PROPOSED/DRAFT Local Coverage Determination (LCD): Epidural Steroid Injections (DL34404)

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Contractor Information

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CGS Administrators, LLC

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Proposed/Draft LCD Information

Document Information

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Jurisdiction
Kentucky

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CMS National Coverage Policy
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.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Introduction:

The epidural space lies outside the dural membrane but inside the spinal canal. It runs the length of the spine and, in addition to traversing nerves, contains fatty tissue and vasculature. The spinal nerve roots can be affected by a number of processes as they travel through the epidural space, including but not limited to compression from herniations of the nucleus pulposis of the intervertebral discs, degenerative changes involving combinations of the spinal ligaments, discs, and zygapophyseal (aka facet) joints, intraspinal synovial cysts, osteophytes, and mechanical derangements of the spine such as spondylolisthesis. As a result of mechanical irritation, inflammation, or other processes, 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) are generally performed to treat pain arising from spinal nerve roots. ESIs can be performed via three distinct techniques, each of which involves introducing a needle into the epidural space by a different route of entry. Specifically, these are termed the interlaminar, caudal, and transforaminal approaches. The procedures typically involve the injection of a solution containing corticosteroids and anesthetic into the epidural space, although saline may be included at times. Transforaminal epidural injections of local anesthetic only are used diagnostically.

ESIs have been shown to reduce radicular pain, and their use may have the effect of lowering surgical rates for specific spinal disorders. The effect of the injections on pain is not curative, but palliative and repeat injections may be beneficial in the management of patients who have a favorable response to an initial injection. The data supporting the use of ESIs in the treatment of axial low back pain without radicular origin is far less robust, and their use in these circumstances should not be considered part of routine management.

The use of imaging guidance, particularly 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. The use of this type of image guidance is considered an integral part of transforaminal injections, which cannot reliably be performed without image guidance. There are circumstances, however, where the use of imaging guidance with contrast media is contra-indicated.

As with other medical procedures, there are specific risks associated with the performance of ESIs, both arising from the procedures themselves as well as the injected agents. These include the potential for allergic reactions, intravascular placement with complications that can include neurologic injury, violation of the dural membrane with the potential for leaks of cerebrospinal fluid or further neurological injury, infection, and systemic reactions or side effects resulting from the biological effects of corticosteroids. When considering the presence of these risks alongside the potential for benefit, both patient selection and appropriate image guidance/contrast verification is of paramount importance in order to minimize risks while treating those individuals for whom ESIs offer significant potential benefit. These factors are reflected in the coverage considerations that follow.

The treatment of individuals with spinal disorders, including pain, can be complex, and all individuals being considered for interventional care for their spine should be undergo a thorough evaluation and be treated following a comprehensive care plan.

For purposes of this policy, a “session” is defined as all ESIs or spinal procedures performed on a single day.

Indications for Coverage:

1. Suspected radicular pain and/or
2. Neurogenic claudication and/or
3. Low back pain with one of the following: substantial imaging abnormalities such as a central disc herniation, severe degenerative disc disease or central spinal stenosis. For a patient with low back pain only, a simple disc bulge or annular tear/ fissure is insufficient to justify performance of an ESI,
4. Documented Visual Analog Scale (VAS) for pain or Numeric Pain Rating Scale (NPRS) ≥ 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**

The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1 (http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf) states that "reasonable and necessary" services are "ordered and/or furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately trained providers.

Patient safety and quality of care mandate that healthcare professionals who perform Epidural Steroid Injections are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure and utilization of the required associated imaging modalities.

**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.
Procedural Requirements:

All Methods
1. All elective (non-emergent) ESIs should be done with image-guidance. Fluoroscopy and CT are the only two validated imaging methods.
2. Contrast medium should be injected during epidural injection procedures. Exceptions to the use of contrast include:
   a. Patients that have a significant history and/or are at high risk for an adverse event if contrast material is used e.g., contrast allergy. The reasons for not using contrast should be documented in the procedure report. In these cases, physicians should consider using a test-dose injection prior to injecting any particulate steroids and/or use only non-particulate steroid solutions.
3. Films that adequately document final needle position and injectate flow must be retained and made available upon request.
4. For each session, no more than 80mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone or equivalent corticosteroid dosing may be used.

