Pharmacy Policy Bulletin: J-0230 Non-Preferred Baclofen Products – Commercial and Healthcare Reform	
Number: J-0230	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0230-011	**Original Date:** 11/06/2019
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Fleqsuvy (baclofen) oral suspension • Lyvispah (baclofen) oral granules • Ozobax (baclofen) oral solution • Ozobax DS (baclofen) oral solution • Baclofen oral solution
FDA-Approved Indication(s):	• Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. • May also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Background:	• 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 the excitatory neurotransmitter release form 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 GABA-B receptor subtype. • Spasticity is a condition in which certain muscles are continuously contracted, causing stiffness or tightness of the muscles and can interfere with normal movement, speech, and gait. It is usually caused by damage to the portion of the brain or spinal cord that controls voluntary movement. • Sudden withdrawal of baclofen can result in serious complications that include hallucinations, seizures, high fever, confusion, muscle stiffness, multiple-organ-system failure, and death. • Prior authorization is utilized to ensure appropriate use per the FDA-labeled indications. Step therapy contains criteria for prior utilization of products that are equally efficacious but less costly. • Baclofen and tizanidine tablets can be crushed for administration benefiting patients with dysphagia or those who have an enteral feeding tube. • Prescribing Considerations:

	○ Fleqsuvy (baclofen), Lyvispah, Ozobax, Ozobax DS and Baclofen oral solution are not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. ○ Initiate treatment with a low dosage, preferably in divided doses, increasing gradually based on clinical response and tolerability. When discontinuing, reduce the dosage slowly. ○ The safety and effectiveness in pediatric patients below the age of 12 have not been established.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Fleqsuvy (baclofen), Lyvispah, Ozobax, Ozobax DS, or Baclofen oral solution may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 12 years of age or older.

B. The member has a diagnosis of spasticity, flexor spasms, pain, clonus, or muscular rigidity resulting from one (1) of the following **(1., 2., or 3.)**:

1. Multiple sclerosis (ICD-10: G35)

2. Spinal cord injury (ICD-10: S34)

3. Other spinal cord diseases (no ICD-10 code)

C. If the member is 18 years of age or older, the member has experienced therapeutic failure, contraindication, or intolerance to plan-preferred generic tizanidine tablets.

D. The member has experienced therapeutic failure or intolerance to plan-preferred generic baclofen tablets.

E. The member has an inability to swallow tablets.

II. Reauthorization

When a benefit, reauthorization of Fleqsuvy (baclofen), Lyvispah, Ozobax, Ozobax DS, or Baclofen oral solution may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

B. The prescriber attests that the member continues to have an inability to swallow tablets.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Fleqsuvy [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; February 2022.

2. Baclofen Suspension [package insert]. Princeton, NJ: Slayback Pharma LLC; December 2022.
3. Lyvispah [package insert]. Roswell, GA: Saol Therapeutics, Inc; November 2021.
4. Ozobax [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC; September 2023.
5. American Association of Neurological Surgeons. Spasticity. Available at: https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spasticity. Accessed March 4, 2025.
6. Tizanidine [package insert]. Weston, FL: Apotex Inc.; December 2024.
7. Baclofen Solution [package insert]. Greenville, SC: Palmetto Pharmaceuticals, Inc.; February 2022.
8. Baclofen Solution [package insert]. Tampa, FL: TruPharma, LLC; October 2023.