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Notice of Independent Review Decision

Date: August 12, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Lumbar epidural steroid injection (ESI) with fluoroscopy right L4-L5

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

Diplomate American Board of Orthopaedic Surgery
Fellowship Trained in Spine Surgery

REVIEW OUTCOME:

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

Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

TDI

- Utilization reviews (06/17/13, 07/08/13)
- Office visits (09/29/2011 – 06/06/13)
- Diagnostics (02/29/12, 03/28/13)
- Review (10/14/12)
- Utilization reviews (06/17/13, 07/08/13)
- Letters (07/24/13)

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who injured at work on xx/xx/xx. He had chronic low back pain with radiation into right lower-extremity. The exact mechanism of injury is unavailable.

There are no records available from 2002 through 2010.

2011: Per IRO dated September 20, 2011, the following was noted: *The patient failed conservative treatment. He had surgery on March 12, 2003, and underwent a fusion procedure. Postoperatively, the patient is noted to have continued pain but was able to return to gainful employment. Historically he has had multiple computerized tomography (CT) myelograms of lumbar spine and he has been treated symptomatically with ESIs. More recent clinic notes indicated the patient underwent lumbar ESIs in 2010, which provided approximately six months of relief. Clinic notes indicated that on February 11, 2011, the patient underwent a repeat lumbar ESI at L4-L5. On April 19, 2011, the patient underwent CT myelogram of the lumbar spine. This study noted a mild retrolisthesis of L4 on L5 with vacuum disc phenomena present. There were postoperative changes of posterior lumbar interbody fusion (PLIF) at L5-S1 with interbody spacer and laminectomy present. The contrast column was noted to be faint. There was a mild loss of lumbar lordosis. There was poor visualization of nerve root sleeves at L4-L5. Post myelogram CT notes disc bulge at L3-L4 with facet hypertrophy and ligamentum flavum thickening resulting in mild spinal stenosis and foraminal encroachment. At L4-L5, there was severe facet disease with broad-based disc bulge and osteophyte with mild retrolisthesis of L4 on L5 producing mild spinal stenosis and moderate bilateral foraminal stenosis. At L5-S1 there were postoperative changes of PLIF without evidence of acute hardware complications. When seen in follow-up on April 11, 2011, it was reported the patient did not receive much benefit from right L4-L5 ESI. He was noted to be walking with flexed posture at the low back. He had decreased range of motion (ROM). Straight leg raise (SLR) was positive bilaterally. The patient had a somewhat wide based gait. He had depressed ankle reflexes and little weakness in plantar flexion and dorsiflexion to both feet. He was subsequently recommended to undergo a posterior L4-L5 decompression, fusion and instrumentation. This apparently was not approved under utilization review. On August 11, 2011, recommended that the patient undergo an L4-L5 ESI in the interval period.*

The request for ESI was denied based on the following rationale: *“The submitted clinical records indicate that the patient has undergone a single level lumbar fusion with instrumentation and has had continued low back pain with evidence of lumbar radiculopathy. The serial clinical records indicate the patient has undergone ESIs in the past without sustained relief. Current evidence based guidelines require the patient receive 50-70% relief for period of 6-8 weeks to establish medical necessity for repeat LESI. The submitted clinical records fail to establish the patient met these criteria, and therefore the patient would not be a candidate for repeat lumbar ESIs under the guidelines. The reviewer finds there is not a medical necessity for repeat Lumbar ESI with Fluoroscopy 64483, 77003, outpatient. Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be upheld.”*

On September 29, 2011, stated that for unknown reasons, he did not get permission for the L4-L5 epidural Depo-Medrol injection even though the patient had severe stenosis and herniated disc at L4-L5 with obvious instability with retrolisthesis with root compression. He had numbness, dysesthesias and weakness in the legs. He had severe chronic mechanical low back disorder. ESIs did provide him some relief to enable him to stay more active and reduce his need for medications. The patient continued to take Ultracet, Motrin and Flexeril. could not find any major difference on the spinal and neurological examination. Although, he still had some neurological deficits. appealed the denial.

