

Subject: Epidural Steroid Injections (ESI) for Back and Neck Pain		Original Effective Date: 7/5/2007
Policy Number: MCR-032	Revision Date(s): 12/17/2008, 12/14/11, 2/27/13, 12/11/13, 6/12/14, 12/16/15, 7/25/17 <i>This MCR is no longer scheduled for revisions.</i>	
Review Date: 12/16/15, 9/15/16, 3/8/18		
MCPC Approval Date: 3/8/18		

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Review (MCR) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ⁵²

An epidural steroid injection (ESI) is the administration of medication most commonly an anesthetic and steroid into the epidural space or adjacent areas of the spinal cord to treat inflammation resulting from conditions that affect the nerve roots. There are three injection techniques for performing epidural steroid injection:

- *Translaminar, translumbar or interlaminar* -The most common approach for performing an epidural injection. The needle placement is between the spinous processes of two vertebrae into the posterior epidural space.
- *Caudal* - This technique has a smaller incidence of spinal dural puncture. The needle placement is through a small opening in the caudal canal at the base of the spinal canal just above the tailbone into the epidural space to treat the cauda equina and lumbar spinal nerves.
- *Transforaminal*-This is the most common technique for diagnostic purposes and for the neck region. The needle placement is through the foraminae which are small bony openings between the vertebrae where the nerve root exits the spinal canal and enters the body.
- *Selective Nerve Root Block (SNRB)*: This technique is used for diagnostic purposes and is the injection of contrast (absent allergy to contrast) followed by the introduction of a local anesthetic by inserting a needle into the neuroforamen under fluoroscopic guidance, ventral to the nerve root. SNRB's are commonly referred to as Transforaminal ESI, although technically SNRB's involve the introduction of anesthetic only.

Epidural steroid injections are performed for both diagnostic and therapeutic purposes. Diagnostic injections are performed to verify the source of pain within a particular region of the spinal column. Pain relief for several weeks following the diagnostic injection is indicative of inflammation within the area. Therapeutic injections are given to prolong pain relief and to reduce the inflammatory process over extended periods of time.

FDA: According to the 2014 FDA Safety Announcement: “There is a warning 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 injections are given to treat neck and back pain, and radiating pain in the arms and legs. We are requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments.”³

INITIAL COVERAGE CRITERIA^{50 53}

**Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.⁵²*

Epidural corticosteroid injections (ESI) may be considered medically necessary for back pain in adults who are age 18 years or older as part of a comprehensive pain management treatment program when all of the following criteria are met:
[ALL]

1. Initial or Diagnostic injection:

- The patient has radicular pain with demonstrable correlation on physical exam and/or imaging due to one of the following conditions: [ONE]
 - Chronic back pain present for a minimum of 3 months; or
 - Post-surgical back pain (i.e. post laminectomy syndrome) due to prior surgery (i.e. lumbar discectomy, laminectomy, or spinal fusion) and at least 6 months have elapsed since surgery; and
- Pain is affecting activity of daily living functional ability: > 4 on the NRS Pain Rating Scale*;

AND

- Has tried and failed conservative therapy (i.e. for the current episode of pain (within the last 3 months) that includes: [ALL]
 - Physical therapy (PT) a minimum of 10-12 sessions over 8 weeks; or
 - There must be documentation submitted that explains why physical therapy is contraindicated:
 - **Note:* PT may be contraindicated if any of the following are present:
 - pain worsened with PT;
 - PT tried but was not able to be tolerated

AND

- Activity modification a minimum of 6 weeks; and
- Drug therapy (i.e. NSAIDS, muscle relaxants, corticosteroids, antidepressants, anticonvulsants, or opiates);

OR

- Has acute back pain with demonstrable correlation on physical exam and/or imaging that precludes the above requirement for therapy (there must be documentation submitted that explains why any of the above conservative therapy is contraindicated)

