



5.75.24

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Neuromuscular Agents	Original Policy Date:	September 7, 2018
Subject:	Diacomit	Page:	1 of 4

Last Review Date: March 12, 2021

Diacomit

Description

Diacomit (stiripentol)

Background

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older taking clobazam. The mechanism by which Diacomit exerts its anticonvulsant effects in humans is unknown. Possible mechanisms of action include direct effects mediated through the gamma-aminobutyric acid (GABA)_A receptor and indirect effects involving inhibition of cytochrome P450 activity with resulting increase in blood levels of clobazam and its active metabolite (1).

Regulatory Status

FDA-approved indication: Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam. There is no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome (1).

Diacomit can cause somnolence. Co-administration of Diacomit with clobazam results in increased levels of clobazam and its active metabolite, which can further increase somnolence. Other CNS depressants, such as alcohol, could potentiate the somnolence effect of Diacomit (1).

Diacomit can cause a significant decline in platelet count and neutrophil count. Hematologic testing should be obtained prior to starting treatment with Diacomit, and then every 6 months (1).

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As with most antiepileptic drugs, Diacomit should generally be withdrawn gradually to minimize the risk of increased seizure frequency and status epilepticus. In situations where rapid withdrawal of Diacomit is required, appropriate monitoring is recommended (1).

Most patients with DS require two or more drugs to achieve seizure control, and choice of drugs should be individualized based on considerations of efficacy as well as side effects, tolerability, and access. Typically, a stepwise approach is taken, using valproate as a first-line drug in most patients and then adding clobazam if seizures remain poorly controlled despite adequate valproate dosing and serum levels (2).

The safety and effectiveness of Diacomit in pediatric patients less than 2 years of age have not been established (1).

Related policies

Epidiolex, Fintepla, Nayzilam, Valtoco

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Diacomit may be considered **medically necessary** in patients 2 years of age and older with seizures associated with Dravet syndrome and if the conditions indicated below are met.

Diacomit is considered **investigational** in patients less than 2 years of age and for all other indications.

Prior-Approval Requirements

Age 2 years of age and older

Diagnosis

The patient must have the following:

Seizures associated with Dravet syndrome (DS)

AND ALL of the following:

1. Must be used in combination with clobazam
 - a. Patient has had an inadequate response to clobazam

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2. Prescriber agrees to monitor blood counts before initiating therapy and then every 6 months while on therapy
3. Inadequate treatment response, intolerance, or contraindication to at least **ONE** of the following medications:
 - a. Valproate / Valproic acid (i.e. Depakote, Depacon)
 - b. Lamotrigine
 - c. Levetiracetam
 - d. Banzal (rufinamide)
 - e. Topiramate
 - f. Felbamate
4. Prescriber will not exceed the FDA labeled dose of 50 mg/kg/day

Prior – Approval *Renewal* Requirements

Age 2 years of age and older

Diagnosis

The patient must have the following:

Seizures associated with Dravet syndrome (DS)

AND ALL of the following:

1. Must be used in combination with clobazam
2. Prescriber agrees to monitor blood counts every 6 months while on therapy
3. Prescriber will not exceed the FDA labeled dose of 50 mg/kg/day

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity Maximum daily dose of 50 mg/kg/day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

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Rationale

Summary

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older taking clobazam. The mechanism by which Diacomit exerts its anticonvulsant effects in humans is unknown. Possible mechanisms of action include direct effects mediated through the gamma-aminobutyric acid (GABA)_A receptor and indirect effects involving inhibition of cytochrome P450 activity with resulting increase in blood levels of clobazam and its active metabolite. The safety and effectiveness of Diacomit in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Diacomit while maintaining optimal therapeutic outcomes.

References

1. Diacomit [package insert]. Beauvais, France: Biocodex; May 2020.
2. Wirrell EC, Laux L, Donner E, et al. Optimizing the Diagnosis and Management of Dravet Syndrome: Recommendations From a North American Consensus Panel. *Pediatr Neurol* 2017; 68:18.

Policy History

Date	Action
September 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review. Removed brand name of clobazam from criteria and reworded max dose of 50 mg/kg/day requirement per SME
June 2020	Annual review
December 2020	Annual review and reference update
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.