

## Notice of Independent Review Decision

### **DATE OF REVIEW:**

02/01/2010

### **IRO CASE #:**

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

Please review the item in dispute: Lumbar epidural steroid injection with fluoroscopic needle injection, lysis of adhesions, and epidurography between 01/15/2010 - 03/16/2010.

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

Doctor of Osteopathy, Board Certified Anesthesiologist, Specializing in Pain Management

### **REVIEW OUTCOME**

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

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

**The requested lumbar epidural steroid injection with fluoroscopic needle injection, lysis of adhesions, and epidurography between 01/15/2010 - 03/16/2010 are not medically necessary.**

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

- TDI/DIVISION OF WORKERS' COMPENSATION referral form
- 01/26/10 MCMC Referral
- 01/25/10 Notice to Utilization Review Agent of Assignment, DWC
- 01/25/10 Notice To MCMC, LLC Of Case Assignment, DWC
- 01/22/10 Request For A Review By An Independent Review Organization
- 01/22/10 Confirmation Of Receipt Of A Request For A Review, DWC
- 01/21/10 physician review letter from ESIS Utilization Review Unit
- 01/20/10 physician review letter, M.D.,
- 01/12/10 notification letter from ESIS Utilization Review Unit
- 01/12/10 physician advisor review, M.D.,
- 01/07/10 Dr. Procedure Orders, Orthopedics
- 12/22/09 Orthopedic Consult, M.D., Orthopedics
- 12/22/09 report from Therapy & Diagnostics
- 12/22/09 X-Ray Lumbar report, M.D.
- 12/21/09 Report of Medical Evaluation, DWC

- 12/21/09 Health Insurance Claim Form
- 12/21/09 report from, M.D.
- 12/15/09 Required Medical Evaluation, M.D.
- 11/13/09 Electrodiagnostic Evaluation/EMG-NCV, Electrodiagnostic Practitioner, Integrative Health & Medical
- 10/14/09 Case Report, M.D., MCMC
- 10/14/09 Notice To Utilization Review Agent Of Assignment, DWC
- 10/14/09 Notice To MCMC, LLC Of Case Assignment, DWC
- 10/14/09 letter from M.D., Recovery Clinic
- 10/13/09 Confirmation Of Receipt Of A Request For A Review, DWC
- 10/12/09 Request For A Review By An Independent Review Organization
- 10/08/09 reconsideration letter, M.D.,
- 10/01/09 Request For Reconsideration, Recovery Clinic
- 09/30/09 Request For Reconsideration, M.D., Recovery Clinic
- 09/25/09 Notification of Determination letter, DO,
- 09/22/09, 10/01/09 Fax Cover sheet with note from Recovery Clinic
- 09/22/09 Preauthorization Review request, Recovery Clinic
- 09/22/09 Consultation and Letter of Medical Necessity, M.D., Back Pain Center, M.D.
- 09/21/09 Physical Therapy Progress Note, M.D., Recovery Clinic
- 08/24/09 lumbar spine MRI, Imaging Center
- Undated memo from ESIS Utilization Review Unit
- Undated Request For Treatment Authorization Form, ESIS Utilization Review Unit
- Undated chart of Lumbar Dominant Symptom and Cervical Dominant Symptom
- Article on Diagnostic and Therapeutic Spinal Injections – Criteria for Successful Outcome
- Article entitled, “The effect of spinal steroid injections for degenerative disc disease”
- Article entitled, “Epidural steroid injections”
- Article entitled, “Nerve Root Blocks in the Treatment of Lumbar Radicular Pain”
- Article entitled, “Epidural steroid injections (ESIs), therapeutic”
- Article entitled, “Definitions of Clinical Findings Used to Place an Individual in a DRE Category”
- Note: Carrier did not supply ODG Guidelines.

