| Reference number(s) |
|---|
| 5893-D |

**This document applies to the following:**

| Formulary | Applies |
|---|---|
| Standard Control (SF) | ☑ |
| Standard Control – Choice (SCCF) | ☑ |
| Preferred Drug Plan Design (PDPD) | ☐ |
| Advanced Control Specialty (ACSF) | ☑ |
| Advanced Control Specialty – Choice (ACSCF) | ☑ |
| Managed Medicaid Template (MMT) | ☐ |
| Marketplace (MF) | ☐ |
| Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE) | ☐ |
| Aetna Individual Lives (IVL) | ☐ |
| Value (VF) | ☐ |

| Formulary | Applies |
|---|---|
| New to Market (NTM) | ☐ |
| Standard Formulary Chart (SFC) | ☐ |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) | ☐ |
| Advanced Control Specialty Formulary Chart (ACSFC) | ☐ |
| Value Formulary Chart (VFC) | ☐ |
| Medical Benefit | ☐ |
| Medical Benefit: Advanced Biosimilars First | ☐ |
| Medical Benefit: Managed Medicaid (MMMB) | ☐ |
| Medicare Part B | ☐ |
| Medicare Part B: Advanced Biosimilars First | ☐ |

# Exceptions Criteria
# Seizure Disorder

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), and Advanced Control Specialty – Choice Formulary (ACSCF).

## Plan Design Summary

This program applies to the seizure disorder products specified in this document. Coverage for targeted product(s) is provided based on clinical circumstances that would exclude the use of the preferred product(s) and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

### Table 1. Seizure Disorder Associated with Dravet Syndrome

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

| | **Product(s)** |
|---|---|
| Preferred | • Epidiolex (cannabidiol) |

| | **Product(s)** |
| --- | --- |
| Target | • Diacomit (stiripentol)<br>• Fintepla (fenfluramine) |

## Table 2. Seizure Disorder Associated with Lennox-Gastaut Syndrome (LGS)

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

| | **Product(s)** |
| --- | --- |
| Preferred | • clobazam (generic)<br>• clonazepam (generic)<br>• Epidiolex (cannabidiol)<br>• lamotrigine (generic)<br>• rufinamide (generic)<br>• topiramate (generic) |
| Target | • Fintepla (fenfluramine) |

# Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

## Seizure Disorder with Dravet Syndrome

### Diacomit

Coverage for Diacomit is provided when any of the following criteria is met:

- Member is currently receiving treatment with Diacomit, excluding when Diacomit is obtained as samples or via manufacturer's patient assistance programs.
- Member is less than 1 year of age.
- Member has a documented inadequate response or intolerable adverse event with the preferred product, Epidiolex.

### Fintepla

Coverage for Fintepla is provided when either of the following criteria is met:

- Member is currently receiving treatment with Fintepla, excluding when Fintepla is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product, Epidiolex.

| Reference number(s) |
| --- |
| 5893-D |

## Seizure Disorder Associated with Lennox-Gastaut Syndrome (LGS)

Coverage for Fintepla is provided when either of the following criteria is met:

- Member is currently receiving treatment with Fintepla, excluding when Fintepla is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products (clobazam, clonazepam, Epidiolex, lamotrigine, rufinamide and topiramate).

# References


1. Clobazam [package insert]. Piscataway, NJ: Camber Pharmaceuticals, Inc.; February 2023.
2. Clonazepam [package insert]. Raleigh, NC: Accord Healthcare, Inc.; October 2023.
3. Diacomit [package insert]. Redwood City, CA: Biocodex, Inc.; June 2024.
4. Epidiolex [package insert]. Palo Alto, CA: Jazz Pharmaceuticals; March 2024.
5. Fintepla [package insert]. Smyrna, GA: UCB, Inc.; December 2023.
6. Lamotrigine [package insert]. Naperville, IL: OWP Pharmaceuticals, Inc.; February 2023.
7. Rufinamide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2023.
8. Topiramate [package insert]. Parsippany, NJ: Ascend Laboratories, LLC.; June 2023.