

Commercial PA Criteria

Effective: September 9, 2022

Prior Authorization: Baclofen oral liquid

Products Affected: Ozobax (baclofen) oral suspension, Ozobax DS (baclofen) oral solution, Lyvispah (baclofen) granules, Fleqsuvy™ (baclofen) oral suspension, baclofen oral suspension, baclofen oral solution

Medication Description: The precise mechanism of action of baclofen is not fully understood. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect. Baclofen is a structural analog of the inhibitory neurotransmitter gamma- aminobutyric acid (GABA) and may exert its effects by stimulation of the GABAB receptor subtype.

Covered Uses:

1. Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax, Lyvispah and Fleqsuvy may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Exclusion Criteria:

1. Treatment of skeletal muscle spasm resulting from rheumatic disorders
2. Patients with a hypersensitivity to baclofen

Required Medical Information:

1. Diagnosis
2. Previous therapies tried

Age Restrictions: 12 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

- A. Patient has a diagnosis of spasticity resulting from multiple sclerosis or spinal cord injuries or diseases; **AND**
- B. The patient has demonstrated an inadequate response to generic oral baclofen tablets; **OR**
- C. Patient is unable to ingest baclofen oral tablets due to one of the following:
 - a. Oral/motor difficulties; **or**
 - b. Dysphagia

References:

1. Ozobax™ oral solution, baclofen oral solution. Metacel Pharmaceuticals Inc (per FDA), Athens, GA, 2019.
2. LYVISPAH™ oral granules, baclofen oral granules. Saol Therapeutics Inc (per FDA), Roswell, GA, 2021.
3. Fleqsuvy™ oral suspension, baclofen oral suspension. Azurity Pharmaceuticals, Inc. Wilmington, MA 01887

December 2023



Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	09/09/2022
2	Update	Name change- from “Brand Oral Baclofen” to “Baclofen oral liquid”, added baclofen oral suspension to Products Affected	Prior Authorization; Products Affected	5/11/2023
3	Update	Added Baclofen oral solution to products affected Added- Baclofen oral solution to products affected Ozobax DS (baclofen) oral solution	Products affected	12/14/2023