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PROPOSED/DRAFT Local Coverage Determination (LCD): Surgery: Epidural Steroid Injections (DL34364)

[PROPOSED/DRAFT]

Please note: This is a Proposed/Draft policy.

Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

Contractor Name

[Cahaba Government Benefit Administrators®, LLC opens in new window](#)

[Back to Top](#)

Contract Number
10202

Contract Type
MAC - Part B

Proposed/Draft LCD Information

Document Information

[PROPOSED/DRAFT]

Source LCD ID
N/A

Proposed LCD ID
DL34364

Proposed LCD Title
Surgery: Epidural Steroid Injections

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Jurisdiction
Georgia

- Title XVIII of the Social Security Act, Section 1833 (e). This section states that no payment shall be made to any provider for any claims that lack the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be reasonable and medically necessary, i.e., reasonable and necessary are those tests used in the diagnosis and management of illness or injury or to improve the function of a malformed body part.
- Medicare Program Integrity Manual (Pub. 100-08), Chapter 13.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Background

The epidural space lies outside the dural membrane but inside the spinal canal. It runs the length of the spine and contains nerves, fatty tissue, and vasculature. The spinal nerve roots can be affected by a number of processes as they travel through the epidural space, including compression from herniations of the nucleus pulposus of the intervertebral discs, degenerative changes involving combinations of the ligaments, discs, and zygapophyseal (aka facet) joints, synovial cysts, osteophytes, and mechanical derangements such as spondylolisthesis. The spinal nerve roots can become a significant and disabling source of radicular pain; and injury to a spinal nerve root can result in pain, weakness, and sensory loss.

Epidural steroid injections (ESIs) treat pain arising from spinal nerve roots. ESIs can be performed three ways, each by a different route of entry. These are termed the interlaminar, caudal, and transforaminal approaches. The procedures involve the injection of corticosteroids and anesthetic (local anesthetic only are used diagnostically).

The effect of the injections on radicular pain is not curative; repeat injections may be beneficial in the management of patients who have a favorable response to an initial injection. ESIs in the treatment of nonspecific low back pain (LBP) should not be considered part of routine management.

Imaging guidance, fluoroscopy or computed tomography, with the use of injectable radio-opaque contrast material has been shown to enhance the accuracy and safety of needle placement for all ESI procedures, particularly transforaminal injections.

Risks include allergic reactions, intravascular placement, violation of the dural membrane with the potential for leaks of cerebrospinal fluid and infection.

All individuals should undergo a thorough evaluation and be treated following a comprehensive care plan.

Indications

1. Radicular pain and/or
2. Neurogenic claudication and/or
3. LBP with one of the following: central disc herniation, severe degenerative disc disease or central spinal stenosis. For a patient with LBP only, a simple disc bulge or annular tear/ fissure is insufficient to justify performance of an ESI, unless other indications in this section are present.
4. Documented Visual Analog Scale (VAS) for pain or Numeric Pain Rating Scale (NPRS) $\geq 3/10$ (moderate to severe pain) with functional impairment in activities of daily living (ADLs).
5. Failure of four weeks of non-surgical, non-injection care. All appropriate non-surgical, non-injection treatments should be considered along with a rationale for interventional treatment. Exceptions to the 4 week wait, beginning at the onset of pain, before receiving an ESI exist, but should be documented. These would include, but are not limited to:

- A. At least moderate pain with significant functional loss at work and/or home.
- B. Severe pain unresponsive to outpatient medical management.
- C. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s).
- D. Prior successful ESI for same specific condition.

Imaging Requirements:

1. Minimum criteria: Plain films to rule out red flag condition.
2. Advanced imaging (MRI, CT) may be appropriate prior to performing an ESI

Provider Qualifications

ESIs can be considered medically reasonable and necessary only if performed by appropriately trained providers.

