SmartPA Criteria Proposal

Drug/Drug Class:	Fintepla Clinical Edit
First Implementation Date:	TBD
Proposed Date:	September 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Fintepla® (fenfluramine)

Why Issue Selected: On June 25, 2020, the FDA approved Fintepla® (fenfluramine) for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. Dravet syndrome (formerly known as severe myoclonic epilepsy of infancy) is a genetic epilepsy which appears during the first year of life in otherwise healthy infants as a prolonged seizure with fever. As the condition progresses other types of seizures typically occur, as well as developmental delays and features of autism spectrum disorder. It is estimated that 1 in 20,000 to 1 in 40,000 people have Dravet syndrome and 3-8% of children who experience their first seizure by 12 months of age may have Dravet syndrome. Approximately 80% of children with Dravet syndrome have a pathogenic variant in the *SCN1A* gene. Three agents, each with different mechanisms of action, are now FDA approved for Dravet syndrome: Epidiolex® (cannabidiol), Diacomit® (stiripentol), and Fintepla (fenfluramine). Prior to the FDA approval of these agents, the 2017 North American Consensus Panel recommendations for the management of Dravet syndrome found clobazam and valproic acid to be optimal first-line therapies. Fintepla is a reformulation of fenfluramine, an anorectic agent removed from the market in 1997 for increased risk of valvular heart disease when prescribed in higher doses and often combined with phentermine. Due to this past increased risk, Fintepla comes with a boxed warning for valvular heart disease and pulmonary arterial hypertension and is available only through the Fintepla REMS program which requires echocardiograms before, during, and after therapy. Due to the high cost, possible adverse events, and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Fintepla therapy.

Program-Specific Information:

Drug	Cost per ml	Cost per month at max dose
FINTEPLA 2.2 MG/ML SOLUTION	$42.60 WAC	$15,336.00 WAC

Type of Criteria:
- ☒ **Increased risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **Clinical Edit**

Data Sources:
- ☐ **Only Administrative Databases**
- ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Fintepla® (fenfluramine)
- Age range: All appropriate MO HealthNet participants aged 2 years or older

Approval Criteria

Initial Therapy:

- Participant aged 2 years or older **AND**
- Prescribed by or in consultation with a neurologist or other specialist in the treated disease state **AND**
- Documented diagnosis of Dravet syndrome **AND**
- Documented trial of valproate (defined as 30 days) **AND**
- Documented trial of clobazam (defined as 30 days) **AND**
- Documented trial of Epidiolex (defined as 30 days) **AND**
- Documented trial of Diacomit (defined as 30 days) **AND**
- Dose does not exceed maximum daily limits:
  - With concomitant Diacomit: 17 mg per day
  - Without concomitant Diacomit: 26 mg per day
- Documentation of the following:
  - Baseline seizure frequency and duration **AND**
  - Baseline echocardiogram **AND**
  - Baseline measure of participant's weight

Continuation of therapy:

- Initial approval is for 6 months, renewal of prior authorization may be given following documentation of the following:
  - Documentation of therapy meeting the goals of therapy **AND**
  - Documentation of reduced seizure burden or improvement in quality of life using a validated scale for the disease state **AND**
  - Documentation of echocardiogram at least every 6 months **AND**
  - Documentation of participant's current weight for demonstration of appropriate dosing within maximum daily limits and lack of inappropriate weight loss for age

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented history of MAOI therapy in the past 45 days
- Documented diagnosis of moderate to severe renal impairment
- Documented diagnosis of hepatic impairment

Required Documentation

Laboratory Results:		Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- FINTEPLA® (fenfluramine) oral solution, [package insert]. Emeryville CA: Zogenix, Inc.; June 2020
- 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;68:18-34.e3. doi:10.1016/j.pediatrneurol.2017.01.025
- Dravet Syndrome Foundation. What is Dravet Syndrome? https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed July 16, 2020.
- Epilepsy Foundation. Dravet Syndrome. https://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome. Accessed July 16, 2020.
- Children's Hospital of Philadelphia. Dravet Syndrome. https://www.chop.edu/conditions-diseases/dravet-syndrome. Accessed July 16, 2020.
- IPD Analytics. New Drug Review: Fintepla (fenfluramine) oral solution, CIV. July 2020