Pharmacy Medical Necessity Guidelines:
Baclofen (Ozobax) Oral Solution

Effective: June 9, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Baclofen (Ozobax) oral solution is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Baclofen oral solution may also be of some value in patients with spinal cord injuries and other spinal cord diseases. Baclofen oral solution is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

COVERAGE GUIDELINES

The plan may authorize coverage of baclofen (Ozobax) oral solution when the following criteria are met:

1. Documentation that baclofen (Ozobax) oral solution is being used for the treatment of spasticity resulting from multiple sclerosis or for treatment of patients with spinal cord injuries or other spinal cord diseases

AND

2. One of the following:
   a) The member has demonstrated an inadequate response to OR is unable to tolerate an adequate trial with two generic muscle skeletal muscle relaxants, one should be generic baclofen tablets

OR

   b) Documented evidence of dysphagia or difficulty swallowing tablets

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Ozobax (baclofen) [prescribing information]. Athens, GA: Metacel Pharmaceuticals, LLC.; May 2020.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: No changes.
2. May 14, 2024: Effective June 1, 2024, updated RxUM fax number. Changed title of MNG from "Ozobax (Baclofen) Oral Solution" to "Baclofen (Ozobax) Oral Solution to reflect generic availability of product. Added brand/generic language to the Limitations section of the MNG.
3. May 13, 2025: No changes
4. June 9, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards

adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services