| Reference number(s) |
|---|
| 3982-A |

# 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

## 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.