



Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource

## MEDICAL POLICY STATEMENT North Carolina Marketplace

Policy Name & Number	Date Effective
Epidural Steroid Injections-NC MP-MM-1362	06/01/2023-04/30/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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## A. Subject

### **Epidural Steroid Injections**

## B. Background

Nearly 84% of adults experience back pain during their lifetime. Long-term outcomes are largely favorable for most patients, but a small percentage of patients' symptoms are persistent. Persistent pain is categorized as subacute when lasting between four and twelve weeks and chronic when persisting for at least three months.

Comprehensive pain management care plans are most effective in managing patient's chronic pain. These plans focus on a person-centered approach and incorporate conservative treatment with other modalities. These multidisciplinary treatments include promoting patient self-management and aim to reduce the impact of pain on a patient's daily life, even if the pain cannot be relieved completely. In addition to conservative therapy, additional treatment options may include nonpharmacologic or pharmacologic treatments, nonsurgical interventions, and surgical interventions. Interventional procedures for the management of pain unresponsive to conservative treatment should be provided only by physicians qualified to deliver these health services.

Epidural steroid injections (ESIs) are a nonsurgical, minimally-invasive intervention for chronic low back pain. ESIs may be administered through the translaminar approach (via the interlaminar space in the spine), the transforaminal approach (through the neuroforamen dorsal to the nerve root), or the caudal approach (through the sacral hiatus at the sacral canal). There is conflicting evidence on the efficacy of ESIs and a lack of consensus on frequency and number of epidural steroid injections from professional organizations. However, clinical experience suggests that some patients obtain more significant relief, making it reasonable to offer a trial of steroid injections when conservative management has failed.

Imaging studies of the symptomatic region may be performed to evaluate suspected specific causes of spinal pain (e.g., herniated disc, spinal stenosis, degenerative vertebral disease, rule out fracture or tumor). However, evidence does not support the routine use of imaging or other diagnostic tests in patients with nonspecific low back pain. Diagnostic imaging and testing is only recommended when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination.

## C. Definitions

- **Conservative Therapy** - A multimodal plan of care including both active and inactive conservative therapies.
  - **Active Conservative Therapies** - Actions or activities that strengthen muscle groups and target key spinal structures, including physical therapy, occupational therapy, physician supervised home exercise program (HEP), and/or chiropractic care.
    - **HEP** - A six-week program requiring an exercise prescription and/or plan and a follow-up documented in the medical record after completion, or

documentation of the inability to complete the HEP due to a stated physical reason (i.e., increased pain, inability to physically perform exercises). Patient inconvenience or noncompliance without explanation does not constitute an inability to complete.

- **Inactive Conservative Therapies** - Passive activities by the patient that aid in treating symptoms associated with pain, including rest, ice, heat, medical devices, TENS use, and/or pharmacotherapy (prescription or over the counter [e.g., non-steroidal anti-inflammatory drugs, acetaminophen]).
  - **Transcutaneous Electrical Nerve Stimulator (TENS)** - A device that utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins. Its use, frequency, duration, and start dates must be documented in the medical record to be considered part of conservative therapy during the period of prior authorization request.
- **Epidural Steroid Injection** - Administration of steroids via a needle inserted in the space between the ligamentum flavum and the dura and administered by translaminar, transforaminal, or caudal approaches. Injections are intended to cause a short-term reduction in pain in the affected region.

#### D. Policy

- I. Epidural steroid injections for labor and delivery in childbirth or post-surgical pain do not require prior authorization.
- II. Initial (Diagnostic) Injection  
CareSource considers an initial (diagnostic) epidural steroid injection (maximum of 2 injections) medically necessary for the management of chronic pain when **ALL** the following clinical criteria are met:
  - A. Pain is located in either the cervical, thoracic, or lumbar spine and is predominantly radiating or shooting in nature;
  - B. Pain is causing functional disability (at least a 6 on a scale of 0 to 10);
  - C. Signs or symptoms consistent with radiculopathy, as indicated by at least one of the following:
    1. Diminished or absent deep tendon reflexes;
    2. Paresthesia, numbness, sensory change, or weakness in dermatomal distribution;
    3. Positive femoral nerve stretch test;
    4. Positive Spurling test;
    5. Positive straight leg raising test;
  - D. Failure of conservative therapy, as evidenced by **ALL** the following:
    1. Documentation in the medical record of at least 6 weeks of active conservative therapy (see definition above) within the past 6 months OR inability to complete active conservative therapy due to contraindication, increased pain, or intolerance;
    2. Documentation in the medical record of at least 6 weeks of inactive conservative therapy (see definition above) within the past 6 months;

