

IMED, INC.

11625 Custer Road • Suite 110-343 • Frisco, Texas 75035
Office 972-381-9282 • Toll Free 1-877-333-7374 • Fax 972-250-4584
e-mail: imeddallas@msn.com

Notice of Independent Review Decision

[Date notice sent to all parties]:

02/19/2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Lumbar ESI L5-S1 (#3) under Fluoroscopy

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:

Utilization review determination dated 12/14/12, 01/16/13
Follow up note dated 05/15/12, 04/24/12, 03/19/12, 06/04/12, 10/08/12, 09/10/12, 08/07/12, 06/27/12, 11/08/12, 11/27/12, 01/04/13
Operative note dated 10/24/12, 07/25/12
MRI lumbar spine dated 03/12/12
EMG/NCV dated 06/12/12

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a female whose date of injury is xx/xx/xx. On this date the patient lifted a 20 lb box of copy paper and noted a pull in her back. MRI of the lumbar spine dated 03/12/12 revealed no annular bulge or focal substance protrusion or herniation with clear foramina and unremarkable facet joints at T12-L1, L1-2, L2-3, and L3-4. At L4-5 there is a 2-3 mm posterior central discal substance protrusion/herniation contacts only the thecal sac. At L5-S1 a 3-4 mm posterior central discal substance protrusion/herniation mildly indents the thecal sac. EMG/NCV dated 06/12/12 revealed lumbar radiculopathy involving the L5 and S1 nerve roots bilaterally. The patient underwent lumbar epidural steroid injection on 07/25/12. Follow up note dated 08/07/12 indicates that she is quite pleased to report significant reduction of pain, improved walking and improved functional following epidural steroid injection therapy. Note dated 09/10/12 indicates that the patient is more than 70% improved. The patient subsequently underwent a second epidural steroid injection on 10/24/12. Follow up note dated 11/08/12 indicates that the patient is more than 70-80% improved with her back, buttock and leg complaints. Follow up note dated 11/27/12 notes the patient is continually reporting more than 70% improvement of her leg pain, 80-90% improvement of her back pain following lumbar epidural steroid injection.

Initial request for lumbar epidural steroid injection was non-certified on 12/14/12 noting that there were no significant findings consistent with radiculopathy such as muscle weakness, sensory changes or reflex changes noted. The electrodiagnostic testing did show a radiculopathy of the L5 and S1 nerve roots; however, the lumbar spine MRI did not document nerve root impingement at the L4-5 and L5-S1 levels. Additionally, the guidelines do not recommend a series of three injections, with no more than two injections recommended initially for therapeutic treatment. Follow up note dated 01/04/13 indicates that she had some mild lumbar interspinous tenderness. She had a mild positive straight leg raising sign on the left. The denial was upheld on appeal dated 01/16/13 noting that although it is appreciated that the patient reported improvement with prior lumbar ESIs, it remains that the guidelines recommend no more than 2 epidural steroid injections in the therapeutic phase. It should also be noted that the 01/04/13 progress report does not demonstrate an exacerbation of symptoms or active radiculopathy to re-initiate epidural steroid injection treatment. objective findings include some mild lumbar interspinous tenderness and mild positive straight leg raising sign on the left. The MRI scan results fail to demonstrate significant disc herniation or neural impingement to support a diagnosis of bilateral L5 and S1 acute radiculopathy as found on the EMG/NCV study.

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 epidural steroid injection is not recommended as medically necessary. There is no current, detailed physical examination

submitted for review to establish the presence of active lumbar radiculopathy. The **Official Disability Guidelines** Low Back Chapter notes that radiculopathy must be documented, and objective findings on examination need to be present. The submitted exam notes only some mild lumbar interspinous tenderness and mild positive straight leg raising sign on the left. The submitted lumbar MRI does not document any significant neurocompressive pathology to corroborate a diagnosis of radiculopathy. Given the current clinical data, the requested epidural steroid injection 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.</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. (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</p>
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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](#))

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

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 trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

(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.)