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Description of the service or services in dispute:
Left L2, L3 and L4 lumbar transforaminal epidural steroid injection with fluoroscopy and monitored anesthesia by an on call Certified Registered Nurse Anesthetist (CRNA)

Description of the qualifications for each physician or other health care provider who reviewed the decision:
Board Certified Orthopedic Surgery

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

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

Patient Clinical History (Summary)
XXXX who was diagnosed with lumbar foraminal stenosis, bilateral L2-L3, L3-L4 and L4-L5; radiculopathy, left L4 and L5; lumbar disc displacement with radiculopathy, right L2 and L3; and spondylolisthesis, L2-L3 and L5-S1.

The patient was injured on XXXX while XXXX. This resulted in pain in the midline and left lumbosacral region. History is remarkable for XXXX. XXXX has been off work since XXXX.

On XXXX, the patient was seen by XXXX for low back pain. XXXX complained of bilateral lower lumbar pain. XXXX rated the pain as 8-9/10. XXXX also complained of left lower extremity pain in the calf laterally and bilateral lower extremity numbness. The associated complaints included abdominal pain, distal numbness, weakness in the limbs and insomnia. On examination, the patient was in moderate distress with an antalgic and slow guarded gait. Light touch sensation was decreased (hypoesthesia) in left L3 dermatome across the front of the thigh and into the inside part of the knee; L4 dermatome into the kneecap area and down to the inside ankle region, L5 dermatome down the outside of the thigh/back of the leg into the leg/shin; and middle of the foot and L2 dermatome. Straight leg raising test in a seated posture was positive bilaterally for radiating leg and low back pain. The range of motion was limited in flexion and extension by pain.

The treatment to date included medications (Cyclobenzaprine, Gabapentin and Hydrocodone-Acetaminophen), thoracolumbar spinal cord stimulator implant in XXXX, posterior lumbar fusion in XXXX, lumbar transforaminal injection on XXXX, lumbar laminectomy at L4-L5 in XXXX and lumbar spine fusion surgery at L4-L5 in XXXX.

On XXXX, a CT scan of the thoracic spine with contrast showed asymmetric left facet degeneration at T1-T2 level; bilateral facet degeneration at T5-T6; and mild retrolisthesis with associated disc bulging and mild bilateral foraminal narrowing at T12-L1. Thoracic x-ray myelogram was negative. Lumbar x-

ray myelogram showed circumferential constriction of the thecal sac. All caudally directed nerve roots were compressed. This was consistent with stenosis. A CT of the lumbar spine with myelogram revealed at L2-L3, mild retrolisthesis with associated disc bulging, moderate to marked bilateral foraminal narrowing and marked central canal stenosis with facet and ligamentum flavum hypertrophic and degenerative change; at L3-L4, status post discectomy and graft with solid anterior and right posterior lateral fusion and decompression of the canal and moderate right foraminal narrowing; at L4-L5, status post discectomy and graft with solid anterior and right posterior lateral fusion, grade 1 retrolisthesis and mild right foraminal narrowing; and at L5-S1, status post discectomy and graft with solid anterior fusion and a mild spondylolisthesis, mild bilateral foraminal narrowing; and bilateral sacroiliac joint fusion anterosuperior.

Per a utilization review by XXXX dated XXXX, the request for left L2, L3, L4 and L5 lumbar transforaminal epidural steroid injections with fluoroscopic guidance and monitored anesthesia care was denied. Per note, the Official Disability Guidelines (ODG) did not support a four-level root block. The patient previously had left L3, L4 and L5 root block with no therapeutic result, so repeating it was not indicated. The EMG showed only L3-L4 radiculopathy and the MRI showed no herniated nucleus pulposus or root impingement at any other level, so there was no clinical support for L2 or L5 root block and no provider contact to modify it. Sedation was not required with injections and the patient had no evidence of any severe medical or psychiatric issue to warrant that.

A reconsideration utilization review was completed by XXXX on XXXX. The requested left L2, L3, L4 and L5 lumbar transforaminal epidural steroid injections with fluoroscopy and monitored anesthesia care were not medically necessary. Per note, "In this case, the injured worker has complaints of back and leg pain, and the provider is requesting a 4-level lumbar transforaminal epidural injections. As per ODG, there is no support for transforaminal injections at more than 2 nerve root levels via a transforaminal approach." Overall, this request was not medically necessary.

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.
I partially agree with this request.

In a review dated XXXX, the reviewer was correct in noting that the ODG limited ESIs to no more than two levels, since the provider request ostensibly requested a 4 level ESI, i.e. L2, 3, 4, 5. The reviewer stated that "MRI showed no herniated nucleus pulposus or root impingement at any other level," However, a myelogram on XXXX showed that all caudally directed nerve roots were compressed. A CT scan post-myelogram, on the same date, showed marked bilateral foraminal narrowing at L23, right foraminal narrowing at L3/4 and L4/5, but no left foraminal stenosis at these levels. A fusion is seen at L5S1 with bilateral foraminal narrowing. The clinical examination shows sensory loss in the left lower extremity (L3, 4, 5), but with decreased reflexes bilaterally (patella, ankle). The reviewer correctly noted that "Sedation was not required with injections and the patient had no evidence of any severe medical or psychiatric issue to warrant that."

In a review dated XXXX, the reviewer corrected noted that the ODG limited ESIs to no more than two levels, since the provider request ostensibly requested 4 levels, L2, 3, 4, 5.

So, a left TF ESI at L3/4 and L4/5 is not indicated because there are no corroborating radiologic findings. A left TF ESI at L2/3 and L5/S1 is reasonable because the clinical findings are corroborated by the radiologic findings. There is no documentation of anxiety, or needle phobia anywhere in the record, so IV sedation cannot be approved without such documentation.

A description and the source of the screening criteria or other clinical basis used to make the decision:

☐ ACOEM-America College of Occupational and Environmental Medicine um knowledgebase

☐ AHRQ-Agency for Healthcare Research and Quality Guidelines DWC-Division of Workers

☐ Compensation Policies and Guidelines European Guidelines for Management of Chronic Low Back Pain

☐ Interqual Criteria

☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards

☐ Mercy Center Consensus Conference Guidelines

☐ Milliman Care Guidelines

☐ ODG-Official Disability Guidelines and Treatment Guidelines

Low Back - Lumbar and Thoracic (Acute and Chronic) (updated 12/28/17)

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.

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, the reduction of medication use and the avoidance of 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, and 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.)

(12) Excessive sedation should be avoided.

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 and 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)
Sedation: The use of sedation during ESI remains controversial. Sedation is less often indicated during lumbar ESI compared with cervical ESI because fewer patients experience a vasovagal reaction, which is likely an indicator of anxiety. (Trentman, 2009) According to a multidisciplinary collaboration led by the FDA, heavy sedation should be avoided in favor of sedation light enough to allow the patient to communicate during the procedure. (Rathmell, 2015) For a more extensive discussion, see the Pain Chapter. See also the Neck Chapter.
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 the 12-month 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) In another systematic review, evidence was only robust for positive effects in patients with chronic radiculopathy, with statistically significant effects on immediate (5 days to ≤2 weeks) improvement in pain, and short-term (>2 weeks to ≤3 months) surgery risk. (Chou, 2015b)

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and 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)