MEDICAL POLICY STATEMENT
GEORGIA MEDICAID

Original Issue Date	Next Annual Review	Effective Date
02/22/2018	07/15/2019	07/15/2018
Policy Name		**Policy Number**
Epidural Steroid Injections (Interlaminar, Transforaminal, or Caudal Epidural Injections)		MM-0217
Policy Type		
MEDICAL	Administrative / Pharmacy	Reimbursement

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) 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 CSMG Co. and its affiliates (including CareSource) 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

Contents of Policy

A. SUBJECT

Epidural Steroid Injections (Interlaminar, Transforaminal, or Caudal Epidural Injections)

B. BACKGROUND

Interventional procedures for management of acute and chronic pain are part of a comprehensive pain management care plan that incorporates conservative treatment in a multimodality approach. 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. Interventional procedures for the management of pain unresponsive to conservative treatment should be provided only by physicians qualified to deliver these health services.

For pain relief, epidural steroid injections (ESIs) can be performed anatomically in the posterior midline between adjacent vertebral bodies (interlaminar [IL] epidural), laterally at the intervertebral foramen near the spinal nerve root ganglion complex of neuronal cell bodies (transforaminal [TF] epidural), or at the terminus of the epidural space near the sacrococcygeal area (caudal epidural injection). Interlaminar and transforaminal ESI's should be used only in the presence of predominant radiculopathy. Many systematic reviews evaluate available evidence for epidural injections to treat pain, with levels of evidence classified as good, fair, or limited (or poor) based on quality-of-evidence criteria developed by the AHRQ and USPSTF. Imaging studies of the symptomatic region are performed to evaluate suspected specific causes of spinal pain, (for example herniated disc, spinal stenosis, or degenerative vertebral disease; and to rule out fracture or tumor). Evidence supports that clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain. However, clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination.

Overall, current research continues to suggest that ESIs remain a treatment for radicular pain, with a limited duration of benefit. This treatment approach appears to improve pain while natural healing occurs. There has been little evidence that this effect extends to improvement of function. Reports indicate that an average of 1 to 3 injections achieves significant improvement in pain. After initial injection, the need for a subsequent injection is generally based upon clinical response to the initial injection. There is limited evidence or consensus on timing and number of epidural steroid injections exists to identify safe and effective management. Reasons for repeat injections must be carefully documented and may include: 1) significant improvement, even if relapses, 2) technical reasons in the absence of an improvement, and 3) persistent pain with imaging findings identifying pathology that should respond to an ESI. In the absence of a compelling technical reason, it is not appropriate to repeat a procedure a third time if there has been no improvement from the two preceding injections. A neurology specialty society working group concluded that, while epidural steroids may result in transient improvement in radicular lumbosacral pain for 2 to 6 weeks post injection, there was no significant impact on function, long-term pain relief (beyond 3 months), or the need for surgery. A published evidence-based review concluded that there is "limited evidence to suggest guidelines for frequency and timing of ESIs, and additional RCTs are required for adequate determination of this goal". "Before the introduction of fluoroscopic guidance for ESIs, there was commonly a recommendation for a second injection. Repeat injection for partial response was generally suggested, although there was little evidence of why it was thought a second injection might be helpful. There are many possibilities for why a repeat injection might be necessary, but none of them has been fully investigated."

Manchikanti et al state that there is no consensus among interventional pain management specialists regarding the type, dosage, frequency, total number of injections, or other

interventions. The authors recommend that administration be based solely on patient response, safety profile of the drug, and pharmacological and chemical properties, such as duration of action and suppression of adrenals. Manchikanti recommends that the suggested frequency of epidural injections should be 2 months or longer between each injection provided that at least 50% relief is obtained for 6 to 8 weeks. Injections should be limited to a maximum of 4 to 6 times per year.

