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Notice of Independent Review Decision

Date: January 15, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Lumbar posterior interbody fusion at L4-L5 and L5-S1 with two-day inpatient stay

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 Disorders and Foot and Ankle Disorders

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 (10/12/12 - 10/29/12)

- Office visits (10/13/11 – 11/28/12)
- Diagnostics (10/13/11 – 08/24/12)
- Review (11/06/12)

- Office visits (08/17/11 – 10/02/12)
- Diagnostics (09/22/11 - 08/24/12)
- Procedure (10/21/11)
- Utilization reviews (10/12/12 - 10/29/12)
- Review (12/28/12)

ODG criteria has been utilized for the denials

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who on xx/xx/xx, fell into a ditch while he was at work. He injured his low back and developed low back pain and leg pain.

2011: On August 17, 2011, evaluated the patient for low back pain. The patient had paraspinal lumbar tenderness and decreased range of motion (ROM) in the back. Examination showed negative straight leg raising (SLR). assessed lumbar sprain, recommended treatment with Zipsor, Skelaxin, moist heat and avoiding excessive weightbearing.

On September 13, 2011, noted that the patient continued to have ongoing low back pain. His pain level had dropped from 7/10 to 5/10, but it was constant in nature. The patient had started on a physical therapy (PT) regime. He was utilizing anti-inflammatories and muscle relaxant. prescribed Ultracet and recommended obtaining magnetic resonance imaging (MRI) of the lumbar spine.

On September 22, 2011, MRI of the lumbar spine impression per was central focal disc protrusion (herniation) at L4-L5 through an inferior annular tear, which elevates the thecal sac, resulting in moderate right foraminal stenosis, slightly indenting on the right L5 nerve root. No evidence of compression fractures.

On October 13, 2011, evaluated the patient for the low back. He had severe pain with all daily activities. He was utilizing Skelaxin, tramadol and hydrocodone for pain. He had no relief with PT. Examination of the lumbar spine showed decreased ROM, moderate vertebral tenderness and moderate hypertonicity. The patient had a moderate-to-severe pain with decreased ROM and bilateral leg sciatica. X-rays showed spondylosis with decreased lumbar lordosis. reviewed the MRI findings. He assessed degenerative disc disease (DDD) of the lumbosacral spine with radiculopathy. He administered a facet injection of Depo-Medrol and Xylocaine in the lumbar spine. He prescribed Vicoprofen and Flector 1.3% patch. The patient was to continue activities as tolerated and follow-up in one week.

On October 18, 2011, noted that the patient had no relief after the facet injection. The patient continued to have severe pain with all daily activities. recommended epidural steroid injection (ESI) of the lumbar spine.

On October 21, 2011, performed the ESI of the lumbar spine.

On November 10, 2011, electrodiagnostic study of the lower extremities was unremarkable.

On November 28, 2011, noted that the patient continued to have moderate pain and decreased ROM. He had a facet injection and ESI to the lumbar spine with no relief of his symptoms. recommended continuing activities as tolerated and referred the patient to a neurosurgeon for evaluation and treatment.

On November 29, 2011, x-rays of the lumbar spine showed decreased lumbar lordosis.

On December 14, 2011, evaluated the patient for low back problems. The patient had low back pain and leg pain. The pain was severe and radiated to both legs. Examination of the legs showed positive SLR bilaterally. ROM of the feet was somewhat decreased, more on the left than right. reviewed the MRI of the lumbar spine which showed a herniated central disc at L4-L5. He discussed treatment options including surgery. He recommended continuing conservative treatment consisting of PT and using an inversion table daily for 20 to 30 minutes.

2012: On January 17, 2012, noted that the patient continued to have lower back pain which was severe in nature. He was utilizing Vicodin for pain and was currently not working. Examination of the lumbar spine showed decreased ROM, moderate paraspinous tenderness and vertebral tenderness. There was moderate hypertonicity noted. SLR was positive bilaterally. The patient continued to have severe pain and decreased ROM and sciatica. He had no relief with PT. He had an appointment for second opinion and was recommended conservative treatment for time being consisting of PT with inversion table. prescribed a muscle relaxer (chlorzoxazone) and opined that the patient appeared to be a surgical candidate.

On February 7, 2012, noted that the patient continued to have severe pain and intermittent sciatica. He had failed conservative treatment consisting of analgesic and anti-inflammatory medication, facet injections, ESIs and PT. opined that the patient appeared to be a surgical candidate and therefore he referred the patient for surgical evaluation and treatment. He prescribed Vicoprofen and recommended continuing activities as tolerated.

