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Notice of Independent Review Decision

Date: February 10, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Remove internal fixation L4-L5-S1, augment fusion with iliac graft and reapply internal fixation.

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

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:

- Utilization reviews (11/27/13, 12/17/13)

- Office visits (04/20/12 – 11/21/13)
- Diagnostic (03/15/12, 10/21/13)
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ODG criteria has been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is male who on xx/xx/xx, fell fracturing his left forearm and also injuring his lower back.

On April 20, 2012, reviewed records and the peer review. had received a call from the radiologist. It appeared that the radiologist never mentioned the lack of fusion. He further opined that there did not appear to be a fusion at the lower levels where the patient had had hardware put in. It appeared that there was no fusion. Certainly, this could be a potential etiology for the patient's difficulty. He recommended re-evaluation to determine if any more studies and/or injections needed to be done in a diagnostic vein. He recommended injecting the hardware to find out if indeed, it was symptomatic and without a fusion, it might pin down the etiology for his problems.

On December 17, 2012, reviewed the computerized tomography (CT) myelogram of the lumbar spine dated March 15, 2012. The study showed L4 through S1 fusion with lack of mature fused bone graft, in particular at the L5-S1 level bilaterally. The hardware was intact without fracture or loosening.

No records are available from May 2012, through January 2013.

2013: On February 5, 2013, received a letter stating that he had the films on the patient reviewed. The radiologist, had agreed with the interpretation of the films that there was a pseudoarthrodesis at L4 through S1. opined that it was confirmed that the fusion still had not healed and recommended proceeding with doing that which was supposed to have been done with the initial surgery.

On September 2013, evaluated the patient and noted the following treatment summary. *The patient fell on xx/xx/xx, fracturing his left forearm which required metal a plate and fusion at the left wrist. His right jaw had not yet fused at a metal plate in his anterior jaw and was suffering from a significant back injury.* There was some pain in his right jaw and his wrist. The major problem was the back injury. There was pain in the low back which was localized and "awful". The pain increased with activity, any weather or change in weather. There was whole left leg numbness and pain radiating from the back down the buttocks to the lateral thigh crossing over to the medial lower leg to the foot. The foot felt like there were ants crawling on him. The patient had spinal fusion and that about three months after surgery, the pain began to return to where was, on a brief restrictions from doing any activity and he had constant pain that was quite severe and incapacitating. had recommended proceeding to fuse the back. The patient's medications included Norco, Aleve, Cymbalta, Lyrica, lisinopril, diuretic and Zoloft. He was allergic to Xanax because it made him feel bad. He had reached maximum medical improvement (MMI) in 2002 with 50% impairment rating. Psychologically, the patient stated that the pain in his back was always there but at times, it became extremely severe causing in the degree irritable, grouchy and having explosive temper. He reported that because of the back injury, he had lost most of activities of which he enjoyed doing. Examination showed tenderness in the right lower back and tenderness in the midline. Straight leg raising referred to his back, left leg more than the right. He had numbness to touch of the whole left

leg. There was evidence of scar on the left forearm and tissue graft over the left forearm wrist. He was unable to move his left wrist. diagnosed lumbar disc disease status post fusion not healed and referred the patient.

On September 25, 2013, a locum provider evaluated the patient and assessed lumbar disc disease. He referred the patient.

On October 2, 2013, evaluated the patient and noted that the patient was able to work for about three months. However, his pain became worse and he had to stop working. The patient was utilizing four to five Norco per day and Lasix, lisinopril, potassium, trazodone, Cymbalta, and Midol complex. The patient had pain in the low back going to the right hip and right lower extremity to the right medial foot. The pain was constant. He had difficulty with sleep and only slept for short periods of time even in his bed or the recliner. He was on no exercise program and had gained weight to 333 from 323 pounds since last year. The patient could only walk one-half mile. He was being seen for his hypertension. Examination revealed obesity, fused left wrist which and little bit of pitting edema in the lower extremities. There was no lumbar spasm and he could walk on heels and toes. He flexed to about 70 degrees but had discomfort on resuming the erect position. The reflexes were symmetric and equal in the upper and lower extremities except that the ankle jerks were with reinforcement. ordered a new CAT scan.

On October 21, 2013, CT scan of the lumbar spine showed bilateral transpedicular screws with bilateral vertical stabilizing rods present at L4, L5, and S1 with well-aligned instrumentation without radiographic evidence of loosening. There was midline laminectomy defect suspected at the L4-L5 level with borderline canal size. There was moderate bilateral foraminal/lateral recess narrowing and facet joints appeared fused. At L4-L5, central canal and foramen were patent. There was no osseous fusion of facet joint evident. Facet joint were degenerated. There was bilateral transpedicular screws with anatomical alignment without loosening. There was a 3 mm retrolisthesis of L3 with respect to L4 with mild central canal stenosis and moderate hypertrophic facet arthrosis. The report is incomplete.

