ALASKA MEDICAID Prior Authorization Criteria

Fintepla® (fenfluramine)

FDA INDICATIONS AND USAGE¹

Fintepla® is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. Fenfluramine increases extracellular serotonin levels and acts as both a serotonergic 5-HT2 receptor agonist and σ 1 receptor antagonist.

APPROVAL CRITERIA 1,2,3

- 1. Patient is 2 years of age or older **AND**;
- 2. The medication is being prescribed by or in consultation with a neurologist **AND**;
- 3. Patient has a confirmed diagnosis of seizures associated with Dravet syndrome AND;
- 4. ICD-10 code is provided and written on the prescription AND;
- 5. The patient has undergone an echocardiogram prior to initiating therapy **AND**;
- 6. The patient has tried for at least one month and failed or contraindication to TWO or more of the following:
 - a. valproate
 - b. clobazam
 - c. topiramate
 - d. levetiracetam

DENIAL CRITERIA^{1,3}

- 1. Failure to meet approval criteria **OR**;
- 2. Patient has moderate to severe renal impairment **OR**;
- 3. Patient has hepatic impairment **OR**;
- 4. Concomitant use of, or within 14 days of the administration of monoamine oxidase inhibitors.

CAUTIONS¹

- Patients should be advised that the drug can cause decreased appetite and decreased weight.
- Monitor for somnolence and sedation. Patients should be advised not to drive or operate machinery.
- Monitor for suicidal behavior and ideation.
- Serotonin Syndrome has been observed particularly with concomitant administration of other serotonergic drugs.
- Blood pressure should be monitored during treatment.

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DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

OUANTITY LIMIT

- Up to 12ml per day (max daily dose is 26mg)
- 360ml per 30 days

REFERENCES / FOOTNOTES:

- 1. Fintepla [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 December 3, 2020.
- 3. Cross JH, Caraballo RH, Nabbout R, Vigevano F, Guerrini R, Lagae L. Dravet syndrome: Treatment options and management of prolonged seizures. Epilepsia. 2019;60(S3):S39-S48.

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