CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Diacomit (stiripentol)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Diacomit (stiripentol) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

DRAVET SYNDROME

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Medication must be used for the treatment of seizures associated with Dravet syndrome; AND
3. Medication is prescribed by pediatric neurologist; AND
4. Member has been inadequately controlled on clobazam and valproate therapies (claims history or chart notes documentation required). *Note:* There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome; AND
5. Chart notes documentation of at least 4 generalized clonic or tonic-clonic seizures per month despite optimized therapy required.
6. **Dosage allowed:** 50 mg/kg/day, administered by mouth in 2 or 3 divided doses. Capsule or powder for oral suspension (250 mg and 500 mg strengths) available.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has decrease in frequency of seizures.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Diacomit (stiripentol) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
10/28/2019	New policy for Diacomit created.

References:

1. Diacomit [prescribing information]. Beauvais, France: BIOCODEX; August 2018.

2. ClinicalTrials.gov Identifier: NCT02607904. An Open-label Extension Trial to Investigate Possible Drug-drug Interactions Between Stiripentol or Valproate and Cannabidiol in Patients With Epilepsy. Available at: https://clinicaltrials.gov/ct2/show/NCT02607904?term=stiripentol&recrs=e&draw=1&rank=2.
3. ClinicalTrials.gov Identifier: NCT02607891. A Study of Possible Drug-drug Interactions Between Stiripentol or Valproate and Cannabidiol in Patients With Epilepsy. Available at: https://clinicaltrials.gov/ct2/show/NCT02607891?term=stiripentol&recrs=e&draw=1&rank=1.
4. Kossoff E. Stiripentol for dravet syndrome: is it worth it?. Epilepsy Curr. 2014;14(1):22–23. doi:10.5698/1535-7597-14.1.22.
5. Rosati A, Boncristiano A, Doccini V, et al. Long-term efficacy of add-on stiripentol treatment in children, adolescents, and young adults with refractory epilepsies: A single center prospective observational study. Epilepsia. 2019 Oct 20. doi: 10.1111/epi.16363.
6. Frampton JE, et al. Stiripentol: A Review in Dravet Syndrome. Drugs. 2019) 1-12.
7. 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.
8. Nickels KC, et al. Stiripentol in the management of epilepsy. CNS drugs. 31.5 (2017): 405-416.

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