Clinical Policy: Fenfluramine (Fintepla)

Reference Number: ERX.NPA.148
Effective Date: 09.01.20
Last Review Date: 08.20
Line of Business: Commercial, Medicaid Revision Log
See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Fenfluramine (Fintepla®) is a serotonin transporter protein modulator and exhibits agonist activity at serotonin 5HT-2 receptors.

FDA Approved Indication(s)
Fintepla is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Fintepla is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Dravet Syndrome (must meet all)**:**

1. Diagnosis of DS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 2 years;
4. Will be used as adjunctive therapy *(see Appendix B)* with at least one other antiepileptic drug;
5. Dose does not exceed either of the following (a or b):
   a. Members not on concomitant Diacomit®: 26 mg (12 mL) per day;
   b. Members on concomitant Diacomit plus clobazam: 17 mg (8 mL) per day.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Dravet Syndrome (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Fintepla for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Fintepla will continue to be used as adjunctive therapy *(see Appendix B)* with at least one other antiepileptic drug;
4. If request is for a dose increase, new dose does not exceed either of the following (a or b):
   a. Members not on concomitant Diacomit: 26 mg (12 mL) per day;
   b. Members on concomitant Diacomit plus clobazam: 17 mg (8 mL) per day.

Approval duration:

Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
DS: Dravet syndrome
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Diacomit® (stiripentol)	50 mg/kg/day PO in 2-3 divided doses	50 mg/kg/day
clobazam (Onfi®, Sympazan®)	Initial: 0.2-0.3 mg/kg/day PO*	0.5-2 mg/kg/day
valproic acid (Depakene®, Depakote®, Stavzor®)	Initial: 10-15 mg/kg/day PO, given in 2-3 equally divided doses*	25-60 mg/kg/day
Epidiolex® (cannabidiol)	Initial: 2.5 mg/kg PO BID Maintenance: 5 mg/kg PO BID	20 mg/kg/day
topiramate (Topamax®, Trokendi® XR, Qudexy® XR)	Initial: 0.5-2 mg/kg/day PO*	8-12 mg/kg/day
levetiracetam (Spritam®, Keppra®)	Initial: 10-20 mg/kg/day PO, divided in 2-3 doses*	60-80 mg/kg/day
Other antiepileptic drugs: clonazepam (Klonopin®), zonisamide (Zonegran®), ethosuximide (Zarontin®), phenobarbital	PO; off-label dosing information not available	Off-label dosing information not available

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity to fenfluramine or any of the excipients in Fintepla, concomitant use of, or within 14 days of the administration of monoamine oxidase inhibitors because of an increased risk of serotonin syndrome
- Boxed warning(s): valvular heart disease, pulmonary arterial hypertension

Appendix D: General Information

- Complete seizure control is typically not achievable in DS, so the primary goal of therapy is to reduce seizure frequency. The following therapies are recommended for the management of DS by a North American consensus panel (January 2017):

	North American Consensus Panel
1st line	Valproic acid or clobazam *If first choice is not effective, then add the other*
2nd line	Addition of Diacomit or topiramate
3rd line	Addition of clonazepam, levetiracetam, zonisamide, ethosuximide, or phenobarbital

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DS	Initial starting and maintenance dose: 0.1 mg/kg PO BID, which can be increased weekly based on efficacy and tolerability.	No concomitant Diacomit: 26 mg/day Concomitant Diacomit and clobazam: 17 mg/day

VI. Product Availability

Oral solution: 2.2 mg/mL

VII. References

1. Fintepla Prescribing Information. Emeryville, CA: Zogenix Inc.; June 2020. Available at: www.Fintepla.com. Accessed July 2, 2020.
2. Wirrell EC, Laux L, Jette N, et al. Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel. Pediatr Neurol. 2017; 68: 18-34.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 2, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.14.20	08.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.