HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Fintepla (fenfluramine)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Fintepla is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older. It exhibits agonist activity at serotonin 5-HT2 receptors. Fintepla has a black box warning for valvular heart disease and pulmonary arterial hypertension.
Dravet syndrome is an epilepsy that usually presents in the first year of life with recurrent seizures which are often prolonged and triggered by fever. With time, other types of seizures may occur, as well as intellectual disability, neurological abnormalities, behavioral issues, and other comorbidities. Complete seizure control is rarely achievable. In 80-85% of cases, variants in the SCN1A gene are present.
Lennox–Gastaut syndrome is a severe developmental epileptic encephalopathy characterized by several seizure types, including drop seizures, as well as cognitive impairment. Seizures usually begin before 8 years of age and persist into adulthood.

Fintepla (fenfluramine) will be considered for coverage when the following criteria are met:

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 or will be done before starting treatment; AND
7. The member has tried and failed, or has contraindication to, valproic acid and clobazam.
8. **Dosage allowed/Quantity limit:** See package insert for titration schedule. QL: 360 mL per 30 days
   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 all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

Lennox-Gastaut Syndrome (LGS)

For **initial** authorization:
1. Member is 2 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Medication must be used for the treatment of seizures associated with a documented diagnosis of Lennox-Gastaut 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 or will be done before starting treatment; AND
7. Chart notes must show trial and failure of at least 2 of the following: valproate, lamotrigine, topiramate, rufinamide, clobazam, felbamate.
8. **Dosage allowed/Quantity limit:** See package insert for titration schedule. QL: 360 mL per 30 days
   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 all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Fintepla (fenfluramine) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
07/28/2020	New policy for Fintepla created.
04/15/2022	Transferred to new template. Created criteria for LGS. DS: Added new reference. Removed trial of Diacomit or topiramate.

References:

1. Fintepla [package insert]. Emeryville, CA: Zogenix, Inc; 2022.
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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
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10. Brigo F, Jones K, Eltze C, Matricardi S. Anti-seizure medications for Lennox-Gastaut syndrome. *Cochrane Database Syst Rev*. 2021;4(4):CD003277. Published 2021 Apr 7. doi:10.1002/14651858.CD003277.pub4
11. Cross JH, Auvin S, Falip M, Striano P, Arzimanoglou A. Expert Opinion on the Management of Lennox-Gastaut Syndrome: Treatment Algorithms and Practical Considerations. *Front Neurol*. 2017;8:505. Published 2017 Sep 29. doi:10.3389/fneur.2017.00505

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