Typical causes of pain that may respond to epidural injection include:

- Degenerative vertebral changes
- Spinal stenosis
- Disc herniation
- Post-laminectomy syndrome with radiculopathy
- Post-traumatic neuropathy of the spinal roots
- Acute obstetric, post traumatic and postoperative pain
- Advanced cancer pain, primary or metastatic
- Acute/sub-acute and chronic pain syndrome including cervical, thoracic and lumbar pain with radiculopathy and intervertebral disc disease (with neuritis or radiculitis) with or without myelopathy that has failed to respond to adequate conservative management.
- Nerve root injuries and neuropathic pain and post traumatic including post laminectomy syndrome (failed back syndrome).
- Spinal cord myelopathy
- Complex regional pain syndrome (CRPS)
- Epidural scarring from prior infection, hemorrhage and/or surgery
- Multiple rib fractures
- Vertebral compression fractures
- Post herpetic neuralgia and herpes zoster
- Phantom limb pain

C. DEFINITIONS

- **Epidural steroid injections:** for persistent or chronic radicular pain involve injection of corticosteroid, local anesthetic, opioid, or combination medication into the epidural space, requiring fluoroscopic imaging and injection of an appropriate agent to achieve a selective reproducible blockage of a specific nerve root. Anatomic locations for epidural injections may involve the interlaminar space at the midline between vertebral bodies, caudal epidural injections, or transforaminal epidural injections. Epidural injections may be diagnostic for localizing and determining the cause of radiating pain and providing short term pain relief.
- **Diagnostic** interlaminar or caudal epidural steroid injections are seldom used. Although the medication injected can sometimes be confined to a limited area, bilateral effects and spread to adjacent levels often occur. When a diagnostic spinal nerve block is performed, post-block assessment of percentage pain relief must be documented. Diagnostic transforaminal epidural injections are appropriate for the following purposes:
  - To differentiate the level of radicular nerve root pain.
  - To differentiate radicular from non-radicular pain
  - To evaluate a discrepancy between imaging studies and clinical findings
  - To identify the source of pain in the presence of multi-level nerve root compression
  - To identify the level of pathology at a previous operative site
- **Therapeutic** interlaminar/transforaminal or caudal epidural injections and infusions of opioid, local anesthetic, or other medications may be used for the treatment of acute and chronic pain or cancer pain.
- **Conservative therapy** is a multimodality plan of care. Start and end dates in the medical record substantiate duration of treatment. **Multimodality care plans include BOTH of the following:**
  - **Active conservative therapies** such as physical therapy, occupational therapy, a physician supervised home exercise program (HEP), or chiropractic care

- **Home Exercise Program (HEP):** includes two components that are both required to meet CareSource policy for completion of conservative therapy:
  - Information provided for an exercise prescription and/or plan documented in the medical record AND follow up documented in the medical record with member with information provided regarding completion of HEP (after suitable six (6) week period), or inability to complete 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")
- **Inactive conservative therapies** such as rest, ice, heat, medical devices, acupuncture, TENS unit, prescription medications.
  - 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.

- A **TENS unit is a Transcutaneous Electrical Nerve Stimulator,** a durable medical equipment device dispensed by prescription. It 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.
- A **"successful" epidural steroid injection** in this policy is defined as 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.
- An **"unsuccessful" epidural steroid injection** in this policy is defined as 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.

D. POLICY

Criteria

A prior authorization is required for each epidural injection for pain management, excluding labor and delivery in childbirth.

I. Epidural corticosteroid injections may be indicated when **ALL of the following** are present:
   A. Pain is located in either the cervical, thoracic, or lumbar spine and *is predominantly* radiating or shooting in nature.
   B. The patient's epidural injection history in the past consecutive 12 months includes less than 6 epidural injections
      1. The patient has no epidural injections in the past consecutive 12 months
      2. The patient has at least 1 and no more than 6 epidural injections of any type in the past consecutive 12 months and meets **ONE of the following** criteria
         2.1. greater than 50% reduction in pain and at least 50% improvement in function by the first or second injection, even if pain relapsed
         2.2. Carefully documented technical reasons that it is appropriate to repeat the procedure even if no prior improvement
         2.3. Patients with persistent pain in whom the imaging findings suggest that the pathology should respond to corticosteroid injection
   C. The patient has documentation addressing ACTIVE conservative therapy as part of a multimodality comprehensive plan of care in the medical record that includes **ONE of the following:**
      1. The patient has received ACTIVE conservative therapy lasting for six (6) weeks or within the past six (6) months with start and end dates in the medical record substantiating the duration of treatment including **ONE of the following:**
         1.1 Active therapies contain one of the following for a minimum duration of 6 weeks
            a. physical therapy

b. occupational therapy
c. a physician supervised home exercise program (HEP) as defined in CareSource policy
d. chiropractic care

