

Generic Name: Stiripentol

Therapeutic Class or Brand Name: Diacomit[®]

Applicable Drugs (if Therapeutic Class):

Anticonvulsant

GPI Code: 7260007000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/13/2021

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of Dravet syndrome and used for the treatment of seizures.
- II. Disease is refractory to first-line treatments (clobazam and valproic acid).
- III. Used with clobazam.
- IV. Age \geq 2 years old.
- V. Prescribed by or in consultation with a neurologist or epileptologist.

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 \leq 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: 3g/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[®] (Stiripentol) [package insert]. 60000 Beauvais, France: Biocodex; August 2018. Available at: <https://www.diacomit.com/downloads/pdf/BBD-00002-092019%20DIACOMIT%20US%20PI.pdf>.
2. Medispan.
3. Wirrell EC, Laux L, Donner E, et al. Optimizing the diagnosis and management of Dravet syndrome: recommendations from a north American consensus panel. *Pediatric Neurology*. 2017;68:18-34.e3.

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.