Contraindications:

1. Major risk factors for cancer.
2. New onset of LBP with history of cancer, multiple risk factors for cancer, or strong clinical suspicion for cancer.
 - A. The patient must be thoroughly evaluated and cancer ruled out as an etiology prior to an ESI.
 - B. If cancer is present, but the pain is clearly unrelated, an ESI may still be indicated if one of the "Indications" previously listed is present.
3. Risk factors for spinal infection including:
 - A. New onset of LBP with fever
 - B. History of intravenous drug use
 - C. History of recent bacterial or fungal infection
 - D. Immunosuppression
4. Risk factors for, or signs of, cauda equina syndrome including:
 - A. New onset urine retention, fecal incontinence, or saddle anesthesia
 - B. Rapidly progressing (or other) neurological deficits
5. A co-existing medical condition that would preclude the safe performance of the procedure.
6. A co-existing medical or other condition that contraindicates the intervention, e.g., epidural hematoma, subarachnoid hemorrhage, epidural mass, spinal cord ischemia, trauma.
7. A co-existing medical or other condition that precludes the safe performance of the procedure, e.g., uncontrolled coagulopathy or active anti-coagulation therapy.
8. Potential presence of a CNS process resulting in the presenting symptoms, e.g., transverse myelitis, central demyelination.
 - A. The patient must be thoroughly evaluated, and a CNS process ruled out as the source of pain or neurologic deficit prior to an ESI.
 - B. If a CNS process is present, but the pain or neurologic deficit is clearly unrelated, an ESI may still be indicated if one of the above "Indications" is present.
 - C. Numbness and/or weakness without paresthesiae/dysesthesiae or pain

Limitations

1. An injection session is defined as all injection services of the spinal canal administered during a 24 hour period for a specific date of service. Therefore:
 - A. In the first year, up to six (6) injection sessions may be performed: up to two (2) diagnostic and up to four (4) therapeutic.
 - B. In the following years, up to four (4) therapeutic injection sessions may be performed.
2. The use of fluoroscopic or computed tomographic (CT) guidance is required when performing injections of the spinal canal. Transforaminal epidural injections with ultrasound guidance (CPT codes 0228T - 0231T) will be denied as investigational.
3. Performance of more than one type of injection for pain treatment, such as epidural, sacroiliac joint injections or lumbar sympathetic injections, on the same day as a diagnostic spinal injection is not considered reasonable and necessary.

[Back to Top](#)

Proposed/Draft Process Information

Associated Information

Documentation Requirements:

1. All patients should have a history and focused physical exam as deemed necessary and indicated by the physician providing the service. This should take into account the procedure to be performed and any changes in the patient's medical status and/or new symptoms that may have developed since their last evaluation with the treating physician and/or their colleague or associate (if previously evaluated in that practice).
 - A. **Pre-Procedure History**
History sufficient to establish indication for ESI and exclude contraindications.
 - B. **Pre-Procedure Physical Examination**
Basic musculoskeletal examination and focused neurological examination sufficient to establish indication for ESI and exclude contraindications.
 - C. **Pre-Procedure Imaging**
Prior imaging results. If an ESI is performed for LBP, substantial imaging abnormalities must be documented, as noted in "Indications for Coverage"
2. All 'Indications' must be clearly documented in the patient's medical record and made available to Medicare upon request.
3. When the documentation does not meet the criteria for the service rendered, or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.
4. Documentation must support CMS 'signature requirements' as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

Utilization Guidelines

1. An injection session is defined as all injection services of the spinal canal administered during a 24 hour period for a specific date of service. Therefore:
 - A. In the first year, up to six (6) injection sessions may be performed: up to two (2) diagnostic and up to four (4) therapeutic.
 - B. In the following years, up to four (4) therapeutic injection sessions may be performed.
2. A therapeutic epidural injection may be repeated only if there was a positive response to the previous procedure, involving either an analgesic or functional benefit to the patient. If there was no improvement in pain, examination findings, or function (in terms of activity level or tolerance) then the previous procedure should not be repeated.
3. Services exceeding the above utilization parameter may be subject to medical review or auto-adjudication.

Sources of Information and Basis for Decision

This Local Coverage Determination (LCD) is the result of collaboration among the Medicare Administrative Contractors, and the template or model is being accepted by Cahaba as part of the effort to implement more uniform LCDs across contractors.

Interlaminar and Caudal ESIs

- Benyamin RM, Manchikanti L, Parr AT, Diwan SA, Singh V, Falco FJE, Datta S, Abdi S, Hirsch JA. The Effectiveness of Lumbar Interlaminar Epidural Injections in Managing Chronic Low Back and Lower Extremity Pain. *Pain Physician*. 2012: Jul/Aug. 15:E363-404.