#### **PATIENT CLINICAL HISTORY [SUMMARY]:**

The injured individual is a male with date of injury xx/xx. The injured individual injured his wrist and back. He had physical therapy (PT) for his wrist fracture but there is no indication he had PT to his back. MRI showed protrusions/herniation of nucleus pulposus at L3-S1. Electromyogram (EMG) showed left greater than right S1 radiculopathy. The Pain physician, in 09/2009, noted bilateral straight leg raising (SLR) and sensory loss in the anterior legs and dorsum of the feet. Orthopaedics in 12/2009 noted bilateral SLR and reduced sensation in the left S1 dermatome. The Designated Doctor Exam (DDE) and Independent Medical Exam (IME) in 12/2009 noted a positive SLR but no specific sensory loss. The Pain physician suggested bilateral L3-S1 transforaminal epidurals while Orthopaedics suggested an epidural steroid injection (ESI) but did not specify what type or level.

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

First, there is no indication PT has been done to the lumbar spine as all the PT notes only discuss right wrist treatment. Second, the DDE and IME of 12/2009 indicated multiple Waddell findings and a negative neurological exam. Third, the Pain physician suggested a bilateral L3-S1 transforaminal epidural (TFE) while the ortho surgeon suggested an ESI (no level indicated or type). Fourth, their findings differ in that the Pain physician indicated sensory loss bilateral in the legs and feet while Orthopaedic indicated reduced sensation in the left S1 dermatome only. Since the ESI is denied, the epidurogram is denied. The lysis is denied as there is no evidence of scar tissue on MRI; there is no indication ESIs have failed or are indicated.

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

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

Official Disability Guidelines for ESI: 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) This recent RCT concluded that both ESIs and PT seem to be effective for lumbar spinal stenosis for up to 6 months. Both ESI and PT groups demonstrated significant improvement in pain and functional parameters compared to control and no significant difference was noted between the 2 treatment groups at 6 months, but the ESI group was significantly more improved at the 2nd week. (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)

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)

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, 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. For unequivocal evidence of radiculopathy, see AMA Guides, 5th Edition, page 382-383. (Andersson, 2000)

(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 required. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of 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.)

Official Disability Guidelines for lysis of adhesions: Not recommended due to the lack of sufficient literature evidence (risk vs. benefit, conflicting literature). Also referred to as epidural neurolysis, epidural neuroplasty, or lysis of epidural adhesions, percutaneous adhesiolysis is a treatment for chronic back pain that involves disruption, reduction, and/or elimination of fibrous tissue from the epidural space. Lysis of adhesions is carried out by catheter manipulation and/or injection of saline (hypertonic saline may provide the best results). Epidural injection of local anesthetic and steroid is also performed. It has been suggested that the purpose of the intervention is to eliminate the effect of scar formation, allowing for direct application of drugs to the involved nerves and tissue, but the exact mechanism of success has not been determined. There is a large amount of variability in the technique used, and the technical ability of the physician appears to play a large role in the success of the procedure. In addition, research into the identification of the patient who is best served by this intervention remains largely uninvestigated. Adverse reactions include dural puncture, spinal cord compression, catheter shearing, infection, excessive spinal cord compression, hematoma, bleeding, and dural puncture. Duration of pain relief appears to range from 3-4 months. Given the limited evidence available for percutaneous epidural adhesiolysis it is recommended that this procedure be regarded as investigational at this time. (Gerdesmeyer, 2003) (Heavner, 1999) (Belozer, 2004) (BlueCross BlueShield, 2004) (Belozer, 2004) (Boswell, 2005) (Boswell, 2007) (The Regence Group, 2005) (Chopra, 2005) (Manchikanti1, 2004) (Epter, 2009) This recent RCT found that after 3 months, the visual analog scale (VAS) score for back and leg pain was significantly reduced in the epidural neuroplasty group, compared to conservative treatment with physical therapy, and the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced 12 months after the procedure in contrast to the group that received conservative treatment. (Veihelmann, 2006)

Preliminary suggested criteria for percutaneous adhesiolysis while under study:

- The 1-day protocol is preferred over the 3-day protocol.



- All conservative treatment modalities have failed, including epidural steroid injections.
- The physician intends to conduct the adhesiolysis in order to administer drugs closer to a nerve.
- The physician documents strong suspicion of adhesions blocking access to the nerve.
- Adhesions blocking access to the nerve have been identified by Gallium MRI or Fluoroscopy during epidural steroid injections.