Diacomit (stiripentol)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Diacomit is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older taking clobazam. There are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome.

POLICY

Criteria for Initial Approval

A. Seizures associated with Dravet syndrome

Authorization of 12 months may be granted for treatment when the following criteria are met:

1. Member is at least 2 years of age
2. Member has seizures associated with Dravet syndrome
3. Member is/will be receiving clobazam in conjunction with the requested drug

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) who have achieved and maintained positive clinical response with the requested medication as evidenced by reduction in frequency or duration of seizures.

Diacomit is considered **not medically necessary** for members who do not meet the criteria set forth above.

Quantity Limits Apply:

Medication	Standard Limit	FDA-recommended dosing
Diacomit 250 mg capsule	360 per 30 days	50 mg/kg/day, administered in 2 or 3 divided doses (i.e., 16.67 mg/kg three times daily or 25 mg/kg twice daily). If the exact dosage is not achievable given the available strengths, round to the nearest possible dosage, which is usually within 50 mg to 150 mg of the recommended 50 mg/kg/day. A combination of the two Diacomit strengths can be used to achieve this dosage. The maximum recommended total dosage is 3,000 mg/day.
Diacomit 500 mg capsule	180 per 30 days	
Diacomit 250 mg powder for oral suspension	360 per 30 days	
Diacomit 500 mg powder for oral suspension	180 per 30 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- N/A

REFERENCES

- Diacomit [package insert]. France: BICODEX; May 2020.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.02.64
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