On February 21, 2012, noted that the patient was status post epidural injections and PT with no relief. The patient had back stiffness and muscle aches. He also had numbness, tingling and weakness. Examination of the lumbar spine showed paraspinal lumbar tenderness with radiculopathy radiating down the left leg. assessed back pain with lumbar radiculopathy. She noted that the patient had signs and symptoms of depression related to the injury. She prescribed Cymbalta, hydrocodone/ibuprofen and chlorzoxazone. She also discussed the use of moist heat or ice, modified activities, medications, stretching/strengthening exercises.

On March 6, 2012, evaluated the patient for left leg pain, low back pain and right leg pain. The patient had low back pain that radiated to the bilateral legs along with weakness and numbness since the day of injury. He was utilizing pain medications with moderate results and had already failed PT and ESI. reviewed the MRI of the lumbar spine which showed central focal disc protrusion at L4-L5 through as inferior annular tear, which elevated the thecal sac resulting moderate right foraminal stenosis. Examination of the lumbar spine showed positive SLR on the right and left, tenderness of the lumbosacral junction and paraspinous

muscle spasms at L4-L5. assessed displacement of lumbar intervertebral disc without myelopathy, back pain with lumbar radiculopathy and joint derangement of other specified site. He noted that the patient had severe pain with flexion and extension. recommended flexion and extension views of the lumbar spine and opined that there was a possibility of fusion at the effected level.

On April 3, 2012, noted that the patient continued to have pain to lower back radiating to bilateral legs. The patient was ambulating without any assistance of a device. He had bilateral leg pain, pinpoint tenderness of the lower back and pain upon flexion. reviewed the EMG study which was unremarkable. He opined that the patient had not reached maximum medical improvement (MMI) after his low back injury. The patient had L4-L5 disc herniation producing severe central back pain without radiculopathy and some soreness to the legs. He opined that the patient would benefit from an anterior lumbar interbody fusion (ALIF) versus posterior lumbar fusion due to severe discogenic disease. The patient had pain for over eight months and had completely failed conservative therapy. recommended obtaining a second opinion and prescribed Vicodin, tramadol and Flexeril.

On June 13, 2012, evaluated the patient regarding his low back problem. The patient continued to have low back pain and bilateral leg pain. This was almost constant and was aggravated by walking. The patient did not tolerate standing for long periods. The pain radiated in a sciatic type of distribution. The pain radiated in sciatic type of distribution. Examination showed positive SLR in both legs. The patient had some tenderness in the lumbosacral region. recommended an MRI of the lumbar spine.

On July 3, 2012, noted that the patient continued to have severe pain with all daily activities. He continued to have pain to his lumbar region. There was obvious evidence of decreased ROM at the level of lumbar spine secondary to pain and stiffness. The patient had a second evaluation who recommended surgery to his lumbar spine. assessed DDD of the lumbosacral spine with radiculopathy, prescribed Vicoprofen and referred the patient to a neurosurgeon for further evaluation and treatment.

On July 27, 2012, noted that the patient continued to have pain to his lower back radiating to the bilateral legs along with soreness of the leg. It was noted that the patient was utilizing more pain medications than before. His pain was aggravated while sitting, walking and laying down for long periods of time. He had pain upon flexion of the spine and pain to bilateral legs. opined that the patient had expired all conservative treatment and continued to have pain to his lower back which was constant in nature. He opined that the patient definitely had a discogenic instability component. He ordered flexion and extension x-rays and lumbar discogram and considering an L4-L5 posterior lumbar interbody fusion (PLIF).

On July 30, 2012, evaluated the patient for low back pain. He noted that the patient had moderate-to-severe pain with all daily activities. The patient was utilizing Vicoprofen, Skelaxin, tramadol, hydrocodone-acetaminophen, Flector

1.3% patch and chlorzoxazone. obtained x-rays of the lumbar spine which showed osteophyte at L1 and L2.

On August 24, 2012, the patient was seen for back pain. The patient was scheduled for lumbar discogram. Examination of the lumbar spine showed exaggerated lordosis, moderate and restricted ROM in all directions due to pain, moderate tenderness of the bilateral paravertebral area, facet joint areas, PSIS areas, sacroiliac (SI) joints, intragluteal areas, iliolumbar and sciatic notch area. There was tenderness over vertebral spinous process. There was moderate muscle spasm bilaterally over the paravertebral area, iliolumbar. SLR test was not performed due to pain. assessed lumbar intervertebral disc displacement, discogenic syndrome NOS and lumbar radiculopathy/ radiculitis.

