



Lioresal[®]
Intrathecal (baclofen injection)

Lioresal[®] Intrathecal Reimbursement Guide



Lioresal[®] Intrathecal Important Safety Information

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.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).



For additional information, email us at lioresalreimbursement@saolrx.com

Kit or Model Number	HCPCS II Codes and Description ^{1,*}	National Drug Code (NDC Number) [^]	Ampules (quantity x volume)	Concentration	Billing Units Per Kit
8561	JO475 Injection, baclofen, 10mg	70257-560-01	1 x 20 mL	500 mcg/mL	1
8562	JO475 Injection, baclofen, 10mg	70257-561-02	2 x 5 mL	2000 mcg/mL	2
8563s Screening Trial	JO476 Injection, baclofen, 50mcg for intrathecal trial	70257-562-55	5 x 1 mL	50 mcg/mL	5
8564	JO475 Injection, baclofen, 10mg	70257-563-01	1 x 20 mL	2000 mcg/mL	4
8565	JO475 Injection, baclofen, 10mg	70257-560-02	2 x 20 mL	500 mcg/mL	2
8566	JO475 Injection, baclofen, 10mg	70257-563-02	2 x 20 mL	2000 mcg/mL	8

*HCPCS II Codes JO475 & JO476 are based on Medicare guidelines and used for commercially available product. Unbranded or compounded medicine have different, unique J-codes², that are not included on this chart. For more information please refer to CMS guidelines or your local Medicare contractor. Please refer to individual private payers for additional questions.

[^]NDC numbers are current as of 2/1/18.



For more information, including **BOX WARNING**, refer to Lioresal® Intrathecal (baclofen injection) prescribing information in brochure pocket, or attached to this file if viewing digitally.



Relevant/Select Modifiers	Modifier Description
-JW ³	Drugs or biologicals from single use packages that are discarded and not administered to the patient, and subsequently appropriately discarded under the CMS discarded drug policy.
-22 ⁴	Increased procedural service
-52 ⁴	Decreased procedural service

CPT Code ^{4,5}	Refill/Analysis/Reprogramming
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill
62368	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming
62369	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill
62370	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); with reprogramming and refill (requiring skill of a physician or other qualified health care professional)

ICD-10	Description
3E0R3GC ⁵	Introduction of other therapeutic substance into spinal canal, percutaneous approach

- <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>
- <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9167.pdf>
- <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>
- CPT® 2017 Professional Edition, American Medical Association
- Centers for Disease Control and Prevention, National Center for Health Statistics. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). <http://www.cdc.gov/nchs/icd/icd10cm.htm>

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For additional information, email us at liosale reimbursement@saolrx.com

⁴Codes 95990 and 95991 are not displayed because they are not used with ITB Therapy™. As defined, these codes are appropriate for analysis, refilling and maintenance of nonprogrammable intrathecal pumps. ITB Therapy™ uses programmable pumps, which require reprogramming at the time of refilling.⁴



Lioresal® Intrathecal (baclofen injection)

Important Safety Information

Indications and Usage

- Lioresal® Intrathecal (baclofen injection) is a muscle relaxant and antispastic that is indicated for use in the management of severe spasticity of cerebral or spinal origin.
- Lioresal® Intrathecal is intended for use by the intrathecal route in single bolus test doses (via spinal catheter or lumbar puncture) and, for chronic use, only in implantable pumps approved by the FDA specifically for the administration of Lioresal® Intrathecal into the intrathecal space.
- Lioresal® Intrathecal via an implantable pump should be reserved for patients unresponsive to oral baclofen therapy or those who experience intolerable CNS side effects at effective doses.
- Patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long term intrathecal baclofen therapy.
- Prior to implantation of a device for chronic intrathecal infusion of Lioresal® Intrathecal, patients must show a response to Lioresal® Intrathecal in a screening trial. Please review the dosing and administration section of the Lioresal® Intrathecal prescribing information for further details.

Contraindications

- Hypersensitivity to baclofen.
- Lioresal® Intrathecal is not recommended for intravenous, intramuscular, subcutaneous or epidural administration.

