HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Diacomit (stiripentol)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Diacomit, approved by the FDA in 2018, is indicated for the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. There are no clinical data to support use as monotherapy. It is supplied as capsules or as powder for oral suspension. The effects of Diacomit are mediated through the gamma-aminobutyric acid $(GABA)_A$ receptor. It is also an inhibitor of cytochrome P450 activity which results in increased blood levels of clobazam.
Dravet syndrome is a developmental and epileptic encephalopathy (DEE) that usually presents in the first year of life with recurrent seizures which are often prolonged and triggered by fever. With time, other types of seizures may occur, as well as intellectual disability, neurological abnormalities, behavioral issues, and other comorbidities. Complete seizure control is rarely achievable. In 80-85% of cases, variants in the *SCN1A* gene are present.

Diacomit (stiripentol) will be considered for coverage when the following criteria are met:

Dravet Syndrome

For **initial** authorization:
1. Member is at least 6 months of age and weigh 7 kg or more; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Medication must be used for the treatment of seizures associated with a documented diagnosis of Dravet syndrome; AND
4. Chart notes must document the member's seizure frequency on current treatment; AND
5. Member has tried and failed or has contraindication to valproic acid; AND
6. Diacomit will be taken in combination with clobazam.
7. **Dosage allowed/Quantity limit**: 50 mg/kg/day, in 2 or 3 divided doses. Max dose 3,000 mg/day. QL: 180 capsules or packets per 30 days

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Diacomit is being used as an adjunct to clobazam; AND
2. Chart notes have been provided that show the member has decrease in frequency of seizures.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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HAP CareSource considers Diacomit (stiripentol) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/28/2019	New policy for Diacomit created.
07/24/2020	Removed requirement for minimum number of seizures. Edited how the specialist requirement is worded. Added max dose. Changed drug trials to match treatment guidelines. Specified concomitant use. Added that chart notes must include weight and baseline seizure frequency
04/12/2022	Transferred to new template. Added references. Added QL. In renewal, changed all initial criteria to adjunct with clobazam.
09/16/2022	Updated age limit.
02/04/2025	Updated references. Removed redundancy of weight documentation. Changed trial of VPA and clobazam to just VPA (Wirrell 2022).

References:

1. Diacomit [prescribing information]. BIOCODEX; 2022.
2. Myers, Kenneth A., et al. Stiripentol efficacy and safety in Dravet syndrome: a 12-year observational study. *Developmental Medicine & Child Neurology.* 60.6 (2018): 574-578.
3. Frampton JE. Stiripentol: A Review in Dravet Syndrome. *Drugs*. 2019;79(16):1785-1796. doi:10.1007/s40265-019-01204-y
4. 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
5. Devi N, Madaan P, Asrar MM, Sahu JK, Bansal D. Comparative short-term efficacy and safety of add-on anti-seizure medications in Dravet syndrome: An indirect treatment comparison. *Seizure*. 2021;91:316-324. doi:10.1016/j.seizure.2021.06.020
6. Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63(7):1761-1777. doi:10.1111/epi.17274
7. Wheless J, Weatherspoon S. Use of Stiripentol in Dravet Syndrome: A Guide for Clinicians. *Pediatr Neurol*. 2025;162:76-86. doi:10.1016/j.pediatrneurol.2024.10.015

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