Commercial/Healthcare Exchange PA Criteria

Effective: September 2nd, 2020

Prior Authorization: Fintepla

Products Affected: Fintepla (fenfluramine) oral solution

Medication Description: Fintepla, a serotonin 5-hydroxytryptamine subtype 2 ($5\text{-}HT_2$) agonist, is indicated for the treatment of seizures associated with Dravet syndrome in patients ≥ 2 years of age. The safety and effectiveness of Fintepla for the treatment of seizures associated with Dravet syndrome were established in 2 randomized, double-blind, placebo-controlled trials (Study 1 and Study 2) in patients 2 to 18 years of age. Fintepla 0.7 mg/kg/day (Study 1) reduced monthly convulsive seizures a median of 79.4% from baseline over 14 weeks. A reduction in convulsive seizures was observed within 3 to 4 weeks of starting Fintepla, and the effect remained generally consistent over the 14-week treatment period. Study 2 (N=85) compared 0.4 mg/kg/day Fintepla with placebo in patients who were inadequately controlled on 2-4 concomitant antiepileptic drugs (including stiripentol and either clobazam, valproate, or both) and had a minimum of 6 convulsive seizures during the baseline period. The primary efficacy endpoint was the change from baseline in the frequency of convulsive seizures per 28 days during the combined 15-week titration and maintenance periods; this showed reduction in monthly convulsive seizures 63.1% from baseline.

Covered Uses: Treatment of seizures associated with Dravet syndrome in patients 2 years of age or older

Exclusion Criteria:

1. Hypersensitivity to fenfluramine
2. Concomitant use of, or within 14 days of the administration of monoamine oxidase inhibitors

Required Medical Information:

1. Diagnosis
2. Previous therapies tried and failed
3. Current therapy regimen

Age Restrictions: 2 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist, specializing in seizure therapy.

Coverage Duration: 12 months

Other Criteria:

Dravet Syndrome

A. Patient has a diagnosis of Dravet syndrome; **AND**
B. Patient has tried or is concomitantly receiving at least two other antiepileptic medications (e.g., valproic acid, clobazam, topiramate, clonazepam, levetiracetam, or zonisamide).

Confidential Information

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References:

1. Fintepla® oral solution [prescribing information]. Emeryville, CA: Zogenix, Inc.; June 2020.
2. Dravet Foundation – Dravet Syndrome. Available at: https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed on August 17, 2020

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/1/2020

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