Transforminal ESIs
1. Diagnostic selective nerve root blocks (anesthetic only), performed in a manner similar to transforaminal ESIs, may be considered to further evaluate the anatomical level of radicular pain.
2. When a diagnostic spinal nerve block is performed, post-block assessment of percentage pain relief must be documented.
   a. Any additional documentation such as post-injection focused neurologic exam to assess for nerve root anesthetization or myotomal weakness is optional but can be included in the physician's report.

Proposed/Draft Process Information

Associated Information

Utilization:

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

Frequency with criteria

1. No more than 3 ESIs may be performed in a 6-month period of time.
2. No more than 6 epidural injection sessions (therapeutic ESIs and/or diagnostic transforaminal injections) may be performed in a 12-month period of time regardless of the number of levels involved.
3. If a prior ESI provided no relief, a second ESI is allowed following reassessment of the patient and injection technique.

Sedation:
1. Local anesthesia or minimal to moderate conscious sedation may be appropriate options.
2. Monitored anesthesia care is recommended on rare occasions with clear documentation of the need for such sedation.

Documentation:
This LCD is subject to provisions in the overarching Pain LCD.

All patients, new and/or established, 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).

Pre-Procedure History

History sufficient to establish indication for ESI and exclude contra-indications.
Pre-Procedure Physical Examination

Basic musculoskeletal examination and focused neurological examination sufficient to establish indication for ESI and exclude contra-indications.

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”

Shared Decision Making / Informed Consent

Patients receiving or considering an ESI should be informed of their options and the risks/benefits of each including, but not limited to medication management, awaiting natural history, exercise-based therapy and surgical interventions. However, there is no mandate to the use of any of these options post-injection. Patients receiving or considering an ESI should be informed of specific potential complications of the proposed approach.

Additional Suggested Procedural Considerations:

1. There is no role for “series of three” ESIs. Response to each ESI should be determined prior to determining the value of a repeat ESI and the specific methods used for subsequent ESIs.
2. Sufficient contrast medium should be used to allow for identification of proper injectate flow and to exclude vascular, subarachnoid or subdural flow.
3. Methods to reduce risk of inadvertent vascular injection of particulate steroids with subsequent spinal cord ischemia exist for the performance of TFESIs. These methods should be understood and their use is strongly encouraged. At a minimum, this entails the use of live fluoroscopy with injection of contrast medium to identify any evidence of central vascular uptake. If available, digital subtraction angiography is recommended to maximize the practitioner’s ability to recognize inadvertent vascular uptake. One should not inject active agents (anesthetic and/or corticosteroid) in the face of central vascular uptake. Safety is enhanced if, at the L3 level and above, only non-particulate corticosteroids are injected when performing transforaminal injections.
4. If a diagnostic transforaminal injection is planned then baseline (pre-injection) identification of the patient’s index pain, intensity of pain (via a visual analog scale or numeric pain rating), neurologic deficits (if they exist) and provocation maneuvers that exacerbate the patient’s index pain should be performed.

The medical record must be made available to Medicare upon request.

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.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits in addition to guidance in this LCD. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare. Whichever guidance is more restrictive should be adhered to.

When requesting an individual consideration through the written redetermination (formerly appeal) process, providers must include all relevant medical records and literature that supports the request. At a minimum two (2) Phase II studies (human feasibility studies suggesting efficacy, pilots) or one (1) Phase III study (primary evidence of safety and efficacy, pivotal) must be submitted for the Medical Director’s review.

Sources of Information and Basis for Decision

References

Interlaminar and Caudal ESIs


Surgery Sparing Effect of ESIs


**Therapeutic Transforaminal Injections**


**Review papers**


**Carrier Advisory Committee (CAC) Meetings**

<table>
<thead>
<tr>
<th>Meeting Date</th>
<th>Meeting Information</th>
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<tr>
<td>10/21/2013</td>
<td>This policy will be presented at the Kentucky CAC meeting.</td>
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<tr>
<td>10/22/2013</td>
<td>This policy will be presented at the Ohio CAC meeting.</td>
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**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 INJECTION(S), OF DIAGNOSTIC OR THERAPEUTIC SUBSTANCE(S) (INCLUDING ANESTHETIC, ANTIISPASMODIC, OPIOID, STEROID, OTHER SOLUTION), NOT INCLUDING NEUROLYTIC SUBSTANCES, INCLUDING NEEDLE OR CATHETER PLACEMENT, INCLUDES CONTRAST FOR LOCALIZATION WHEN PERFORMED, EPIDURAL OR SUBARACHNOID; CERVICAL OR THORACIC

62311 INJECTION(S), OF DIAGNOSTIC OR THERAPEUTIC SUBSTANCE(S) (INCLUDING ANESTHETIC, ANTIISPASMODIC, OPIOID, STEROID, OTHER SOLUTION), NOT INCLUDING NEUROLYTIC SUBSTANCES, INCLUDING NEEDLE OR CATHETER PLACEMENT, INCLUDES CONTRAST FOR LOCALIZATION WHEN PERFORMED, EPIDURAL OR SUBARACHNOID; LUMBAR OR SACRAL (CAUDAL)

62318 INJECTION(S), INCLUDING INDWELLING CATHETER PLACEMENT, CONTINUOUS INFUSION OR INTERMITTENT BOLUS, OF DIAGNOSTIC OR THERAPEUTIC SUBSTANCE(S) (INCLUDING ANESTHETIC, ANTIISPASMODIC, OPIOID, STEROID, OTHER SOLUTION), NOT INCLUDING NEUROLYTIC SUBSTANCES, INCLUDES CONTRAST FOR LOCALIZATION WHEN PERFORMED, EPIDURAL OR SUBARACHNOID; CERVICAL OR THORACIC

62319 INJECTION(S), INCLUDING INDWELLING CATHETER PLACEMENT, CONTINUOUS INFUSION OR INTERMITTENT BOLUS, OF DIAGNOSTIC OR THERAPEUTIC SUBSTANCE(S) (INCLUDING ANESTHETIC, ANTIISPASMODIC, OPIOID, STEROID, OTHER SOLUTION), NOT INCLUDING NEUROLYTIC SUBSTANCES, INCLUDES CONTRAST FOR LOCALIZATION WHEN PERFORMED, EPIDURAL OR SUBARACHNOID; LUMBAR OR SACRAL (CAUDAL)

**ICD-9 Codes that Support Medical Necessity**

**Group 1 Paragraph:** Allowed Including, but not limited to, the following:

**Group 1 Codes:**

053.13 POSTHERPETIC POLYNEUROPATHY

053.8 HERPES ZOSTER WITH UNSPECIFIED COMPLICATION

053.9 HERPES ZOSTER WITHOUT COMPLICATION

349.2* DISORDERS OF MENINGES NOT ELSEWHERE CLASSIFIED

353.4 LUMBOSACRAL ROOT LESIONS NOT ELSEWHERE CLASSIFIED

722.10 DISPLACEMENT OF LUMBAR INTERVERTEBRAL DISC WITHOUT MYELOPATHY

722.52 DEGENERATION OF LUMBAR OR LUMBOSACRAL INTERVERTEBRAL DISC

722.83 POSTLAMINECTOMY SYNDROME OF LUMBAR REGION

724.02 SPINAL STENOSIS, LUMBAR REGION, WITHOUT NEUROGENIC CLAUDICATION

724.03 SPINAL STENOSIS, LUMBAR REGION, WITH NEUROGENIC CLAUDICATION

724.2 LUMBAGO

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724.3  SCIATICA
724.4  THORACIC OR LUMBOSACRAL NEURITIS OR RADICULITIS UNSPECIFIED
729.2  NEURALGIA NEURITIS AND RADICULITIS UNSPECIFIED

**Group 1 Medical Necessity ICD-9 Codes Asterisk Explanation:** **ICD-9-CM code 349.2 is to be used to describe lumbar epidural fibrosis**

ICD-9 Codes that DO NOT Support Medical Necessity

**Paragraph:** Excluded Including, but not limited to, the following:
1. Cauda equina syndrome
2. Epidural abscess

**Codes:**
324.0  INTRACRANIAL ABSCESS
344.60  CAUDA EQUINA SYNDROME WITHOUT NEUROGENIC BLADDER
344.61  CAUDA EQUINA SYNDROME WITH NEUROGENIC BLADDER

Associated Documents

Attachments
N/A

Related Local Coverage Documents
N/A

Related National Coverage Documents
N/A

Keywords
- Epidural
- Steriod
- Injections
- 62310
- 62311
- 62318
- 62319

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