BlueCross BlueShield
Federal Employee Program

FINTEPLA
(fenfluramine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Fintepla (fenfluramine) and the metabolite, norfenfluramine, increase extracellular levels of serotonin through interaction with serotonin transporter proteins, and exhibit agonist activity at serotonin 5HT-2 receptors. The mechanisms by which Fintepla exerts its therapeutic effects in the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome are unknown (1).

Regulatory Status

FDA-approved indications: Fintepla is indicated for the treatment of seizures associated with Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older (1).

Fintepla has a boxed warning regarding valvular heart disease and pulmonary arterial hypertension. There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine, and valvular heart disease and pulmonary arterial hypertension. Echocardiogram assessments are required before, during, and after treatment with Fintepla. Assessments should be done every 6 months during treatment with Fintepla, and 3 to 6 months after the final dose of Fintepla. Fintepla is available only through a restricted program called the Fintepla REMS (1).

Fintepla can also cause decreased appetite and decreased weight, somnolence, sedation, lethargy, suicidal behavior and ideation, serotonin syndrome, increase in blood pressure and glaucoma (1).

As with most antiepileptic drugs, the Fintepla dose should generally be decreased gradually upon discontinuation to minimize the risk of increased seizure frequency and status epilepticus (1).

Most patients with Dravet syndrome require two or more drugs to achieve seizure control, and choice of drugs should be individualized based on considerations of efficacy as well as side effects, tolerability, and access. Typically, a stepwise approach is taken, using valproate as a first-line drug in most patients and then adding clobazam if seizures remain poorly controlled despite

adequate valproate dosing and serum levels (2).

Lennox-Gastaut syndrome (LGS) is often refractory to treatment so many patients require polypharmacy. Medication selection is based on safety, tolerability, and efficacy. Therefore, patients often require other treatment options, including anticonvulsant medications not approved for treatment of LGS, such as Onfi (clobazam), valproate / valproic acid and levetiracetam (3).

Patients, prescribers, and pharmacies should be enrolled in the Fintepla REMS program (1).

The initial starting and maintenance dosage is 0.1 mg/kg twice daily, which can be increased weekly based on efficacy and tolerability. Patients not on concomitant stiripentol who are tolerating Fintepla at 0.1 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 0.35 mg/kg twice daily (maximum daily dosage of 26 mg). Patients taking concomitant stiripentol and clobazam who are tolerating Fintepla at 0.1 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 0.2 mg/kg twice daily (maximum daily dosage of 17 mg) (1).

The safety and effectiveness of Fintepla in pediatric patients less than 2 years of age have not been established (1).

Summary

Fintepla (fenfluramine) is indicated to treat seizures associated with Dravet syndrome and Lennox-Gastaut syndrome. Fintepla is only available through the Fintepla REMS program due to boxed warnings regarding valvular heart disease and pulmonary arterial hypertension. The safety and effectiveness of Fintepla in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Fintepla while maintaining optimal therapeutic outcomes.

References

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1. Fintepla [package insert]. Smyrna, GA: UCB, Inc.; December 2023.
2. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations from a North American Consensus Panel. Pediatr Neurol 2017; 68:18.
3. Montouris G. Rational approach to treatment options for Lennox-Gastaut syndrome Epilepsia, 52(Suppl. 5):10–20, 2011.