***The Numeric Rating Scale (NRS-11): Rating Pain Level**

- 0: No Pain
- 1 – 3: Mild Pain (nagging, annoying, interfering little with ADLs)
- 4 – 6: Moderate Pain (interferes significantly with ADLs)
- 7 – 10: Severe Pain (disabling; unable to perform ADLs)

2. Injection and Frequency Criteria:

- Initial or Diagnostic: 2 injections per region maximum with procedures 1-2 weeks apart

- ❑ Repeat or Therapeutic: If after the 2 initial injections are given and significant functional pain relief of at least 50% measured by a decrease in pain medications and increase in physical function; and is maintained for at least 6 weeks, additional injections may be considered medically necessary when all of the following frequency criteria is met: [ALL]
 - No more than 2 additional ESIs may be performed in a 12-month period of time; and
 - No more than 4 injections total per region per year defined as:
 - No more than 2 initial and 2 repeat epidural injection sessions (transforaminal/interlaminar injections), inclusive of all regions and all levels (cervical, thoracic, and lumbar), may be performed in a 12-month period of time. If a pain practitioner performs epidural injections in the cervical and/or thoracic regions at the same time frame in the patient as lumbar ESI's the practitioner should be particularly cognizant of the cumulative steroid dose to the patient from all levels injected; and
 - If a prior ESI provided no relief, a second ESI is allowed following reassessment of the patient and injection technique including transforaminal/interlaminar.
 - Note: an interlaminar/transforaminal ESI after a failed transforaminal/interlaminar ESI or vice versa may be considered medically appropriate one time only if there is no response 2-4 weeks after the initial injection.)

3. *Levels per session

- ❑ No more than two transforaminal injections may be performed at a single setting (e.g. single level bilaterally or two levels unilaterally); and
- ❑ One caudal or lumbar interlaminar injection per session and not in conjunction with a transforaminal injection.

*Note:

- ❑ A session is defined as all injection procedures performed on one day
- ❑ A region is defined as all injections performed in cervical/thoracic or all injections performed in lumbar (not sacral) spinal areas.

Note: Guideline recommendations are mainly obtained from the Official Disability Guidelines (2017).⁵³

COVERAGE EXCLUSIONS⁵⁰⁻⁵³

Epidural Steroid Injections (ESIs) are considered not medically necessary and may not be authorized for the any of the following conditions:

- ❑ For non-radicular back pain
- ❑ ESI is used for treatment of non-radicular spinal pain, myofascial pain syndrome, spinal stenosis, or post herpetic neuralgia
- ❑ Repeat ESI performed in the absence of 50% functional improvement in pain or function for at least 6-8 weeks upon reassessment
- ❑ Repeat ESI performed more frequently than once weekly

The following are considered contraindications to the procedure and require physician documentation:

- ❑ Known allergies to contrast agents, local anesthetics or corticosteroids

- History of bleeding disorders or current use of medications that may increase the risk of bleeding should be evaluated for potential exclusion
- Active infection locally or systemically, spinal stenosis resulting in intraspinal obstruction, or previous fusion at the indicated spinal level
- No epidural space, an altered epidural space as a result of previous surgery, spinal compression or congenital anatomic anomalies
- Other spinal pathology such as spinal tumors, cauda equina syndrome, spinal cord compression
- Co-morbidities that can be exacerbated by steroid use such as severe congestive heart failure, diabetes, and poorly controlled hypertension and other unstable medical conditions
- Fluoroscopy use in pregnant women

