Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 27, 2010 May 7, 2012, July 7, 2022

LIORESAL® (intrathecal) /GABLOFEN® (baclofen)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

- Patient must be ≥ 4 years of age.
- Patient must have severe spasticity of spinal or cerebral origin (i.e., multiple sclerosis, cerebral palsy, spinal cord injury, or traumatic brain injury) which has proven to be unresponsive or ineffective to the maximal dosing of oral baclofen OR documentation of unacceptable side effects from or intolerance to oral baclofen at an effective dose.
    - Patients with spasticity due to traumatic brain injury must wait at least one year after the injury before consideration of long-term intrathecal baclofen therapy.
- Must have a positive response to a screening trial. A positive response is defined as a significant decrease in muscle tone and/or frequency of and/or severity of spasms as indicated in official medical documentation.
- Medication must be prescribed by a neurologist.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved or stable clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSAGE AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/