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Notice of Independent Review Decision

October 31, 2012

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Implant neuro-electrodes (2 units), analyze neurostimulator, simple (1 unit), analyze neurostimulator (1 unit), implant neurostimulator electronic (16 units), spinal cord stimulator trial, spinal monitoring, L3-L4 laminectomy, transforaminal lumbar interbody fusion at L3-L4 and L4-L5 and five-day inpatient stay.

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

Board Certified Orthopedic Surgeon

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.

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Diagnostics (03/29/11 - 04/25/11)
- Office visits (04/25/11 - 08/22/12)
- Utilization reviews (08/30/12 - 09/12/12)

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- Diagnostics (03/29/11 - 04/25/11)
- Office visits (04/25/11 - 08/16/12)
- Utilization reviews (08/30/12 - 09/12/12)

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who injured his low back and neck on xx/xx/xx while he was working. He was going up and down a ladder and another worker moved the ladder to where it was in an unstable position and he did not realize it and fell about ten to twelve feet landing on concrete.

2006 – 2010: No records are available.

2011: On March 29, 2011, cervical and lumbar myelogram and computerized tomography (CT) scan was performed. The findings were as follows: Post-surgical changes including a carbon cage interbody fusion at C5-C6 as well as bilateral laminectomy and bilateral posterolateral rod and pars screw fixations at C5-C6. The interbody and posterolateral fusions appeared to be confluent. Residual 2-3 mm posterolateral osteophytes, greater on the right were noted with ossification in the posterior longitudinal ligament at C5, but the residual mid-sagittal dural diameter was 10 mm. There was slight flattening of the ventral surface of the spinal cord at C5 related to the residual hard disc at this level. Ventral extradural defects were also present on the myelogram at C3-C4, C4-C5 and C6-C7. The largest defect and greatest stenosis was below the fusion at C6-C7 where a combined 2-3 mm combined hard and soft disc protrusion produced borderline spinal cord impingement and left 8-9 mm residual mid-sagittal dural diameter. There was also a dorsal impression on the dural sac at C6-c7 resulting from bilateral flaval prominence. The foramina at C6-C7 were not compromised. There were anterior osteophytes at C6-C7 not impinging on neural structures. At C3-C4, there was a diffuse 2-mm disc protrusion associated with ossification in the posterior longitudinal ligament. Ventral dural deformity was mild, without central stenosis or spinal cord impingement. The residual mid-sagittal dural diameter was 9 mm. Mild right facet joint hypertrophy was present at C3-C4 without foraminal stenosis or root sleeve underfilling. At C4-C5, there was combination of ossification in the posterior longitudinal ligament and 1-2 mm disc protrusion producing mild ventral dural deformity and borderline spinal cord impingement, leaving 9 mm residual mid-sagittal dural diameter. Shallow ventral extradural defects were present on the myelogram at L1-L2, L2-L3, L3-L4 and L4-L5. There was also anterior spondylosis at L1-L2, L2-L3 and L3-L4 and central stenosis at L3-L4 and L4-L5. Central stenosis was probably greatest at L4-L5 where the disc maintained a normal dorsal concavity centrally but protruded laterally toward the left foramen. If there was a left L4 radiculopathy this might be significant. Neither L4 root sleeve filled distally on the myelogram. CT at L4-L5 demonstrated bilateral mild flaval prominence and abundant epidural fat. The residual mid-sagittal dural diameter was narrowed to 6-7 mm predominately due to the epidural lipomatosis. At L3-L4, the disc also maintained a normal dorsal concavity and the ventral defect at L3-L4 were therefore considered a disc bulge. There might be lateral protrusion toward the right foramen at L3-L4; if there was a right L3 radiculopathy this might be significant. There was anterior spondylosis at L3-L4 and minimal retrolisthesis. Mild bilateral flaval prominence was present at L3-L4. The residual mid-sagittal dural diameter was about 6 mm. There were Schmorl's nodes in the L4 superior endplate. At L1-L2 and L2-L3, there was anterior spondylosis but the discs maintained a normal dorsal concavity. There

was probably slight retrolisthesis in extension at L1-L2 and L2-L3 without stenosis. At L5-S1, the disc was normal in contour. There was mild bilateral facet joint hypertrophy and spurring at L5-S1 and bilateral mild flaval prominence. Conjoined roots were present on the right at L5 and S1 resulting in root sleeve asymmetry on the myelogram.

