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[Date notice sent to all parties]:

9/3/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: L5-S1 ESI under fluoroscopy, sedation

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

REVIEW OUTCOME:

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

XUpheld

(Agree)

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

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male whose date of injury is XX/XX/XXXX. The patient fell from a lift approximately 9 feet on this date. The patient suffered a distal fibula fracture on the right. He was also diagnosed with cervical and lumbar strain/sprain syndrome. The patient underwent anterior cervical discectomy and fusion C3-C6 on 07/30/14. CT of the lumbar spine dated 08/04/14 revealed a degenerative grade I spondylolisthesis of L5 on S1. Disc space height and vacuum disc changes are identified. A 2 mm posterior disc protrusion is seen. There is narrowing of the central canal to 9-10 mm. Moderate severe bilateral neural foraminal narrowing is seen. Note dated 11/05/14 indicates that the patient underwent appropriate physical therapy. The patient underwent cervical epidural steroid injection on 12/16/14. Follow up note dated 05/14/15 indicates that he continues with moderate cervical and lumbar pain. MRI of the lumbar spine dated 06/01/15 revealed at L5-sq there is a 4 mm right foraminal disc protrusion which impinges upon the inferior surface of the exiting right L5 nerve root. There is a mild degree of degenerative facet joint hypertrophy at this segment. The patient underwent cervical epidural steroid injection on 06/02/15. Report of medical evaluation dated 06/08/15 indicates that lumbosacral range of motion is decreased significantly. There is a 7 cm scar with a 2 cm bone graft from a 2000 back surgery. Seated straight leg raising is to 80 degrees on the right and 90 degrees on the left. Supine straight leg raising is 20 on the right and 30

degrees on the left. Deep tendon reflexes are 3+ bilateral patellar tendons and 2+ bilateral Achilles tendons. Light touch, sharp touch and vibration are felt more on the right side than the left side. Diagnoses are listed as cervical sprain/strain, low back sprain/strain superimposed upon pre-existing condition of spondylolisthesis, right shoulder contusion, right knee strain, right ankle lateral fibular fracture. The patient has not reached maximum medical improvement. Follow up note dated 07/09/15 indicates that he continues to walk with an antalgic limp. He has been noticing some weakness in the right leg. He has a positive straight leg raising sign.

Initial request for L5-S1 epidural steroid injection under fluoroscopy, sedation was non-certified on 06/29/15 noting that the documentation submitted for review fails to show that the patient has anxiety to warrant the use of IV sedation during an epidural steroid injection. A recent evaluation of the patient was not documented within the most recent clinical examination to show that he has radicular symptoms at the L5-S1 level such as decreased muscle strength or sensation in this dermatomal/myotomal distribution. The denial was upheld on appeal dated 08/04/15 noting that there is incomplete information regarding the patient's response to most recent epidural steroid injection. No objective information was submitted regarding the patient's functional improvement.

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

Based on the clinical information provided, the request for L5-S1 epidural steroid injection under fluoroscopy, sedation is not recommended as medically necessary, and the two previous denials are upheld. There is no comprehensive assessment of treatment for the patient's low back pain completed to date or the patient's response thereto submitted for review. The Official Disability Guidelines require that a patient be initially unresponsive to conservative treatment prior to the performance of a lumbar epidural steroid injection. There is no indication that the patient has received any recent active treatment. The Official Disability Guidelines require documentation of radiculopathy on physical examination corroborated by imaging studies and/or electrodiagnostic results. There is no current, detailed physical examination submitted for review with radicular findings as required by the Official Disability Guidelines. Therefore, medical necessity is not established in accordance with current evidence based guidelines.

IRO REVIEWER REPORT TEMPLATE -WC

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

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

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

ODG Low Back Chapter

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) According to a high quality RCT, in the treatment of symptoms of lumbar spinal stenosis, epidural injections of glucocorticoids plus lidocaine offered minimal or no benefit over epidural injections of lidocaine alone at 6 weeks. At 3 weeks, the glucocorticoid-lidocaine group had greater improvement than the lidocaine-alone group, but the differences were clinically insignificant. Despite a rapid increase in the use of epidural glucocorticoid injections for lumbar spinal stenosis, there is little evidence of effectiveness from clinical trials. (Friedly, 2014)

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) Transforaminal epidural steroid injections, despite being generally regarded as superior to interlaminar injections, are not significantly better in providing pain relief or functional improvement, according to a new systematic review. (Chien, 2014)

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: Radiculopathy must be documented, as indicated in the ODG criteria. In addition, 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) Injections for spinal pain have high failure rates, emphasizing the importance of patient selection. Individuals with centralized pain, such as those with fibromyalgia and chronic widespread pain, and poorly controlled depression, may be poor candidates. (Brummett, 2013)

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) The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014) This study shows that ESIs had a significant beneficial effect as an additional treatment for lumbosacral radicular syndrome in general practice, but the effect was too small to be considered clinically relevant to patients, so the authors do not recommend ESIs as a regular intervention in general practice. (Spijker-Huiges, 2014) A high quality RCT concluded that gabapentin and ESIs for radicular pain both resulted in modest improvements in pain and function, which persisted through three months. Some differences favored ESIs, but these tended to be small and transient. They recommended a trial with neuropathic drugs as a reasonable first line treatment option. (Cohen, 2015) The AHRQ comparative effectiveness study on injection therapies for LBP concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain. (Chou, 2015) See the Neck Chapter, where ESIs are not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit.

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, muscle relaxants & neuropathic drugs).

(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.)