CareSource

# PHARMACY POLICY STATEMENT
## Arkansas PASSE

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|---|---|
| DRUG NAME | Fintepla (fenfluramine) |
| BILLING CODE | Must use valid NDC code |
| BENEFIT TYPE | Pharmacy |
| SITE OF SERVICE ALLOWED | Home |
| COVERAGE REQUIREMENTS | Prior Authorization Required (Non-Preferred Product)<br>QUANTITY LIMIT – See "dosage allowed" |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Fintepla (fenfluramine) and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

## DRAVET SYNDROME

For **initial** authorization:

1. Member is 2 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of seizures associated with Dravet Syndrome; AND
4. Member's weight must be documented in chart notes for dosing; AND
5. Chart notes must document the member's seizure frequency on current treatment; AND
6. Chart notes must show that an electrocardiogram (ECG) has been done or will be done before starting treatment; AND
7. The member has tried and failed (or has contraindication to) at least one anti-epileptic drug.
8. **Dosage allowed:** See package insert for titration schedule[1]
   a) Without Diacomit (stiripentol): 0.35mg/kg twice daily, up to 26mg/day.
   b) Concomitant Diacomit (stiripentol) and clobazam: 0.2mg/kg twice daily, up to 17mg/day.

***If member meets all the requirements listed above, the medication will be approved for 3 months.***

For **reauthorization**:

1. Chart notes must document a reduction in convulsive seizure frequency since starting Fintepla.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Fintepla (fenfluramine) not medically necessary for the treatment of diseases that are not listed in this document.**

| DATE | ACTION/DESCRIPTION |
|---|---|
| **07/28/2020** | New policy for Fintepla created. |

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| **12/21/2021** | Updated trial and failure to one anti-epileptic. |

References:


1. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc; 2020.
2. IPD analytics. Accessed 7/21/20.
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*. 2017;68:18-34. doi:10.1016/j.pediatrneurol.2017.01.025
4. Wirrell EC, Nabbout R. Recent Advances in the Drug Treatment of Dravet Syndrome. *CNS Drugs*. 2019;33(9):867-881. doi:10.1007/s40263-019-00666-8
5. Knupp KG, Wirrell EC. Treatment Strategies for Dravet Syndrome [published correction appears in CNS Drugs. 2018 Aug;32(8):783. Abstract corrected]. *CNS Drugs*. 2018;32(4):335-350. doi:10.1007/s40263-018-0511-y
6. Cross JH, Caraballo RH, Nabbout R, Vigevano F, Guerrini R, Lagae L. Dravet syndrome: Treatment options and management of prolonged seizures. *Epilepsia*. 2019;60 Suppl 3:S39-S48. doi:10.1111/epi.16334
7. Lagae L, Sullivan J, Knupp K, et al. Fenfluramine hydrochloride for the treatment of seizures in Dravet syndrome: a randomised, double-blind, placebo-controlled trial. *Lancet*. 2019;394(10216):2243-2254. doi:10.1016/S0140-6736(19)32500-0
8. Nabbout R, Mistry A, Zuberi S, et al. Fenfluramine for Treatment-Resistant Seizures in Patients With Dravet Syndrome Receiving Stiripentol-Inclusive Regimens: A Randomized Clinical Trial [published online ahead of print, 2019 Dec 2]. *JAMA Neurol*. 2019;77(3):300-308. doi:10.1001/jamaneurol.2019.4113


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