CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

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) QUANTITY LIMIT – See "dosage allowed"
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Fintepla (fenfluramine) is a **non-preferred** product 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. Member has a diagnosis of seizures associated with Dravet Syndrome; AND
3. Member's weight must be documented in chart notes for dosing; AND
4. Chart notes must document the member's seizure frequency on current treatment; AND
5. Chart notes must show that an electrocardiogram (ECG) has been done or will be done before starting treatment; AND
6. The member has tried and failed (or has contraindication to) ALL of the following drugs (alone or in combination):[2,3,5]
   a) First line: valproic acid AND clobazam;
   b) Second line: Diacomit (requires prior authorization) OR topiramate.
7. **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.

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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