BACLOFEN POWDER
(baclofen)

RATIONALE FOR INCLUSION IN PA PROGRAM

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.

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

**References**

2. Lioresal Intrathecal [package insert]. Stein, Switzerland: Novartis Pharma Stein AG ;
   November 2013.