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5.75.029

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	November 1, 2019
Subject:	Baclofen	**Page:**	1 of 5

Last Review Date: December 8, 2023

Baclofen oral

Description

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

Fleqsuvy, Lyvispah, 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, Lyvispah, or Ozobax may cause an autonomic dysreflexic episode (1-3).

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

Related policies
Baclofen Powder

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

Fleqsuvy, Lyvispah, 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 5mg / mL oral suspension	12 x 120mL bottles (1440 mL) per 90 days **OR** 5 x 300mL bottles (1500 mL) per 90 days **OR**
Ozobax 5mg / 5mL oral solution	16 x 473 mL bottles (7568 mL) per 90 days **OR**
Lyvispah 5 mg oral granules	360 units per 90 days
Lyvispah 10 mg oral granules	
Lyvispah 20 mg oral granules	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Fleqsuvy, Lyvispah, 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, Lyvispah, and Ozobax in pediatric patients less than 12 years of age have not been established (1-2).

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

References

1. Ozobax [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC; May 2020.
2. Lyvispah [package insert]. Roswell, GA: Saol Therapeutics, Inc.; November 2021.
3. Fleqsuvy [package insert]. Wilmington, MA: Azurity Pharmaceuticals, Inc.; February 2022.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.