Clinical Policy: Intrathecal Baclofen (Gablofen, Lioresal Intrathecal)

Reference Number: PA.CP.PHAR.149
Effective Date: 01/18
Last Review Date: 10/18

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for the use of intrathecal baclofen injection (Gablofen® and Lioresal® Intrathecal).

FDA Approved Indication(s)
Gablofen* and Lioresal Intrathecal** are indicated for use in the management of severe spasticity of cerebral or spinal cord origin.

- Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump.
- For spasticity of spinal cord origin, chronic infusion of Gablofen/Lioresal Intrathecal via an implantable pump should be reserved for patients unresponsive to oral baclofen therapy, or those who experience intolerable central nervous system side effects at effective doses.
- Patients with spasticity due to traumatic brain injury (TBI) should wait at least one year after the injury before consideration of long-term intrathecal baclofen therapy.

Gablofen and Lioresal Intrathecal are intended for use by the intrathecal route as follows:

- In single bolus test doses (via spinal catheter or lumbar puncture);
- For chronic use, only in implantable pumps approved by the FDA specifically for the administration of Gablofen/Lioresal Intrathecal into the intrathecal space, including the Medtronic SynchroMed® II Programmable Pump‡.

**Gablofen is indicated in adults and pediatric patients age 4 years and above; Safety and effectiveness of Lioresal Intrathecal in pediatric patients below the age of 4 have not been established.*
***Lioresal Intrathecal therapy may be considered an alternative to destructive neurosurgical procedures.*
‡See Medtronic SynchroMed® II Programmable Pump information at http://professional.medtronic.com/pt/neuro/itb/prod/index.htm#.WAUxFuArKhc.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness Corporation® that Gablofen and Lioresal Intrathecal are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Severe Spasticity of Spinal or Cerebral Origin (must meet all):

1. Diagnosis of severe spasticity of cerebral or spinal cord origin (e.g., due to spinal cord injury, multiple sclerosis, hypoxic-ischemic encephalopathy, cerebral palsy, TBI);
2. Prescribed by or in consultation with a neurologist;
3. If the spasticity is due to TBI, > 1 year has passed since the injury;
4. Member was unresponsive or experienced clinically significant adverse effects to oral baclofen therapy;

5. Failure of one of the following conventional therapies (a, b, or c), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. A benzodiazepine (e.g., diazepam, clonazepam);
   b. Dantrolene;
   c. Tizanidine;
6. Baclofen will be used in one of the following ways (a or b):
   a. Screening trial (i and ii):
      i. Prescribed formulation is one of the following:
         a) Gablofen: 50 mcg/mL (1 mL syringe);
         b) Lioresal Intrathecal: 0.05 mg/mL (1 mL ampule);
      ii. Dose does not exceed 100 mcg;
   b. Maintenance therapy (i and ii):
      i. Prescribed formulation is one of the following:
         a) Any Gablofen vial/syringe except the 1 mL syringe;
         b) Any Lioresal Intrathecal ampule except the 1 mL ampule;
      ii. Member responded positively to an intrathecal baclofen screening dose (bolus of ≤ 100 mcg) as evidenced by decrease in muscle tone/frequency or spasm severity.

Approval duration:
Up to 3 screening trials over 14 days
Maintenance regimen: 3 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. Severe Spasticity of Spinal or Cerebral Origin (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documented adherence with scheduled refill visits;
3. Member is responding positively to therapy;
4. Baclofen is requested for continuance of maintenance therapy;
5. Prescribed formulation is one of the following (a or b):
   a. Any Gablofen vial/syringe except the 1 mL syringe;
   b. Any Lioresal Intrathecal ampule except the 1 mL ampule;

Approval duration:
Maintenance regimen: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

Background

Description/Mechanism of Action:
Intrathecal baclofen injection (Gablofen and Lioresal Intrathecal) is a muscle relaxant and antispastic; its pharmacological class is gamma-aminobutyric acid (GABA) ergic agonist. The precise mechanism of action of baclofen as a muscle relaxant and antispasticity agent is not fully understood. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from primary afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect. Baclofen is a structural analog of the inhibitory neurotransmitter GABA, and may exert its effects by stimulation of the $GABA_B$ receptor subtype.

Baclofen, when introduced directly into the intrathecal space, permits effective cerebrospinal fluid concentrations to be achieved with resultant plasma concentrations 100 times less than those occurring with oral administration. In people, as well as in animals, baclofen has been shown to have general central nervous system (CNS) depressant properties as indicated by the production of sedation with tolerance, somnolence, ataxia, and respiratory and cardiovascular depression.

Formulations:

Solution, Intrathecal:

Vials and syringes are intended for single use and are free of preservatives, antioxidants or other potentially neurotoxic additives.

Gablofen:

50 mcg/mL: 1 mL syringe (for screening tests)
10,000 mcg/20 mL: 20 mL syringe or 20 mL vial
20,000 mcg/20 mL: 20 mL syringe or 20 mL vial
40,000 mcg/20 mL: 20 mL syringe or 20 mL vial

Lioresal:

0.05 mg/mL: 1 mL ampule (for screening tests)
10 mg/20 mL: 20 mL ampule
10 mg/5 mL: 5 mL ampule
40 mg/20 mL: 20 mL ampule

Oral baclofen formulations:

Suspension, Oral:

First-Baclofen 1: 1 mg/mL (120 mL)
First-Baclofen 5: 5 mg/mL (60 mL, 120 mL)

Tablet, Oral:

Generic: 10 mg, 20 mg

Appendices

Appendix A: Abbreviation Key

CNS: central nervous system
GABA: gamma-aminobutyric acid
TBI: traumatic brain injury

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J0475	Injection, baclofen, 10 mg
J0476	Injection, baclofen, 50 mcg for intrathecal trial

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: removed requirement for physical therapy due to inability to objectively verify; removed specialist requirement by a "physician adequately trained for baclofen infusion"; references reviewed and updated.	07/18	

References
1. Gablofen Prescribing Information. Bethlehem, PA: Piramal Critical Care, Inc.; March 2017. Available at http://www.gablofen.com/. Accessed July 24, 2018.
2. Lioresal Intrathecal Prescribing Information. Minneapolis, MN: Medtronic, Inc.; December 2016. Available at http://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/neurological/intrathecal-baclofen-therapy/indications-safety-warnings/full-prescribing-information.html. Accessed July 24, 2018.
3. SynchroMed II Programmable Infusion Pump. Medtronic, Inc., Minneapolis, MN. Available at http://professional.medtronic.com/pt/neuro/itb/prod/#.WAZHK-ArKhc. Accessed July 24, 2018.
4. Chang E, Ghosh Nilasha, Yanni D, et al. A review of spasticity treatments: pharmacological and interventional approaches. Crit Rev Phys Rehabil Med. 2013; 25(1-2)11:22. doi:10.1615/CritRevPhysRehabilMed.2013007945.