

# Drug Therapy Guidelines

## Diacomit® (stiripentol)

*Applicable*

<b>Medical Benefit</b>		<b>Effective:</b> 12/1/18
<b>Pharmacy- Formulary 1</b>	x	<b>Next Review:</b> 9/19
<b>Pharmacy- Formulary 2</b>	x	<b>Date of Origin:</b> 12/18
<b>Pharmacy- Formulary 3/Exclusive</b>	x	<b>Review Dates:</b> 9/18
<b>Pharmacy- Formulary 4/AON</b>	x	

### I. Medication Description

Diacomit (stiripentol) is a structurally unique oral antiepileptic indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years and older who are also taking clobazam. There are no clinical data to support stiripentol monotherapy in Dravet syndrome.

The mechanism by which Diacomit exerts its anticonvulsant effect in humans is unknown. Possible mechanisms of action include direct effects mediated through the gamma-aminobutyric acid (GABA)<sub>A</sub> receptor and indirect effects involving inhibition of cytochrome P450 activity with resulting increase in blood levels of clobazam and its active metabolite.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

### III. Policy

Coverage of Diacomit is provided in accordance with the following criteria:

- Medication is prescribed by a neurologist **AND**
- Member is 2 years of age or older **AND**
- Medication is prescribed for the treatment of seizures associated with confirmed diagnosis of Dravet syndrome **AND**
- Member has been inadequately controlled on clobazam and valproate (unless contraindicated) despite optimized therapy **AND**
- Member is receiving concurrent clobazam therapy.

### IV. Quantity Limitations

Coverage will be provided as follows:

- Capsules:
  - 250mg: up to 360 capsules per 30 days
  - 500mg: up to 180 capsules per 30 days
- Powder for oral suspension (packets):
  - 250mg: up to 360 packets per 30 days
  - 500mg: up to 180 packets per 30 days

**V. Coverage Duration**

Initial coverage is available for up to 3 months and may be renewed.

**VI. Coverage Renewal Criteria**

Coverage may be renewed in 12-month increments based upon the following criteria:

- Member has experienced a significant decrease in the frequency of seizures **AND**
- Stabilization of disease or absence of disease progression has been documented **AND**
- No unacceptable toxicity from the drug has been observed.

**VII. Billing/Coding Information**

Diacomit is available as follows:

- Capsules: 250mg and 500 mg
- Powder for oral suspension (packets): 250mg and 500 mg

**VIII. Summary of Policy Changes**

12/1/18: new policy

**IX. References**

1. Chiron C, Marchand MC, Tran A, et al. Stiripentol in severe myoclonic epilepsy in infancy: a randomised placebo-controlled syndrome-dedicated trial. STICLO study group. *Lancet*. 2000;356(9242):1638-1642.
2. Fisher JL. The anti-convulsant stiripentol acts directly on the GABA(A) receptor as a positive allosteric modulator [published online ahead of print June 10, 2008]. *Neuropharmacology*. 2009;56(1):190-197.
3. Product Information: Diacomit®(stiripentol). Beauvais, France: Biocondex. August 2018.
4. UpToDate Online, accessed September 2018
5. Clinical Pharmacology Online, accessed September 2018
6. Facts and Comparisons Online, accessed September 2018
7. Wirrell, E, 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

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*