2012: On February 2, 2012, noted the patient was seen four months ago. Worker's comp had never given permission for the posterior L4-L5 decompression, fusion and instrumentation, which the patient definitely needed because of severe lumbosacral pain and bilateral radiating hip and leg pain with numbness, dysesthesias and weakness in the legs. Lumbar myelogram and CT scan showed severe disease at L4-L5 with a very narrow disc space with central canal stenosis and bilateral root compression with retrolisthesis with vacuum disc phenomenon with no problems at the area at L5-S1 where he had surgery nine years ago. The patient was becoming incapacitated by his pain. He walked with a flexed posture at the low back. SLR was positive bilaterally. He had developed numbness and weakness in the lower extremities. refilled Ultracet, Motrin and Flexeril.

On February 29, 2012, magnetic resonance imaging (MRI) of the lumbar spine showed the following: (1) L1-L2 disc space: Mild broad-based bulging of the disc causing mild encroachment upon the anterior aspect dural sac and neural, foramina. (2) L3-L4 disc space: Desiccation of the disc was noted. There was moderate narrowing of the. Disc. There was broad-based bulging of the disc causing moderate encroachment upon the anterior aspect of the dural sac and mild-to-moderate encroachment upon the neural foramina bilaterally. There were mild degenerative changes present involving the facet joints. (4) L4-L5 disc space: Prominent narrowing of the disc was noted. There was broad-based bulging of the disc causing moderate-to-prominent encroachment of the anterior aspect of the dural sac and neural foramina. There were degenerative changes present involving the facet joints. Findings caused prominent bilateral neural foraminal stenosis. There was thickening of the ligamentum flavum and these findings caused mild-to-moderate spinal canal stenosis. (5) L5-S1 disc space: Postoperative change secondary to PLIF procedure was noted. There were bilateral pedicle screws present at L5 and S1 transfixing posterior compression plates extending from L5 to S1. Bilateral inter-disc spacers were seated within the L5-S1 disc space. The dural sac and neural foramina were maintained. (6) There was a 1 cm cystic intensity mass involving the anterolateral cortex of the midpole of the right kidney possibly representing a renal cyst; however, further evaluation with sonography was recommended.

On April 12, 2012, the patient had gotten a bit worse. He had very severe lumbosacral pain with radicular pain down both legs, mainly on the right. He had

developed weakness of bilateral foot and great toe dorsiflexion. He walked with a flexed posture at the low back. SLR was positive bilaterally at around 30 degrees. There was decreased sensation in the bilateral L5 dermatomes. The patient had severe mechanical pain in the lumbar region, exacerbated by walking, standing and activities. Lumbar MRI showed severe problems at L4-L5 with collapse of the L4-L5 disc with severe stenosis and herniated disc with severe bilateral foraminal constriction and central canal stenosis. He had lesser findings at L3-L4 and L5-S1 where he had surgery and there were no problems. discussed treatment options with patient. He recommended trying to get permission for the right L4-L5 epidural Depo-Medrol injection, but stated that ultimately the patient would require surgery.

On July 26, 2012, the patient had excellent results from the right L4-L5 epidural Depo-Medrol injection at the level where he had a severe stenosis and herniated disc with central canal impingement and bilateral foraminal constriction with radiculopathies and neurologic deficits. He was now having increasing pain and another injection was indicated, since the patient was trying to do some light work. He was still utilizing Ultracet, Motrin and Flexeril.

On October 14, 2012, an IRO upheld the denial for lumbar ESI at the right L4-L5.

On December 13, 2012, noted the patient was getting worse with increasingly severe lumbosacral pain with bilateral radiating hip and leg pain, particularly on the right with associated numbness, dysesthesias and weakness in the legs. SLR was positive bilaterally at less than 45 degrees. The patient was developing bilateral weakness of the foot and great toe dorsiflexion, which was of concern. He had severe problems at L4-L5 with some stenosis, herniated disc and root compression with a chronic mechanical low back disorder and instability and would need a posterior decompression, fusion and instrumentation at some point. suggested trying a right L4-L5 epidural Depo-Medrol injection.

