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 and if the conditions indicated below are met.

Baclofen is 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
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2013</td>
<td>New addition to PA</td>
</tr>
<tr>
<td>December 2013</td>
<td>Editorial review</td>
</tr>
<tr>
<td>December 2014</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>December 2015</td>
<td>Annual review</td>
</tr>
<tr>
<td>September 2016</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td></td>
<td>Policy number change from 5.06.13 to 5.75.11</td>
</tr>
<tr>
<td><strong>Section:</strong></td>
<td>Prescription Drugs</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Subsection:</strong></td>
<td>Neuromuscular Drugs</td>
</tr>
<tr>
<td><strong>Subject:</strong></td>
<td>Baclofen Powder</td>
</tr>
</tbody>
</table>

September 2017    Annual editorial review and reference update  
September 2018    Annual review 
September 2019    Annual review

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.