PRIOR AUTHORIZATION POLICY

POLICY: Antiseizure Medications – Fintepla Prior Authorization Policy
- Fintepla® (fenfluramine oral solution – Zogenix)

REVIEW DATE: 04/23/2025

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] It is estimated that 1 out of 15,700 infants born in the US are affected with Dravet syndrome. 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] As the seizures continue, most of the children develop some level of developmental disability and other conditions associated with the syndrome. 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, reductions in overall seizure frequency, and minimization of treatment side effects.[4,5] Some patients respond to the ketogenic diet and/or vagus nerve stimulation.

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] An expert panel considers valproic acid to be the first-line treatment for Dravet syndrome.[4] Clobazam, Diacomit, and Fintepla can be considered as either first- or second-line ASMs. Cannabidiol was supported either as first- or second-line treatment. There was modest consensus among caregivers, but no consensus among physicians to support topiramate as first-, second-, or third-line therapy. 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, 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 (PERC) 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 pharmacological 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. Cannabidiol may be considered a second-line therapy, specifically when combined with clobazam; otherwise, it is generally listed as a third-line treatment. Lamotrigine is considered a second-line therapy when used alongside valproate to enhance therapeutic synergy or in patients at risk of cognitive and behavioral side effects; otherwise, it can be utilized as a third- or fourth-line therapy depending on individual patient profiles. Rufinamide is a second-line option, particularly in cases where valproate or clobazam must be avoided, though it may be used as a third- or fourth-line option if these medications are tolerated. Topiramate can be considered from second- to fourth-line therapy, depending on the patient's cognitive profile, as well as the suitability and availability of other ASMs. Additional later-line options include levetiracetam, brivaracetam, Fycompa® (perampanel tablet, oral suspension), zonisamide, fenfluramine, and felbamate. In managing Lennox-Gastaut syndrome, monotherapy is rarely effective, 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. In addition to pharmacological options, non-pharmacological therapies offer significant benefits in managing Lennox-Gastaut syndrome and include neuromodulation, resective surgery, corpus callosotomy, and the ketogenic diet.

POLICY STATEMENT

Prior Authorization is recommended for prescription 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Fintepla is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Dravet Syndrome.** Approve if the patient meets ONE the following (A or B):
   - **A)** Initial Therapy. Approve for 1 year 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 or Diacomit; AND

iii. Fintepla is prescribed by or consultation with a neurologist; OR

B) Patient is Currently Receiving Fintepla. Approve for 1 year 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 if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 1 year 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, felbamate, lamotrigine, rufinamide, topiramate, valproic acid, levetiracetam, zonisamide, Fycompa, vigabatrin.

iii. The medication is prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving Fintepla. Approve for 1 year if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Fintepla is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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