2013: On March 11, 2013, the patient reported increasingly severe lumbosacral pain with bilateral radicular hip and leg pain. The patient was developing more weakness of bilateral foot and great toe dorsiflexion. SLR was positive bilaterally between 30 and 45 degrees. The patient had a wide-based gait. He walked with a somewhat flexed posture at the low back. It had been a year since any studies were done that showed the severe posttraumatic L4-L5 stenosis, herniated disc, root compression with chronic mechanical low back disorder with instability and neurologic deficit. opined that the patient should have had a posterior decompression, fusion and instrumentation long ago to try to prevent this increasingly severe neurologic deficit and severe chronic pain syndrome. The patient's ongoing medications included Ultracet, Motrin and Flexeril. suggested follow-up diagnostic studies and a CT scan of the lumbar spine for preoperative planning.

On March 28, 2013, CT scan of the lumbar spine showed postoperative changes compatible with a PLIF at L5-S1. There was slight posterior subluxation of L4 on L5. There was preservation of the vertebral body heights. Disc degenerative

changes were prominent at L4-L5 which had progressed when compared to the previous study. There was mild loss of disc height at all lumbar levels. There was a mild disc bulge at L3-L4. There was felt to be a disc bulge/osteophyte complex at L4-L5 and bilateral lateral recess narrowing. There was moderate bilateral foraminal encroachment at L4-L5, left greater than right.

On June 6, 2013, reviewed the CT scan. He reported that the patient had posterior surgery at L5-S1 ten years ago and that level was fine. The patient continued to have increasingly severe low back pain and bilateral hip and leg pain and had developed some weakness in the right foot and great toe dorsiflexion. opined that the patient would need L4-L5 surgery at some point. He recommended trying epidural Depo-Medrol injection and refilled Ultracet, Motrin and Flexeril.

Per utilization review dated June 17, 2013, the request for lumbar ESI at right L4-L5 was denied with the following rationale. *"The clinical information submitted for review fails to meet the evidence based guidelines for the requested service. The mechanism of injury was not specifically stated. The patient's medication regimen includes Ultracet, Motrin, and Flexeril. Surgical history includes interbody fusion at L5-S1, date of procedure not stated. The diagnostic studies include MRI of lumbar spine dated February 29, 2012 and CT of the lumbar spine dated March 28, 2013 signed which revealed specifically at the L4-L5 level there was felt to be disc bulge/osteophyte complex and bilateral lateral recess narrowing. There was no significant central stenosis at any lumbar level and there was moderate bilateral foraminal encroachment at L4-L5, left greater than right. No other significant foraminal narrowing was noted. Other therapies include multiple injections. The request for O/P lumbar ESI right L4-L5 64483 is non-certified. The clinical documentation submitted for review evidences the patient continues to present with lumbar spine pain complaints status post a work-related injury in xx/xxxx. The clinical notes document the patient has received previous ESIs at the L4-L5 level, most recently in April 2011 which the provider documented was ineffective for the patient's pain complaints and again in May 2012, which the provider documented offered the patient excellent results. The provider again recommended in December 2012 an ESI at the L4-L5; however, documentation of whether or not this was carried out was not noted. The provider documents the patient ambulates with a flexed posture at the low back. The provider continually documents the patient will require surgical interventions at L4-L5; however, the patient would like to continue utilizing ESIs. However, the newest imaging study of the patient's lumbar spine does not evidence any nerve root compression to support an ESI at this point in the patient's treatment. Additionally, the clinical notes do not indicate the patient is utilizing any active therapeutic interventions for his lumbar spine pain complaints. Guidelines indicate the purpose of ESI is to reduce pain and inflammation thereby facilitating progress in more active treatment programs, reduction in medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. The clinical notes lacked evidence of objective functional improvement status post previous injections for the patient at the L4-L5 level, as noted by a decrease in the patient's*

utilization of his medication and increase in function. Given all of the above, the request for O/P lumbar ESI right L4-L5 64483 is non-certified.”

