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Notice of Independent Review Decision

July 27, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Right L5-S1 transforaminal epidural steroid injection

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Diplomate, American Board of Physical Medicine and Rehabilitation and Pain Medicine

REVIEW OUTCOME:

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

☒ Overturned (Disagree)

Medical documentation **supports** the medical necessity of the health care services in dispute.

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 xx-year-old who was injured on xx/xx/xx. The patient immediately felt low back pain with tingling and numbness.

Magnetic resonance imaging (MRI) of the lumbar spine without contrast dated xx/xx/xx, documented mild degenerative changes most pronounced at L4-L5 and L5-S1. No magnetic resonance evidence of cord compression was seen.

evaluated the patient on October 22, 2014, mid to lower back pain, numbness and tingling to the outside of the right foot, pain and numbness down the right leg. gait was antalgic without assistance.

There was tenderness to palpation along the spinous processes of the lower thoracic spine, tenderness to palpation along the paraspinous musculature of the lumbar spine, point tenderness at the right sacroiliac (SI) joint. Right hip pain was reproduced with internal and external rotation of the femur. There was decreased sensation to light touch and pinch along the lateral aspect of the right leg, the lateral malleolus and dorsum of the lateral aspect of the right foot. The diagnoses were lumbar radiculopathy, bulging lumbar disc, SI joint inflammation and hypertension. recommended therapy with emphasis on stretching and reconditioning, lumbar epidural steroid injection (ESI) and SI joint injection, a course of nonsteroidal anti-inflammatory drugs (NSAIDs) such as Naprosyn or ibuprofen, weight loss and obtaining electromyography (EMG) studies of the lower extremities to rule out radiculopathy.

evaluated the patient on November 26, 2014, for lumbar ESI x3. The claimant reported low back pain and leg pain; groin felt as if needles were sticking her perineum only on the right and into the vaginal vault. The patient stated she had noted bowel and urine leakage with less control. On examination, the claimant was 5'3" tall, weighed 286 pounds and had a BMI of 50.7. low back examination was remarkable for positive straight leg raising (SLR) and pelvic rock tests. Labs were ordered including urine drug screen (UDS), PTT, INR, comprehensive metabolic panel (CMP) and complete blood count (CBC).

In a follow-up on December 19, 2014, the patient stated she had received a cardiac clearance for her procedure. She reported low back stiffness and radicular right leg pain. recommended moving forward with lumbar ESI x3 followed by SI joint injections x3.

On December 29, 2014, noted the patient's status was unchanged from previous. She reported she was currently having pain in the lower back and buttocks, right more than left. Pain was rated as 6/10. The patient stated she was a single mom taking care of her son who she homeschooled. performed an ESI at L4-L5 at the midline under fluoroscopy.

The patient underwent a PT evaluation on January 12, 2015. It was noted that from November 4, 2014, the patient had attended six sessions of therapy. The plan was to provide additional two weeks of therapy for four weeks.

In a follow-up on January 16, 2015, the patient stated following the ESI, she felt 100% pain relief for five days. She stated she was still receiving 25% less pain that she started with. She was now able to sleep a little better, but was still unable to walk or stand for long periods. A back brace was ordered to try to prolong the time the patient was able to stand or walk. recommended proceeding with the SI joint injection as recommended.

According to the soap note dated March 18, 2015, noted complaints of low back pain rated as 9/10. Examination revealed 5/5 motor testing bilaterally. There was tenderness to palpation (TTP) over the posterior sacroiliac spine (PSIS), positive Faber, Fair, and Straight leg raise on the right side. it was noted the claimant had not been able to return to work. she had completed a second round of PT and had some improvement but still was hurting at 9/10 and intolerable. The patient was given Lyrica,

Elavil and Norco.

On April 6, 2015, performed an SI joint injection on the right under fluoroscopy with arthrogram.

According to the electrodiagnostic evaluation dated April 14, 2015, noted the patient presented with greater than seven months history of back pain radiating to the right buttock, perineum, lateral thigh and distal lateral lower leg. The patient described the symptoms as intermittent, severe numbness, tingling, and burning pain in the lower back radiating to the right hip and leg with associated lower extremity numbness and tingling. The symptoms were exacerbated by repetitive activity and standing. Review of systems was positive for numbness, tingling and/or pain in the lower extremities, high blood pressure and asthma. Physical examination revealed gait was normal. Strength testing revealed 5/5 bilateral lower extremities. Sensation testing revealed light touch intact in all peripheral nerve and dermatomal distributions bilaterally. Muscle stretch revealed hyporeflexia bilaterally. There was full lower extremity ROM bilaterally. Provocative testing revealed positive straight leg raise test, FABER and FAIR test on the right. The patient denied tobacco use. The patient was diagnosed with lumbago, unspecified thoracic or lumbosacral neuritis or radiculitis, and sacroiliitis, not elsewhere classified.

Electromyography/Nerve Conduction velocity ((EMG/NCV) studies dated April 14, 2015, documented evidence of a chronic (greater than 3 month's duration) L5 and S1 radiculopathy on the right. There was no electrodiagnostic evidence of any other focal nerve entrapment or generalized peripheral neuropathy in the right lower limb. Treatment plan included a right L5-S1 transforaminal ESI.

On April 21, 2015, reviewed the EMG results and planned to set up the patient for a right L5-S1 transforaminal ESI.

On April 27, 2015, the request for a transforaminal ESI at L5-S1 on the right was denied. Rationale: *"According to ODG Low Back epidural steroid injections (ESIs), therapeutic criteria for the use of epidural steroid injections 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."*

An appeal for a transforaminal ESI at L5-S1 on the right was denied on May 21, 2015, with the following rationale: *"The notes provided in the patient's medical record clearly document that they have had a trial of lumbar epidural steroid injection (L4-5 LESI x 3) during December 2014-January 2015. The patient had 100% relief but that lasted only 5 days, after which, the notes indicate the patient only had 25% relief that lasted longer than 5 days. The current request is for repeat LESI, right L5-S1 transforaminal route. Since the initial blocks did not provide lasting relief (at least 6-8 weeks), per ODG, additional blocks are not recommended. Therefore, the requested appeal for a right L5-S1 transforaminal epidural steroid injection is upheld."*

evaluated the patient on June 2, 2015, for pain in the right leg going down in the L5 dermatome. It was noted the patient had tried bedrest, transcutaneous electrical nerve stimulation (TENS) unit, heat

application, medications, two rounds of PT. reviewed the MRI as showing a disc herniation between L4-L5 that was central but more eccentric to the left. ordered a lumbar computerized tomography (CT) myelogram to confirm a right-sided compressive pathology as much as to the left side. the patient was also to obtain dynamic lumbar spine x-rays.

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

Patient had injury with disc pathology and neurological findings which qualified for injections. Repeat injections are warranted if there is a symptom free period and to assist other treatments per ODG.

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

☒ **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) 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) (Delport, 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.)