Mass General Brigham
Health Plan

Diacomit (stiripentol)
Effective 11/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Diacomit (stiripentol) is an anticonvulsant medication 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 the use of Diacomit as monotherapy in Dravet syndrome.

Coverage Guidelines
Authorization may be granted for members who are new to the plan within the past 90 days currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted when all of the following criteria are met:

1. Member is at least 6 months of age or older
2. Member has diagnosis of Dravet syndrome
3. Requested medication is prescribed by or in consultation with a neurologist
4. Member's treatment regimen will include clobazam
5. Member has had an inadequate response or adverse reaction to at least ONE of the following anticonvulsants OR has a contraindication to ALL of the following anticonvulsants:
    a. Clonazepam
    b. Divalproex/valproic acid
    c. Ethosuximide
    d. Levetiracetam
    e. Phenobarbital
    f. Topiramate
    g. Zonisamide

<u>Continuation of Therapy</u>
Requests for reauthorization will be approved when all of the following criteria are met:

1. Documentation member has had a positive response to therapy (e.g., decrease in number or frequency of seizures member is experiencing)

Limitations

1. Initial approvals and reauthorizations will be granted for 36 months
2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Diacomit 250 mg capsule	12 capsules per day
Diacomit 500 mg capsule	6 capsules per day
Diacomit 250 mg packet	12 packets per day
Diacomit 500 mg packet	6 packets per day

References

1. Diacomit (stiripentol) [prescribing information]. Beauvais, France: Biocondex; July 2022
2. Fisher JL. The effects of stiripentol on GABA(A) receptors. Epilepsia 2011; 52 Suppl 2:76
3. Inoue Y, Ohtsuka Y, STP-1 Study Group. Long-term safety and efficacy of stiripentol for the treatment of Dravet syndrome: A multicenter, open-label study in Japan. Epilepsy Res 2015; 113:90
4. Jullien V, Chhun S, Rey E, et al. Pharmacokinetics of clobazam and N-desmethylclobazam in children with dravet syndrome receiving concomitant stiripentol and valproic Acid. Clin Pharmacokinet 2015; 54:527
5. Wirrell EC, Laux L, Franz DN, et al. Stiripentol in Dravet syndrome: results of a retrospective U.S. study. Epilepsia 2013; 54:1595.

Review History

11/20/19 – Reviewed at P&T. Effective 02/01/2020
11/18/2020- Reviewed at P&T
11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.
08/13/2025 – Reviewed and updated at August P&T. Updated language for members who are new to the Plan. Updated verbiage for prescriber specialty and concomitant use with clobazam. Added reauthorization criteria, requiring documentation that the member has had a positive response to therapy. Added quantity limits to the Limitations section of the policy. Effective 11/01/2025.