **seizures associated with**:[1]

- **Dravet syndrome**.
- **Lennox-Gastaut syndrome**.

Disease Overview
Dravet syndrome is a rare genetic epileptic encephalopathy (dysfunction of the brain) marked with frequent and/or prolonged seizures.[2,3] The seizures generally begin in the first year of life in an otherwise healthy infant. Affected individuals can develop many seizure types: myoclonic, tonic-clonic, absence, atypical absence, atonic, focal aware or impaired awareness (previously called partial seizures), and status epilepticus.[3] Two or more antiseizure medications (ASMs) are often needed to control the seizures; most of the seizures are refractory to medications. The goals of treatment are cessation of prolonged convulsions, reduction in overall seizure frequency, and minimization of treatment side effects.[4,5]

Lennox-Gastaut syndrome, a severe epileptic and developmental encephalopathy, is associated with a high rate of morbidity and mortality.[6,7] Lennox-Gastaut syndrome most often begins between 3 and 5 years of age.[6-9] Affected children experience several different types of seizures, most commonly atonic seizures (sudden loss of muscle tone and limpness) and tonic seizures.[6,9] The three main forms of treatment of Lennox-Gastaut syndrome are ASMs, dietary therapy (typically the ketogenic diet), and device/surgery (e.g., vagus nerve stimulation, corpus callostomy).[9] None of the therapies are effective in all cases of Lennox-Gastaut syndrome and the disorder has proven particularly resistant to most therapeutic options.

Guidelines
Dravet Syndrome
At this time, there are three drugs approved for the treatment of seizures associated with Dravet syndrome: Diacomit® (stiripentol capsules, powder for oral suspension), Epidiolex® (cannabidiol oral solution), and Fintepla.[1,10,11] An international consensus on diagnosis and management of Dravet syndrome was published in 2022; physician and caregiver perspectives were considered.[4] There was strong consensus that valproic acid is an appropriate first-line ASM and clobazam can be considered either first- or second-line. Additional consensus for the first-line setting among physicians included Fintepla (strong) and Diacomit (moderate). Physicians did not reach consensus regarding the use of Epidiolex as either first- or second-line treatment. It was noted with moderate consensus that lamotrigine is contraindicated in Dravet syndrome.

The Dravet Foundation states that Diacomit, Epidiolex, and Fintepla are considered first-line agents for the treatment of Dravet syndrome.[2] If control is still inadequate, other therapies to consider are clonazepam, levetiracetam, and zonisamide.[2,4] Sodium channel blockers (e.g., carbamazepine, oxcarbazepine, lamotrigine, and phenytoin) can worsen seizures in Dravet syndrome. Additionally, vigabatrin and tiagabine may increase the frequency of myoclonic seizures and should be avoided.

Lennox-Gastaut Syndrome
Currently, the FDA-approved drugs for this condition are Fintepla, clobazam, clonazepam, rufinamide (Banzel®, generic), Epidiolex, felbamate, lamotrigine, and topiramate.[8] To address the lack of treatment algorithm, the Lennox-Gastaut syndrome Special Interest Group of the Pediatric Epilepsy Research Consortium formed a core working group focused on ASM selection in this patient population (2025). Despite the lack of specific FDA labeling for Lennox-Gastaut syndrome, valproic acid remains a mainstay in treatment.[8,9] Valproic acid is considered a first-line pharmacologic therapy but should be avoided in women of childbearing potential due to potential teratogenic effects.[8] Clobazam is recommended as a first-line option, particularly for managing disabling drop seizures, while it may be considered a second-line option in other cases. Epidiolex may be considered a second-line therapy, specifically when combined with clobazam; otherwise, it is generally listed as a third-line treatment. Many other options are cited in the second- or later-line settings including lamotrigine, rufinamide, topiramate, levetiracetam, brivaracetam, perampanel (Fycompa®, generic), zonisamide, Fintepla, and felbamate; refer to the consensus algorithm for additional detail. Monotherapy is rarely effective in managing Lennox-Gastaut

syndrome, which necessitates the use of combination therapy with two or three ASMs with varying mechanisms of action. However, where possible, no more than two ASMs should be used concomitantly; use of multiple ASMs raise the risk of side effects and/or drug-drug interactions.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Fintepla. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Fintepla as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Fintepla to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Fintepla is considered medically necessary when ONE of the following are met:

