

## Clinical Policy: Intrathecal Baclofen (Gablofen, Lioresal)

Reference Number: CP.PHAR.149

Effective Date: 12.01.15

Last Review Date: 11.18

Line of Business: Medicaid, HIM-Medical Benefit

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

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

### 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<sup>®</sup> II Programmable Pump<sup>‡</sup>.

\*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<sup>®</sup> II Programmable Pump information at <http://professional.medtronic.com/pt/neuro/itb/prod/index.htm#.WAUxFuArKhc>.

### Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Gablofen and Lioresal intrathecal injections 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, orthopedist, physiatrist, or physical medicine and rehabilitation specialist;
3. Age  $\geq$  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, or c), unless all are contraindicated or clinically significant adverse effects are experienced:
  - a. A benzodiazepine (e.g., diazepam, clonazepam);
  - b. Dantrolene;
  - c. Tizanidine;
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  $\leq$  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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**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;
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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**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 policies – CP.PMN.53 for Medicaid and HIM-Medical Benefit or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

TBI: traumatic brain injury

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
baclofen	5 mg PO TID; increase slowly every 3 days by 5 mg PO TID up to 40 to 80 mg/day given in 3 to 4 divided doses	150 mg/day
benzodiazepines (e.g., diazepam, clonazepam)	<i>Refer to prescribing information</i>	<i>Refer to prescribing information</i>
dantrolene (Dantrium®)	25 mg PO QD; a gradual dose titration of 25 mg PO QD for 7 days, 25 mg PO TID for 7 days, 50 mg PO TID for 7 days, and 100 mg PO TID QD is recommended.	400 mg/day
Tizanidine (Zanaflex®)	2 mg PO QD; dose can be repeated at 6 to 8 hour intervals as needed to a maximum of 3 doses/24 hrs. Gradually increase the dose by 2 to 4 mg at each dose, with 1-4 days in between dose increases until satisfactory reduction in muscle tone is achieved.	36 mg/day

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Black Box Warning: do not discontinue abruptly.
  - Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.
- Do not use via intravenous, intramuscular, subcutaneous, or epidural route of administration.

**V. Dosage and Administration**

Drug Name	Dosing Regimen	Maximum Dose
Intrathecal baclofen (Gablofen, Lioresal Intrathecal)	<p>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.</p> <p>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 &lt; 12 years, average dose was 274 mcg/day) and 90 mcg/day to 703 mcg/day for spasticity of cerebral origin (for children &lt; 12 years, average dose was 274 mcg/day).</p>	Not available

**VI. Product Availability**

Drug	Availability
Baclofen intrathecal injection (Gablofen)	Injection (solution): 50 mcg/1 mL Injection (vial): 10,000 mcg/20 mL, 20,000 mcg/20 mL, 40,000 mcg/20 mL
Baclofen intrathecal injection (Lioresal Intrathecal)	Injection (solution): 0.05 mg/mL, 10 mg/20 mL, 10 mg/5 mL, 40 mg/20 mL

**VII. 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.

**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 for intrathecal use
J0476	Injection, baclofen, 50 mcg for intrathecal use

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
4Q 2018 annual review: added HIM-Medical Benefit line of business; removed requirement for physical therapy due to inability to objectively verify; removed specialist requirement by a “physician adequately trained for baclofen infusion”; expanded specialist requirement to include orthopedist, physiatrist, or physical medicine and rehabilitation specialist; references reviewed and updated.	07.31.18	11.18

**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.

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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.

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**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.

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