CVS Caremark®

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| Reference number(s) |
| 5545-A |

# Specialty Guideline Management Diacomit

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Diacomit | stiripentol |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications1

Diacomit is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

All other indications are considered experimental/investigational and not medically necessary.

## Coverage Criteria

### Seizures Associated With Dravet Syndrome1

Authorization of 12 months may be granted for treatment of seizures associated with Dravet syndrome in members 6 months of age and older.

## Continuation of Therapy

Authorization of 12 months may be granted for continuation of treatment in members (including new members) 6 months of age or older requesting reauthorization for seizures associated with Dravet syndrome when the member has achieved or maintained a positive clinical response (e.g., decrease in seizures).

## Other

Member must be taking clobazam concurrently with another anti-seizure medication and cannot use the requested medication as monotherapy in Dravet syndrome.

## References

1. Diacomit [package insert]. San Mateo, CA: Biocodex, Inc.; July 2022.