Select Warnings and Precautions

- It is mandatory that all patients, caregivers, and treating physicians receive adequate information regarding the risks of the mode of treatment. Instruction should be given on signs and symptoms of overdose, procedures to be followed in the event of an overdose, and proper home care of the pump and insertion site.
- Due to the possibility of life-threatening CNS depression, cardiovascular collapse, and/or respiratory failure, physicians must be adequately trained and educated in chronic intrathecal infusion therapy.
- Patients should be infection-free prior to both a screening trial and a pump implantation. The presence of infection may interfere with an assessment of the patient's response to bolus Lioresal® Intrathecal, increase the risk of surgical complications and complicate dosing.
- Reservoir refilling must be performed by fully trained and qualified personnel following the directions provided by the pump manufacturer. Extreme caution must be used when filling an FDA approved implantable pump, following strict aseptic technique and ensuring refill directly into the reservoir and not the catheter access port.
- An attempt should be made to discontinue concomitant oral antispasticity medication to avoid possible overdose or adverse drug interactions, either prior to screening or following implant and initiation of chronic Lioresal® Intrathecal infusion.
- Following pump implantation, and for each adjustment of the dosing rate of the pump and/or concentration of Lioresal® Intrathecal, the patient should be monitored closely until it is certain the patient's response to the infusion is acceptable and reasonably stable.
- Early symptoms of baclofen withdrawal may include return of baseline spasticity, pruritus, hypotension and paresthesias.
- Priapism may develop or recur if treatment with intrathecal baclofen is interrupted.
- Signs of overdose may appear suddenly or insidiously, and a massive overdose may present as coma. Less sudden and/or less severe forms of overdose may present with signs of drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.



Important Safety Information (continued)

- Should overdose appear likely, the patient should be taken immediately to a hospital for assessment and emptying of pump reservoir.
- Except in overdose related emergencies, the dose of Lioresal® Intrathecal should ordinarily be reduced slowly if the drug is discontinued for any reason.

Adverse Reactions

Common Adverse Reactions

- The most frequent drug adverse events vary by indication but include: hypotonia (34.7%), somnolence (20.9%), headache (10.7%), convulsion (10.0%), dizziness (8.0%), urinary retention (8.0%), nausea (7.3%), and paresthesia (6.7%). Dosing and programming errors may result in clinically significant overdose or withdrawal. Acute massive overdose may result in coma and may be life threatening.
- Drowsiness has been reported in patients on Lioresal® Intrathecal. Patients should be cautioned regarding the operation of automobiles or other dangerous machinery and activities made hazardous by decreased alertness. Patients should also be cautioned that the central nervous system depressant effects of Lioresal® Intrathecal may be additive to those of alcohol and other CNS depressants.

Serious Adverse Reactions

- Seizures have been reported during overdose and with withdrawal from Lioresal® Intrathecal as well as in patients maintained on therapeutic doses of Lioresal® Intrathecal.
- Fatalities have been reported with Lioresal® Intrathecal use.

Postmarketing Experience

- The following adverse events have been reported during post-approval use of Lioresal® Intrathecal.
 - Musculoskeletal - The onset of scoliosis or worsening of a pre-existing scoliosis has been reported.
 - Urogenital - Sexual dysfunction in men and women including decreased libido and orgasm dysfunction have been reported.

Use in Specific Populations

- There are no adequate and well controlled studies in pregnant women. Lioresal® Intrathecal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing mothers should exercise caution, as oral baclofen has been shown to pass into milk at therapeutic doses.
- Safety and effectiveness in pediatric patients below the age of 4 have not been established.
- Patients suffering from psychotic disorders, schizophrenia, or confusional states should be treated cautiously with Lioresal® Intrathecal and kept under careful surveillance.
- Lioresal® Intrathecal should be given with caution in patients with impaired renal function. Dose reduction may be necessary.
- Lioresal® Intrathecal should be used with caution in patients with a history of autonomic dysreflexia.

For more information, including **BOX WARNING**, refer to Lioresal® Intrathecal (baclofen injection) prescribing information in brochure pocket, or attached to this file if viewing digitally.



Saol is committed to helping patients access ITB TherapySM with Lioresal[®] Intrathecal (baclofen injection). In support of that, Saol has partnered with Needymeds to facilitate access to Lioresal[®] Intrathecal for patients that are uninsured or rendered uninsured for Lioresal[®] Intrathecal at no cost.

Qualification criteria includes income limit, no insurance coverage for Lioresal[®] Intrathecal, and a prescription from a qualified healthcare provider.

This program does not provide copay assistance.

Applications are available through Needymeds:
<http://www.needymeds.org/papforms/liopae2614.pdf>



www.lioresal.com



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