Division: Pharmacy Policy	Subject: 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 ≥ 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 or at 1-877-964-3649.