



MEDICAL POLICY STATEMENT KENTUCKY MARKETPLACE

Policy Name	Policy Number	Date Effective
Epidural Steroid Injections	MM-0161	08/01/2021-06/30/2022
Policy Type		
MEDICAL	Administrative	Pharmacy
		Reimbursement

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.....	2
B. Background.....	2
C. Definitions	3
D. Policy.....	3
E. Conditions of Coverage	10
F. Related Polices/Rules.....	10
G. Review/Revision History.....	10
H. References.....	10



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 patient's symptoms are categorized as chronic. Chronic pain is defined by the International Association for the Study of Pain as: "pain that persists beyond normal tissue healing time, which is assumed to be three months".

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.

Professional Society Recommendations

The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

American College of Physicians (ACP) (April 2017)

The ACP's recommendations for Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Practice Guideline are as follows:

- Clinicians and patients should select nonpharmacological treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desire, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence);
- Clinicians and patients should initially select nonpharmacological treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relation, electromyography biofeedback, low –level laser therapy, operant therapy, cognitive behavioral therapy or spinal manipulation; and
- In patients with chronic low back pain who have had an inadequate response to nonpharmacological therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients.



American Society of Anesthesiologists (ASA) (2010)

The ASA Task Force on Pain Management issued general practice guidelines for chronic pain management in 2010 as follows:

- Epidural steroid injections with or without local anesthetics may be used as part of a multimodal treatment regimen to provide pain relief in selected patients with radicular pain or radiculopathy; and
- Transforaminal epidural injections should be performed with appropriate image guidance to confirm correct needle position and spread of contrast before injecting a therapeutic substance.

C. Definitions

- **Epidural Steroid Injections** - administration of steroids via a needle inserted in the space between the ligamentum flavum and the dura. The injections may be administered by translaminar, tranforaminal or caudal approach.
- **Conservative Therapy** - is a multimodality plan of care. Multimodality care plans include ALL of the following:
 - **Active Conservative Therapies** - such as physical therapy, occupational therapy, a physician supervised home exercise program (HEP) or chiropractic care.
 - **Inactive Conservative Therapies** - such as rest, ice, heat, medical devices and TENS unit and prescription medications.
- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** - is 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.
- **“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.
- **“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

- I. Epidural Steroid Injections
 - A. CareSource considers Epidural Steroid Injections medically necessary when all of the clinical criteria in this policy are met.
 - B. The maximum epidurals of all types of epidural injections a member can receive in a rolling twelve (12) months is a total of six (6), regardless of the number of levels involved.
 1. 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. Epidural corticosteroid injections may be indicated when **ALL** of the following clinical criteria are met:



1. Pain is located in either the cervical, thoracic or lumbar spine and is
2. predominantly radiating or shooting in nature.
The patient's epidural injection history in the past consecutive twelve (12) months includes less than six (6) epidural injections, including:
 - a. The patient has had no epidural injections in the past consecutive twelve (12) months OR
 - b. The patient has had at least one (1), but no more than six (6) epidural injections of any type in the past consecutive twelve (12) months and meets ONE of the following criteria:
 01. 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;
 02. There are carefully documented reasons that it is appropriate to repeat the procedure, even if no prior improvement; and/or
 03. The patient has persistent pain in which the imaging findings suggest that the pathology should respond to corticosteroid injection.
3. 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:
 - a. The patient has received ACTIVE conservative therapy lasting for six (6) weeks within the past six (6) months including ONE of the following:
 01. Physical therapy;
 02. Occupational therapy;
 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 six (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").
 04. Chiropractic care. OR
 - b. The medical record documents at least ONE (1) of the following exceptions to the six (6) weeks conservative therapy requirement in the past six (6) months which may include:
 01. Pain from Herpes Zoster as the indication for the procedure;
 02. Moderate pain with significant functional loss at work or home;
 03. Severe pain unresponsive to outpatient medical management;
 04. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s); or
 05. Prior successful injections for same specific condition with relief of at least three (3) months' duration.
4. 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.
 - a. The patient has received INACTIVE conservative therapy lasting for six (6) weeks within the past six (6) months including ONE of the following:
 01. Rest;



- 02. Ice;
- 03. Heat;
- 04. Medical devices;
- 05. TENS unit use as defined in this policy;
 - (1) 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.
- 06. Pain medications (prescription or over the counter) such as: non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen. Opioid narcotics are not required for consideration.
- D. For Interlaminar or Caudal Epidural Injections
 - 1. More than one (1) epidural injection per treatment date will not be authorized.
- E. For Transforaminal Epidurals or Selective Nerve Root Blocks (SNRB's)
 - 1. Transforaminal Epidurals provided to more than two (2) vertebral levels per treatment date, whether unilateral or bilateral, will not be authorized and will not be covered..
- F. Repeat Therapeutic Injections
 - 1. Epidural injections may be repeated only when considered medically necessary and the following criteria is met:
 - a. There must be at least 3 weeks between injections in order to reach pharmacodynamics effect;
 - b. Prior injection had a positive response by decreasing pain and increasing functional improvement by at least 50%. Documentation of suitable pain score reduction and functional improvements or other documented rationale is required.
 - c. No more than three (3) procedures in a twelve (12)-week period of time per region;
 - d. The patient continues to have ongoing pain or documented functional disability (≥ 6 on a scale of 0 to 10); and
 - e. The patient is actively engaged in other forms of conservative non-operative treatment;
 - 01. Unless pain prevents the patient from participating in conservative therapy, which must be documented in the contemporaneous medical record.
- G. 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.
 - 1. Ultrasound guidance for epidural injections is considered inappropriate.
- H. 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.
 - 1. Coverage for monitored anesthesia is not considered medically necessary and will not be provided
 - a. If anesthesia services are provided they must be delivered by CareSource credentialed providers, including anesthesiologists and/or Certified Registered Nurse Anesthetists (CRNA).



- I. 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.
- J. 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; and
 - 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.

II. Clinical Evidence

Anatomic considerations

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 Agency for Healthcare Research and Quality and United States Preventive Services Task Force (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.

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.

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.

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

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.

A recent revision to the Institute for Clinical Systems Improvement (ICSI) emphasized “cautious and responsible use of opioids in the presence of acute or subacute low back pain.” CareSource does not consider prescribed oral opioid(s) as



a mandatory component of multidisciplinary, multimodality, comprehensive pain management. The ICSI guidelines revision also urged increasing the utilization of validated pain and function scales to help differentiate treatment approaches in order to improve the patient's ability to function. Finally the ICSI recommended clinicians to “increase the use of collaborative decision-making to allow patients to make more informed decisions about their care.

III. 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

F. Related Policies/Rules

G. Review/Revision History

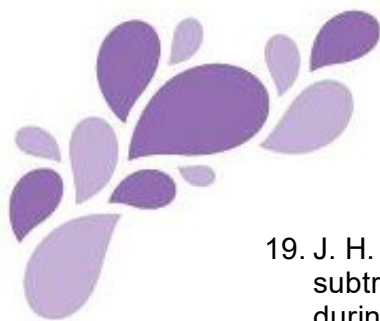
DATES		ACTION
Date Issued	01/27/2015	New Policy
Date Revised	03/06/2019	Annual Update: Removed "start and end dates". Addition of PA clarification and documentation requirements.
	05/13/2020	Annual Update: Updated language around benefit limits.
	04/28/2021	Annual Update: Removed PA language
Date Effective	08/01/2021	
Date Archived	06/30/2022	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

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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.

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