MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
01/27/2015	**01/27/2017**	**01/27/2016**
Policy Name		**Policy Number**
Epidural Steroid Injections (Interlaminar, Transforaminal, or Caudal Epidural Injections)		**MM-0007**
Policy Type		
☒ **Medical**	☐ **Administrative**	☐ **Payment**

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A. SUBJECT

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

B. BACKGROUND

For pain relief, epidural injections of local anesthetic, corticosteroids, or both agents, 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)[1, 2]. 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. [3-5] Imaging studies of the symptomatic region evaluate causes of spinal pain, (examples include herniated disc, spinal stenosis, or degenerative vertebral disease; and rule out fracture or tumor).

Epidural injections are indicated for management of acute and subacute pain as part of a comprehensive pain management program. Interventional procedures for management of pain should be part of a comprehensive pain management care plan that incorporates an initial trial of conservative treatment utilizing appropriate medications, physical therapy modalities and behavioral support as needed. Interventional procedures for the management of pain unresponsive to conservative treatment should be provided only by physicians qualified to deliver these health services.[6-8]

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.[9, 10] Limited evidence or consensus on timing and number of

epidural steroid injections exists to identify safe and effective management. 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.[11]

Typical causes of pain that may respond to epidural injection [8] include:

- degenerative vertebral changes
- spinal stenosis
- disc herniation
- post-laminectomy syndrome with radiculopathy
- post-traumatic neuropathy of the spinal roots

C. DEFINITIONS

Epidural steroid injections for persistent or chronic radicular pain involve injection of medication into the epidural space, potentially at more than one spinal level; this requires 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.

D. POLICY

Criteria

A member is considered a candidate for epidural steroid injection therapy if the member has the appropriate clinical findings above, and has had a limited number of prior epidural steroid injections, as indicated by 1 or more of the following:

- No prior history of epidural steroid injections
- Prior history of not more than a series of 2 epidural steroid injections, at least 3 weeks apart if inadequate pain relief in same region (e.g., cervical or lumbar region)
- Prior history of not more than 3 epidural steroid injections with history of 3 months or more pain relief from prior injections

For chronic neck pain, evidence for cervical epidural injections varies, populations studied are heterogenous, and controlled trials are limited.[12, 13] 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.[7, 14] An interdisciplinary approach may provide more benefit than injections alone.[2] 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.[13] A recent randomized trial for cervical interlaminar epidurals demonstrated safety and efficacy. [13]

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.[15] Cervical interlaminar epidural steroid injections are recommended to be performed at C7-T1, but preferably not higher than the C6-C7 level.[15] 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 [16, 17] 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.[18-20]

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.[21]

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.[7] Lumbar ESIs may be more effective than caudal ESIs for treating low back pain.[22] 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.[23, 24]

A “successful” epidural steroid therapy includes greater than 50% reduction in pain within the duration of effectiveness for the anesthetic used and at least 50% improvement in function by the first or second injection. Epidural injections are indicated for management of acute and subacute pain as part of a comprehensive pain management program:

For Interlaminar or Caudal Epidural Injections (CPTs 62310-62311)

- More than 1 epidural injection per treatment date will not be authorized.
- Bilateral injections and modifiers will not be recognized and coverage will be denied.
- Prior authorization will be required for each epidural injection by the same or any physician.
- Greater than 3 interlaminar epidural injections within a *rolling 12 month* period will not be covered.
- Repeat injections sooner than 3 weeks may not reach pharmacodynamic effect of the corticosteroid and will not be covered.
- Requests for repeat injections before 3 weeks without documentation of suitable pain score reduction and functional improvements will not be covered.

For Transforaminal Epidurals or Selective Nerve Root Blocks (SNRB’s) (CPTs 64479-64484)

- 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.
- Bilateral injections require the appropriate modifier
- Prior authorization is required for treatment sessions per each spine region.
- Greater than 3 transforaminal epidural injections within a *rolling 12 months* will not be covered.
- Repeat injections sooner than 3 weeks may not reach pharmacodynamic effect of the corticosteroid and will not be covered.
- Requests for repeat injections beyond 3 weeks of injection without suitable documentation of pain score and functional status will not be covered.

Image guidance and any injection of contrast are inclusive components of epidural injections.

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. Monitored anesthesia will be denied for all epidural injections as not medically necessary.
If anesthesia services are provided they must be delivered by CareSource contracted and credentialed providers, including anesthesiologists and/or CRNAs.

Clinical evaluations and care of candidate patients for epidural injections should also address:

- No acute spinal cord compression
- No local spinal or paraspinal malignancy
- No coagulopathy
- No current use of anticoagulants or antiplatelet therapy
- No local or systemic infection

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 and are not covered..[12, 25-27] In contrast, lumbar TFs are associated with moderate risk with some efficacy.[28-30] Cervical, thoracic, and lumbar IL epidurals, as well as caudal epidurals, are associated with low risk with some efficacy.[2, 12, 22, 31-36] A systematic review for *thoracic* epidural injection in treating chronic thoracic pain considered the evidence for intervention fair and limited for post-thoracotomy pain.[37] Interventions in managing chronic thoracic pain are also less frequent, contributing to the paucity of literature for evidence-based practice. [38]

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.[39]

The FDA launched the Safe Use Initiative in 2009[40] 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,[41] though not without some controversy.[42-44] After the FDA’s warning in April, 2014, its affiliated Multi-society Pain Workgroup (MPW) later approved 17 recommendations for interventional pain,[45]; these were met with criticisms published by the International Spine Intervention Society (ISIS) and the American Society for Interventional Pain Physicians (ASIPP).[39, 44]

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.[27] 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.[27] Cervical transforaminal injections are risky because arterial supply may be densely concentrated in and around the intervertebral foramen.[46] 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 [46] should be used.

Cervical transforaminal ESIs have sparse literature for cervical radicular pain,[12] 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.[26, 39, 47]

Cervical interlaminar epidural is permitted (CPT 62310), BUT NOT transforaminal epidurals in the cervical or thoracic spine (CPTs 64479 and 64480), as cervical TF's are contraindicated per the FDA, and thoracic TF's have little or no published evidence to support their use for chronic pain.

Clinical Indications for Procedure

A. Epidural corticosteroid injections may be indicated when **2 or more of the following** are present:
   1. Pain is located in either the cervical or lumbar spine and is radiating or shooting in nature.
   2. The patient's epidural injection history in the past 12 months includes 1 or 2 epidural injection treatment sessions
   3. The patient has had no epidural injection history in the past 12 months and **ALL of the following** apply:
      3.1 The patient has received conservative treatment lasting for 3 months or longer within the past 6 months, including **2 or more of the following:**
         a. Physical therapy sessions
         b. Chiropractor visits
         c. Exercise program
         d. Medications for pain
      3.2 Relevant imaging studies of the painful spinal region were completed within the 12 months prior to the date of this request.

CONDITIONS OF COVERAGE

CPT 62310, 62311, 64479, 64480, 64483, 64484, 0228T, 0229T, 0230T, 0231T

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued:	01/27/2015
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Date Revised:	07/28/2015 – Criteria changes

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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.