# MEDICAL POLICY STATEMENT
# Georgia Medicaid

| Policy Name & Number | Date Effective |
|---|---|
| Epidural Steroid Injections-GA MCD-MM-0217 | 08/01/2022-06/30/2023 |
| **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.



Table of Contents

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 it lasts between four and twelve weeks and chronic when it persists 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 multimodality plan of care. Multimodality care plans include both active and inactive conservative therapies.
  - **Active Conservative Therapies** - Include physical therapy, occupational therapy, and/or a physician supervised home exercise program (HEP)
  - **Inactive Conservative Therapies** - Include rest, ice, heat, medical devices, TENS unit, and/or prescription medications.
- **Epidural Steroid Injections** - Administration of steroids via a needle inserted in the space between the ligamentum flavum and the dura. The injections may be admistered by translaminar, tranforaminal, or caudal approach.
  - **"Successful" Epidural Steroid Injection** - An injection that achieves greater than 50% reduction in pain within the duration of effectiveness for the anesthetic

used and at least 50% improvement in function accomplished by the first or second injection.

- **"Unsuccessful" Epidural Steroid Injection** - An injection that did not achieve greater than 50% reduction in pain within the duration of effectiveness for the anesthetic used nor at least 50% improvement in function accomplished by the first or second injection. This may occur because an epidural is not effective therapy for the patient's pain syndrome, or due to technical reasons which may or may not be clarified by radiologic images of the pain-generating pathology.

- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** - A durable medical equipment device dispensed by prescription. 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.

D. Policy

I. Epidural Steroid Injections for labor and delivery in childbirth or post-surgical pain do not require prior authorization.

II. Initial Injection

A. CareSource considers epidural steroid injections medically necessary for the management of chronic pain when **ALL** the following clinical criteria are met:

1. Pain is located in either the cervical, thoracic, or lumbar spine and is predominantly radiating or shooting in nature;
2. The patient has documentation, including dates of service, addressing ACTIVE conservative therapy as part of a multimodality comprehensive plan of care in the medical record, meeting **ONE** of the following criteria:
   a. The patient has received ACTIVE conservative therapy lasting for 6 weeks within the past 6 months including **ONE** of the following:
      01. Physical therapy;
      02. Occupational therapy; or
      03. A physician supervised Home Exercise Program (HEP), including the following two requirements:
         (1). An exercise prescription and/or plan documented in the medical record;
         (2). A follow up documented in the medical record regarding completion of an HEP (after suitable 6-week period), or inability to complete a 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 "inability to complete");
   b. The medical record documents **at least ONE** of the following exceptions to the 6 weeks conservative therapy requirement in the past 6 months which may include:
      1) Pain from Herpes Zoster as the indication for the procedure;
      2) Moderate pain with significant functional loss at work or home;
      3) Severe pain unresponsive to outpatient medical management;
      4) Inability to tolerate non-surgical, non-injection care due to co- existing medical condition(s);
      5) Prior successful injections for same specific condition with relief of at least 3 months' duration;

3. The patient has documentation, including dates of service, addressing INACTIVE conservative therapy as part of a multimodality comprehensive plan of care in the medical record lasting for 6 weeks within the past 6 months including ONE of the following:
   a. Rest;
   b. Ice;
   c. Heat;
   d. Medical devices;
   e. TENS unit use as defined in this policy:
      01. If a TENS unit is part of the care plan, the frequency of use, and duration of use with dates must be documented in the medical record. General statements in the medical record such as "Patient has a TENS unit" do not document use, and will not suffice to meet this policy criterion;
   f. Pain medications (prescription or over the counter) (e.g., non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen). Opioid narcotics are not required for consideration.

III. Subsequent Injections
CareSource considered repeat epidural steroid injections medically necessary when **ALL** the following criteria are met:
   A. The patient continues to have ongoing pain or documented functional disability (≥ 6 on a scale of 0 to 10);
   B. The patient has had no more than 6 epidural injections of any type in the past consecutive 12 months and meets **ONE** of the following criteria:
      1. The patient has experienced at least a greater than 50% reduction in pain and at least a 50% improvement in function by the first or second injection, even if pain relapsed. Documentation of suitable pain score reduction and functional improvements or other documented rationale is required;
      2. There are carefully documented reasons that it is appropriate to repeat the procedure, even if no prior improvement;
      3. The patient has persistent pain in which the imaging findings suggest that the pathology should respond to corticosteroid injection;
   C. There must be at least 3 weeks between injections in order to reach pharmacodynamic effect;
   D. No more than 3 procedures in a 12-week period of time per region are considered medically appropriate;
   E. The patient must be actively engaged in other forms of conservative non-operative treatment, unless pain prevents the patient from participating in conservative therapy, which must be documented in the contemporaneous medical record.

IV. Frequency Restrictions
   A. The maximum number of all types of epidural injections a member can receive in a rolling 12 months is a total of 6, regardless of the number of levels involved.
   B. Requests for repeat injections beyond 3 weeks without documentation of suitable pain score reduction and functional improvements, or other documented rationale as described in this policy will not be covered.

C. For interlaminar or caudal epidural injections, more than 1 epidural injection per treatment date will not be authorized.
D. For transforaminal epidurals or selective nerve root blocks (SNRB's), more than 2 vertebral levels per treatment date, whether unilateral or bilateral, will not be authorized and will not be covered.

V. Exclusions/Limitations
A. 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.
B. Ultrasound guidance for epidural injections is considered inappropriate.
C. 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.
D. Coverage for monitored anesthesia is not considered medically necessary and will not be provided.
E. If anesthesia services are provided, they must be delivered by CareSource credentialed providers, including anesthesiologists and/or Certified Registered Nurse Anesthetist (CRNA).
F. 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.
1. If a device is not functioning properly, an escalation in pain may warrant evaluation and management of the implanted device.
G. 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. No local spinal or paraspinal malignancy;
3. No coagulopathy;
4. No current use of anticoagulants or antiplatelet therapy;
5. No local or systemic infection;
6. Selected body imaging evaluations to evaluate the area of pain, particularly for acute pain, or to evaluate escalations in chronic baseline pain.
a. 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.
H. 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 disorders or anti-coagulation therapy.

VI. Inconclusive or Non-Supportive Evidence
A. Evidence reported in the medical literature, however, 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

| DATES | | ACTION |
|---|---|---|
| **Date Issued** | 02/22/2018 | New Policy |
| **Date Revised** | 03/06/2019<br><br>05/13/2020<br><br><br>04/28/2021<br><br><br>03/16/2022 | Annual Update: Removed chiropractic care as a conservative therapy option.<br>Annual Update: No policy criteria revisions. Only formatting and restructuring of policy information.<br>Annual Update: Removed PA language.<br>Reorganization of clinical criteria, but no content changes.<br>Annual Review: updated formatting and references, consolidated background and evidence, separated indications into initial and subsequent injections, frequency restrictions, and limitations/exclusions.<br>Added contraindications |
| **Date Effective** | 08/01/2022 | |
| **Date Archived** | 06/30/2023 | 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. |

## 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.

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

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. Retrieved March 10, 2022 from www.ncbi.nlm.nih.gov.
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. Retrieved March 10, 2022 from www.ncbi.nlm.nih.gov.
5. Chou R. (2021 June 11). Subacute and chronic low back pain: nonsurgical interventional treatment. UpToDate. Retrieved March 10, 2022 from 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 fluroscopically 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:410.1093/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.0000000000021283.

GA-MED-P-1271918 Issue Date 02/22/2018 Approved DCH 04/29/2022



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