Generic Name: Stiripentol

Therapeutic Class or Brand Name: Diacomit

Applicable Drugs (if Therapeutic Class): Anticonvulsant

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/13/2021

Date Last Reviewed / Revised: 9/1/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - VI 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 (ie, clobazam and valproic acid).

III. Diacomit will be used in combination with clobazam.

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

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

VI. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a 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 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 that the medication is effective.

APPENDIX

- N/A.

REFERENCES

1. Diacomit. Prescribing information. BIOCODEX, Inc; 2022. Accessed September 16, 2022. 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