

Notice of Independent Review Decision

January 16, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

O/P Lumbar Spine SNRB Bilateral L5-S1 w/ sedation 27096-50 77003-26
(99144PNR)

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

The physician performing this review is Board Certified, American Board of Orthopedic Surgery. The physician has been in practice since 1982 and is licensed in Texas and Oklahoma.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

Upon independent review, I find the previous adverse determination should be Upheld.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Records Received: 33 page fax 12/27/13 Department of Insurance IRO request, 57 pages received via fax 12/30/13 URA response to disputed services including administrative and medical. Dates of documents range from xx/xx/xx (DOI) to 12/27/13.

PATIENT CLINICAL HISTORY [SUMMARY]:

This female was injured xx/xx/xx. The patient reported back and leg pain and was seen by a chiropractor for decompression treatment. The patient reported also

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having physical therapy. When seen 11/13/13 the patient reported initially having some improvement, then beginning to get worse again, right worse than left. The patient reported mainly numbness in the legs with occasional right leg weakness. On that date, the physical examination noted paravertebral tenderness with lumbar range of motion being painful and restricted at flexion of 50% of normal, extension 25% of normal. Straight leg raise was positive on the right at 75 degrees with pain in the back and buttock. On neurological examination, strength, sensation, and reflexes were all normal. X-rays of the lumbar spine revealed degenerative disk disease at L3-4 and L4-5 and to a greater degree at L5-S1 with a small retrolisthesis at L3-4. The MRI was reviewed, which does note a significant herniation at L5-S1 to the right but does displace the right S1 nerve root with significant deformity of the thecal sac.

The treatment plan was a bilateral L5-S1 selective nerve root block, both therapeutic and diagnostic.

Prior peer reviews noted there was lack of an adequate trial of pharmacotherapy before considering the requested injection, and for the sedation, there was lack of documentation of significant anxiety or needle phobia supporting that request.

The second peer review noted lack of documentation of compelling examination evidence suggestive of a radiculopathy. There was a lack of documentation addressing the prior issues for noncertification, which were still unresolved.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

At this time, I agree with both prior peer reviews. One, there is a lack of documentation of prior pharmacotherapy and lack of documentation of anxiety or needle phobia supporting the sedation. In line with the second, there is lack of objective physical examination findings suggestive of a radiculopathy as defined by the *AMA Guides, Fifth Edition*, pages 382 and 383. Lacking any current documentation addressing prior peer review concerns, their recommendation remains appropriate. The outpatient selective nerve root block at L5-S1 for both diagnostic and therapeutic purposes is noncertified.

The criterion utilized in the analysis is the *ODG* low back chapter on epidural steroid injections and the *ODG* pain chapter on epidural steroid injections.

ODG -TWC

ODG Treatment

Integrated Treatment/Disability Duration Guidelines

Low Back - Lumbar & Thoracic (Acute & Chronic)

Epidural steroid injections (ESIs), therapeutic	Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) with use in conjunction with active rehab efforts. Not recommended
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for spinal stenosis or for nonspecific low back pain. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, but ESIs have not been found to be as beneficial a treatment for the latter condition. According to SPORT, ESIs are associated with less improvement in spinal stenosis. ([Radcliff, 2013](#))

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months. ([Armon, 2007](#)) Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function or return to work. There is no high-level evidence to support the use of epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. ([Benzon, 1986](#)) ([ISIS, 1999](#)) ([DePalma, 2005](#)) ([Molloy, 2005](#)) ([Wilson-MacDonald, 2005](#))

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. ([Hopwood, 1993](#)) ([Cyteval, 2006](#)) Indications for repeating ESIs in patients with chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

For spinal stenosis: The use of epidural steroid injection (ESI) in patients with lumbar spinal stenosis is common, but there is little evidence in the literature to demonstrate its long-term benefit. Despite equivalent baseline status, ESIs are associated with significantly less improvement at 4 years among all patients with spinal stenosis. Furthermore, ESIs were associated with longer duration of surgery and longer hospital stay. There was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. There was no distinct surgical avoidance noted with ESI. ([Radcliff, 2013](#)) This systematic review found the data was limited to suggest that ESI is effective in lumbar spinal stenosis. ([Bresnahan, 2013](#)) An RCT addressed the use of ESIs for treatment of spinal stenosis, and there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. ([Koc, 2009](#)) According to the APS/ ACP guidelines, ESIs are not for nonspecific low back pain or spinal stenosis. ([Chou, 2008](#))

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. ([Riew, 2000](#)) ([Vad, 2002](#)) ([Young, 2007](#)) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. ([Colorado, 2001](#)) ([ICSI, 2004](#)) ([McLain, 2005](#)) ([Wilson-MacDonald, 2005](#)) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. ([Manchikanti, 2011](#)) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. ([Iversen, 2011](#))

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure. ([Manchikanti, 1999](#)) ([Colorado, 2001](#)) ([ICSI, 2004](#)) ([Molloy, 2005](#)) ([Young, 2007](#))

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have

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pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. ([Jamison, 1991](#)) ([Abram, 1999](#)) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. ([Carette, 1997](#)) ([Bigos, 1999](#)) ([Rozenberg, 1999](#)) ([Botwin, 2002](#)) ([Manchikanti, 2003](#)) ([CMS, 2004](#)) ([Delpont, 2004](#)) ([Khot, 2004](#)) ([Buttermann, 2004](#)) ([Buttermann2, 2004](#)) ([Samanta, 2004](#)) ([Cigna, 2004](#)) ([Benzon, 2005](#)) ([Dashfield, 2005](#)) ([Arden, 2005](#)) ([Price, 2005](#)) ([Resnick, 2005](#)) ([Abdi, 2007](#)) ([Boswell, 2007](#)) ([Buenaventura, 2009](#)) Also see [Epidural steroid injections, “series of three”](#) and [Epidural steroid injections, diagnostic](#). ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. ([Kinkade, 2007](#)) Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. ([Chou, 2008](#)) As noted above, injections are recommended if they can facilitate a return to functionality (via activity & exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under [Physical therapy](#), or at least not require more than 2 additional visits to reinforce the home exercise program.

With discectomy: Epidural steroid administration during lumbar discectomy may reduce early neurologic impairment, pain, and convalescence and enhance recovery without increasing risks of complications. ([Rasmussen, 2008](#)) Not recommended post-op. The evidence for ESI for post lumbar surgery syndrome is poor. ([Manchikanti, 2012](#))

Patient selection: ESIs are more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In such patients, a success rate of 75% renders ESI an attractive temporary alternative to surgery, but in patients with significant compression of the nerve root, the likelihood of benefiting from ESI is low (26%). This success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration. ([Ghahreman, 2011](#))

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to recommend that radiculopathy be corroborated by imaging studies and/or electrodiagnostic testing. ([Cohen, 2012](#))

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. ([Mandel, 2013](#))

Recent research: An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. ([Staal-Cochrane, 2009](#)) Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. ([Deyo, 2009](#)) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. ([Chou3,](#)

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[2009](#)) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. ([Sayegh, 2009](#)) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. ([Weiner, 2012](#)) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant differences in either leg pain or disability at 12 months follow-up. ([Pinto, 2012](#)) According to this systematic review, ESIs without the drug (epidural nonsteroid injections), often used as a placebo treatment, were as effective as ESIs and better than no epidural injections. ([Bicket, 2013](#)) This meta-analysis suggested that ESI did not improve back-specific disability more than a placebo or other procedure long-term (6 months), and did not significantly decrease the number of patients who underwent subsequent surgery. ([Choi, 2013](#))

Criteria for the use of Epidural steroid injections:

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

- (1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.
- (2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
- (3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
- (4) *Diagnostic Phase:* At the time of initial use of an ESI (formally referred to as the “diagnostic phase” as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
- (5) No more than two nerve root levels should be injected using transforaminal blocks.
- (6) No more than one interlaminar level should be injected at one session.
- (7) *Therapeutic phase:* If after the initial block/blocks are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. ([CMS, 2004](#)) ([Boswell, 2007](#))
- (8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.
- (9) Current research does not support a routine use of a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.
- (10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or

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	<p>trigger point injections as this may lead to improper diagnosis or unnecessary treatment.</p> <p>(11) Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)</p>
<p>Epidural steroid injections, “series of three”</p>	<p>Not recommended. Original recommendations that suggested a “series of three injections” generally did so prior to the advent of fluoroscopic guidance. These previous recommendations were based primarily on case studies and anecdotal evidence (Class IV and V data). (Abram, 1999) (Warr, 1972) (Hickey, 1987) There does not appear to be any evidence to support the current common practice of a series of injections. (Novak, 2008) Contemporary research studies with higher levels of evidence (including two controlled trials) have suggested that on average, two or less ESIs are required in patients with successful outcomes from the use of ESIs to treat disc related lumbar radiculopathy. (Lutz, 1998) (Vad, 2002) (Riew, 2000) While all of these latter studies have utilized repeat injections, there has been no evidence-based research to explain why this practice is required, or the mechanism for possible action. Since the introduction of fluoroscopically guided ESIs, it has been suggested that there is little evidence to repeat an accurately placed epidural injection in the presence of mono-radiculopathy, regardless of whether there is partial or no response. (McLain, 2005) A recent randomized controlled trial of blind ESIs found no evidence to support repeat injections, because at six weeks there was no significant difference found between the ESI group and a placebo controlled group in terms of any measured parameter. (Price, 2005) A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain may be secondary to a different generator, or in the case of multilevel pathology. (McLain, 2005) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (Cuckler, 1985) With fluoroscopic guidance, there is little support to do a second epidural if there is no response to the first injection. There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended.</p>
<p>Epidural steroid injections, diagnostic</p>	<p>Recommended as indicated below. Diagnostic epidural steroid transforaminal injections are also referred to as selective nerve root blocks, and they were originally developed as a diagnostic technique to determine the level of radicular pain. In studies evaluating the predictive value of selective nerve root blocks, only 5% of appropriate patients did not receive relief of pain with injections. No more than 2 levels of blocks should be performed on one day. The response to the local anesthetic is considered an important finding in determining nerve root pathology. (CMS, 2004) (Benzon, 2005) When used as a diagnostic technique a small volume of local is used (<1.0 ml) as greater volumes of injectate may spread to adjacent levels. When used for diagnostic purposes the following indications have been recommended:</p> <ol style="list-style-type: none"> 1) To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below: 2) To help to evaluate a radicular pain generator when physical signs and symptoms differ from that found on imaging studies; 3) To help to determine pain generators when there is evidence of multi-level nerve root compression; 4) To help to determine pain generators when clinical findings are consistent with radiculopathy (e.g., dermatomal distribution) but imaging studies are inconclusive; 5) To help to identify the origin of pain in patients who have had previous spinal

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surgery.

ODG -TWC

ODG Treatment

Integrated Treatment/Disability Duration Guidelines

Pain (Chronic)

<p>Epidural steroid injections (ESIs)</p>	<p>Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). See specific criteria for use below. [NOTE: This treatment for Low back & Neck pain is primarily covered in those respective chapters.] Most current guidelines recommend no more than 2 ESI injections. This is in contradiction to previous generally cited recommendations for a “series of three” ESIs. These early recommendations were primarily based on anecdotal evidence. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Current recommendations suggest a second epidural injection if partial success is produced with the first injection, and a third ESI is rarely recommended. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function. See the Low Back Chapter for more information and references. The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) See also Epidural steroid injections, “series of three”. Also see the Neck and Upper Back Chapter.</p> <p><i>Sedation:</i> There is no evidence-based literature to make a firm recommendation as to sedation during an ESI. The use of sedation introduces some potential diagnostic and safety issues, making unnecessary use less than ideal. A major concern is that sedation may result in the inability of the patient to experience the expected pain and paresthesias associated with spinal cord irritation. This is of particular concern in the cervical region. (Hodges 1999) Routine use is not recommended except for patients with anxiety. The least amount of sedation for the shortest duration of effect is recommended. The general agent recommended is a benzodiazepine. (Trentman 2008) (Kim 2007) (Cuccuzzella 2006) While sedation is not recommended for facet injections (especially with opioids) because it may alter the anesthetic diagnostic response, sedation is not generally necessary for an ESI but is not contraindicated. As far as monitored anesthesia care (MAC) administered by someone besides the surgeon, there should be evidence of a pre-anesthetic exam and evaluation, prescription of anesthesia care, completion of the record, administration of medication and provision of post-op care. Supervision services provided by the operating physician are considered part of the surgical service provided.</p> <p>Criteria for the use of Epidural steroid injections:</p> <p><i>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.</i></p> <p>1) Radiculopathy must be documented by physical examination <u>and</u> corroborated by</p>
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imaging studies and/or electrodiagnostic testing.

2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).

3) Injections should be performed using fluoroscopy (live x-ray) for guidance.

4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.

5) No more than two nerve root levels should be injected using transforaminal blocks.

6) No more than one interlaminar level should be injected at one session.

7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and [functional improvement](#), including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. ([Manchikanti, 2003](#)) ([CMS, 2004](#)) ([Boswell, 2007](#))

8) Current research does not support a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

9) Epidural steroid injection is not to be performed on the same day as trigger point injection, sacroiliac joint injection, facet joint injection or medial branch block.

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A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)