



PRIOR AUTHORIZATION POLICY

- POLICY:** Antiseizure Medications – Diacomit Prior Authorization Policy
- Diacomit® (stiripentol capsules and powder for oral suspension – Biocodex)

REVIEW DATE: 02/11/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Diacomit, an antiseizure medication (ASM), is indicated for the treatment of seizures associated with **Dravet syndrome** in patients ≥ 6 months of age and weighing ≥ 7 kg taking clobazam.¹ There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

Disease Overview

Dravet syndrome is a rare genetic epileptic encephalopathy (dysfunction of the brain) marked with frequent and/or prolonged seizures.^{2,3} The seizures generally begin in the first year of life in an otherwise healthy infant. Affected individuals can develop many seizure types: myoclonic, tonic-clonic, absence, atypical absence, atonic, focal aware or impaired awareness (previously called partial seizures), and status epilepticus.³ Two or more ASMs are often needed to control the seizures; most of the seizures are refractory to medications. The goals of treatment are

cessation of prolonged convulsions, reduction in overall seizure frequency, and minimization of treatment side effects.^{4,5}

Clinical Efficacy in Other Refractory Seizures

In one study (n = 212), Diacomit was studied in children with different types of epilepsy syndromes (including Lennox-Gastaut Syndrome [LGS]; infantile spasms; infection-related or anoxo-ischemic epilepsy syndromes; tuberous sclerosis complex; Sturge-Weber syndrome; Doose syndrome; cortical malformation/dysplasia; and epilepsy with myoclonic absences) whose seizures were refractory to more than two ASMs (including vigabatrin).⁶ In the 88 patients who completed the 3-month placebo-controlled study, 56.8% of patients with partial epilepsy responded (with 14% becoming seizure-free) compared with 41.9% of patients with generalized epilepsy and 38.4% of patients with myoclonic epilepsy. Diacomit has also been administered to patients with refractory epileptic encephalopathies due to etiologies other than Dravet syndrome.⁷ A single-blind, exploratory trial evaluated Diacomit in combination with standard treatment in 16 patients with LGS and 8 patients with symptomatic generalized epilepsy of the Lennox-Gastaut type.⁸ There were 15 evaluable patients with LGS. The overall results identified some benefit for LGS where 60% of patients were responders (based on 50% responder rate). Diacomit treatment produced a mean 62% seizure reduction and a median 80% reduction from baseline. Additionally, a published study of Diacomit added to carbamazepine in childhood partial epilepsy (n = 67) demonstrated seizure response in 32 patients with conditions including herpetic encephalitis, LGS, and tuberous sclerosis complex.⁹

Guidelines/Recommendations

At this time, there are three drugs approved for the treatment of seizures associated with Dravet syndrome: Diacomit, Epidiolex[®] (cannabidiol oral solution), and Fintepla[®] (fenfluramine oral solution).^{1,10,11} An international consensus on diagnosis and management of Dravet syndrome was published in 2022; physician and caregiver perspectives were considered.¹² There was strong consensus that valproic acid is an appropriate first-line ASM and clobazam can be considered either first- or second-line. Additional consensus for the first-line setting among physicians included Fintepla (strong) and Diacomit (moderate). Physicians did not reach consensus regarding the use of Epidiolex as either first- or second-line treatment. It was noted with moderate consensus that lamotrigine is contraindicated in Dravet syndrome.

The Dravet Foundation states that Diacomit, Epidiolex, and Fintepla are considered first-line agents for the treatment of Dravet syndrome.² If control is still inadequate, other therapies to consider are clonazepam, levetiracetam, and zonisamide.^{2,4} Sodium channel blockers (e.g., carbamazepine, oxcarbazepine, lamotrigine, and phenytoin) can worsen seizures in Dravet syndrome. Additionally, vigabatrin and tiagabine may increase the frequency of myoclonic seizures and should be avoided.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Diacomit. All approvals are provided for the duration noted below. 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 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Diacomit® (stiripentol capsules and powder for oral suspension - Biocodex) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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 ALL of the following (i, ii, and iii):

- i.** Patient is \geq 6 months of age and weighs \geq 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).

Approve for 1 year if the patient meets ONE of the following (A or B):

Note: The specific rare conditions which fall under this approval condition are 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.

A) Initial Therapy: Approve if the patient meets ALL of the following (i, ii, and iii):

- i.** Patient is \geq 6 months of age and weighs \geq 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, rufinamide, felbamate, clobazam, perampanel, 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.

CONDITIONS NOT COVERED

Diacomit® (stiripentol capsules and powder for oral suspension - Biocodex) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Diacomit® capsules and oral suspension [prescribing information]. Redwood City, CA: Biocodex; July 2022.
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4. Knupp KG, Wirrell EC. Treatment Strategies for Dravet Syndrome. *CNS Drugs*. 2018;32(4):335-350.
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8. Center for Drug Evaluation and Research. Clinical review of Diacomit. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/206709Orig1s000,207223Orig1s000 MedR.pdf. Accessed on February 3, 2026.
9. Chiron C, Tonnelier S, Rey E, et al. Stiripentol in childhood partial epilepsy: randomized placebo-controlled trial with enrichment and withdrawal design. *J Child Neurol*. 2006;21(6):496-502.
10. Epidiolex® oral solution [prescribing information]. Palo Alto, CA: Jazz; June 2025.
11. Fintepla® oral solution [prescribing information]. Smyrna, GA: UCB; October 2025.
12. Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63(7):1761-1777.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	02/07/2024
Annual Revision	No criteria changes.	02/19/2025
Annual Revision	Treatment-Refractory Seizures/Epilepsy (Specific Rare Conditions): The specific rare conditions which fall under this approval condition were moved to a Note. Additionally, under examples of other antiseizure medications, Banzel was updated to rufinamide and Fycompa was updated to perampanel to reflect generic availability of these products.	02/11/2026

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