SUMMARY OF MEDICAL EVIDENCE ⁴⁻⁴²

Cervical

The published literature includes randomized controlled trials and systematic reviews examining ESIs for cervical radiculopathy (CR). Sample sizes in adults ranged from 24 to 160 patients. The studies included patients with CR for whom conservative therapies had failed (i.e., rest, analgesics, anti-inflammatory medications, PT, and exercise). Clinical symptoms were often correlated with MRI or other radiographic findings. Patient ages ranged from 40 to 51 years. There are no randomized controlled trials evaluating the use of ESIs in the pediatric population. The duration of CR symptoms varied, with some patients having acute symptoms (e.g., 15 days duration) and others reporting a longstanding condition (≥ 1 year). Most studies included patients with CR symptoms that had not responded to ≥ 6 months of conservative treatment. Most studies evaluated a combined ESI and anesthetic injection and follow-up times varied considerably among studies, ranging from 3 weeks to 68 months, with most studies including ≤ 12 months follow-up. In studies that compared ESI (steroid plus anesthetic) with epidural injection of anesthetic only, no beneficial effects of the steroids were detected on any outcome measures. Some suggested superior pain relief from administration of steroids plus anesthetic by catheter compared with injection, but only in patients who reported pain for > 6 months. ESIs did not improve disability or reduce the need for surgery in most of the studies. The overall body of evidence regarding epidural steroid injection (ESI) for cervical radiculopathy (CR) does not show beneficial effect of ESIs on pain or disability associated with CR compared with epidural injection with anesthetic only. Despite the lack of evidence regarding ESIs for CR, the procedure has become standard in the pain management community.

Lumbar

The published literature includes randomized controlled trials and systematic reviews examining ESIs for lumbar radiculopathy (LR). Sample sizes in adults ranged from 48-228 patients. The studies included patients with low back pain and sciatica for whom conservative treatment had failed (i.e., rest, analgesics and anti-inflammatory medications, physical therapy, and exercise). Clinical symptoms were often correlated with magnetic resonance imaging (MRI) or computerized tomography (CT) scan results. The patients generally ranged from 40 to 50 years of age. There are no randomized controlled trials evaluating the use of ESIs in the pediatric population. ESIs were performed via the interlaminar, transforaminal, or caudal route. The outcome measures varied, but most pain assessments used the (visual analog scale [VAS] score) and the degree of disability (Oswestry Disability Index [ODI] score). Several studies also assessed the need for subsequent surgery. Follow-up times varied considerably among studies, ranging from 3 weeks to 2 years. The majority of the studies reported pain relief following epidural anesthetic with or without steroids. The overall body of evidence regarding epidural steroid injection (ESI) for lumbar radiculopathy (CR) shows that while epidural steroid injections (ESIs) are associated with some pain relief; most studies suggest that the effects are attributable to the

anesthetic rather than the steroids. Despite the lack of evidence regarding ESIs for LR, the procedure has become standard in the pain management community.

The 2015 AHRQ comparative effectiveness study on injection therapies for LBP concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain.²⁸

Professional Society Guidelines indicate that caudal, interlaminar, and transforaminal epidural injections are generally good for managing disc herniation or radiculitis for; fair for axial or discogenic pain without disc herniation, radiculitis or facet joint pain with caudal, and interlaminar epidural injections, and limited for transforaminal epidural injections; fair for spinal stenosis with caudal, interlaminar, and transforaminal epidural injections; and fair for post surgery syndrome with caudal epidural injections and limited with transforaminal epidural injections.⁴⁷

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
64479	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, single level
64480	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
64483	Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, single level
64484	Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level

Government Agency

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3. FDA Drug Safety Communication: FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain. April 2014 Safety Announcement. Accessed at: <http://www.fda.gov/Drugs/DrugSafety/ucm394280.htm>

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Other Resources

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 - Epidural steroid injections for low back pain and sciatica. Jan, 2015. Updated Jan, 2017; Archived March 2018.
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 - Neck and Upper Back (Acute & Chronic).
 - Low Back - Lumbar & Thoracic (Acute & Chronic)

Revision/Review History

7/17: Reduced PT requirement from 20 sessions to 10-12 sessions over 8 weeks, changed improvement scales to significant functional pain relief of 50% measured by a decrease in pain medication and increase in functional ability,

changed therapeutic frequency criteria from 3 injections in 6 months to 2 injections allowed in 12 months, removed loss of bladder control as an indication, removed cervical ESIs higher than the C6-7 level from exclusions, and removed the requirement for a comprehensive psychosocial assessment. Coding tables updated. Changes are based on 2017 ODG Guidelines per AMR review.

3/8/18 Policy reviewed, no changes to criteria.