On October 30, 2013, reviewed CT scan which did not show a fusion at L5-S1. The facets were fused at L4-L5 however, with L5-S1 having a pseudoarthrosis; the patient probably had his pain generated from the L5-S1 level. recommended re-operation at the L5-S1 level and augmentation of the fusion at L4-L5.

On November 6, 2013, noted movements exacerbated the back pain. The patient had trouble sitting and could not walk far. Bending was difficult for him. Just to stand in the same position bothered him considerably. Examination showed painful movement, tenderness of the lowest portion of the lumbar area, scars in the midline (stretched) and one over the right iliac area. called to see the patient and hopefully get him stabilized. The patient weight was down to 227 pounds from 233 when he was last seen.

On November 21, 2013, evaluated the patient for stabbing and constant lower back pain. History was positive for depression, high blood pressure, sleep apnea, carpal tunnel release, hand infection surgery, appendectomy, face cosmetic surgery, lumbar fusion and surgery for arm fracture. Examination revealed a very large gentleman at 5'7" tall and 326 pounds. He had a guarded range of motion (ROM) and a well-healed midline incision and a right posterior iliac crest bone graft donor side scar. Neurological assessment revealed abnormal sensation on the right lower extremity below the knee. X-rays of the lumbar spine showed pedicle screws loosening (the left sacral screw as a halo effect around it strongly suggesting loosening, similar changes were seen at the L4 and the right AP view showing no visible bone in the lateral gutters and confirmed the screw lucency). reviewed lumbar CT scan that revealed no evidence of bridging bone at either L4 or L5-S1, fixation devices present and appearing in adequate position and loosening suggested at L5 and S1. There was no failure of hardware noted. diagnosed nonunion of fracture and complication of implant. He felt that the fusion had not healed and now the patient had pain and symptomatic hardware due to hardware loosening. He recommended undergoing additional surgery which would include redoing the fusion and replacing the internal fixation devices. The patient smoked about one pack a day and he was strongly recommended to discontinue that as completely as possible. A bone growth stimulator was indicated as an adjunct to the fusion success.

In a letter dated November 21, 2013, stated that the patient was already on a weight reduction problem which should have been continued. The patient did have some vague symptoms that would be suggestive of nerve root irritation on the right. However, felt that extensive surgery within the spinal canal would be necessary.

Per utilization review dated November 27, 2013, request for removal of internal fixation L4, L5 and S1 and exploration of fusion, augmentation of fusion with iliac crest graft and reapply internal fixation and three day inpatient stay and external bone stimulator was denied with the following rationale: *"Medical necessity has not been established. This patient has nonunion of previous bony fusion at L4, L5 and S1 as documented by CT scan. However, there is no hardware failure. This patient is a current pack a day smoker. There is no documentation of previous attempts at smoking cessation. It is not recommended to proceed with surgical intervention with the patient's smoking history and current smoking status. Also, ODG states that until further research is conducted there remains insufficient evidence to recommend fusion for chronic low back pain in the absence of stenosis and spondylolisthesis and this treatment for this condition remains under study. ODG states that smoking is a risk factor for adjacent segment degeneration. It also states that for any potential fusion surgery. It is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. Recommend non-certification."*

Per reconsideration review dated December 17, 2013, the request for a removal of internal fixation L4, L5, S1 and exploration of fusion, augmentation of fusion

with iliac crest graft and reapplication of internal fixation and three day stay and extensor bone stimulator was denied with the following rationale: *"The case was discussed. The request for revision surgery with inpatient stay as well as bone growth stimulator does not appear to meet the criteria for ODG at this point. By history, the claimant is a gentleman who underwent previous surgery approximately five years ago. He apparently has been seeing who states that radiology studies show a non-union. The most recent study we have is a CAT scan dated November 21, 2013. This is unfortunately, a bad copy but does show what appears to be stable instrumentation at the L4 and L5 level. There is a question on the report as to an L5-S1 no osseous fusion of the facet joints. After speaking, he is unclear as to whether or not the claimant is going through any type of psychological screening or if he has discontinued smoking as well at this point. Based on the ODG, patient for preoperative surgical indications are recommended to have psychological screening. In this case, all pain generators should be identified and treated as well which would lend to a diagnostic and possible therapeutic hardware injection as well in this case. Because of the reasons detailed above, it does not appear to be recommended at this point to proceed with surgery based on the current guidelines and medical records available for review. Three day stay and external bone stimulator were not medical necessary as the surgical procedure was not medically necessary."*

2014: On January 15, 2014, evaluated the patient for instability of the prior surgical area from L4 to S1. He felt that the area needed to be cleaned out, hardware removed, augmenting the fusion with iliac graft and reapplying internal fixation. The spine surgeon, had seen him and had agreed for hardware injections. felt that neuropsychological testing was not necessary.

