Banzel (rufinamide), Onfi (clobazam) and Sympazan (clobazam)

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 policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Sympazan (clobazam), Onfi (clobazam) and Banzel (rufinamide) policy is to ensure appropriate selection of patients for Sympazan, Onfi or Banzel use based on product labeling and/or clinical guidelines and/or clinical studies. The U.S. Food and Drug Administration (FDA) has approved Sympazan, Banzel and Onfi for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS). Compendial uses include Dravet syndrome and treatment-resistant adult focal epilepsy. A North American Consensus Panel recommends the use of clobazam as a first-line treatment option for Dravet Syndrome. In addition, the American Academy of Neurology and the American Epilepsy Society consider Banzel to be an effective second-line option for adjunctive treatment of treatment-resistant adult focal epilepsy. Banzel, a triazole derivative that modulates the activity of sodium channels and subsequently prolongs the inactive state of the channel, is indicated for use in patients 1 year of age and older. It is contraindicated in patients with Familial Short QT Syndrome. Onfi and Sympazan, are a benzodiazepine, indicated for use in patients 2 years of age and older.

POLICY

Initial Criteria for Approval

I. Brand and generic Banzel may be considered **medically necessary** for the treatment of seizures associated with Lennox-Gastaut Syndrome when all of the following criteria are met:
   a) Diagnosis of seizures associated with Lennox-Gastaut Syndrome
   b) At least one year of age
   c) Patient is taking another antiepileptic drug (AED) for the treatment of seizures associated with Lennox-Gastaut Syndrome

Approval will be for **36 months.**

II. Brand and generic Banzel may be considered **medically necessary** for the treatment of treatment-resistant adult focal epilepsy when all of the following criteria are met:
    a) Diagnosis of focal seizures
    b) At least 18 years of age
    c) Patient is taking another antiepileptic drug (AED) for the treatment of focal seizures
    d) Patient has failed first-line therapy prior to request for Banzel
        - Failure is defined as an inability to achieve sustained seizure freedom despite adequate trials of two tolerated and appropriately chosen and used AED schedules (whether as monotherapies or in combination)

Approval will be for **36 months.**

III. Brand and generic Onfi may be considered **medically necessary** for the treatment of seizures associated with Lennox-Gastaut syndrome when all of the following criteria are met:
    a) Diagnosis of seizures associated with Lennox-Gastaut Syndrome
    b) At least 2 years of age
    c) Patient is taking another antiepileptic drug (AED) for the treatment of seizures associated with Lennox-Gastaut Syndrome

Approval will be for **36 months.**

IV. Brand and generic Onfi may be considered **medically necessary** for the treatment of seizures associated with Dravet syndrome when all of the following criteria are met:
    a) Diagnosis of seizures associated with Dravet syndrome
    b) At least 2 years of age

Approval will be for **36 months.**

V. Sympazan may be considered **medically necessary** for the treatment of seizures associated with Lennox-Gastaut syndrome when all of the following criteria are met:
    a) Diagnosis of seizures associated with Lennox-Gastaut Syndrome
    b) At least 2 years of age
    c) Patient is taking another antiepileptic drug (AED) for the treatment of seizures associated with Lennox-Gastaut Syndrome
    d) Patient is unable to take both clobazam tablets and oral suspension due to an allergy, intolerance, or contraindication to the excipients

Approval will be for **36 months.**

VI. Sympazan may be considered **medically necessary** for the treatment of seizures associated with Dravet syndrome when all of the following criteria are met:
    a) Diagnosis of seizures associated with Dravet syndrome
    b) At least 2 years of age
    c) Patient is unable to take both clobazam tablets and oral suspension due to an allergy, intolerance, or contraindication to the excipients

Approval will be for **36 months.**

Continuation of Therapy

Brand and generic Banzel, Onfi, and Sympazan are considered **medically necessary** 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.

Approval will be for **36 months.**

Brand and generic Banzel, Onfi, and Sympazan are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply:

Drug Name	Generic Name	Strength	Drug Form	Quantity Limit
Banzel	rufinamide	200 mg, 400 mg	tablet	240 tablets/30 days
		40 mg/mL	suspension	2400 mL/30 days
Onfi	clobazam	10 mg	tablet	120 tablets/30 days
		20 mg	tablet	60 tablets/30 days
		2.5mg/mL	suspension	480 mL/30 days
Sympazan	clobazam	5 mg	oral film	1 box or 60 films/30 days
		10 mg	oral film	1 box or 60 films/30 days
		20 mg	oral film	1 box or 60 films/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-CM diagnostic codes.

- Code(s), if applicable.

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POLICY HISTORY

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