- E. Imaging (e.g., x-ray, CT, MRI), if performed, demonstrates there are no conditions present that would preclude the safety of the performance of the procedure.

### III. Subsequent (Therapeutic) Injections

CareSource considers therapeutic epidural steroid injections medically necessary when **ALL** the following criteria are met:

- A. The diagnostic or last therapeutic injection for current episode of pain provided significant functional pain relief of at least 50% as measured by a significant decrease in pain level, decrease in pain medications, and/or increase in physical function;
- B. The member continues to have ongoing pain or documented functional disability (at least a 6 on a scale of 0 to 10);
- C. At least 3 weeks have passed since the prior injection in order to reach pharmacodynamic effect;
- D. No more than 3 procedures in a 12-week period of time per region;
- E. The patient continues to engage in conservative therapy (see definition above).

### IV. Limitations and Exclusions

- A. The maximum number of all epidural injections a member can receive in 12 months is 6, regardless of the number of levels involved.
- B. For interlaminar or caudal epidural injections, no more than 1 epidural injection per treatment date should be performed.
- C. For transforaminal epidurals or selective nerve root blocks (SNRBs), no more than 2 vertebral levels per treatment date, whether unilateral or bilateral, should be performed.
- D. Real-time image guidance and any injection of contrast are inclusive components of epidural injections and are not compensated for separately or unbundled for coverage.
- E. Ultrasound guidance for epidural injections is considered inappropriate.
- F. Conscious sedation, if required for co-morbidities or patient/physician preference, may be provided without a medical necessity review but services will be considered part of the procedure and are not eligible for additional reimbursement if administered by a second provider.
- G. Monitored anesthesia is considered not medically necessary.
- H. Patients with indwelling implanted spinal cord stimulators or pain pumps must have a device interrogation report and an interpretation submitted with medical records and included in the prior authorization request for proposed interventional pain injections. If a device is not functioning properly, an escalation in pain may warrant evaluation and management of the implanted device.
- I. Clinical evaluations and care of candidate patients for epidural injections should also address, at the discretion of the physician and according to prevailing standards of medical care:
  - 1. No acute spinal cord compression.
  - 2. Selected body imaging evaluations to evaluate the area of pain, particularly for acute pain, or to evaluate escalations in chronic baseline pain.

3. Appropriate imaging to rule out red flag conditions may be indicated if potential issues of trauma, osteomyelitis or malignancy or other diagnoses are a concern.
- J. Contraindications include any of the following:
  1. Pain related to cancer etiology.
  2. Local or systemic infection.
  3. Cauda equina syndrome.
  4. Spinal trauma (e.g., hematoma, hemorrhage, mass, ischemia).
  5. Coagulopathy.
- V. Inconclusive or Non-Supportive Evidence
  - A. Evidence reported in the medical literature is inconclusive as to the use of epidural injections for long term relief or treatment of chronic pain. Long-term continuation (epidural injections beyond 1 year) may be subject to medical necessity review.
  - B. For both cervical and lumbar transforaminal (TF) ESIs, using particulate steroid is associated with a rare risk of catastrophic neurovascular complications such as stroke or death. Cervical transforaminal injections are risky because arterial supply may be densely concentrated in and around the intervertebral foramen. TF ESIs can be performed without contrast in patients with documented contraindication to its use. In these circumstances particulate steroids are contraindicated and only the preservative free, particulate free steroids which are available should be used.
  - C. Cervical transforaminal ESIs have sparse literature for cervical radicular pain, and, if performed, should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction angiography (DSA) in a frontal plane, before injecting any substance potentially hazardous to the patient. Particulate steroids should not be used for cervical TF injections as per the contraindication established by the FDA warning.
- E. Conditions of Coverage  
NA
- F. Related Policies/Rules  
NA
- G. Review/Revision History