Computerized tomography (CT) scan of the lumbar spine showed the following findings: (1) Mild spondylotic changes in the lumbar spine. Marginal osteophyte formation noted at multiple levels. (2) At L1-L2, changes of discogram seen which appeared within normal limits. (3) At L2-L3, changes of discogram noted with contrast limiting central part of the disc which was within normal limits. (4) At L3-L4, small posteriorly extending annular tear not extending up the peripheral fibers. (5) At L4-L5, posteriorly extending small annular tear seen not extending up to the peripheral fibers. Mild posterior disc bulge was seen. Possible annular tear noted extending up to the peripheral fiber on the right lateral aspect which could also be artifactual due to contrast injection from the needle tract. There was mild narrowing of bilateral neural foramina. (6) At L5-S1, changes of discogram seen which appeared intact. Mild posterior disc bulge was present likely causing epidural fat indentation.

On October 2, 2012, noted that the patient continued to have low back pain radiating to the bilateral legs with numbness and tingling. The patient had soreness like feeling which was constant in nature. He had pain to the spine and numbness and tingling of the bilateral legs. reviewed the CT/discogram which showed extravasation to L4-L5 and pain to L5-S1. opined that the patient had expired all conservative treatment and would benefit from posterior lumbar interbody fusion (PLIF) at L4-L5-S1 bilaterally.

Per utilization review dated October 12, 2012, the request for inpatient two days, posterior lumbar interbody fusion bilateral at L4-L5 and L5-S1 was denied with the following rationale: *"Sensory symptoms of numbness/tingling are not described in a specific nerve root distribution. Electro-diagnostic studies done on November 10, 2011, three months post-injury were normal. No clear-cut radiculopathy has been documented. There were no objective focal neurologic deficits on the most recent exam of October 2, 2012. CT discography was performed on August 24, 2012. This study does not clearly define this patient's pain generators. The patient was noted to have concordant pain from L3-L4 through L5-S1, but annular tears without extravasation were documented only at L3-L4 and L4-L5. No frank protrusion was documented at any level. Previous flexion/extension films, reported October 13, 2011, and November 29, 2011, documented no spinal instability. Based on lack of clear definition of this patient's pain generators as*

well as no clearly defined radiculopathy, the requested services cannot be approved. Official Disability Guidelines are not met. Physician Advisor attempted a peer to peer phone consultation left call back information and due date with Diana on October 9, 2012, and October 11, 2012.”

Per reconsideration review dated October 29, 2012, the request for inpatient two days lumbar posterior interbody fusion at L4-L5, L5-S1 was denied with the following rationale: *“The peer reviewed guidelines indicate that prior to consideration of spinal fusion there should be evidence of neural arch defect or segmental instability which can be objectified by imaging studies and all pain generators should be addressed. The claimant has stated ongoing lower extremity symptoms of numbness, tingling, and weakness. EMG studies documented normal study. Flexion-extension views do not objectify any segmental instability to the lumbar spine. The claimant had concordant pain from L3-L4 to L5-S1. There were no frank disc protrusions documented by CT evaluation. No clear clinical radiculopathy was objectified by physical examination findings. As physical examination findings are vague and do not correlate with diagnostic imaging and electrodiagnostic studies, and there is no evidence of spinal instability documented by flexion-extension x-rays; the request for posterior lumbar interbody fusion at L4-L5 and L5-S1 is not medically supported. Physician Advisor attempted a peer-to-peer phone consultation on October 23, 2012, and October 29, 2012, left call back information”*

On November 13, 2012, performed a designated doctor evaluation (DDE) and opined that the patient was not at MMI. opined that the patient needed surgical intervention before MMI.

On November 20, 2012, noted that the patient had ongoing low back pain which was sharp and radiating in nature. The pain radiated to the left leg/foot and right leg/foot. The symptoms were worse with flexion, extension, inactivity, sitting, standing, and lying down. Review of systems (ROS) was positive for back pain, stiffness and muscle aches. Examination of the lumbar spine showed paraspinal lumbar tenderness and difficulty bending, tandem walk and toe walking. SLR test was unable to perform due to pain. assessed back pain with lumbar radiculopathy. It was noted that surgery was pending insurance clearance. recommended hydrocodone-ibuprofen and chlorzoxazone and discussed use of moist heat or ice, modified activities, medications, and stretching/strengthening exercises. The patient was to remain off work.

