SmartPA Criteria Proposal

Drug/Drug Class:	Anticonvulsants, Dravet Syndrome PDL Edit
First Implementation Date:	April 1, 2021
Proposed Date:	December 15, 2022
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: Dravet syndrome (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, movement and balance issues, delayed language and speech issues, behavioral and developmental delays, growth and nutritional issues, sleep difficulties, chronic infections, sensory integration disorders, and dysautonomia (disruptions of the autonomic nervous system, with difficulty regulating body temperature, heart rate, blood pressure, etc.). Diacomit®, indicated only for DS, must be used in combination with clobazam. Epidiolex® has additional indications for 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 United States. Fintepla® has an additional indication for LGS as well and is only available through a REMS program that requires echocardiograms before, during, and after therapy.

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**
- For Epidiolex:
  - Documented diagnosis of Dravet syndrome, Lennox-Gastaut syndrome (LGS), or Tuberous sclerosis complex (TSC) **AND**
  - Trial of 2 or more anti-epileptic agents (includes clobazam, clonazepam, felbamate, lamotrigine, rufinamide, topiramate, valproate derivatives, or vigabatrin)
- For non-preferred agents:
  - Failure to achieve desired therapeutic outcomes with trial of 1 preferred agent
    - Documented trial period of preferred agents **OR**
    - Documented ADE/ADR to preferred agents **AND**
  - ~~**Documentation of baseline seizure frequency and duration AND**~~
  - Documented therapeutic trial (defined as 30 days) of both valproate and clobazam **AND**
  - For Diacomit:
    - ~~**Participant aged 2 years or older AND**~~
    - Documented diagnosis of Dravet syndrome **AND**
  - For Fintepla:
    - Participant aged 2 years or older **AND**
    - **Documented diagnosis of Lennox-Gastaut syndrome (LGS) OR**
    - For documented diagnosis of Dravet syndrome: Documented therapeutic trial of Diacomit (defined as 30 days)
  - ~~**Initial approval of prior authorization for Diacomit and Fintepla is 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

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: CENTRAL NERVOUS SYSTEM: Anticonvulsants, Dravet Syndrome”, Gainwell Technologies; Last updated October 13, 2022.
- Evidence-Based Medicine Analysis: “Anticonvulsants, Dravet Syndrome Agents”, UMKC-DIC; September 2022.
- 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 November 7, 2022.
- Epilepsy Foundation. Dravet Syndrome. https://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome. Accessed November 7, 2022.
- Children’s Hospital of Philadelphia. Dravet Syndrome. https://www.chop.edu/conditions-diseases/dravet-syndrome. Accessed November 7, 2022.
- IPD Analytics. New Drug Review: Fintepla (fenfluramine) oral solution, CIV. July 2020.
- Epidiolex (cannabidiol) [package insert]. Carlsbad, CA: Greenwich Biosciences, Inc.; February 2022.
- Diacomit (stiripentol) [package insert]. Gentilly, France: Biocodex; July 2022.
- Fintepla (fenfluramine) [package insert]. Emeryville CA: Zogenix, Inc.; June 2022.