Surgery Sparing Effect of ESIs

- Riew K, Park J, Cho Y, et al. Nerve Root Blocks in The Treatment of Lumbar Radicular Pain. A Minimum Five-Year Follow-Up. *J Bone Joint Surg Am*. 2006: Aug. 88A(8)1722-1725.
- Riew K, Yin Y, Gilula L, et al. The Effect of Nerve-Root Injections on the Need for Operative Treatment of Lumbar Radicular Pain. A Prospective, Randomized, Controlled, Double-Blind Study. *J Bone Joint Surg Am*. 2000: Nov. 82-A(11)1589-1593.

Therapeutic Transforaminal Injections

- Ghahreman A, Bogduk N. Predictors of a Favorable Response to Transforaminal Injection of Steroids in Patients With Lumbar Radicular Pain Due to Disc Herniation. *Pain Med*. 2011: 12:871-879.
- Ghahreman A, Ferch R, Bogduk N. The Efficacy of Transforaminal Injection of Steroids for the Treatment of Lumbar Radicular Pain. *Pain Med*. 2010: 11:1149-1168.

Review papers

- MacVicar J, King W, Landers MH, Bogduk N. The Effectiveness of Lumbar Transforaminal Injection of Steroids: A Comprehensive Review with Systematic Analysis of the Published Data *Pain Medicine*. 2013: Jan. 14(1) 14-28.
- Datta S, Manchikanti L, Falco FJE, Calodney AK, Atluri S, Benyamin RM, Buenaventura R, Cohen SP. Diagnostic Utility of Selective Nerve Root Blocks in the Diagnosis of Lumbosacral Radicular Pain: Systematic Review and Update of Current Evidence. *Pain Physician* 2013: April. 16:SE97-SE124.
- Cohen SP, Bicket MC, Jamison D, Wilkinson I, Rathmell JP. Epidural Steroids A Comprehensive, Evidence-Based Review. *Reg Anesth Pain Med*. 2013: May/June. 38(3)175-200.

Other

- Consultations with the representatives to the Carrier Advisory Committee and other Medicare contractors.
- Other Medicare Contractor's Local Coverage Determinations.

Carrier Advisory Committee (CAC) Meetings

Meeting Date	Meeting Information
11/05/2013	Open Meeting Alabama Carrier Advisory Committee Meeting
11/07/2013	Tennessee Carrier Advisory Committee Meeting
11/15/2013	Georgia Carrier Advisory Committee Meeting

Comment Period Start Date

11/15/2013

Comment Period End Date

12/31/2013

Released to Final LCD Date

N/A

Reason for Proposed LCD

- Automated Edits to Enforce Reasonable & Necessary Requirements
- Creation of Uniform LCDs With Other MAC Jurisdiction
- Provider Education/Guidance

Proposed Contact

Cahaba Government Benefit Administrators®, LLC Comments for Draft LCDs

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[Back to Top](#)

Coding Information

[PROPOSED/DRAFT]

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

62310 Inject spine cerv/thoracic
62311 Inject spine lumbar/sacral
62318 Inject spine w/cath crv/thrc
62319 Inject spine w/cath lmb/scrl
64479 Inj foramen epidural c/t
64480 Inj foramen epidural add-on
64483 Inj foramen epidural l/s
64484 Inj foramen epidural add-on

Group 2 Paragraph: The CPT codes listed below will be denied as investigational:

Group 2 Codes:

[0228T - 0231T opens in new window](#) Njx tfrml epri w/us cer/thor - Njx tfrml epri w/us lumb/sac

ICD-9 Codes that Support Medical Necessity

Group 1 Paragraph: There are numerous reasonable and necessary conditions that might warrant the use of these procedures but which are too many to list. However, an appropriate ICD-9-CM diagnosis must be submitted with each claim and failure to do so may result in denial or delay in claim processing.

ICD-9 codes must be coded to the highest level of specificity. Consult the 'Official ICD-9-CM Guidelines for Coding and Reporting' in the current ICD-9-CM book for correct coding guidelines. This LCD does not take precedence over the Correct Coding Initiative (CCI).

Group 1 Codes:

XX000 Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity

Paragraph: See narrative above for "ICD-9 Codes that Support Medical Necessity".

N/A

[Back to Top](#)

[Associated Documents](#)

Attachments

N/A

Related Local Coverage Documents

N/A

Related National Coverage Documents

N/A

[Back to Top](#)

Keywords

N/A

[Back to Top](#)

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