Baclofen Powder

Description

Baclofen Powder

Background

Baclofen is a muscle relaxant and antispastic used for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity. Baclofen may also be of some value in patients with spinal cord injuries and other spinal cord diseases (1).

Baclofen is commercially available as 10mg and 20mg oral tablets and for intrathecal injection in concentrations of 0.05 mg/ml, 0.5 mg/ml, and 2 mg/ml (1-2).

Regulatory Status

FDA approved indication: Baclofen (oral) is a muscle relaxant and antispastic used for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity (1).

Baclofen (intrathecal) is indicated for use in the management of severe spasticity. This includes spasticity of spinal cord origin, spasticity of cerebral origin (2).

Safety and efficacy in patients younger than 12 years of age has not been established for the oral dosage form (1).

Safety and efficacy in patients younger than 4 years of age has not been established for the intrathecal dosage form (2).
Off-label (non-FDA approved) compounded topical preparations of baclofen have not been proven to be safe or effective.

**Related policies**
Cyclobenzaprine powder, Tizanidine 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.

Baclofen powder may be considered **medically necessary** in patients for the alleviation of signs and symptoms of spasticity; the requested oral dose does not exceed 20mg/unit; the requested intrathecal dose does not exceed a concentration of 2mg/ml; and the requested strength is not commercially available or not available commercially due to shortage.

Baclofen is considered **investigational** when used for conditions not related to spasticity or when used as a topical application.

**Prior-Approval Requirements**

**Diagnosis**
Spasticity

**AND ONE** of the following:

1. The requested **ORAL** dose does not exceed 20 mg/ unit
2. The requested **INTRATHECAL** dose does not exceed a concentration of 2mg/ml

**AND ONE** of the following:

1. The requested strength is not commercially available
2. **NOT** available commercially due to shortage

**Prior – Approval ** Renewal Requirements

Same as above
Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Baclofen (oral) is a muscle relaxant and antispastic used for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus and muscular rigidity. Baclofen (intrathecal) is indicated for use in the management of severe spasticity. This includes spasticity of spinal cord origin, spasticity of cerebral origin. There are no clinically controlled studies confirming that topical application of Baclofen is safe and effective (1-2).

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

References

Policy History

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Section: Prescription Drugs
Subsection: Central Nervous System Drugs
Subject: Baclofen Powder

December 2014 Annual editorial review
December 2015 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2015 and is effective January 1, 2016.

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