Reference number(s)
5545-A

SPECIALTY GUIDELINE MANAGEMENT

DIACOMIT (stiripentol)

POLICY

I. 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 Indication
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.

II. CRITERIA FOR INITIAL APPROVAL

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

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continuation of treatment in members (including new members) 6 months of age and 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).

IV. OTHER

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

V. REFERENCE

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