# SPECIALTY GUIDELINE MANAGEMENT

# **FINTEPLA** (fenfluramine)

#### **POLICY**

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

## **FDA-Approved Indications**

Fintepla is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.

All other indications are considered experimental/investigational and not medically necessary.

### **II. DOCUMENTATION**

Submission of the following information is necessary to initiate the prior authorization review:

- A. For new starts only:
  - 1. Prior and current antiepileptic therapy
  - 2. Medical record documentation (i.e., chart notes or laboratory report) indicating the clinical assessments outlined in section IV have been performed.
- B. For new starts and continuation requests: Medical record documentation (i.e., chart notes, imaging report, or laboratory report) of electroencephalography (EEG), magnetic resonance imaging (MRI), or SCN1A gene mutation
- C. For continuation requests: chart notes demonstrating a reduction in frequency or duration of seizures.

### **III. PRESCRIBER SPECIALTIES**

This medication must be prescribed by or in consultation with a neurologist.

## IV. CRITERIA FOR INITIAL APPROVAL

### Seizures associated with Dravet syndrome

Authorization of 6 months may be granted for treatment of seizures associated with Dravet syndrome when all of the following criteria are met:

- A. Member has a documented inadequate response to prior therapy with at least one anti-epileptic drug or other antiseizure treatment including vagal nerve stimulation or a ketogenic diet.

  Examples of antiepileptic drugs: clobazam, levetiracetam, stiripentol, topiramate, valproate
- B. Member has received documented clinical assessments that include all of the following:
  - 1. EEG, MRI, or SCN1A gene mutation confirmed by genetic testing
  - 2. Age at seizure onset, seizure types, frequency of episodes, and duration of seizures
  - 3. Review of risk factors, other causes of seizures (e.g., other medical conditions and medications), family history, and developmental history

Fintepla 3982-A SGM P2021.docx

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### V. CONTINUATION OF THERAPY

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

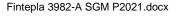
- A. Documentation of EEG, MRI, or SCN1A gene mutation confirmed by genetic testing has been submitted
- B. Member has achieved and maintained positive clinical response with therapy with the requested medication as evidenced by reduction in frequency or duration of seizures

## VI. OTHER

Due to well documented potential for serious adverse effects, phentermine and fenfluramine are not recommended to be used concurrently. Member cannot use the requested medication concomitantly with phentermine.

#### VII. REFERENCES

- 1. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc.; June 2020.
- 2. National Institute for Health and Care Excellence (2012). Epilepsies: diagnosis and management. NICE Guideline [CG137]. Updated April 2018. Available at: https://www.nice.org.uk/guidance/cg137. Accessed May 07, 2021.
- 3. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. Pediatric Neurology 68 (2017) 18-34.



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