Applicable Drugs: Diacomit (stiripentol)

Non-preferred: N/A

Date of Origin: 9/13/2021

Date Last Reviewed / Revised: 12/12/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - VII are met)

I. Documented diagnosis of Dravet syndrome and used for the treatment of seizures.

II. Documentation that disease is refractory to first-line treatments (i.e., clobazam and valproic acid).

III. Diacomit will be used in combination with clobazam.

IV. Minimum age and weight requirement: ≥ 6 months and weight ≥ 7 kg.

V. Treatment is prescribed by or in consultation with a neurologist or epileptologist.

VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VII. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Appetite/weight loss: Loss of appetite and weight loss have been observed in 46% and 27% of patients (mean age: 9.2 years), respectively, during clinical trials; monitor the growth rate of pediatric patients closely. Valproate dose reduction by 30% may help minimize appetite and weight loss.
- Blood Dyscrasias: Neutropenia and thrombocytopenia have been observed in clinical trials; monitor CBC prior to initiation and during therapy.
- Suicidal ideation: Pooled analysis of trials involving various antiepileptics (regardless of indication) showed an increased risk of suicidal thoughts/behavior (incidence rate: 0.43% treated patients compared to 0.24% of patients receiving placebo); risk observed as early as 1 week after initiation and continued through duration of trials (most trials ≤24 weeks). Monitor all patients for notable changes in behavior that might indicate suicidal thoughts or depression; notify health care provider immediately if symptoms occur.

Quantity / Days Supply Restrictions

- Stiripentol 250mg, 500mg capsules and 250mg, 500mg oral packets:
    - Maximum dose: 3,000 mg/day.

Approval Length

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and showing maintenance or improvement on the medication.

Appendix

- N/A.

References

1. Diacomit. Prescribing information. BIOCODEX, Inc; 2022. Accessed December 12, 2025.. https://www.diacomit.com/downloads/pdf/DIACOMIT_US_PI.pdf
2. 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
3. 1.Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. Epilepsia. 2022;63(7). doi:https://doi.org/10.1111/epi.17274

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.