

Diacomit (stiripentol) **Effective 02/01/2020** ☐ MassHealth UPPL Plan □ Prior Authorization ⊠Commercial/Exchange **Program Type** ☐ Quantity Limit □ Pharmacy Benefit ☐ Step Therapy **Benefit** ☐ Medical Benefit This medication has been designated specialty and must be filled at a contracted Specialty Limitations specialty pharmacy. **Medical and Specialty Medications** All Plans Phone: 877-519-1908 Fax: 855-540-3693 Contact Information **Non-Specialty Medications All Plans** Phone: 800-711-4555 Fax: 844-403-1029 **Exceptions** N/A

Overview

Stiripentol is an anticonvulsant medication used in conjunction with clobazam for patients with Dravet syndrome. The mechanism of the anticonvulsant effect is unknown but may be due to enhancement of GABAergic inhibitory neurotransmission.

Coverage Guidelines

1. Authorization may be granted for members who are currently receiving treatment with Diacomit excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

- 2. Authorization may be granted for members who meet all the following criteria and documentation has been provided:
 - a. The member is at least 2 years of age
 - b. The member has diagnosis of Dravet syndrome
 - c. The prescriber is a neurologist or consult notes from a neurology office are provided
 - d. Diacomit will be used in combination with clobazam
 - e. The member has had an inadequate response or adverse reaction to one of the following anticonvulsants or a contraindication to ALL of the following anticonvulsants:
 - Clonazepam
 - Divalproex/valproic acid
 - Ethosuximide
 - Levetiracetam
 - Phenobarbital
 - Topiramate
 - Zonisamide

Limitations

1. Approvals will be granted for 36 months

References

- 1. Diacomit (stiripentol) [prescribing information]. Beauvais, France: Biocondex; May 2020
- 2. 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
- 3. Fisher JL. The effects of stiripentol on GABA(A) receptors. Epilepsia 2011; 52 Suppl 2:76
- 4. Wirrell EC, Laux L, Franz DN, et al. Stiripentol in Dravet syndrome: results of a retrospective U.S. study. Epilepsia 2013; 54:1595.
- 5. 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
- 6. Numis AL, Sankar R. Stiripentol. In: Pellock's pediatric epilepsy: diagnosis and therapy, Fourth edition, Pellock JM, Nordli DR Jr, Sankar R, Wheless JW (Eds), Springer Publishing Company, New York 2017. p.897

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.

