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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 04/22/2010

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified) doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Outpatient lumbar epidural steroid injection (ESI) times one (1)

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o 09-22-08 Initial Examination report from
- o 10-01-08 Lumbar Myelogram/CT scan read by
- o 10-06-08 Medical Report from
- o 10-15-08 Medical Report from
- o 10-29-08 History and Physical from
- o 10-29-08 Intraoperative Evoked Potentials Monitoring Report from
- o 10-29-08 Radiology report, intraoperative films, read by
- o 10-29-08 Operative Report from
- o 10-31-08 Discharge Summary from
- o 11-24-08 PT Evaluation from PT
- o 11-24-08 Medical Report from
- o 01-30-09 PT progress report from PT
- o 02-02-09 Radiology report, lumbar series, read by
- o 02-02-09 Medical Report from
- o 04-06-09 Medical Report from
- o 06-08-09 Medical Report from
- o 06-25-09 Medical Report from
- o 08-10-09 Medical report from
- o 08-19-09 Radiology report, lumbar CT myelogram, read by
- o 09-21-09 Medical report from
- o 10-06-09 Operative Report from
- o 01-25-10 Medical report from
- o 01-27-10 Fax request for LESI with fluoroscopy from
- o 02-02-10 Adverse Determination Letter from xxxxx

- o 02-15-10 Letter requesting reconsideration from
- o 02-17-10 Fax request for appeal from
- o 02-24-10 Adverse Determination letter for Reconsideration from xxxxxx
- o 03-29-10 Confirmation of Receipt of Request for IRO from TDI
- o 03-11-10 Request for IRO from the Claimant
- o 04-05-10 Notice of Case Assignment of IRO from TDI

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records and prior reviews, the patient is a -year-old who sustained an industrial injury to the low back on xxxxxx when he slipped while spraying weeds and almost fell. His primary provider is a neurosurgeon.

At initial examination on xxxxx the provider noted low back pain that radiated into the left leg and foot with numbness, dysesthesias and a feeling of weakness. The patient reports primarily leg pain that is worsening. He continues to work. He has had facet injections and epidural steroid injections. Lumbar MRI of 3.5 months prior showed multilevel disc pathology, particularly at L3-4 and L4-5, where there is high grade lateral recess stenosis with central canal stenosis and a protruding disc. The most significant high grade stenosis was seen at left L4-5 with compression of the L5 nerve root. He has tried multiple medications and is currently using hydrocodone 10 mg. The steroid injections have not given him any benefit. He is also using Lopressor, Lisinopril, Nexium, Norvasc, Symvastatin and Viagra. He is 5' 8" and 170 pounds. He smokes a pack per day. He has a left antalgic gait. Straight leg raising on the right causes some posterior thigh pain at about 60 degrees and left straight leg raise elicits pain at 30 - 40 degrees. There is decreased sensation along the lateral aspect of the distal left leg and into the dorsum and lateral foot. There is some left weakness with plantar flexion and dorsiflexion of the foot. He has severe left lumbar radiculopathies, probably L5. Recommendation is for lumbar myelogram and CT scan.

Lumbar myelogram was performed October 1, 2008 and revealed significant central canal stenosis L2 through L5, particularly at L3-4 and L4-5. There was significant central canal stenosis and root compression. CT scan showed moderate to prominent spinal canal stenosis and moderate to prominent neural foraminal stenosis at L1-2. Severe spinal canal stenosis and moderate to prominent bilateral neural foraminal stenosis at L2-3. Severe spinal canal stenosis and prominent bilateral neural foraminal stenosis at L3-4. Prominent spinal canal stenosis and moderate to prominent bilateral neural foraminal stenosis at L4-5. At L5-S1 there was mild central bulging of the disc noted causing mild encroachment upon central aspect anterior portion of the dural sac. Neural foramina and facet joints are maintained.

On October 6, 2008 treatment options were discussed and recommendation was for an L2 through L5 decompression with multilevel bilateral root decompression and posterolateral fusion without instrumentation. On October 15, 2008 the provider noted the surgery had been authorized.

