

Notice of Independent Review Decision

DATE OF REVIEW: 07/05/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Bilateral Transforaminal Epidural Steroid Injection L4-5 L5-S1 under sedation

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. He is certified in pain management. He is a member of the Texas Medical Board. He has a private practice of Physical Medicine & Rehabilitation, Electrodiagnostic Medicine & Pain Management in Texas. He has published in medical journals. He is a member of his state and national medical societies

REVIEW OUTCOME

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

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.

Upon independent review, I find that the previous adverse determination should be upheld. The *ODG* guidelines have not been met for this service.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

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Records Received: 17 page fax 06/13/11 Texas Department of Insurance IRO request, 9 page fax 06/16/11 URA response to disputed services including administrative and medical. Dates of documents range from 5/05/11 to 6/13/11.

PATIENT CLINICAL HISTORY [SUMMARY]:

The medical records reflect that this individual is a female who sustained a work-related injury xx/xx/xx. The patient is currently status post lumbar fusion at L5-S1 from July 2003 and currently has a spinal cord stimulator. The patient underwent nerve conduction studies 10/20/08, which indicated the presence of chronic L5 radiculopathy with no evidence of an entrapment or compressive neuropathy and no evidence of a large peripheral polyneuropathy. In recent evaluation, the patient indicates low back pain with pain that radiates into the legs, primarily radiating down the right buttock and down the right leg. Pain is reported on a scale of 0 to 10 without medication at 7. The patient has been noted on examinations to have behavior aberrations that have been detailed as the following:

- At the office visit on 12/12/08, she stated she had been given a referral by one of her other physicians. She could not tell or report whom it was for and stated that she refused to go. She does not care what it is for, but she was tired of seeing different doctors and them doing the same things for her. She stated that she would not go to this other physician because that physician does not know her.
- The doctor's report also indicated information reports from Rehab and Wound Clinic that she was not compliant with physical therapy and she had been discharged.
- Failed urine drug screen on 09/24/09.
- On visit of 11/17/09, she stated that she was out of medication at least three days early.
- Current medications have been indicated to include Percocet, Lunesta, Pristiq, and Amrix.
- The patient was noted to have undergone a transforaminal ESI at L5 and S1 11/18/10. The patient has reported pain symptom relief from the prior ESI, but there is no objective documentation of reduction in pain medication or increase in functional activities.
- The patient does have a spinal cord stimulator in place.

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

The ODG criteria indicate that the information to establish medically reasonable and necessary repeat epidural steroid injections is to include objective evidence

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of prior improvement from similar treatments that include objective evidence of reduction of pain medication and increase in objective functional measure outcomes. Additionally, the *ODG* indicates the findings by objective measures of corresponding clinical examination, imaging study, and/or electrodiagnostic studies of a specific radiculopathy. This is not present in the records reviewed. Also, the epidural steroid injection would preferably be associated with specific activity or exercise procedures to enable the patient to have periods of pain relief while engaging in functional activity exercises. The *ODG* criteria are not met for repeat epidural steroid injection.

ODG Criteria: Epidural Steroid Injection
Dyll IRO

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](#))

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([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](#))

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.)

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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)