

FINTEPLA (fenfluramine)

Pre - PA Allowance

None

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
- 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
 - Patients taking concomitant stiripentol plus clobazam: 17 mg per day



FINTEPLA (fenfluramine)

Prior - Approval Limits

Quantity 1,080 mL per 90 days

Duration 12 months

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

Prior - Approval Renewal Limits

Same as above