Per reconsideration review dated July 8, 2013, the appeal for O/P lumbar ESI right L4-L5 64483 was denied with the following rationale. “The clinical information submitted for review fails to meet the evidence based guidelines for the requested service. The patient's mechanism of injury was not provided in the medical records. The patient's medications were noted to include Ultracet, Motrin and Flexeril. The patient's surgical history is noted to include fusion and L5-S1 decompression in 2003. Diagnostic studies are noted to include an official CT of the lumbar spine report dated April 19, 2011 as read suggested multilevel degenerative disc disease. An official lumbar myelogram report dated April 19, 2011 as read suggested thecal sac deformity. An official MRI of the lumbar spine report dated February 29, 2012 as read suggested at L1-L2, a mild broad-based bulging of the disc noted to cause mild encroachment upon the anterior aspect dural sac and neural foramina. At L3-L4, moderate narrowing of the disc with broad-based bulging noted causing moderate encroachment upon the anterior aspect dural sac and mild-to-moderate encroachment upon the neural foramina bilaterally. Mild degenerative changes were present involving the facet joints. At the L4-L5 disc space, broad-based bulging of the disc was noted to cause moderate to prominent encroachment upon the anterior aspect of the dural sac and neural foramina. Prominent bilateral neural foraminal stenosis was noted. Thickening of the ligamentum flavum was noted to cause mild-to-moderate spinal stenosis. At the L5-S1 disc space, postoperative change secondary to PLIF procedure was noted. Bilateral inter-disc spacers were seated within the L5-S1 disc space. The dural sac and neural foramina were noted to be maintained. An official CT of the lumbar spine without contrast report dated March 28, 2013 as read suggested disc bulge/osteophyte complex at L4-L5 and bilateral lateral recess narrowing. No significant central stenosis at any lumbar level was noted. Moderate bilateral foraminal encroachment at L4-L5, left greater than right was noted. No significant foraminal narrowing was noted. Other therapies are noted to include an ESI at L4-L5 on May 4, 2012. The request for appeal outpatient lumbar ESI right L4-L5 64483 is non-certified. This request was previously denied due to the submitted clinical notes lacked evidence of objective functional improvement status post previous injections for the patient at the L4-L5 level. The patient is a male who reported an injury on xx/xx/xx. Guidelines recommend repeat injections be based on continued objective documented pain relief, decreased need for pain medications and functional response. The documentation submitted for review indicated the patient had undergone an ESI at L4-L5 on May 4, 2011. The clinical note dated May 11, 2011 indicated the patient to continue to take multiple medications without improvement as noted by severe mechanical lumbar pain with radicular hip and leg pain with numbness, dysesthesias and weakness in the legs. ESI is to reduce pain and inflammation, to facilitate progress in to a more active treatment program, reduction of medication use and to avoid surgery. The documentation submitted for review did not indicate the patient had attended any supervised physical therapy (PT), instruction in home exercise or other active treatment programs. Guidelines do not recommend ESI as a treatment alone as it offers no significant long-term

functional benefit. Based on the documentation submitted for review, pain relief of at least 50 percent to 70 percent for at least 6 to 8 weeks with progression into an active therapeutic program was not identified. As such, the request for appeal outpatient lumbar ESI right L4-L5 64483 is non-certified.”

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

The patient is a gentleman who had a work injury on xx/xx/xx, and underwent an L5 S1 operative intervention with fusion on March 12, 2003, with instrumentation. There are no records available from xxxx through 2010 except for this brief note.