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

The patient is gentleman who had fall in xx/xxxx, with multiple injuries including a left forearm fracture, jaw fracture and spine injury. The patient apparently underwent operative intervention for his lumbar spine with an instrumented fusion from L4-S1. There were no records in the forwarded records.

The records for review began in April 20, 2012, noting that the radiologist had never mentioned the lack of fusion on the myelogram CT scan. stated that there appeared to be a fusion at the lowest level of the spine and he proposed that the patient potentially have injection at the hardware to find out where his symptoms were. On December 17, 2012, did a reread of the CT myelogram of the lumbar spine from March 15, 2012. He noted that the L4-S1 fusion did not show any loosening of the hardware.

The fusion from L4-S1 showed lack of fused bone. There was no description of the myelogram result regarding nerve root contact or displacement or lack of fill.

reevaluated the patient on February 5, 2013. He noted reread of the films and recommended proceeding with repeat surgery.

On September 2013, noted the history of treatment. The patient's injury was on xx/xx/xx. The patient's major problems per the patients report was the back injury. The patient reported whole left leg numbness and pain radiating from the back to the lateral thigh crossing over to the medial lower leg to the foot. The foot had a sensation of ants crawling on it. The patient was being provided multiple medications. The patient was placed at maximum medical improvement back in 2002. The patient reported that he had significant irritability when his back became more symptomatic. The patient on straight leg raise had pain referred to the back and then the left leg more than the right leg. On sensation testing, the whole left leg was numb exam.

A locum tenems physician evaluated the patient on September 25, 2013, and referred the patient. He noted that the patient's height was 5'6" with weight of 333 pounds, a BMI of at least 53 by my records and chart.

In October 2013, noted the patient's symptoms going to the right hip and right lower extremity to the right medial foot. The patient had gained weight to 333 pounds over the past year from 323 pound previously. The patient however, on range of motion was able to flex to 70 degrees but had discomfort on resuming the erect posture. The reflexes were symmetrical but hypoactive. A new CT scan was ordered and completed on October 21, 2013, showing that there was no hardware loosening and the facets were fused at L4-L5. There was 3 mm of retrolisthesis of L3 with respect to L4 with mild central canal stenosis and hypertrophic facets at L3-L4.

reviewed this CT scan noting that the patient did not have a fusion at L5-S1. stated that the pain generator was probably L5-S1. He proposed reoperation at L5-S1 and augmentation of the fusion at L4-L5.

He also subsequently proposed that the patient be seen. On November 21, 2013, evaluated the patient noting that the patient was a large gentleman 5'7" and 326 pounds. Now the patient was reported to have a guarded range of motion. There was abnormal sensation in the right lower extremity below the knee. assessed that the x-rays showed left sacral screws had a halo suggesting loosening as well as there was no visible bone in the lateral gutters. There were also similar changes at the L4 level for the halo of the screw apparently.

No failure of hardware was mentioned and it was noted that the patient was a smoker of about one pack per day. on November 21, 2013, proposed the patient would require revision surgery of L4-S1 and that extensive surgery within the canal would not be necessary.

There were two preauthorization reviews also in the records noting that the patient did not meet criteria for reoperation.

On January 15, 2014, stated that the patient had instability at the prior surgical area from L4 to S1. did not consider neuropsychological testing to be necessary as proposed by one of the pre-certification reviews.

Summary: This patient has had spine fusions from L4 to S1 many years ago. The rationale for his now having symptoms due to a pseudoarthrosis of L5-S1 almost xx years post injury makes little physiological sense. Moreover, the examination findings were inconsistent with each other. The patient has a morbid obesity of over 50 BMI. He is overloading his spine. Moreover, in addition the patient is a smoker which is basically a contraindication to proceeding with fusion surgery. In addition, there is definite inconsistency in the reports of the hardware being loosened. found no evidence of loosening on the October 21, 2013, CT scan and that the facets at L4-L5 were fused. The patient has not had any flexion/extension views to support any suggestion of instability as mentioned on January 15, 2014. The patient's range of motion documented is basically normal, except for some discomfort on arising from the flexed position while states the patient has guarded range of motion. The sensation exam to the left lower extremity was significantly abnormal in the whole leg yet said there was abnormal sensation in the right lower extremity but at the same time did not consider the patient to warrant any type of intracanal intervention despite these neurological symptoms. I noted that there was no electrodiagnostic study to show whether or not there was any type of electrophysiological basis for the patient's symptoms.

The suggestion that repair for a pseudoarthrosis at L5-S1 would have any significant benefit for this patient is not established by the medical literature specifically regarding pseudoarthrosis. In addition, the proposed surgery is unlikely to have any benefit in this patient's long-term care, nor is it predictable that fusion would even heal, despite the patient's proposed use of the bone growth stimulator. The patient should definitely discontinue any smoking as a prelude to any surgery even if it was medically necessary. However, based on these records for review, the medical necessity of this surgery is not confirmed or consistent with the records in total or evidenced-based literature. Thus the request is not approved and the previous adverse determinations are 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**