



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 11, 2021  June 16, 2022

## **FINTEPLA® (fenfluramine)**

**LENGTH OF AUTHORIZATION:** ONE YEAR

**REVIEW CRITERIA:**

- Patient must be  $\geq 2$  years of age.
- Patient has a diagnosis of Dravet Syndrome (DS) **OR**
- Patient has diagnosis of Lennox-Gastaut Syndrome (LGS)

**CONTINUATION OF THERAPY**

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 2.2 mg/mL oral solution.
- Because of the risk of valvular heart disease and pulmonary arterial hypertension, Fintepla is only available through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS) called the FINTEPLA REMS. More information is available at [www.FinteplaREMS.com](http://www.FinteplaREMS.com) or at 1-877-964-3649.