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**Notice of Independent Review Decision**

**Date notice sent to all parties:**

June 11, 2013

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Appealed: Lumbar spine ESI @ L5 (right side) – series 3 62311, 72275

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

Board Certified Anesthesiologist; Board Certified Pain Medicine

**REVIEW OUTCOME:**

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

X Upheld (Agree)

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

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

Cover sheet and working documents

Progress notes dated 09/12/12, 09/13/12, 09/26/12, 10/08/12, 10/15/12, 10/29/12, 11/19/12, 12/04/12, 01/15/13, 01/30/13

Office visit note dated 04/23/13

Utilization review determination dated 05/01/13, 05/09/13

MRI lumbar spine dated 10/04/12

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male whose date of injury is xx/xx/xx. The mechanism of injury is described as lifting. The patient was seen and diagnosed with sprain of back and

thoracic region. MRI of the lumbar spine dated 10/04/12 revealed at L4-5 intervertebral disc space has mild narrowing. The moderately dehydrated intervertebral disc has a posterior broad-based subligamentous protruded herniation producing moderate central spinal stenosis and severe impingement of the neural exit canals bilaterally. At L5-S1 the intervertebral disc space has mild to moderate narrowing most marked posteriorly. The moderate to severely dehydrated intervertebral disc has a posterior broad-based subligamentous protruded disc herniation producing moderate left and severe right neural exit canal impingement. No significant central spinal stenosis is seen at this level. The patient underwent a course of physical therapy with only mild benefit of symptoms. Office visit note dated 04/23/13 indicates that current medications are Norco and Flexeril. On physical examination paravertebral muscles are non-tender. Lumbar range of motion is painful and restricted to 25% of normal throughout. Straight leg raises are normal bilaterally with no issues. Waddell's test shows non-specific tenderness, simulation/axial loading, distraction: seated straight leg raising, regional disturbances and overreaction present. Lower extremities strength is symmetrically present. Deep tendon reflexes are symmetrically present and normal. Sensation is intact.

Initial request for lumbar spine epidural steroid injection at L5 (right side) series of 3 was non-certified on 05/01/13 noting that there is no indication the patient had the epidural steroid injection that was approved in 12/12. Until that is known, another epidural steroid injection is not supported. The neuro exam is currently normal which also does not support doing an epidural steroid injection as per ODG criteria. The denial was upheld on appeal dated 05/09/13 noting that current evidence based guidelines do not support a series of three epidural steroid injections. The patient's physical examination fails to establish the presence of active lumbar radiculopathy, and there are no imaging studies/electrodiagnostic results provided to support the diagnosis. The patient presents with multiple positive Waddell's tests which is suspicious for symptom magnification.

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

Based on the clinical information provided, the request for lumbar spine epidural steroid injection at L5 (right side)-series 3 62311, 72275 is not recommended as medically necessary. The patient's physical examination on 04/23/13 reports negative straight leg raising, intact deep tendon reflexes, strength and sensation. There are no radicular findings on physical examination. It is also noted that the patient had multiple positive Waddell's tests which is indicative of symptom

magnification. The Official Disability Guidelines do not support a series of three epidural steroid injections as subsequent injections are based upon the patient's response to prior epidural steroid injections. Given the current clinical data, the requested series of three lumbar epidural steroid injections is not indicated as medically necessary.

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

**X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

**X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

ODG Low Back Chapter

<p>Epidural steroid injections (ESIs), therapeutic</p>	<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. (<a href="#">Radcliff, 2013</a>)</p> <p><u>Short-term symptoms:</u> 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. (<a href="#">Armon, 2007</a>) 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. (<a href="#">Benzon, 1986</a>) (<a href="#">ISIS, 1999</a>) (<a href="#">DePalma, 2005</a>) (<a href="#">Molloy, 2005</a>) (<a href="#">Wilson-MacDonald, 2005</a>) 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. (<a href="#">Koc, 2009</a>)</p>
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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.

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 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](#))

**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 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

	<p>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. (<a href="#">CMS, 2004</a>) (<a href="#">Boswell, 2007</a>)</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>
<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). (<a href="#">Abram, 1999</a>) (<a href="#">Warr, 1972</a>) (<a href="#">Hickey, 1987</a>)</p> <p>There does not appear to be any evidence to support the current common practice of a series of injections. (<a href="#">Novak, 2008</a>)</p> <p>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. (<a href="#">Lutz, 1998</a>) (<a href="#">Vad, 2002</a>) (<a href="#">Riew, 2000</a>) 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. (<a href="#">McLain, 2005</a>) 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. (<a href="#">Price, 2005</a>) A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain</p>

	<p>may be secondary to a different generator, or in the case of multilevel pathology. (<a href="#">McLain, 2005</a>) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (<a href="#">Cuckler, 1985</a>) 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>
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