SmartPA Criteria Proposal

Drug/Drug Class:	Anticonvulsants, Dravet Syndrome PDL Edit
First Implementation Date:	TBD
Proposed Date:	December 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: As of June 2020, the FDA has granted authorization of three pharmacologic therapies for the treatment of Dravet syndrome (DS): Diacomit®, Epidiolex®, and Fintelpa®. DS, a rare genetic form of epilepsy afflicting 1 in 15,700 births in the United States appears during the first year of life in otherwise healthy infants as a prolonged seizure with fever. Quality of life for an individual with DS can be severely impacted as the condition is often associated with a multitude of comorbidities including frequent and prolonged seizures, developmental delays and, chronic infections. While Epidiolex is approved for use in patients 1 year of age and older, Fintepla and Diacomit are only indicated in patients 2 and older and the latter must be used in combination with clobazam. Fintepla is only available through a REMS program that requires echocardiograms before, during, and after therapy.

Of the three agents for DS, Epidiolex is the only product with additional indications of Lennox-Gastaut syndrome (LGS) and Tuberous sclerosis complex (TSC). While LGS is also a form of epilepsy, TSC is a genetic condition that results in the formation of non-cancerous tumors in various parts of the body such as the brain, kidney, heart, eyes, lungs, and skin. Both are considered rare conditions with LGS accounting for 1-4% of all childhood epilepsy cases and TSC affecting approximately 40,000 to 80,000 individuals in the US. Although all three agents appear to exert their therapeutic effects via varying methods, their exact mechanisms of actions are not thoroughly understood. Phase III clinical trials seeking additional indications in the anti-epileptic field are currently underway for both Epidiolex and Fintepla,

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Epidiolex®	• Diacomit® • Fintepla®

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: Anticonvulsants, Dravet Syndrome
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current preferred therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial of 1 preferred agent
    - Documented trial period of preferred agents
    - Documented ADE/ADR to preferred agents **OR**
- For Epidiolex:
    - Documented diagnosis of Dravet Syndrome, Lennox-Gastaut syndrome (LGS), or Tuberous sclerosis complex (TSC) in the past year **AND**
    - Trial of 2 or more anti-epileptic agents (includes clobazam, clonazepam, divalproex sodium, felbamate, rufinamide, sodium valproate, or vigabatrin) **OR**
- For Non-Preferred Agents:
    - Participant aged 2 years or older **AND**
    - Documented diagnosis of Dravet syndrome **AND**
    - Documented therapeutic trial (defined as 30 days) of both valproate and clobazam **AND**
    - For Fintepla: Documented therapeutic trial of Diacomit (defined as 30 days) **AND**
    - Documentation of the baseline seizure frequency and duration **AND**
    - Initial approval of prior authorization is for 6 months, renewal of prior authorization may be up to 1 year with documentation of reduced seizure burden or improvement in quality of life using a validated scale for the disease state

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Diacomit and Fintepla: Documentation of moderate to severe hepatic or renal impairment
- For Fintepla: Documented history of MAOI therapy in the past 45 days
- Therapy will be denied if all approval criteria are not met
- Claim exceeds quantity limitations:

Drug Description	Generic Equivalent	Max Dosing Limitation
DIACOMIT 250 MG CAPSULE	STIRIPENTOL	12 capsules per day
DIACOMIT 250 MG POWDER PACKET	STIRIPENTOL	12 packets per day
DIACOMIT 500 MG CAPSULE	STIRIPENTOL	6 capsules per day
DIACOMIT 500 MG POWDER PACKET	STIRIPENTOL	6 packets per day
EPIDIOLEX 100 MG/ML SOLUTION	CANNABIDIOL	200 mL per fill
FINTEPLA 2.2 MG/ML SOLUTION	FENFLURAMINE	• With concomitant Diacomit: 17 mg per day • Without concomitant Diacomit: 26 mg per day

Required Documentation

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

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. FINTEPLA® (fenfluramine) [package insert]. Emeryville CA: Zogenix, Inc.; June 2020.
2. DIACOMIT® (stiripentol) [package insert]. Gentilly, France: Biocodex; May 2020.
3. EPIDIOLEX® (cannabidiol) [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; October 2020.
4. 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.
5. Dravet Syndrome Foundation. What is Dravet Syndrome? https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed July 16, 2020.
6. Epilepsy Foundation. Dravet Syndrome. https://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome. Accessed July 16, 2020.
7. Children’s Hospital of Philadelphia. Dravet Syndrome. https://www.chop.edu/conditions-diseases/dravet-syndrome. Accessed July 16, 2020.
8. IPD Analytics. New Drug Review: Fintepla (fenfluramine) oral solution, CIV. July 2020.