PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Diacomit (stiripentol)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients 6 months of age and older taking clobazam (Onfi). There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.
Dravet syndrome is an epilepsy 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 (weighing 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. Member's weight must be documented in chart notes for dosing; AND
5. Chart notes must document the member's seizure frequency on current treatment; AND
6. The member has tried and failed, or has contraindication to, valproic acid and clobazam[9,10]; AND
7. Diacomit will be taken in combination with clobazam.
8. **Dosage allowed/Quantity limit**: 50 mg/kg/day, in divided doses. Capsule or powder for oral suspension (250 mg and 500 mg strengths) available. Max recommended dose is 3,000mg per day. (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.

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.

References:

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12. Cross JH, Caraballo RH, Nabbout R, Vigevano F, Guerrini R, Lagae L. Dravet syndrome: Treatment options and management of prolonged seizures. *Epilepsia*. 2019;60 Suppl 3:S39-S48. doi:10.1111/epi.16334
13. 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

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