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5.60.045

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	July 31, 2020
Subject:	Fintepla	**Page:**	1 of 6

Last Review Date: December 13, 2024

Fintepla

Description

Fintepla (fenfluramine)

Background
Fintepla (fenfluramine) and the 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 Fintepla exerts its therapeutic effects in the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome are unknown (1).

Regulatory Status
FDA-approved indications: Fintepla is indicated for the treatment of seizures associated with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older (1).

Fintepla has a boxed warning regarding valvular heart disease and pulmonary arterial hypertension. There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine, and valvular heart disease and pulmonary arterial hypertension. Echocardiogram assessments are required before, during, and after treatment with Fintepla. Assessments should be done every 6 months during treatment with Fintepla, and 3 to 6 months after the final dose of Fintepla. Fintepla is available only through a restricted program called the Fintepla REMS (1).

Fintepla can also cause decreased appetite and decreased weight, somnolence, sedation, lethargy, suicidal behavior and ideation, serotonin syndrome, increase in blood pressure and glaucoma (1).

As with most antiepileptic drugs, the Fintepla dose should generally be decreased gradually upon discontinuation to minimize the risk of increased seizure frequency and status epilepticus (1).

Most patients with Dravet syndrome require two or more drugs to achieve seizure control, and choice of drugs should be individualized based on considerations of efficacy as well as side effects, tolerability, and access. Typically, a stepwise approach is taken, using valproate as a first-line drug in most patients and then adding clobazam if seizures remain poorly controlled despite adequate valproate dosing and serum levels (2).

Lennox-Gastaut syndrome (LGS) is often refractory to treatment so many patients require polypharmacy. Medication selection is based on safety, tolerability, and efficacy. Therefore, patients often require other treatment options, including anticonvulsant medications not approved for treatment of LGS, such as Onfi (clobazam), valproate / valproic acid and levetiracetam (3).

Patients, prescribers, and pharmacies should be enrolled in the Fintepla REMS program (1).

The initial starting and maintenance dosage is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability. Patients not on concomitant stiripentol who are tolerating Fintepla at 0.1 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 0.35 mg/kg twice daily (maximum daily dosage of 26 mg). Patients taking concomitant stiripentol and clobazam who are tolerating Fintepla at 0.1 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 0.2 mg/kg twice daily (maximum daily dosage of 17 mg) (1).

The safety and effectiveness of Fintepla in pediatric patients less than 2 years of age have not been established (1).

Related policies
Diacomit, Epidiolex, Nayzilam, Valtoco

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Fintepla may be considered **medically necessary** if the conditions indicated below are met.

Fintepla may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 2 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Seizures associated with Dravet syndrome (DS)
2. Seizures associated with Lennox-Gastaut syndrome (LGS)

AND ALL of the following:

1. Patient and prescriber are enrolled in the Fintepla REMS program
2. Patient is currently on **TWO** concomitant anti-seizure medications **OR** has had an inadequate treatment response, intolerance, or contraindication to at least **TWO** of the following medications:
    a. Clobazam
    b. Valproate / Valproic acid (i.e., Depakote, Depacon)
    c. Lamotrigine
    d. Levetiracetam
    e. Banzal (rufinamide)
    f. Topiramate
    g. Felbamate
    h. Stiripentol (Dravet syndrome **only**)
3. **NO** dual therapy with monoamine oxidative inhibitors
    a. Patients currently on monoamine oxidative inhibitors must be tapered off at least 14 days prior to starting Fintepla
4. Prescriber agrees to monitor echocardiogram before initiating therapy, every 6 months while on therapy, and 3 to 6 months after the final dose
5. **NOT** being used for weight loss
6. Prescriber will not exceed the FDA labeled maintenance dose of:
    a. Patients not on concomitant stiripentol: 26 mg per day

b. Patients taking concomitant stiripentol plus clobazam: 17 mg per day

Prior – Approval *Renewal* Requirements

Age 2 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Seizures associated with Dravet syndrome (DS)
2. Seizures associated with Lennox-Gastaut syndrome (LGS)

AND ALL of the following:

1. Patient experienced a reduction in frequency of seizures
2. **NO** dual therapy with monoamine oxidase inhibitors
3. Prescriber agrees to monitor echocardiogram every 6 months while on therapy, and 3 to 6 months after final dose
4. **NOT** being used for weight loss
5. Prescriber will not exceed the FDA labeled maintenance dose of:
    a. Patients not on concomitant stiripentol: 26 mg per day
    b. Patients taking concomitant stiripentol plus clobazam: 17 mg per day

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 1,080 mL per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Fintepla (fenfluramine) is indicated to treat seizures associated with Dravet syndrome and Lennox-Gastaut syndrome. Fintepla is only available through the Fintepla REMS program due to boxed warnings regarding valvular heart disease and pulmonary arterial hypertension. The safety and effectiveness of Fintepla in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Fintepla while maintaining optimal therapeutic outcomes.

References
1. Fintepla [package insert]. Smyrna, GA: UCB, Inc.; December 2023.
2. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations from a North American Consensus Panel. Pediatr Neurol 2017; 68:18.
3. Montouris G. Rational approach to treatment options for Lennox-Gastaut syndrome Epilepsia, 52(Suppl. 5):10‑20, 2011.

Policy History

Date	Action
July 2020	Addition to PA
September 2020	Annual review
December 2020	Annual review
March 2021	Annual editorial review. Revised t/f medication list to include stiripentol and added the option for the patient to be on two concomitant anti-seizure medications per FEP
March 2022	Annual review
April 2022	Addition of indication: seizures associated with Lennox-Gastaut syndrome per PI update
June 2022	Annual review
March 2023	Annual review and reference update. Changed policy number to 5.60.045
December 2023	Annual review and reference update
March 2024	Annual review and reference update
December 2024	Annual review. Per SME, changed REMS requirement to number one

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.