DATE		ACTION
<b>Date Issued</b>	11/30/2022	
<b>Date Revised</b>	03/15/2023	Annual review: reorganized criteria, simplified conservative therapy, added provocation tests, added pain scale to diagnostic injection criteria. Approved at Committee.
<b>Date Effective</b>	06/01/2023	
<b>Date Archived</b>	04/30/2024	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

## H. References

1. Bono CM, Ghiselli G, Gilbert TJ, et al. An evidence-based clinical guideline for the diagnosis and treatment of cervical radiculopathy from degenerative disorders. *Spine J.* 2011;11(1):64-72. doi:10.1016/j.spinee.2010.10.023.
2. Chou R, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007 Oct;147(7):478-491. doi:10.7326/0003-4819-147-7-200710020-00006.
3. Chou R, et al. Epidural corticosteroid injections for radiculopathy and spinal stenosis: a systematic review and meta-analysis. *Ann Intern Med.* 2015 Sept;163(5):373-381. doi:10.7326/M15-0934.
4. Chou R, et al. Nonpharmacologic therapies for low back pain: a systematic review for an American College of Physicians Clinical Practice Guideline. *Ann Intern Med.* 2017 Apr;166(7):493-505. doi:10.7326/M16-2459.
5. Chou R. (2021 June 11). Subacute and chronic low back pain: nonsurgical interventional treatment. UpToDate. Retrieved February 20, 2023 from [www.uptodate.com](http://www.uptodate.com).
6. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976).* 2009;34(10):1066-1077. doi:10.1097/BRS.0b013e3181a1390d.
7. Cohen SP, et al. Epidural steroid injections, conservative treatment, or combination treatment for cervical radicular pain: a multicenter, randomized, comparative-effectiveness study. *Anesthesiology.* 2014 Nov;121(5):1045-55. doi:10.1097/ALN.0000000000000409. PMID: 25335172.
8. Conger A, Cushman DM, Speckman RA, et al. The effectiveness of fluoroscopically guided cervical transforaminal epidural steroid injection for the treatment of radicular pain; a systematic review and meta-analysis. *Pain Med.* 2020 Jan;21(1):41-54. doi:10.1093/pm/pnz127.
9. Helm S, Harmon PC, Noe C, et al. Transforaminal epidural steroid injections: a systematic review and meta-analysis of efficacy and safety. *Pain Phys.* 2021;24:S209-S232. Hong JH, Huh B, Shin HH. Comparison between digital subtraction angiography and real-time fluoroscopy to detect intravascular injection during lumbar transforaminal epidural injections. *Reg Anesth Pain Med.* 2014;39(4):329-332. doi:10.1097/AAP.0000000000000096.
10. Kennedy DJ, Plastaras C, Casey E, et al. Comparative effectiveness of lumbar transforaminal epidural steroid injections with particulate versus nonparticulate corticosteroids for lumbar radicular pain due to intervertebral disc herniation: a prospective, randomized, double-blind trial. *Pain Med.* 2014;15(4):548-555. doi:10.1111/pme.12325.
11. Kennedy DJ, Levin J, Rosenquist R, et al. Epidural Steroid Injections are Safe and Effective: Multisociety Letter in Support of the Safety and Effectiveness of Epidural Steroid Injections. *Pain Med.* 2015;16(5):833-838. doi:10.1111/pme.12667.
12. Lee JH, Shin K, Bahk SJ, et al. Comparison of clinical efficacy of transforaminal and caudal epidural steroid injection in lumbar and lumbosacral disc herniation: a



