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5.75.029

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	November 1, 2019
Subject:	Baclofen	**Page:**	1 of 5

Last Review Date: December 12, 2025

Baclofen oral

Description

Fleqsuvy (baclofen) oral suspension, Ozobax (baclofen) oral solution

This policy does not apply to any other forms of baclofen not listed above

Background
Baclofen is a muscle relaxant and antispasmodic used for the alleviation of signs and symptoms of spasticity. 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 $GABA_B$ receptor subtype (1-3).

Regulatory Status
FDA-approved indications: Fleqsuvy and Ozobax are gamma-aminobutyric acid (GABA-ergic) agonists indicated for the treatment of spasticity resulting from multiple sclerosis (MS), particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity. Fleqsuvy and Ozobax may also be of some value to patients with spinal cord injuries and other spinal cord diseases (1-3).

Limitations of Use:
Fleqsuvy and Ozobax are not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders (1-3).

Adverse reactions may occur with abrupt withdrawal of baclofen including hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity.

Dosages should be reduced slowly when discontinuing baclofen unless the clinical situation justifies a rapid withdrawal (1-3).

Fleqsuvy and Ozobax should be used with caution in patients who have had a stroke. Baclofen has not significantly benefited patients with stroke. These patients have also shown poor tolerability to the drug (1-3).

Fleqsuvy and Ozobax should also be used with caution in patients with epilepsy. Deterioration in seizure control has been reported in patients taking baclofen (1-3).

Fleqsuvy and Ozobax can cause exacerbation of the following: psychotic disorders, schizophrenia, or confusional states. Fleqsuvy and Ozobax should be used with caution in patients with these conditions and patients should be kept under careful surveillance (1-3).

Fleqsuvy and Ozobax should be used with caution in patients with a history of autonomic dysreflexia. The presence of nociceptive stimuli or abrupt withdrawal of Fleqsuvy or Ozobax may cause an autonomic dysreflexic episode (1-3).

The safety and effectiveness of Fleqsuvy and Ozobax in pediatric patients less than 12 years of age have not been established (1-3).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Fleqsuvy and Ozobax may be considered **medically necessary** if the conditions indicated below are met.

Fleqsuvy and Ozobax may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Spasticity related to multiple sclerosis (MS)
2. Spinal cord injury or other spinal cord disease

AND ALL of the following:

a. Patient is unable to swallow or has difficulty swallowing baclofen tablets
b. Prescriber agrees to monitor for:
   i. Psychotic disorders, schizophrenia, and confusional states
   ii. Autonomic dysreflexia
   iii. Epilepsy

Prior – Approval Renewal Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Drug/Strength	Quantity
Fleqsuvy 5 mg/mL oral suspension	12 x 120mL bottles (1440 mL) per 90 days **OR** 5 x 300mL bottles (1500 mL) per 90 days **OR**
Ozobax 5 mg/5 mL oral solution	16 x 473 mL bottles (7568 mL) per 90 days **OR**
Ozobax 10 mg/5 mL oral solution	16 x 237 mL bottles (3792 mL) per 90 days **OR** 8 x 473 mL bottles (3784 mL) per 90 days **OR**

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Fleqsuvy and Ozobax contain the active ingredient baclofen, a muscle relaxant and antispasmodic used for the alleviation of signs and symptoms of spasticity. 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 $GABA_B$ receptor subtype. The safety and effectiveness of Fleqsuvy and Ozobax in pediatric patients less than 12 years of age have not been established (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Fleqsuvy, and Ozobax while maintaining optimal therapeutic outcomes.

References

1. Ozobax [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
2. Ozobax DS [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC: October 2023.
3. Fleqsuvy [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; February 2023.

Policy History

Date	Action
November 2019	Addition to PA
December 2019	Annual review
March 2020	Annual review
September 2021	Annual review and reference update
February 2022	Renamed policy to Ozobax Lyvispah (baclofen) and added Lyvispah oral granules to policy
March 2022	Annual editorial review and reference update. Renamed policy to Baclofen oral and added Fleqsuvy oral suspension to policy
June 2022	Annual review
March 2023	Annual review. Changed policy number to 5.75.029
December 2023	Annual review
January 2024	Addition of Ozobax DS 10 mg/5 mL to policy. Also changed Lyvispah quantity chart to mg per day dosing
March 2024	Annual review

December 2024	Annual review and reference update
March 2025	Annual review
December 2025	Annual review. Per FEP, removed Lyvispah due to discontinuation

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.