

FINTEPLA (fenfluramine)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 6 months may be granted for the treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome when all the following criteria are met:

- A. Member is at least 2 years of age **AND**
- B. Therapy is prescribed by or given in consultation with a neurologist **AND**
- C. Fintepla will not be taken concurrently with, or within 14 days, of the administration of monoamine oxidase inhibitors **AND**
- D. Member is not using the requested medication concomitantly with phentermine due to the potential for serious adverse effects **AND**
- E. Member has a documented inadequate response to prior therapy with at least two anti-epileptic drugs (e.g., valproic acid, clobazam, Diacomit, topiramate, Epidiolex, levetiracetam) **AND**
- F. Member has a documented inadequate response to anti-seizure treatment including vagal nerve stimulation **OR** a ketogenic diet **AND**
- G. Member has received documented clinical assessments that include all of the following:
 - a. EEG, MRI, or SCN1A gene mutation confirmed by genetic testing
 - b. Age at seizure onset, seizure types, and frequency of episodes
 - c. Review of risk factors, other causes of seizures (e.g., other medical conditions and medications), family history, and developmental history

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members (including new members) who meet both of the following:

- A. Documentation of EEG, MRI, or SCN1A gene mutation confirmed by genetic testing has been submitted
- B. Member has achieved and maintained positive clinical response with therapy with the requested medication as evidenced by reduction in frequency or duration of seizures

III. QUANTITY LIMIT

- 360 mL/month (12 mL every 1 day)

IV. COVERAGE DURATION

- Initial: 6 months
- Renewal: 12 months

V. REFERENCES

Fintepla (fenfluramine) [package insert]. Smyrna, GA: UCB Inc; December 2023.