

Clinical Policy: Baclofen (Gablofen, Lioresal)

Reference Number: LA.PHAR.149

Effective Date:

Last Review Date: 01.21

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 (GABA)-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[®] 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

Prior authorization is required. 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 Louisiana Healthcare Connections that Gablofen and Lioresal are medically necessary when the following criteria are met:

I. Initial Approval Criteria

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- A. Requests for Gablofen or Lioresal (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 clinically significant adverse effects are experienced or all are contraindicated:
 - 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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Gablofen and Lioresal requests only: Member meets all of the following (a, b, and c):
 - a. Documented adherence with scheduled refill visits;

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- b. Baclofen is requested for continuance of maintenance therapy;
 - c. Prescribed formulation is one of the following (i or ii):
 - i. Any Gablofen vial/syringe except the 1 mL syringe;
 - ii. Any Lioresal Intrathecal ampule except the 1 mL ampule;
- Approval duration: 6 months (Gablofen, Lioresal)
- B. Other diagnoses/indications (must meet 1 or 2):**
- 1. Currently receiving medication via Louisiana Healthcare Connections 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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

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 – LA.PMN.53 for Medicaid 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 require prior authorization.

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
<u>baclofen oral tablets</u>	<u>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</u>	<u>150 mg/day</u>
<u>benzodiazepines (e.g., diazepam, clonazepam)</u>	<u>Varies</u>	<u>Varies</u>
<u>dantrolene (Dantrium®)</u>	<u>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.</u>	<u>400 mg/day</u>
<u>Tizanidine (Zanaflex®)</u>	<u>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</u>	<u>36 mg/day</u>

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<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Dose Limit/ Maximum Dose</u>
	<u>dose increases until satisfactory reduction in muscle tone is achieved.</u>	

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

- Contraindication(s): Gablofen, Lioresal only – do not use via intravenous, intramuscular, subcutaneous, or epidural routes of administration.
- Boxed warning(s): Gablofen and Lioresal only – 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.

V. Dosage and Administration

<u>Drug Name</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>Intrathecal baclofen (Gablofen, Lioresal Intrathecal)</u>	<p><u>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.</u></p> <p><u>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).</u></p>	<u>Not available</u>

VI. Product Availability

<u>Drug</u>	<u>Availability</u>
<u>Baclofen intrathecal</u>	<u>Injection (solution): 50 mcg/1 mL (used for initial screening doses)</u>

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<u>Drug</u>	<u>Availability</u>
<u>injection (Gablofen)</u>	<u>Injection (vial or syringe): 10,000 mcg/20 mL, 20,000 mcg/20 mL, 40,000 mcg/20 mL</u>
<u>Baclofen intrathecal injection (Lioresal Intrathecal)</u>	<u>Injection ampules: 0.05 mg/mL (used for initial screening doses), 10 mg/20 mL, 10 mg/5 mL, 40 mg/20 mL</u>

VII. References

1. Gablofen Prescribing Information. Bethlehem, PA: Piramal Critical Care, Inc.; December 2019. Available at <http://www.gablofen.com/>. Accessed August 21, 2020.
2. Lioresal Intrathecal Prescribing Information. Minneapolis, MN: Medtronic, Inc.; January 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020075s0371bl.pdf. Accessed August 21, 2020.
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.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J0475</u>	<u>Injection, baclofen, 10 mg</u>
<u>J0476</u>	<u>Injection, baclofen, 50 mcg for intrathecal use</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>
<u>Converted corporate to local policy</u>	<u>01.21</u>

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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.

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