The patient underwent surgery on October 29, 2008. The intraoperative evoked potential study noted abnormal baseline recordings, reflecting a preexisting neurologic disorder such as peripheral polyneuropathy or bilateral lumbosacral polyradiculopathy. The most severely compressed nerve root appeared to be left L5. The surgery involved laminectomy with fusions L2 through L5. He did well post-operatively and reported no further radiating leg pain at discharge.

Three weeks post-op the patient was noted to be walking well and having good strength. He was ready to initiate PT.

He was assessed in PT on November 24, 2008. A two-month program was planned of three times per week treatment (24 sessions). He initiated one month of pool therapy on December 4, 2008 and then transitioned to one month of land-based rehabilitation. On January 30, 2009 after two months of therapy the therapist noted improvements but also stated, his pain level has not improved much over the past month.

Radiographs on February 2, 2009 note the surgery, disc space narrowing at L3-4 and L4-5 and lateral displacement of the L3 vertebral body on L4 without acute findings. Reevaluation on the same date noted he is stronger and able to walk further with less hip and leg pain, although he has residual discomfort in the left leg. He has finished PT. He is not yet ready to return to work.

Seven months post-op the patient is noted on June 8, 2009 to be working. He has some aching pain in the left hip and buttock area and in the left leg. Leg strength is good. The Darvocet is insufficient for pain relief and he is prescribed hydrocodone 5 mg, Flexeril and Motrin. He is a good candidate for a left-sided lumbar epidural Depo-Medrol injection to reduce his inflammation.

The patient returned on June 25, 2009 reporting left leg pain in the L5 dermatome into the dorsum of the foot. A little weakness of the left foot and great toe dorsiflexion were noted. His gait is antalgic and straight leg raising elicits pain at between 45 and 60 degrees. A left L4-5 LESI was denied and will be appealed.

Lumbar myelogram/CT scan was performed on August 19, 2009. CT scan findings are significant for: Post-operative changes are noted. At L2-3 there is moderate bulging of the disc causing moderate encroachment upon the dural sac and neural foramina. At L3-4 moderate to prominent narrowing of the disc is noted with gas present within the disc and posterior hypertrophic spurring is seen. There is also approximately 4 mm posterior subluxation of L3 on L4. Moderate broad-based bulging of the disc is causing moderate encroachment upon the dural sac and left neural foramen and mild encroachment upon the right neural foramen. At L4-5 there is prominent narrowing of the disc space with gas present within the disc. Posterior

hypertrophic spurring is present and there is approximately 2 to 3 mm posterior subluxation of L4 on L5. Asymmetrical bulging of the disc is noted centrally and to the left of the midline causing prominent encroachment upon the left anterolateral aspect of the dural sac and orifice of the left neural foramen as well as prominent encroachment upon the remainder of the left neural foramen. The right neural foramen is maintained. At L5-S1, there is mild central bulging of the disc which causes mild encroachment upon the central aspect of the anterior portion of the dural sac. Dilatation of the abdominal aorta is noted.

The medical report of September 21, 2009 notes CT scan showed root compression on the left at L3-4 and L4-5. Recommendation is again made for a left L4-5 LESI. The patient was subsequently administered an epidural injection on October 6, 2009. A handwritten note indicates that the response to this injection was 70% pain relief for about two weeks.

The reevaluation report of January 25, 2010 indicates the patient was provided [a second?] epidural injection on December 9, 2009. He got quite a bit of help from this injection and desires another injection. He is using hydrocodone 5 mg, Flexeril and Motrin. The neurological examination remained unchanged. A follow-up epidural was recommended.

Request for outpatient lumbar epidural steroid injection times one was considered in review on February 2, 2010 with recommendation for non-certification. The patient is status post laminectomy with fusions L2 - L5 on 10/29/08. The LESI of 10/06/09 was noted to have provided 70% relief. On 01/25/10 the provider noted an L4-5 LESI performed on 12/09/09 provided quite a bit of help, with improved activity and less need for medications. No changes were noted on spinal or neurological exams, but no detailed physical exam findings were documented. The request does not meet ODG criteria. ODG does not support a series of 3 LESI. Repeat LESI are supported for patients who receive at least 50% relief for at least 6-8 weeks. The percentage and duration of response to previous LESI is not documented. New or recurrent symptoms are not documented.