FDA-Approved Indications

1. **Dravet Syndrome.** Approve for 1 year if the patient meets ONE the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 2 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has tried or is concomitantly receiving at least two other antiseizure medications; OR
         Note: Examples of other antiseizure medications include valproic acid, topiramate, clonazepam, levetiracetam, zonisamide.
       - **b)** Patient has tried or is concomitantly receiving one of clobazam, Epidiolex (cannabidiol oral solution) or Diacomit (stiripentol capsules, powder for oral suspension); AND
     - **iii.** Fintepla is prescribed by or consultation with a neurologist; OR
   - **B)** Patient is Currently Receiving Fintepla. Approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

2. **Lennox-Gastaut Syndrome.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 2 years of age; AND
     - **ii.** Patient has tried or is concomitantly receiving at least two other antiseizure medications; AND
       Note: Examples of other antiseizure medications include clobazam, Epidiolex (cannabidiol oral solution), felbamate, lamotrigine, rufinamide, topiramate, valproic acid, levetiracetam, zonisamide, perampanel, vigabatrin.
     - **iii.** The medication is prescribed by or in consultation with a neurologist; OR
   - **B)** Patient is Currently Receiving Fintepla. Approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

Conditions Not Covered

Fintepla for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Fintepla® oral solution [prescribing information]. Smyrna, GA: UCB; October 2025.
2. Dravet Foundation – Dravet Syndrome. Available at: https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed on January 28, 2026.
3. Shafer PO. Epilepsy Foundation – Dravet Syndrome. Updated August 2020. Available at: http://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome. Accessed on January 29, 2026.
4. Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63(7):1761-1777.
5. Knupp KG1, Wirrell EC. Treatment Strategies for Dravet Syndrome. *CNS Drugs*. 2018;32(4):335-350.
6. Sirven JI, Shafer PO. Epilepsy Foundation – Lennox-Gastaut Syndrome. Updated February 2020. Available at: https://www.epilepsy.com/learn/types-epilepsy-syndromes/lennox-gastaut-syndrome-lgs. Accessed on January 29, 2026.
7. Cross JH, Auvin S, Falip M, et al. Expert opinion on the management of Lennox-Gastaut syndrome: treatment algorithms and practical considerations. *Front Neurol*. 2017;8:505.
8. Samanta D, Bhalla S, Bhatia S, et al. Antiseizure medications for Lennox-Gastaut Syndrome: Comprehensive review and proposed consensus treatment algorithm. *Epilepsy Behav*. 2025;164:110261.
9. Wheless JW. National Organization for Rare Diseases (NORD) – Lennox-Gastaut syndrome. Updated May 20, 2024. Available at: https://rarediseases.org/rare-diseases/lennox-gastaut-syndrome/. Accessed on January 28, 2026.
10. Diacomit® capsules, powder for oral suspension [prescribing information]. Redwood City, CA: Bicodex; July 2022.
11. Epidiolex® oral solution [prescribing information]. Palo Alto, CA: Jazz; June 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Dravet Syndrome, Lennox-Gastaut Syndrome.** **Updated** terminology used for alternative therapy requirement **Added** 'Patient is Currently Receiving Fintepla' criteria Title change from Fenfluramine.	8/1/2024
Annual Revision	No content changes	7/15/2025
Annual Revision	**Dravet Syndrome:** In the list of other antiseizure medications tried, the generic names for Epidiolex (cannabidiol oral solution) and Diacomit (stiripentol capsules, powder for oral suspension) were added for clarity. **Lennox-Gastaut Syndrome:** Under examples of other antiseizure medications, Fycompa was updated to perampanel to reflect generic availability. The generic name for Epidiolex (cannabidiol oral solution) was added for clarity.	5/1/2026

The policy effective date is in force until updated or retired.