MEDICAL MUTUAL®

# Drug Policy

| Policy: | Fintepla (fenfluramide) | Annual Review Date: 04/17/2025<br>Last Revised Date: 04/17/2025 |
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## OVERVIEW

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. There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and valvular heart disease and pulmonary arterial hypertension. Echocardiogram assessments are required before, during, and after treatment with FINTEPLA. FINTEPLA is available only through a restricted program called the FINTEPLA REMS. It is contraindicated to use FINTEPLA within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome. FINTEPLA contains fenfluramine, a Schedule IV controlled substance.

## POLICY STATEMENT

This policy involves the use of Fintepla. Prior authorization is recommended for pharmacy benefit coverage of Fintepla. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

## RECOMMENDED AUTHORIZATION CRITERIA

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

**1. <u>Initial therapy</u>**

**Criteria.** *Patient must meet the following criteria*

**A.** The patient is 2 years of age or older; AND
**B.** The patient has a diagnosis of Dravet Syndrome (Severe Myoclonic Epilepsy in Infancy) or Lennox-Gastaut Syndrome (LGS): AND
**C.** Fintepla is prescribed by or in consultation with a neurologist or a provider who specializes in the treatment of Dravet Syndrome or Lennox-Gastaut Syndrome (LGS); AND

**D.** Fintepla will not be used concomitantly or within 14 days of the administration of an MAOI; AND
**E.** The patient has undergone an echocardiogram prior to initiating therapy with Fintepla; AND
**F.** The patient meets one of the following:
  **a.** Valvular heart disease AND pulmonary arterial hypertension were not observed on ECHO; OR
  **b.** Valvular heart disease and/or PAH is observed on ECHO and the prescriber attests that the benefits of therapy with Fintepla outweigh the risks; AND
**G.** If the diagnosis is Dravet Syndrome: the patient has been inadequately controlled on at least ONE antiepileptic drug (AED) or other antiseizure treatment including vagal nerve stimulation or a ketogenic diet; AND
**H.** If the diagnosis is LGS: the patient has been inadequately controlled on at least ONE antiepileptic drug (AED), with or without vagal nerve stimulation and/or ketogenic diet

**2. Continuation of therapy**
**Criteria.** *Patient must meet the following criteria*

**A.** The patient has been using Fintepla for at least 6 months (patients who have been using Fintepla for less than 6 months should refer to initial therapy criteria above); AND
**B.** The patient has had a beneficial response to therapy per the prescriber (e.g. reduced seizure severity, frequency, and/or duration); AND
**C.** The patient has a diagnosis of Dravet Syndrome (Severe Myoclonic Epilepsy in Infancy) or Lennox-Gastaut Syndrome (LGS): AND
**D.** Fintepla is prescribed by or in consultation with a neurologist or a provider who specializes in the treatment of Dravet Syndrome or Lennox-Gastaut Syndrome (LGS); AND
**E.** The patient has undergone a follow-up echocardiogram after at least 6 months of therapy of Fintepla and the ECHO was performed within the past 6 months (NOTE: the FDA-approved prescribing information states echocardiograms should be repeated every 6 months while patients are using Fintepla therapy); AND
**F.** The patient meets one of the following:
  **a.** Valvular heart disease AND pulmonary arterial hypertension were not observed on ECHO; OR
  **b.** Valvular heart disease and/or PAH is observed on ECHO and the prescriber attests that the benefits of continuing therapy with Fintepla outweigh the risks

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 6 months
**B)** *Extended Approval:* 6 months

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Fintepla has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Fintepla [prescribing information]. Emeryville, CA: Zogenix Inc.; April 2025.
2. Cross JH, Caraballo RH, Nabbout R, Vigevano F, Guerrini R, Lagae L. Dravet syndrome: Treatment options and management of prolonged seizures. Epilepsia. 2019;60(S3):S39–S48.
3. Fenfluramine. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 26 December 2024. Accessed 15 April 2025.
4. Dravet Foundation – Dravet Syndrome. Available at: https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed on 19 April 2023.
5. Lennox-Gastaut Syndrome Foundation – Lennox-Gastaut Syndrome. Available at: https://www.lgsfoundation.org/about-lgs-2/what-is-lennox-gastaut-syndrome/. Accessed on 19 April 2023.