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Notice of Independent Review Decision

DATE OF REVIEW: 2/8/10

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Outpatient repeat Caudal Epidural Steroid Injection

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

Certified by the American Board of Anesthesiology with subspecialty certification in Pain Medicine

REVIEW OUTCOME

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

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

Injury date	Claim #	Review Type	ICD-9 DSMV	HCPCS/ NDC	Upheld/ Overturned
		Prospective			Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Correspondence throughout appeal process, including first and second level decision letters, reviews, letters and requests for reconsideration, and request for review by an independent review organization.

Physicians' notes dated 2/20/09 -12/9/09

Presurgical History and Physical dictated 9/17/09

Procedure/operative notes dated 10/30/09, 9/18/09, 12/10/08

X-ray report dated 8/6/09

EMG/NCS report dated 6/19/09

Official Disability Guidelines cited Low Back, ESIs, Criteria for the use of Epidural Steroid injections

PATIENT CLINICAL HISTORY:

The patient is a female whose date of injury is xx/xx/xx. On this date the patient was cleaning a truck bed when she slipped and fell. The earliest clinical record submitted for review indicates that the patient underwent a caudal epidural steroid injection on 12/10/08. The patient returned for follow up on 02/20/09 and reports that the epidural steroid injection helped a great deal. The patient complains of some pain in the right lateral thigh and calf, and continues to work full time

“without problem”. On physical examination there is diffuse tenderness over the lumbar paraspinal segments. Straight leg raising is positive for pain over the right lateral thigh and calf. Gait is somewhat antalgic. The patient was provided Mobic and Neurontin.

The patient was seen on 04/17/09 and complains of low back pain with radiation into the right lateral thigh and calf. The patient has not been able to work since 03/19/09. MRI of the lumbar spine reportedly revealed disc herniation lateralizing the right side at L4 and L5 causing some neural encroachment; however, the report of this study is not submitted for review. The patient was recommended to undergo surgical evaluation at this time. The patient was seen again on 05/22/09 with complaints of increased radicular pain. The patient was recommended to undergo EMG/NCV. Office visit note dated 06/19/09 indicates that the patient was evaluated and underwent an injection which caused a great deal of pain.

The patient underwent an EMG/NCV of the lower extremities on 06/19/09 which is reported to be a normal study.

The patient was seen on 07/02/09. The patient complains of pain in the right sacroiliac joint region with secondary referred pain into the right buttock and right posterior lateral thigh and calf down to the foot. The presumed diagnosis is reportedly sacroiliac joint syndrome. The patient’s physical examination is significant for positive FABER and positive forward thrust testing. It is noted that a sacroiliac joint injection performed on 06/18/09 did not provide any significant benefit to the patient.

The patient was seen by on 07/22/09 with complaints of low back pain and radiation into the right lateral thigh and calf. It is reported that the EMG/NCV study shows an L5 radiculopathy.

The patient underwent CT of the lumbar spine on 08/06/09. This study revealed mild annular bulge at L4-5 and L5-S1 without evidence of actual disc herniation; and mild facet arthrosis. Office visit note dated 08/18/09 reports that the CT scan showed no significant anomalies with small annular bulges at L4-5 and L5-S1 but no encroachment.

Office visit note dated 08/25/09 indicates that the patient’s most severe pain “continues as it has from day one in the region of the sacroiliac joint”. The patient has reportedly failed an intensive regimen of physical therapy and several medications. The patient’s physical examination is correlative with a right sacroiliac joint syndrome.

The patient underwent right sacroiliac joint injection and arthrogram on 09/18/09. The arthrogram shows good filling of the sacroiliac joint. There is no extravasation of contrast from the joint spaces and no evidence of fracture, acute change or dislocation. The patient was seen in follow up on 10/14/09 and reports that the injection did not provide much relief in her symptoms. On physical examination there is diffuse tenderness over the lumbar paraspinal segments; straight leg raising is positive for pain over the right lateral thigh and calf; decreased sensation over the right lateral calf and the patient has a limping gait. The patient was recommended to undergo a caudal epidural steroid injection.

The patient underwent lumbar epidural steroid injection on 10/30/09. The patient was seen in follow up on 12/09/09 and reported at least 40-50% improvement. Physical examination is unchanged. The patient continues to take Hydrocodone and Robaxin.

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

In the Reviewer’s opinion, the request for outpatient repeat caudal epidural steroid injection is not supported by the submitted clinical information. The Reviewer noted that there is a lack of documentation regarding the patient’s previous response to two epidural steroid injections as evidenced by decreased medication use or improved function. There is no objective documentation of radiculopathy on physical examination and no indication of neurocompression on lumbar CT scan. The Official Disability Guidelines support epidural steroid injections only with objective evidence of radiculopathy on physical examination correlated by imaging studies. Repeat epidural steroid injections are supported with evidence of continued objective documented pain relief, decreased need for pain medications, and functional response. The submitted clinical records fail to provide evidence of active radiculopathy, indication of neurocompression on CT scan and adequate response to previous epidural steroid injections.

REFERENCES:

The 2010 Official Disability Guidelines, 15th edition, The Work Loss Data Institute. Online edition.

Epidural steroid injections (ESIs), therapeutic	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. <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) 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) <u>Use for chronic pain:</u> 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
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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.)

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)