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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Neuromuscular Agents	**Original Policy Date:**	September 7, 2018
Subject:	Diacomit	**Page:**	1 of 5

Last Review Date: March 7, 2025

Diacomit

Description

Diacomit (stiripentol)

Background

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. 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 taking clobazam who are 6 months of age and older and weighing 7 kg or more. 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).

As with most antiepileptic drugs, Diacomit should generally be withdrawn gradually to minimize the risk of increased seizure frequency and status epilepticus.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 6 months of age or weighing less than 7 kg 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** if the conditions indicated below are met.

Diacomit may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 months of age and older

Diagnosis

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
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. Banzel (rufinamide)
    e. Topiramate
    f. Felbamate
4. Patient weight ≥ 7 kg
5. Prescriber will not exceed the FDA labeled dose of 50 mg/kg/day

Prior – Approval *Renewal* Requirements

Age 6 months age and older

Diagnosis

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. Patient weight ≥ 7 kg
4. 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

Rationale

Summary

Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam 6 months of age and older and weighing 7 kg or more. 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 6 months of age or weighing less than 7 kg 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; July 2022.
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
March 2022	Annual review
July 2022	Per PI update indicated age changed to patients 6 months and older weighing at least 7 kg
September 2022	Annual review
December 2022	Annual review

March 2023	Annual review
December 2023	Annual review
March 2024	Annual review
December 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.