There was an IRO dated September 20, 2011. It noted that the patient had been evaluated on multiple occasions with several studies and treated previously with ESIs. The patient had two ESIs in 2010. The patient on February 11, 2011, had a lumbar ESI at L4-L5. He had a subsequent myelogram CT scan of the lumbar spine showing mild retrolisthesis of L4 on L5 with vacuum disc phenomena present at that level and a posterior lumbar interbody fusion (PLIF) noted at L5-S1. The post-myelogram CT scan showed disc bulging at L3-L4 with facet hypertrophy and mild spinal stenosis while at L4-L5 this patient's facet disease was considered to be more prominent with broad-based disc bulge and osteophyte and mild retrolisthesis of L4 on L5 producing a mild spinal stenosis and moderate bilateral foraminal stenosis. On April 11, 2011, the patient had a follow-up visit after an ESI which showed that the patient did not have much benefit of that ESI. There was further discussion with the patient regarding L4-L5 decompression, fusion and instrumentation at L4-L5.

after denial of the decompression surgery and fusion at L4-L5 proposed further ESI. This was denied at the IRO level.

then reported on September 29, 2011, that the patient has severe spinal stenosis at L4-L5 with a herniated disc at that level with obvious instability with retrolisthesis.

On February 2, 2012, the patient was re-assessed who reported that the lumbar myelogram CT scan had shown severe disease at L4-L5 with a very narrow disc space and central stenosis with bilateral root compression. Further medication management was also performed prescribing Ultracet, Motrin and Flexeril.

On February 29, 2012, an MRI of the lumbar spine was completed. This study showed disc desiccation at L3-L4 with moderate narrowing of the disc and broad-based bulging of the disc with moderate encroachment on the anterior aspect of the dural sac and mild-to-moderate encroachment on the neural foramen bilaterally. L4-L5 showed a moderate-to-prominent encroachment upon the anterior aspect of the dural sac and neural foramen. There was thickening of the ligamentum flavum and this resulted in mild-to-moderate spinal stenosis at the L4-L5 level.

On April 12, 2012, reported that the patient had gotten worse symptomatically. The patient was having radicular symptoms in both legs, although the right was worse. proposed right L4-L5 epidural injection. There was no operative report of this injection although the July 26, 2012, office note proposed that there was excellent result from that L4-L5 injection.

There was another IRO review regarding another ESI that had been denied at lower levels of review. The IRO on October 14, 2012, upheld the denial of the right L4-L5 ESI.

then saw the patient on December 13, 2012, and reported that the patient was getting worse with more prominent lumbosacral pain as well as dysesthesias and weakness. Another epidural injection was proposed.

On March 11, 2013, the patient was again re-assessed who noted that the patient should have a posterior decompression, fusion and instrumentation. The patient was ordered a CT scan of the lumbar spine for pre-operative planning.

On March 28, 2013, the CT scan of the lumbar spine was read by the radiologist to show preservation of vertebral body height, but there was prominent disc degeneration at L4-L5 which had progressed compared to the previous study. However, there was no significant spinal stenosis noted at any level per the report.

On June 6, 2013, noted that the patient's CT scan supported the need for an L4-L5 surgery at some point.

Two utilization reviews were also forwarded which mapped out the rationale for denial of this request for a further epidural steroid injection. It was noted that the patient's benefit with the epidurals had not been adequately documented as far as duration of benefit and percentage benefit, nor had the patient been integrated into a further rehab program.

Summary: This patient is now essentially xx years post fusion at L5-S1. The records document low back pain with some radicular symptoms. The narrowing in the neural foramen at L4-L5 would affect the L4 nerve root if there was entrapment. The CT scan that was performed on March 28, 2013, did not define any specific spinal canal stenosis centrally. There appears to be variation of opinion regarding the severity of this patient's back disorder at L4-L5 and especially regarding the entrapment of nerve tissue. The patient's flexion extension x-rays have not been obtained or at least reported to document any type of instability at this level.

The patient has been repeatedly proposed to undergo operative intervention. The request for this epidural steroid injection at L4-L5 on the right side is not validated by the records that are available for review. Thus, the adverse determination for the request for the epidural steroid injection is upheld at L4-L5.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES