

Notice of Independent Review Decision

May 7, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Caudal Epidural Steriod Injection 62311 77003

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 1998 and is licensed in Texas, Oklahoma, Minnesota and South Dakota.

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 overturned.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Records Received: 17 page fax 04/22/13 Texas Department of Insurance IRO request, 24 pages of documents received via fax on 04/22/13 URA response to disputed services including administrative and medical. Dates of documents range from xx/xx/xx (DOI) to 04/22/13.

PATIENT CLINICAL HISTORY [SUMMARY]:

Roberta Crisp is a female with complaints of back pain and leg pain reportedly following a work-related injury on xx/xx/xx. She reportedly tripped over boxes,

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landing on her right knee as well as her back. She reportedly had immediate onset of pain, which persists to some degree to this day, apparently. She has had physical therapy. She had a previous epidural injection, which gave her several days of excellent relief. She has an on MRI moderate to severe facet arthropathy at L4-5 with a degenerative spondylolisthesis at that level. There is facet arthropathy and foraminal stenosis at the L5-S1 level as well.

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

The medical records available for review from the treating physician, clearly indicate the presence of radiculopathy as evidenced by positive straight leg raising test, diminished sensation in what would appear to be the L5 distribution, and weakness of the gastrocsoleus on the left at 4/5 strength. Additionally, imaging studies indicate the presence of spondylolisthesis at the L4-5 level along with foraminal stenosis noted on the MRI at both the L4-5 and L5-S1 levels. Though the patient had undergone previous epidural steroid injection with short-term relief, that particular injection was given a year ago. In the presence of the patient's continued and ongoing radicular findings, it is my opinion that ODG guidelines allow for a caudal epidural steroid injection at this time.

ODG -TWC

ODG Treatment

Integrated Treatment/Disability Duration Guidelines

Low Back - Lumbar & Thoracic (Acute & Chronic)

Epidural steroid injections (ESIs), therapeutic	<p>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. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, although ESIs have not been found to be as beneficial a treatment for the latter condition. In fact, according to SPORT, ESIs are associated with less improvement in spinal stenosis. (Radcliff, 2013)</p> <p><i>Short-term symptoms:</i> 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) A recent RCT of 29 patients divided into three groups addressed the use of ESIs for treatment of spinal stenosis. A control group with no treatment was compared to a group receiving passive physical therapy for two weeks and another receiving an interlaminar ESI at the stenotic level. At two weeks the group that received the ESI had significantly better pain relief than the other two groups. When the three groups were compared there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. The authors stated that improvement only appeared to be in the early phase of treatment. (Koc, 2009)</p> <p><i>Use for chronic pain:</i> 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</p>
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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.

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 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](#))

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. ([Devo, 2009](#)) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. ([Chou3, 2009](#)) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. ([Sayegh, 2009](#)) 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](#)) 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](#)) 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

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	<p>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)</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, reduction of medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.</i></p> <p>(1) Radiculopathy must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.</p> <p>(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).</p> <p>(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.</p> <p>(4) <i>Diagnostic Phase:</i> 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.</p> <p>(5) No more than two nerve root levels should be injected using transforaminal blocks.</p> <p>(6) No more than one interlaminar level should be injected at one session.</p> <p>(7) <i>Therapeutic phase:</i> 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)</p> <p>(8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.</p> <p>(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.</p> <p>(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 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>
Epidural steroid injections, “series of three”	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

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	<p>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>
Epidural steroid injections, diagnostic	<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 surgery.

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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)