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5.75.11

Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 6, 2013
Subject:	Baclofen Powder	**Page:**	1 of 4

Last Review Date: June 16, 2022

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
Baclofen, 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 and if the conditions indicated below are met.

Baclofen powder may be considered **investigational** for all other indications.

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
Same as above

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

1. Lioresal [package insert]. East Hanover, N.J.: Novartis Pharmaceuticals; April 2006.
2. Lioresal Intrathecal [package insert]. Roswell, GA:Saol Therapeutics Inc.; January 2019.

Policy History

Date	Action
October 2013	New addition to PA
December 2013	Editorial review
December 2014	Annual editorial review
December 2015	Annual review
September 2016	Annual editorial review
	Policy number change from 5.06.13 to 5.75.11

September 2017	Annual editorial review and reference update
September 2018	Annual review
September 2019	Annual review
March 2020	Annual review
March 2021	Annual review
March 2022	Annual review
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.