Clinical Policy: Intrathecal Baclofen (Gablofen, Lioresal)

Reference Number: CP.PHAR.149
Effective Date: 12.01.15
Last Review Date: 11.17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Baclofen (Gablofen®, Lioresal® Intrathecal) is a muscle relaxant and antispastic. Baclofen's pharmacological class is a gamma-aminobutyric acid ergic agonist.

FDA approved indication

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 FDA baclofen pump information under "baclofen" at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/TextResults.cfm.
‡See Medtronic SynchroMed® II Programmable Pump information at http://professional.medtronic.com/pt/neuro/itb/prod/index.htm#.WAUxFuArKhc.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Gablofen and Lioresal Intrathecal are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Severe Spasticity of Cerebral or Spinal Cord 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 or physician adequately trained in intrathecal baclofen infusion therapy;
3. Age ≥ 4 years;
4. If the spasticity is due to TBI, > 1 year has passed since the injury;
5. Member was unresponsive or experienced clinically significant adverse effects to oral baclofen therapy;
6. Failure of one of the following conventional therapies (a, b, c, or d), unless all are contraindicated or clinically significant adverse effects are experienced:
   a. A benzodiazepine (e.g., diazepam, clonazepam);
   b. Dantrolene;
   c. Tizanidine;
   d. Physical therapy;
7. 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:
Screening: 14 days (up to 3 screening trials)
Maintenance: 3 months

B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documented adherence with scheduled refill visits;
3. Member is responding positively to therapy (e.g., no increased spasticity or unacceptable toxicity while on 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: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
TBI: traumatic brain injury

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Intrathecal baclofen (Gablofen, Lioresal Intrathecal)	Screening dose: initial: 50 mcg (or 25 mcg for very small patient) intrathecally by barbotage over a period of at least 1 minute. If the initial response is less than desired, a second bolus of 75 mcg intrathecally may be given 24 hours after the first dose, and observe for 4 to 8 hours. If the response is still inadequate, a final bolus of 100 mcg intrathecally may be given 24 hours later. Patients who do not respond to the 100 mcg dose should not be considered candidates for an implanted pump for chronic infusion. Maintenance therapy: Titrate patients individually; lowest dose with an optimal response should be used, generally 300 mcg/day to 800 mcg/day for spasticity of spinal cord origin (for children < 12 years, average dose was 274 mcg/day) and 90 mcg/day to 703 mcg/day for spasticity of cerebral origin (for children < 12 years, average dose was 274 mcg/day).	Not available

VI. Product Availability

Drug	Availability
Baclofen (Gablofen)	Injection (syringe): 50 mcg/mL

	Injection (syringe and vial): 500 mcg/mL, 1,000 mcg/mL, and 2,000 mcg/mL
Baclofen (Lioresal Intrathecal)	Injection (ampules): 0.05 mg/mL (50 mcg/mL), 10 mg/20 mL (500 mcg/mL), 10 mg/5 mL (2000 mcg/mL), or 40 mg/20 mL (2000 mcg/mL)

VII. References

1. Gablofen Prescribing Information. Bethlehem, PA: Piramal Critical Care, Inc.; March 2017. Available at http://www.gablofen.com/. Accessed July 26, 2017.
2. Lioresal Intrathecal Prescribing Information. Minneapolis, MN: Medtronic, Inc.; September 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 26, 2017.
3. SynchroMed II Programmable Infusion Pump. Medtronic, Inc., Minneapolis, MN. Available at http://professional.medtronic.com/pt/neuro/itb/prod/#.WAZHK-ArKhc. Accessed July 26, 2017.
4. Adams MM, Hicks AL. Spasticity after spinal cord injury. Spinal Cord (2005) 43, 577–586.
5. Satkunam LE. Rehabilitation medicine: 3. Management of adult spasticity. Radhakrishna M, Satkunam L, eds. *CMAJ: Canadian Medical Association Journal*. 2003;169(11):1173-1179.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy developed, neurologist reviewed	11.15	12.15
Policy converted to new template. Removed age criteria. Added dosing information per PIs. Added "up to three screening trials" to the initial approval period per PIs. Removed positive response to screening from continuation criteria.	11.16	12.16
Added age restriction per PI; Removed "baclofen will not be compounded with other medications" and requirement related to hypersensitivity to baclofen per safety approach. Re-auth: added requirement of positive response to therapy.	07.26.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.