- systematic review and meta-analysis. *Spine J.* 2018 Dec;18(12):2343-2353. doi:10.1016/j.spinee.2018.06.720.
13. Manchikanti L, Falco FJ, Diwan S, et al. Cervical radicular pain: the role of interlaminar and transforaminal epidural injections. *Curr Pain Headache Rep.* 2014 Jan;18(1):389. doi: 10.1007/s11916-013-0389-9. PMID: 24338702.
14. Manchikanti L, Knezevic NN, Boswell MV, et al. Epidural Injections for Lumbar Radiculopathy and Spinal Stenosis: A Comparative Systematic Review and Meta-Analysis. *Pain Physician.* 2016 Mar;19(3):E365-410. PMID: 27008296.
15. Manchikanti L, Cash KA, Pampati V, et al. Two-year follow-up results of fluoroscopic cervical epidural injections in chronic axial or discogenic neck pain: a randomized, double-blind, controlled trial. *Int J Med Sci.* 2014;11(4):309-320. Published 2014 Feb 6. doi:10.7150/ijms.8069.
16. Manchikanti L, Benyamin RM, Falco FJ, et al. Do Epidural Injections Provide Short- and Long-term Relief for Lumbar Disc Herniation? A Systematic Review. *Clin Orthop Relat Res.* 2015;473(6):1940-1956. doi:10.1007/s11999-014-3490-4.
17. Manchikanti L, Falco FJ, Pampati V, et al. Lumbar interlaminar epidural injections are superior to caudal epidural injections in managing lumbar central spinal stenosis. *Pain Physician.* 2014;17(6):E691-E702.
18. Manchikanti L, Cash KA, Pampati V, et al. Transforaminal epidural injections in chronic lumbar disc herniation: a randomized, double-blind, active-control trial. *Pain Physician.* 2014;17(4):E489-E501.
19. Manchikanti L, Cash KA, McManus CD, et al. Thoracic interlaminar epidural injections in managing chronic thoracic pain: a randomized, double-blind, controlled trial with a 2-year follow-up. *Pain Physician.* 2014;17(3):E327-E338.
20. Manchikanti L, Candido KD, Singh V, et al. Epidural steroid warning controversy still dogging FDA. *Pain Physician.* 2014;17(4):E451-E474.
21. Manchikanti L, Knezevic NN, Navani A, et al. Epidural Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Comprehensive Evidence-Based Guidelines. *Pain Physician.* 2021 Jan;24(S1): S27-S208.
22. Nishio I. Cervical transforaminal epidural steroid injections: a proposal for optimizing the preprocedural evaluation with available imaging. *Reg Anesth Pain Med.* 2014;39(6):546-549. doi:10.1097/AAP.0000000000000164.
23. Qassem, Amir, et al. Noninvasive treatments for acute, subacute and chronic low back pain: A clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine.* April 2017. doi:10.7326/M16-2367.
24. Staal JB, et al. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. *Spine.* 2009 Jan;34(1):49-59. doi:10.1097/BRS.0b013e3181909558.
25. Taskaynatan MA, Tezel K, Yavuz F, et al. The effectiveness of transforaminal epidural steroid injection in patients with radicular low back pain due to lumbar disc herniation two years after treatment. *J Back Musculoskelet Rehabil.* 2015;28(3):447-451. doi:10.3233/BMR-140539.
26. Verheijen EJA, Bonke CA, Amorij, et al. Epidural steroid compared to placebo injection for sciatica: a systematic review and meta-analysis. *Euro Spine J.* 2021 May;30:3255-3264. doi:10.1007/s00586-021-06854-9.

27. Watters WC 3rd, Resnick DK, Eck JC, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion. J Neurosurg Spine. 2014;21(1):79-90. doi:10.3171/2014.4.SPINE14281.
28. Woo JH, Park HS. Cervical transforaminal epidural block using low-dose local anesthetic: a prospective, randomized, double-blind study. Pain Med. 2015;16(1):61-67. doi:10.1111/pme.12582.
29. Yang S, Kim W, Kong HH, et al. Epidural steroid injection versus conservative treatment for patients with lumbosacral radicular pain: a meta-analysis of randomized controlled trials. Med. 2020 Jul;99(30):e21283. doi:10.1097/MD.00000000000021283.

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