BlueCross BlueShield
Federal Employee Program

BACLOFEN ORAL

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

RATIONALE FOR INCLUSION IN PA PROGRAM

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 (1-4).

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 (1-4).

Limitations of Use:

Fleqsuvy, Lyvispah, and Ozobax are not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders (1-4).

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 (1-4).

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 (1-4).

Fleqsuvy, Lyvispah, and Ozobax should also be used with caution in patients with epilepsy.

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Deterioration in seizure control has been reported in patients taking baclofen (1-4).

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 (1-4).

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 (1-4).

The safety and effectiveness of Fleqsuvy, Lyvispah, and Ozobax in pediatric patients less than 12 years of age have not been established (1-4).

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 (1-4).

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. Ozobax DS [package insert]. Athens, GA: Metacel Pharmaceuticals, LLC: October 2023.
3. Lyvispah [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2023.
4. Fleqsuvy [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; February 2023.