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Notice of Independent Review Decision

[Date notice sent to all parties]:

01/23/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: 3rd bilateral L5-S1 TF ESI

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION: Board Certified Anesthesiologist; Board Certified Pain Medicine

REVIEW OUTCOME:

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

Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Clinical note dated 05/17/13
Clinical note dated 05/22/13
Clinical note dated 07/02/13
Clinical note dated 08/02/13
Clinical note dated 09/04/13
Clinical note dated 10/01/13
Clinical note dated 10/16/13
Clinical note dated 11/05/13
Clinical note dated 11/20/13
Therapy note dated 05/10/13
Therapy note dated 05/13/13
MRI of the lumbar spine dated 05/20/13
Adverse determinations dated 11/26/13 & 12/10/13

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who reported an injury regarding his low back. The clinical note dated 05/17/13 indicates the patient stating the low back pain was radiating into the gluteal area. The patient rated the pain as 7/10. The patient described the pain as an aching, burning, and dull sensation with a tightness quality. The note does mention the patient having undergone physical therapy as well as the use of a TENS unit and massage therapy. The note mentions the patient utilizing Norco, Robaxin, and Naproxen for pain relief. The MRI of the lumbar spine dated 05/20/13 revealed a focal left paracentral subligamentous disc herniation measuring 6-8mm at the L5-S1 level. This was noted to be minimally contacting the traversing left S1 nerve root. The clinical note dated 05/22/13 mentions the patient continuing with a burning type pain radiating to the gluteal area bilaterally. The patient was recommended for an L5-S1 epidural injection at that time. The clinical note dated 07/02/13 mentions the patient rating his low back pain as 6/10. Radiating pain continued to the buttocks. The clinical note dated 08/02/13 indicates the patient rating the pain as 7/10. The patient was recommended for electrodiagnostic studies at that time. The clinical note dated 09/04/13 mentions the patient's medication regimen providing adequate pain relief. The procedural note dated 10/01/13 indicates the patient undergoing a transforaminal epidural steroid injection at the L5-S1 level. The clinical note dated 10/16/13 mentions the patient rating his pain as 4/10. The patient stated the previous epidural injection did provide 80% pain relief. The procedural note dated 11/05/13 mentions the patient undergoing a 2nd epidural injection at the L5-S1 level. The clinical note dated 11/20/13 mentions the patient having a 60% relief of pain from the previous epidural injection. The patient continued to rate the pain as 7/10 at that time. The patient continued with complaints of radiating pain to the gluteal area bilaterally. The patient was noted to have a positive straight leg raise bilaterally at 50 degrees.

The utilization review dated 11/26/13 resulted in a denial as no information was submitted regarding the patient's neurologic deficits or evidence of radiculopathy.

The utilization review dated 12/10/13 resulted in a denial for an epidural injection as the duration of relief from the previous epidural injection was not submitted.

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

The documentation submitted for review elaborates the patient complaining of low back pain with radiation of pain to both buttocks. The patient is noted to have undergone 2 previous epidural injections. Currently, no high quality studies exist supporting a series of 3 epidural injections. Additionally, no information was submitted regarding the patient's clinical findings regarding any radiculopathy. No information was submitted regarding the length of time the patient had received regarding a benefit from the 2nd epidural injection. As such, it is the opinion of this

reviewer that the request for a 3rd epidural injection at L5-S1 is not recommended .

IRO REVIEWER REPORT TEMPLATE -WC

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

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

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. Not recommended for spinal stenosis or for nonspecific low back pain. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, but ESIs have not been found to be as beneficial a treatment for the latter condition. According to SPORT, ESIs are associated with less improvement in spinal stenosis. (Radcliff, 2013)

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)

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.

For spinal stenosis: The use of epidural steroid injection (ESI) in patients with lumbar spinal stenosis is common, but there is little evidence in the literature to demonstrate its long-term benefit. Despite equivalent baseline status, ESIs are associated with significantly less improvement at 4 years among all patients with spinal stenosis. Furthermore, ESIs were associated with longer duration of surgery and longer hospital stay. There was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. There was no distinct surgical avoidance noted with ESI. (Radcliff, 2013) This systematic review found the data

was limited to suggest that ESI is effective in lumbar spinal stenosis. (Bresnahan, 2013) An RCT addressed the use of ESIs for treatment of spinal stenosis, and there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. (Koc, 2009) According to the APS/ ACP guidelines, ESIs are not for nonspecific low back pain or spinal stenosis. (Chou, 2008)

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) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. (Manchikanti, 2011) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. (Iversen, 2011)

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) Not recommended post-op. The evidence for ESI for post lumbar surgery syndrome is poor. (Manchikanti, 2012)

Patient selection: 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)

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to recommend that radiculopathy be corroborated by imaging studies and/or electrodiagnostic testing. (Cohen, 2012)

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. (Mandel, 2013)

Recent research: 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) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. (Weiner, 2012) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant differences in either leg pain or disability at 12 months follow-up. (Pinto, 2012) According to this systematic review, ESIs without the drug (epidural nonsteroid injections), often used as a placebo treatment, were as effective as ESIs and better than no epidural injections. (Bicket, 2013) This meta-analysis suggested that ESI did not improve back-specific disability more than a placebo or other procedure long-term (6 months), and did not significantly decrease the number of patients who underwent subsequent surgery. (Choi, 2013)

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 (due to herniated nucleus pulposus, but not spinal stenosis) 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.)