Pharmacy Policy Bulletin: J-0907 Diacomit (stiripentol) – Commercial and Healthcare Reform	
Number: J-0907	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0907-009	**Original Date:** 11/07/2018
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Diacomit (stiripentol)
FDA-Approved Indication(s):	• Treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age and older and weighing more than 7 kg. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

Background:	• The mechanism of action of Diacomit is unknown, but it is thought to act through the gamma-aminobutyric acid $(GABA)_A$ receptor and through inhibition of cytochrome P450 resulting in increased blood levels of clobazam and its active metabolites.
	• Dravet syndrome, formerly known as severe myoclonic epilepsy of infancy (SMEI), is a rare, catastrophic, lifelong form of epilepsy that begins in the first year of life with frequent and prolonged seizures, leading to behavioral and developmental delays.
	• A 2022 international consensus on diagnosis and management of Dravet syndrome recommends valproate as first line therapy; fenfluramine, stiripentol, or clobazam as second line therapy; pharmaceutical grade cannabidiol as third line; and topiramate or ketogenic diet as fourth line. The following drugs should be avoided in Dravet syndrome: carbamazepine, oxcarbazepine, lamotrigine, and phenytoin.
	• Prescribing Considerations:
	  ○ The member should be under the supervision of a neurologist or pediatric and epilepsy specialist.
	  ○ There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Diacomit may be approved when one (1) of the following criteria are met **(A. or B.)**:

A. The member meets all of the following **(1. Through 5.):**
   1. The member is 6 months of age to 2 years of age.
   2. The member weighs ≥ 7 kg.
   3. The member has a diagnosis of Dravet Syndrome (ICD-10: G40.83).
   4. The member has experienced inadequate response to plan-preferred clobazam monotherapy.
   5. The member is using Diacomit in combination with clobazam.

B. The member meets all of the following **(1. through 4.):**
   1. The member is 3 years of age or older.
   2. The member has a diagnosis of Dravet Syndrome (ICD-10: G40.83).
   3. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(a. and b.)**
      a. Valproic acid or divalproex sodium
      b. Plan-preferred clobazam
   4. The member is using Diacomit in combination with clobazam.

II. Reauthorization

When a benefit, reauthorization of Diacomit may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member has experienced a reduction in seizure frequency.
B. The member is using Diacomit in combination with clobazam.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Diacomit [package insert]. Beauvais, France: BICODEX; June 2024.
2. Dravet Syndrome Foundation. What is Dravet Syndrome? Available at: https://www.dravetfoundation.org/what-is-dravet-syndrome/. Accessed July 17, 2025.
3. Epilepsy Foundation. Dravet Syndrome. Available at: https://www.epilepsy.com/what-is-epilepsy/syndromes/dravet-syndrome. Accessed July 17, 2025.
4. 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.
5. Wirrell E, Hood V, Knupp K, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63:1761–1777.