Becket Systems

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Review Outcome

Description of the service or services in dispute:

64483 x 2- Injection(s), anesthetic agent and / or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT) x 2.
Bilateral L5 transforaminal epidural steroid injections x 2.

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

Board Certified Anesthesiology

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

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

Patient Clinical History (Summary)

XX who was diagnosed with other intervertebral disc displacement of the lumbar region (M51.26). XX was involved in a XX on XXXX.

On XXXX, XX was seen by XX for worsening low back and bilateral lower extremity pain. XX felt well with minor complaints and required no assistance with daily activities. At the time, the pain was rated at 7/10 and a maximum at 10/10. XX reported lower back pain. The symptoms were located in the low back bilaterally, on the right side more than the left. The pain radiated to the buttocks, bilateral posterior thighs, bilateral lower legs and feet. The pain was described as severe, aching, stinging, throbbing and constant. The pain was reported to have started on XXXX and was precipitated by XX. The symptoms were exacerbated by back motion, prolonged standing and walking. The symptoms were relieved by rest, non-steroidal anti-inflammatory drugs and opioid analgesics. The associated symptoms included leg numbness, foot numbness, leg weakness, back stiffness, leg pain and paravertebral muscle spasms. On examination, a slow and cautious gait was noted. Additionally, there was decreased sensation to light touch on the right L4 and S1. There was tenderness in the bilateral paraspinal muscles. The strength was 3/5 for the right iliopsoas and 4/5 for the right anterior tibialis. The range of motion was 10 degrees extension and 30 degrees flexion. Kemp's test was positive bilaterally. Slump test was positive for radiculopathy bilaterally. Per the note, XX received 80% relief lasting XX from the last bilateral L5 transforaminal epidural steroid injections. XX stated XX was able to be more active after the last injection and was also able to decrease XX pain medication usage. XX stated XX would go XX without needing any medication following XX injection. XX was taking XX at least two times a day at the time and had limited activity due to pain. XX noted that the examination findings correlated with the pain and believed XX would benefit from repeat injections. XX agreed with the plan.

The treatment to date included medications (XX, XX, XX, XX / XX), physical therapy and bilateral L5 transforaminal epidural steroid injections (the last one provided 80% relief lasting XX).

An MRI of the lumbar spine dated XXXX showed severe degenerative spondylosis with high-grade central canal narrowing at L4-L5 and grade I anterolisthesis of L5 on S1.

Per a utilization review decision letter and a peer review dated XXXX, the requested service was denied by XX. Based on the clinical information submitted for the review and using the evidence-based, peer-reviewed guidelines, the request was non-certified. There was limited documentation of objective functional improvement to justify the need for a repeat injection. There was also no evidence of a decreased need for pain medications. Thus, the request was not substantiated.

Notice of Independent Review Decision

Case Number: XXXXXX Date of Notice: XXXX

Per a reconsideration review decision letter and peer review dated XXXX, the requested service was denied by XX. Based on the clinical information submitted for this review and using the evidence-based, peer-reviewed guidelines, the request was non-certified. The documentation submitted did not demonstrate decreased pain medication use in conjunction with XX previous injections. In fact, it showed increased use of XX, as well as a positive urine drug screen (UDS) for XX after XX most recent injection in XXXX. It was also not clear what functional deficits were being addressed, as XX did not have any documented limitations, nor evidence of active rehabilitation efforts in conjunction with XX prior injections to show efficacy and warrant repeat injection. The request remained unsupported and the previous non-certification was upheld.

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

I agree with the prior reviews denying the request for a bilateral L5 transforaminal epidural steroid injection x 2. This patient has had three lumbar ESIs since the DOI. In the first review dated XXXX, the reviewer correctly identified that lack of documentation of objective functional improvement to justify the need for a repeat injection. The reviewer also noted the lack of evidence of a decreased need for pain medications. In the second review dated XXXX, the reviewer noted 3 key issues: *1* – the documentation showed an increased use of XX after the interventions; *2* – the urine drug screen was positive for XX after XX most recent injection in XXXX; *3* – the lack of clarity over the functional goals and the functional limitations. I also noted that XX denied the use of any drugs in XX follow-up visits, although XX is using XX. The request for 2 ESIs is excessive since the ODG does not support a series of ESI's.

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

ODG® 2018 - Official Disability Guidelines® (23rd annual edition) & ODG® Treatment in Workers' Comp (16th annual edition)

ODG Treatment; Integrated Treatment/Disability Duration Guidelines
Low Back - Lumbar and Thoracic (Acute and Chronic) (updated 12/28/17)
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.
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, 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)

Epidural steroid injections, “series of three”

Not recommended. Original recommendations that suggested a “series of three injections” generally did so prior to the advent of fluoroscopic guidance. These previous recommendations were based primarily on case studies and anecdotal evidence (Class IV and V data). (Abram, 1999) (Warr, 1972) (Hickey, 1987)

There does not appear to be any evidence to support the current common practice of a series of injections. (Novak, 2008) Contemporary research studies with higher levels of evidence (including two controlled trials) have suggested that on average, two or less ESIs are required in patients with successful outcomes from the use of ESIs to treat disc related lumbar radiculopathy. (Lutz, 1998) (Vad, 2002) (Riew, 2000) While all of these latter studies have utilized repeat injections, there has been no evidence-based research to explain why this practice is required, or the mechanism for possible action. Since the introduction of fluoroscopically guided ESIs, it has been suggested that there is little evidence to repeat an accurately placed epidural injection in the presence of mono-radiculopathy, regardless of whether there is partial or no response. (McLain, 2005) A recent randomized controlled trial of blind ESIs found no evidence to support repeat injections, because at six weeks there was no significant difference found between the ESI group and a placebo-controlled group in terms of any measured parameter. (Price, 2005)

A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain may be secondary to a different generator, or in the case of multilevel pathology. (McLain, 2005) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (Cuckler, 1985) With fluoroscopic guidance, there is little support to do a second epidural if there is no response to the first injection. There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended.

☐ 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)