2. Or, 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:
   2.1 pain from Herpes Zoster as the indication for the procedure
   2.2 at least moderate pain with significant functional loss at work or home
   2.3 severe pain unresponsive to outpatient medical management
   2.4 inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s)
   2.5 prior successful injections for same specific condition with relief of at least 3 months' duration (start and end dates are documented in the medical record).
3. PASSIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record lasting for six (6) weeks or more within the past six (6) months with start and end dates in the medical record substantiating the duration of treatment that includes at least **ONE of the following:**
   3.1 rest
   3.2 ice
   3.3 heat
   3.4 medical devices
   3.5 acupuncture
   3.6 TENS unit use as defined in CareSource policy
   3.7 prescription pain medications

II. For Interlaminar or Caudal Epidural Injections
   A. More than 1 epidural injection per treatment date will not be authorized.
   B. Bilateral injections and modifiers will not be recognized and coverage will be denied.
   C. Prior authorization will be required for each epidural injection by the same or any physician.
   D. Repeat injections sooner than 3 weeks may not reach pharmacodynamic effect of the corticosteroid and will not be covered.
   E. Requests for repeat injections before 3 weeks without documentation of suitable pain score reduction and functional improvements, or other documented rationale as described in "Policy" section will not be covered.

III. For Transforaminal Epidurals or Selective Nerve Root Blocks (SNRB's)
   A. Transforaminal Epidurals provided to more than 2 vertebral levels per treatment date, whether unilateral or bilateral, will not be authorized and will not be covered.
   B. Bilateral injections require the appropriate modifier
   C. Prior authorization is required for treatment sessions per each spine region.
   D. Repeat injections sooner than 3 weeks may not reach pharmacodynamic effect of the corticosteroid and will not be covered.
   E Requests for repeat injections before 3 weeks without documentation of suitable pain score reduction and functional improvements, or other documented rationale as described in "Policy" section will not be covered.

The maximum epidurals 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.

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. Ultrasound guidance for epidural injections is inappropriate.

Conscious sedation, if required for co-morbidities or patient/physician preference, may be provided without prior authorization but services will be considered part of the procedure and are not eligible for additional reimbursement if administered by a second provider. Coverage for monitored anesthesia will not be provided as not medically necessary. If anesthesia services are provided they must be delivered by CareSource credentialed providers, including anesthesiologists and/or CRNAs.

Patients with indwelling implanted spinal cord stimulators or pain pumps must have a device interrogation report and an interpretation submitted with medical records for a 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.

Clinical evaluations and care of candidate patients for epidural injections should also address, at the discretion of the physician, according to prevailing standards of medical care:

A. No acute spinal cord compression
B. No local spinal or paraspinal malignancy
C. No coagulopathy
D. No current use of anticoagulants or antiplatelet therapy
E. No local or systemic infection
    1. Selected body imaging evaluations to evaluate the area of pain, particularly for acute pain, or to evaluate escalations in chronic baseline pain. 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.

IV. Frequency of Repeat Therapeutic Injections

Epidural injections may be repeated only as medically necessary and with proof that: prior injection had a positive response by significantly decreasing pain; the patient continues to have ongoing pain or documented functional disability (≥ 6 on a scale of 0 to 10); and the patient is 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);* and injections meet the following criteria:

A. There must be at least 21 days between injections;
B. No more than 3 procedures in a 12-week period of time per region

V. Anatomic considerations

For chronic neck pain, evidence for cervical epidural injections varies; populations studied are heterogeneous; and controlled trials are limited. For cervical axial or discogenic pain, spinal stenosis, and post-surgery syndrome, evidence was only fair for the use of local anesthetic with or without steroids. An interdisciplinary approach may provide more benefit than injections alone. Despite a paucity of evidence, cervical epidural injections are one of the most commonly performed nonsurgical interventions in the management of chronic axial or disc-related neck pain. A recent randomized trial for cervical interlaminar epidurals demonstrated safety and efficacy.

Cervical interlaminar (IL) ESIs are associated with a rare risk of catastrophic neurologic injury. All cervical interlaminar (IL) epidural steroid injections should be performed using image-guidance, with appropriate antero-posterior, lateral or contra-lateral oblique views, and a test- dose of contrast medium. Cervical interlaminar epidural steroid injections are recommended to be performed at C7-T1, but preferably not higher than the C6-C7 level. No cervical interlaminar epidural steroid injection should be undertaken, at any segmental level, prior to reviewing imaging studies to demonstrate adequate epidural space for needle placement at the intended level. Cervical and lumbar IL-ESIs can be performed without contrast in patients with documented contra-indication(s) (e.g. significant history of contrast allergy or anaphylactic reaction).

Lumbar transforaminal ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction angiography (DSA), in a frontal plane, prior to injecting any substance that may be hazardous to the patient. A non-particulate steroid (e.g. dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections however in some situations particulate steroids may also be used. All *lumbar interlaminar* ESIs should be performed using image-guidance, with appropriate AP, lateral or contralateral oblique views, and a test-dose of contrast medium.

Evidence for the efficacy of *caudal epidurals* is good for short- and long-term relief of chronic pain due to disc herniation or radiculitis with local anesthetic and steroids. Systematic review also provided fair evidence for caudal epidural injections in managing chronic axial or discogenic pain, spinal stenosis, and post-surgery, or failed back, syndrome.

For lumbar spine pain present for 6 months or more, an evidence-based guideline assessing the efficacy of caudal, lumbar interlaminar, and lumbar transforaminal epidural injections found good evidence in support of the interventions for radiculitis from disk herniation. Lumbar ESIs may be more effective than caudal ESIs for treating low back pain. A neurosurgery specialty society workgroup recommends epidural corticosteroid injections as a therapy to provide temporary symptomatic pain relief in selected patients. Their report conceded that studies show results for radicular pain are better than for isolated back pain.

Inconclusive or Non-Supportive Evidence

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.

Cervical TFs are associated with a high risk but limited efficacy. In contrast, lumbar TFs are associated with moderate risk with some efficacy. Cervical, thoracic, and lumbar IL epidurals, as well as caudal epidurals, are associated with low risk with some efficacy. A systematic review for *thoracic* epidural injection in treating chronic thoracic pain considered the evidence for intervention fair and limited for post- thoracotomy pain. Interventions in managing chronic thoracic pain are also less frequent, contributing to the paucity of literature for evidence-based practice.

In April 2014, the U.S. Food and Drug Administration (FDA) regulatory branch, in a Drug Safety Communication, warned that “injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The effectiveness and safety of epidural administration of corticosteroids have not been established, and the FDA has not approved corticosteroids for this use.” Off-label use of injectable corticosteroids (ICs) for epidural injections is a common practice in the U.S.

The FDA launched the Safe Use Initiative in 2009 Subsequent workgroups provided evidence-based recommendations on interventional pain procedures. Modifications have occurred with attempts to adhere to The Institute of Medicine’s eight standards for the development of systematic guidelines, though not without some controversy. After the FDA’s warning in April, 2014, its affiliated Multi-society Pain Workgroup (MPW) later approved 17 recommendations for interventional pain, these were met with criticisms published by the International Spine Intervention Society (ISIS) and the American Society for Interventional Pain Physicians (ASIPP).

In November, 2014, the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) of the FDA reviewed the risk of serious neurologic adverse reactions associated with epidural steroid injections (ESI) for pain management administered to reduce inflammation. The committee supported, by a vote of 15-Yes to 7-No, with one abstention, the addition of a contraindication to the labeling of injectable corticosteroids for use in

epidural administration. The committee specifically supported a contraindication for the use of the transforaminal approach to the cervical spine for ICs that are suspensions (otherwise known as particulate ICs).

For both cervical and lumbar transforaminal 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.

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 (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

HCPCS
CPT

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

G. REVIEW/REVISION HISTORY

DATES		ACTION
Date Issued	02/22/2018	New Policy.
Date Revised		
Date Effective	07/15/2018	

H. REFERENCES

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