Ozobax Solution

Description

Ozobax (baclofen) solution

Background
Ozobax (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).

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

Limitations of use: Ozobax is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders (1).

Adverse reactions may occur with abrupt withdrawal of Ozobax including: hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity. Dosages should be reduced slowly when discontinuing Ozobax unless the clinical situation justifies a rapid withdrawal (1).
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).

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

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

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

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

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.

Ozobax solution may be considered medically necessary in patients for the alleviation of signs and symptoms of spasticity and if the conditions indicated below are met.

Ozobax is considered investigational for all other indications.

Prior-Approval Requirements
Age 12 years of age or older

Diagnosis

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  16 bottles (7,568 ml) per 90 days
Duration  12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Ozobax (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\textsubscript{B} receptor subtype. The safety and effectiveness of Ozobax in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Ozobax (baclofen) while maintaining optimal therapeutic outcomes.
References


Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.