



## IMED, INC.

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### Notice of Independent Review Decision

**DATE OF REVIEW:** 11/07/11

**IRO CASE NO.:**

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

Item in dispute: Reconsideration of Forte's NON-AUTHORIZATION of outpatient lumbar (caudal) ESI at L5-S1. Original decision UPHELD. Recommend NON-AUTHORIZATION.

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

Board Certified Orthopedic Surgeon and Rehabilitation  
Board Certified in Physical Medicine

**REVIEW OUTCOME**

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

Denial Upheld

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

1. 02/20/09 – MRI Lumbar Spine
2. 03/03/10 – Electrodiagnostic Studies
3. 08/24/10 – MRI Lumbar Spine
4. 08/30/11 – Clinical Note – Sue Bidy, FNP-C
5. 09/07/11 – Notice of Utilization Review Findings
6. 09/20/11 – Clinical Note – Sue Bidy, FNP-C
7. 09/28/11 – Notice of Utilization Review Findings
8. **Official Disability Guidelines**

**PATIENT CLINICAL HISTORY (SUMMARY):**

The employee is a male with complaints of low back pain and right knee pain.

MRI of the lumbar spine performed on 02/20/09 was unremarkable without evidence of disc disease, spinal canal stenosis, or neural foraminal stenosis.

Electrodiagnostic studies performed 03/03/10 revealed evidence of left L5 radiculopathy.

An MRI of the lumbar spine performed 08/24/10 showed generalized facet hypertrophy throughout the lumbar spine, most apparent at L4-5 and L5-S1. There was subtle bilateral facet edema at L4-5 on inversion.

The employee was seen for follow-up on 08/30/11. The employee reported 50-60% improvement following the epidural steroid injection while sedentary. The employee reported increased pain with increased activity. Physical examination revealed tenderness to palpation of the lumbar spine and transverse process. There was pain to palpation of the sciatic notch bilaterally. Lumbar range of motion was limited. There was tenderness to palpation of the bilateral sacroiliac joints. The employee was assessed with lumbar spondylosis and lumbar radiculopathy. The employee was recommended for repeat caudal epidural steroid injection.

The request for lumbar caudal epidural steroid injection was denied by utilization review on 09/07/11 due to lack of definitive documentation of at least 50% relief from the prior injection.

The employee was seen for follow up on 09/20/11. The note states the employee reported 50-60% improvement from a caudal epidural steroid injection performed 08/19/11. The leg pain continued to be 50% improved, but the employee reported increased back pain. Physical examination revealed tenderness to palpation of the lumbosacral spine and the bilateral spinous processes. There was tenderness to palpation of the bilateral sciatic notch. Lumbar range of motion was abnormal. Straight leg raise was reported to be positive bilaterally. There was tenderness to palpation of the bilateral sacroiliac joints. There was no decreased response to tactile stimulation of the leg/foot. The employee was able to heel and toe walk. There was pain to palpation of the bilateral lumbar facets. The employee was assessed with lumbar radiculopathy. The employee was recommended for repeat caudal epidural steroid injection.

The request for lumbar caudal epidural steroid injection was denied by utilization review on 09/28/11 due to varied response from the injection, essentially normal MRI of the lumbar spine, and no dermatomal findings on physical examination.

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

The clinical documentation provided for review does not support the medical need for additional caudal and L5-S1 epidural steroid injections. The employee's clinical documentation does not provide sufficient objective evidence of unequivocal lumbar radiculopathy as recommended in current evidence based guidelines. The employee's MRI studies do not provide any findings consistent with neurocompressive pathology that is consistent with the provided EMG/NCV studies. The employee's most recent objective evaluation also does not provide findings consistent with lumbar radiculopathy. As the clinical documentation provided for review does not meet recommendations within current evidence based guidelines, medical necessity is not established for the request.

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

Official Disability Guidelines, Online Version, Low Back Chapter.

**Epidural Steroid Injections:** 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.

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) 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)

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 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)

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. (Deyo, 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)

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.)