On February 15, 2010 the provider reported a repeat LESI was denied. He had significant benefit from a LESI that was done "three months ago" and he needs a booster injection to relieve his pain and his need for medications and to make him more functional. He still takes hydrocodone 5 mg, Flexeril and Motrin.

Request for reconsideration outpatient lumbar epidural steroid injection times one was considered in review on February 24, 2010 with recommendation for non-certification. The patient was spraying weeds when he slipped and injured his back. There is no indication that he actually fell. MRI showed degenerative changes. He had a lumbar decompression laminectomy from L2-L5 with fusion. He continued to have leg pain post-op, and the same physical findings. Myelogram of 9/21/09 showed compression of the left L3-4 and L4-5 roots. He has had two LESI. On 02/02/10 a repeat LESI was denied because ODG does not support a series of 3 LESI's and there was no indication of result from prior injection except to state that he got "quite a bit of help from lumbar epidural Depo-Medrol" injection. The patient does not appear to be involved in an active program of therapy in the form of a home exercise program. There is no record of whether he is working. There has been no change in the neurological findings over a period of 2 years; therefore chronic changes are unlikely to respond to cortisone. There had been no record of the degree of response to LESI in the past other than "quite a bit of help."

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

ODG supports ESI's 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. Generally, ESI's are provided to patient's who are headed for surgery but seek a means of temporary relief so they can engage in further aggressive rehabilitation efforts and perhaps avoid a surgery.

The patient is approximately 18 months status post three-level decompression L2-5 with multilevel bilateral root decompression and posterolateral fusion without instrumentation. The intraoperative evoked potential study noted abnormal baseline recordings, reflecting a preexisting neurologic disorder such as peripheral polyneuropathy or bilateral lumbosacral polyradiculopathy. The patient also has cardiac conditions as evidenced by his medications and a dilating abdominal aorta seen on imaging yet continues to smoke a pack per day. He has not been reported to be engaged in a home exercise program. In June 2009, seven months post op, Darvocet was insufficient for pain relief and he initiated hydrocodone 5 mg, Flexeril and Motrin. He continues to use these medications. There was indication of left L5 radiculopathy in June 2009 similar to his pre-surgical symptoms. Per CT/myelogram he continues to have mild right neural stenosis at L3-4 and left neural stenosis at L4-5. A left L4-5 epidural injection on October 6, 2009 resulted in 70% pain relief for about two weeks only. He "He got quite a bit of help" from a second injection of December 9, 2009. However, the response is not quantified and the medications remain the same.

The first-line reviewer noted, no changes were noted on spinal or neurological exams, but no detailed physical exam findings were documented and, ODG does not support a series of 3 LESI's. The second-line reviewer noted, the patient does not appear to be involved in an active program of therapy in the form of a home exercise program. There is no record of whether he is working. There has been no change in the neurological findings over a period of 2 years. Therefore chronic changes are unlikely to respond to cortisone. Also, there was no record of the degree of response to LESI's in the past other than "quite a bit of help."

Per ODG, 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. It does appear as noted prior, that cortisone is not likely to be of benefit for a patient with no change in neurologic findings over a period of 2 years. Additionally, the patient does not meet the duration and quantity of response to the prior injections and a series of three injections is not supported. And finally, the patient is apparently not engaged in an active rehab program. ODG criteria have not been met for a third LESI.

Therefore, my recommendation is to agree the previous non-certification for outpatient lumbar epidural steroid injection (ESI) times one (1).

The IRO's decision is consistent with the following guidelines:

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

The Official Disability Guidelines (04-08-2010) Lumbar 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. 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. 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.

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. 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. This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations.

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure.

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. 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.

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. Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. 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.

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. Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo.

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.)