On November 28, 2012, noted that the patient continued to have back pain, muscle cramps, muscle weakness and muscle aches. The patient had pain to the lower back radiating to bilateral legs. He was not able to walk short or long periods of time due to his pain. The pain medications were controlling the pain for a while. He had pain upon flexion and extension of the spine, positive leg raise bilaterally and pinpoint tenderness and burning sensation to mid back. Examination showed atypical SLR test bilaterally. There was tenderness of the lower midline lumbar region, pain upon flexion and extension of the spine and weakness upon dorsal flexion bilaterally. There were paraspinal spasms at L4-

L5. It was noted that the recommended surgery was never approved by the insurance. The patient had a second opinion who had agreed with the surgery. resubmitted the surgery request under IRO and opined that he could not give percentage of disability.

Per Prospective IRO review response dated December 28, 2012, opined that the performance of inpatient two days lumbar posterior interbody fusion at L4-L5 and L5-S1 in a patient with no evidence of radiculopathy on physical examination and lack of corroborated instability on imaging studies is not supported and is not medically reasonable or necessary at this time.

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

The patient is gentleman who on xx/xx/xx, had a work injury when he fell. He had a low back sprain/strain noted. His care began who evaluated him on August 17, 2011 for back pain. The exam showed a negative straight leg raise but lumbar tenderness. The patient was prescribed medications. Light duty was ordered.

The patient then had a MRI ordered and completed on September 22, 2011, showing a central disc protrusion at L4-L5 with inferior annular tear. This resulted in moderate right foraminal narrowing with slight indentation of the right L5 nerve root area. No fracture was noted.

The patient was then evaluated who proceeded to do injection treatment to include facet injections as well as epidural steroid injections, neither of which gave prolonged relief.

On December 14, 2011, evaluated the patient for neurosurgical consultation. noted the patient's MRI showed a central disc protrusion/herniation. Options including that of surgery were discussed.

The patient was referred subsequently in February 2012 for surgical opinion as well. also continued to evaluate the patient and provide medication support as well as supportive care.

On March 6, 2012, evaluated the patient noting the patient had low back pain as well as bilateral leg pain. The straight leg raise was positive bilaterally. He noted the patient had a disc displacement with lumbar radiculopathy. He proposed flexion-extension views and that fusion was a consideration at the affected level.

then reassessed the patient in April 2012 and proposed a second opinion. had proposed that the patient would be a candidate for an anterior lumbar interbody fusion versus posterior lumbar interbody fusion due to the severe discogenic pain. Please note that an EMG had been performed which was negative for any radiculopathy.

reassessed the patient on June 13, 2012. He noted the patient had difficulty with any prolonged walking or standing. The patient had positive straight leg raise in both legs.

on July 27, 2012, proposed that the patient have a lumbar discogram to help identify a pain generator.

On August 24, 2012, did a discogram at five levels. The rationale for five levels was not explained. The patient had a post-discogram CT scan performed the same day. It was noted that the discogram had caused concordant pain at L3-L4, L4-L5 and L5-S1. The post-discogram CT scan showed at L3-L4 a small posterior annular tear but not extending to the peripheral fibers while at L4-L5, there was also posterior annular tear not extending to the peripheral fibers but there was contrast along apparent needle tract on the right at L4-L5.

On October 2, 2012, noted that the patient had utilized all the conservative care and would be a candidate for the posterior lumbar interbody fusion at L4-L5 and L5-S1.

Pre-authorization was performed two times with both preauthorization reviews denying the medical necessity for the proposed fusion at L4-L5 and L5-S1.

on November 13, 2012, performed a designated doctor exam and noted that he considered the patient not to be at maximum medical improvement and that the patient would need surgical intervention before MMI.

The patient was re-assessed on November 28, 2012. He noted that the patient had a second opinion who had agreed with the surgery.

There was also a prospective IRO review response dated December 28, 2012, in the records for review.

Please note that there were no indications of any psychological assessment on this patient. Moreover, there was no discussion of the impact or importance of the L3-L4 annular abnormality and the consequences of performing this two-level fusion at L4-L5 and L5-S1 on the adjacent level which was also abnormal.

There is no instability noted on the flexion-extension views. The patient does not have electrodiagnostic confirmation of any objective radiculopathy. The necessity for a two-level spine fusion at L4-L5 and L5-S1 is not supported by the ODG nor by these records for review. Thus the request for the L4-L5 and L5-S1 fusion is not approved and the adverse determination that had been previously determined is upheld.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES