

July 2, 2021

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To Whom It May Concern:

The undersigned medical specialty societies, comprising physicians who utilize and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, would like to take this opportunity to express our strong support for epidural procedures for pain management, and reiterate their importance to Medicare patients' quality of life.

Our societies have a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved.

Significant relief of neck and back pain, improved quality of life, with restoration of function and decreased utilization of other healthcare resources is an outcome that should be readily available to patients covered by Medicare. When epidural interventions are performed in a disciplined, responsible manner, they achieve outcomes that are clinically, socially, and economically worthwhile.

We commend the Medicare Administrative Contractors for inviting comments and presentations from physicians and experts earlier this year; and giving appropriate and careful consideration to the evidence available about the important role these procedures play in treating patients with neck and back pain. The result is a proposed local coverage determination that preserves and promotes access to epidural procedures. We would like to offer the following comments to provide clarification and ensure that the procedures are made available to appropriately selected patients in a manner that will result in improved outcomes and quality of life.

COVERED INDICATIONS

- History, physical exam, and imaging to support radiculopathy and/or neurogenic claudication
 - Physical exam findings are not adequate for establishing a diagnosis of lumbar radiculopathy and should not be **required**.¹⁻³ Of the physical exam tests used, the straight leg raise is the most sensitive for radiculopathy with a sensitivity of 64% (56-71%) and specificity of 57% (47-66%).¹

- Radiculopathy should be replaced with radicular pain. These terms are often used interchangeably; however, these procedures have proven to be successful in treating radicular pain, not radiculopathy.
- Many patients have severe radicular pain without physical examination abnormalities. Neurologic deficits are not common and are not necessary to support a diagnosis of radicular pain. In addition, straight leg raise is a specific test for radicular pain but is not very sensitive, thus it is often not present. Most important, patients with radicular pain who do not have a positive straight leg raise or neurologic deficits are just as likely to respond to epidural injections as those who do.
- Suggest omitting “central” disc herniation. Radicular pain due to disc herniation, whether central and paracentral, is an appropriate indication for an epidural steroid injection (ESI).
- Suggest adding spondylolisthesis as a diagnosis for which ESI is indicated.
 - Suggest rewording as follows:
 - History and/or physical examination, and diagnostic imaging supporting one of the following:
 - Lumbar, cervical, or thoracic radicular pain and/or neurogenic claudication due to disc herniation, spondylolisthesis, osteophyte or osteophyte complexes, severe degenerative disc disease producing foraminal or central spinal stenosis, OR ...
- Requirement of 4 weeks pain duration
 - The statement is confusing as written, and it is unrealistic to expect a patient with acute radicular pain from a disc herniation to delay an ESI. These are the patients most likely to benefit from the procedure. If patients are unable to return to work or perform normal activities of daily living (ADLs), the procedure may be considered prior to the 4-week interval and documentation should indicate this clearly.
 - Suggest the following wording:
 - Pain duration of at least four (4) weeks, with exception made for severe radicular pain where a 4-week delay cannot be tolerated,⁴ or acute herpes zoster refractory to conservative management where a four (4)-week wait is not required.
- Requirement to use contrast (#2)
 - We fully support this requirement, except for patients who have a documented contrast allergy or are pregnant.
 - Suggest rewording as follows:
 - The ESIs must be performed under CT or fluoroscopic guidance with contrast, unless the patient has a documented contrast allergy or pregnancy. Ultrasound guidance without contrast may be considered in these and similar circumstances.
- Repeat injections (#5)
 - If after an initial injection, the patient’s pain returns prior to 3 months, it is reasonable to attempt to reinstate relief with a repeat injection. If a 3-month

threshold is required after an initial injection, a significant number of patients, who would otherwise obtain relief from a second injection, will proceed to surgery.⁵ We would suggest the following wording:

- Repeat ESIs are appropriate when 1-2 prior ESIs provided prolonged reduction in radicular pain (i.e., 50% relief for at least 3 months) for the condition being treated. ESIs should not be repeated within 14 days. If the patient obtains partial relief from a single ESI, a repeat ESI after 14 days can be performed. If a patient does not obtain any relief from a single ESI, a repeat ESI after 14 days can be performed using a different approach and/or medication, with the rationale and medical necessity for the second ESI documented in the medical record.
- ESI injectant (#6)
 - If the injections do not include steroid, they are not epidural “steroid” injections (ESIs), so suggest replacing “ESI injectant” with “epidural injectate”.
 - The current wording is confusing and stipulates that anti-inflammatories are required and contrast is not. Also, it should be clear that contrast is injected first to confirm epidural placement. The subsequent therapeutic injection includes corticosteroids, local anesthetics, etc. In keeping with the very appropriate requirement to use contrast for most patients (#2), we suggest rewording to:
 - An initial injection of contrast is required to confirm epidural placement, unless the patient has a contraindication to contrast. The subsequent injection may include corticosteroids, local anesthetics, saline, and/or anti-inflammatories.
- Requirement of other conservative treatment (#7)
 - While some patients will certainly benefit from multimodal treatment, others who experience relief from an ESI may not require additional conservative treatment. We suggest rewording to indicate that ESIs *may be* performed in conjunction with conservative treatments.
- Diagnostic spinal nerve blocks
 - We suggest the following be included under indications:
 - Diagnostic spinal nerve blocks are performed by injecting local anesthetic onto a single spinal nerve to help confirm or rule-out the source of the patient’s pain, often to assist in surgical planning. These blocks utilize the same CPT codes as transforaminal ESIs (64479-64484) and should be allowed in patients that may have failed a therapeutic ESI when the medical necessity is documented in the medical records.

LIMITATIONS

- Injections performed without image guidance or by ultrasound (#1)
 - Suggest allowing for ultrasound guidance in patients with documented contraindication to contrast media (e.g., allergy, pregnancy).

- Limit to 4 ESIs per 12 months (#6)
 - Suggest considering allowance of 3 ESIs per 6 months and 6 ESIs per 12 months, regardless of the number of levels involved
- Series of ESIs (#11)
 - While we do not support a “series of 3”, we do support repeat injections if previous injections were successful in achieving pain relief and functional improvement or only one prior injection was unsuccessful (see above). Suggest rewording as follows:
 - It is not medically reasonable and necessary to prescribe a predetermined series of ESIs.
- Steroid dose (#12)
 - The dosages recommended are inaccurate. Data from studies looking at dosages implemented in transforaminal injections have been inappropriately extrapolated here to interlaminar injections.
 - Suggest rewording as follows to allow for slightly higher dosages, consistent with the previous version of the LCD:
 - Steroid dosing should be the lowest effective amount, not to exceed 80mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone per session.
- Treatment exceeding 12 months (#13)
 - This limitation is unreasonable, and the requirements add a significant documentation burden to explain that a patient does not wish to proceed to surgery. We suggest omitting.
 - Requiring the pain physician to communicate with the primary care provider to discuss whether the patient is eligible for prolonged repeat steroid use places undue burden on physicians and should not be required.

PROVIDER QUALIFICATIONS

While we appreciate that all healthcare professionals have a very important role to play in team-based care within our medical system, **training provided to non-physicians does not provide requisite background and experience in accurately selecting patients; safely performing technically demanding procedures; and immediately recognizing, evaluating, and addressing potentially serious, life-altering complications.** For this reason, we recommend the following language:

Patient safety and quality of care mandate that healthcare professionals who perform epidural injection procedures for chronic pain (not surgical anesthesia) are appropriately trained by an accredited allopathic or osteopathic medical residency/fellowship program in an ABMS or an AOA accredited specialty whose core curriculum includes the performance and management of the procedures addressed in this policy. 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 pharmacokinetics as well as proficiency in diagnosis and management of chronic pain

related disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

SOCIETY GUIDANCE

It should be noted that the North American Spine Society revised their coverage policy recommendations in 2020 and these should be reviewed and replace the 2013 and 2011 references listed on pages 25-26.⁶

Please correct typos on the following society names:

- American Society of Anesthesiologists
- American Association of Neurological Surgeons and Congress of Neurological Surgeons
- Spine Intervention Society

The undersigned societies appreciate the opportunity to provide these comments and would welcome the opportunity to again work with the Medicare Administrative Contractors to revise the coverage criteria included in the LCDs to ensure appropriate access to epidural procedures for Medicare patients. If you have any questions or wish to discuss any of our suggestions, please contact Belinda Duszynski, Senior Director of Policy and Practice at the Spine Intervention Society, at bduszynski@SpineIntervention.org.

Sincerely,

American Academy of Pain Medicine
American Academy of Physical
Medicine and Rehabilitation
American Society of Anesthesiologists
American Society of Regional
Anesthesia and Pain Medicine
North American Neuromodulation
Society

North American Spine Society
Pain Society of the Carolinas
Society of Interventional Radiology
Spine Intervention Society
Tennessee Pain Society

References:

1. Hooten WM, Cohen SP. Evaluation and treatment of low back pain: A clinically focused review for primary care specialists. *Mayo Clin Proc* 2015;90:1699-1718.
2. Vroomen PC, de Krom MC, Knottnerus JA. Diagnostic value of history and physical examination in patients suspected of sciatica due to disc herniation: a systematic review. *J Neurol*. 1999 Oct;246(10):899-906.
3. van der Windt DA, Simons E, Riphagen II, Ammendolia C, Verhagen AP, Laslett M, Devillé W, Deyo RA, Bouter LM, de Vet HC, Aertgeerts B. Physical examination for lumbar radiculopathy due to disc herniation in patients with low-back pain. *Cochrane Database Syst Rev*. 2010 Feb 17;(2):CD007431.

4. Kennedy DJ, Plastaras C, Casey E, Visco CJ, Rittenberg JD, Conrad B, Sigler J, Dreyfuss P. Comparative effectiveness of lumbar transforaminal epidural steroid injections with particulate versus nonparticulate corticosteroids for lumbar radicular pain due to intervertebral disc herniation: a prospective, randomized, double-blind trial. *Pain Med.* 2014 Apr;15(4):548-55.
5. Mattie R, Schneider BJ, Smith C. Frequency of Epidural Steroid Injections. *Pain Med.* 2020 May 1;21(5):1078-1079.
6. North American Spine Society. Coverage Policy Recommendations: Epidural Steroid Injections and Selective Spinal Nerve Blocks. 2020.
<https://www.spine.org/PolicyPractice/CoverageRecommendations/PayorAccess.aspx>