MEDICAL MUTUAL®

Drug Policy

Policy: SD	Diacomit (stiripentol)	Annual Review Date: 10/17/2024 Last Revised Date: 10/17/2024

OVERVIEW

Diacomit, an antiepileptic drug (AED), is indicated for the treatment of seizures associated with Dravet syndrome in patients ≥ 2 years of age taking clobazam. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome. The mechanism by which Diacomit exerts its anticonvulsant effect is not known. Possible mechanisms of action include direct effects mediated through the gamma-aminobutyric acid $(GABA)_A$ receptor and indirect effects involving inhibition of cytochrome P450 (CYP) activity with resulting increase in blood levels of clobazam and its active metabolite.

POLICY STATEMENT

This policy involves the use of Diacomit. Prior authorization is recommended for pharmacy benefit coverage of Diacomit. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Diacomit as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Diacomit be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Diacomit is recommended in those who meet the following criteria:

1. **Dravet Syndrome.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy: Approve if the patient meets the following (i, ii, and iii):
     - **i.** Patient is ≥ 6 months of age and weighs ≥ 7 kg; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient is taking concomitant clobazam; OR
       - **b)** Patient is unable to take clobazam due to adverse events as determined by the prescriber; AND
     - **iii.** The medication is prescribed by or in consultation with a neurologist; OR
   - **B)** Patient is Currently Receiving Diacomit: Approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

Other Uses with Supportive Evidence

2. **Treatment-Refractory Seizures/Epilepsy (specific rare conditions)** [i.e., Lennox-Gastaut Syndrome; infantile spasms; tuberous sclerosis complex; Sturge-Weber syndrome; Doose syndrome; infection-related or anoxo-ischemic epilepsy syndromes; cortical malformation/dysplasia; epileptic encephalopathies associated with sodium channel mutations; and epilepsy with myoclonic absences]. Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy: Approve if the patient meets the following (i, ii, and iii):
     - **i.** Patient is ≥ 6 months of age and weighs ≥ 7 kg; AND
     - **ii.** Patient has tried at least two other antiseizure medications; AND
       Note: Examples of other antiseizure medications include valproic acid, lamotrigine, topiramate, clonazepam, Banzel® (rufinamide tablet, oral suspension), felbamate, clobazam, Fycompa® (perampanel tablet, oral suspension), vigabatrin, levetiracetam, zonisamide.
     - **iii.** The medication is prescribed by or in consultation with a neurologist; OR
   - **B)** Patient is Currently Receiving Diacomit: Approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Diacomit has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or

performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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