

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 kilogram (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.

Reference number(s)
5545-A

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 seizure frequency).

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]. Gentilly, France: Biocodex; June 2024.