On April 25, 2011, evaluated the patient. The patient was status post two cervical surgeries, anterior C5-C6 fusion and posterior C5-C6 fusion. Since that time he had developed ongoing posterior paracervical neck pain with intermittent bilateral upper extremity paresthesias which were worse on the right. The patient stated that he felt numbness and tingling extending all the way down the distal right hand and fingertips. He was utilizing OxyContin, Lyrica, Soma, Ambien and lorazepam. Examination of the cervical spine showed well-healed anterior horizontal and posterior longitudinal scars with no evidence of edema, ecchymotic bruising or erythema. Digital palpation showed localized trigger points and tender spots over the bilateral posterior paracervical musculature. performed electromyography/nerve conduction velocity (EMG/NCV) that showed primarily abnormal problems in the right upper extremity with positive electrodiagnostic evidence of a right C6-C7 radiculopathy which was both acute and chronic in nature.

2012: On January 5, 2012, evaluated the patient for ongoing neck and low back pain. History indicated that the patient had never had a surgery in his lumbar spine. He had injections and therapy. He had finished the PRIDE where opined that there was no need for further surgery. He had planned to wean the patient off narcotics. The patient had undergone CT myelogram of the cervical and lumbar spine that showed definitive severe abnormalities. The patient presently had neck pain with right greater than left arm pain, lumbar pain with numbness in the feet and radiating pain that extended inferiorly down to his legs bilaterally and posteriorly. He was currently managed medically with. He was utilizing OxyContin, Lyrica, lorazepam, amitriptyline, Ambien, oxymorphone. had performed posterior cervical C5-C6 fusion whereas performed anterior C5-C6 fusion. The patient reported that his back hurt more than his neck presently. He had failed non-operative treatments and decompression and fusion would be indicated. He had a psychological evaluation pending prior to scheduling his surgery. Examination of the cervical spine showed decreased sensory in the right upper extremity and left upper extremity. The patient had an antalgic gait and used cane while walking. Examination of the lumbar spine showed decreased right leg sensory whereas the left leg sensory was normal. Straight leg raise (SLR) on the right side was positive. reviewed the CT myelogram findings and diagnosed solid fusion at C5-C6, stenosis with cord impingement at C6-C7, stenosis at C3-C4 and C4-C5 and 6-mm canal diameter at L3-L4, L4-L5 with back and bilateral leg radicular pain and myelopathy and failure of non-operative treatments, therapy, and injections. He recommended continuing medications per and considering psychological evaluation prior to C6-C7 ACDF and L3-L4 laminectomy, and a TLIF L3-L4, L4-L5.

On February 28, 2012, performed a psychological evaluation and opined that the patient presented with a severe psychological and behavioral risk factors for poor outcome from spine surgery. Using the block protocol, he was recommended for noninvasive intervention only or for discharge from surgical care. The dilemma in this case was that the patient had severe spinal stenosis and muscle wasting and needed surgery, if nothing else, just to stabilize him from further deterioration. This situation did sometimes arise and it posed a dilemma and challenge for all his providers. recommended at least six to eight weeks of therapy and medication to initiate the cognitive behavioral interventions as well as multiple meetings to explain and reinforce the nature of the surgery and potential outcomes. This would reduce psychological and behavioral risk factors for the surgery.

On March 13, 2012, evaluated the patient for neck and low back pain that was throbbing, constant and aggravated by physical activity. The patient complained of headaches and pain on the left side of his neck as well as left lower back. assessed cervical disc disease, postlaminectomy pain syndrome of the cervical spine, cervical radiculopathy, lumbar radiculopathy, and cervical spine stenosis. He refilled medications and recommended follow-up in one month.

On April 5, 2012, evaluated the patient for neck and back pain. noted the following treatment history: *"The patient had two cervical surgeries at C5-C6 with ACDF followed by PCF at C5-C6. He never had surgery in his low back or lumbar spine. He had injections and therapy that satisfied non-operative treatment per ODG. The patient had computerized tomography (CT) myelogram on March 29, 2011, that revealed objective findings that provided an etiology to this patient's pain. The cervical findings indicated a healed solid C5-C6 fusion with adjacent stenosis at all levels above and below the fusion, with C3-C4, C4-C5, 9 mm canal and C6-C7 with 8 to 9 mm canal and spinal cord impingement at that level. The lumbar portion of the study revealed severe stenosis with disc bulges at the right L3-L4 and left L4-L5 with 6 mm canal at both levels. These were definite severe abnormalities that could explain why this patient had pain and these were the pain generators in his lumbar spine.* The patient currently reported neck pain with right greater than left arm pain, lumbar pain with numb feet and radiating pain that extended inferiorly down his legs bilaterally and posteriorly. The patient was utilizing oxycodone, Lyrica, lorazepam, amitriptyline, Ambien, and oxymorphone. He also had electromyography (EMG) on April 25, 2011, that showed right C6-C7 radiculopathy that correlated with his CT myelogram and complaints of neck and right arm pain. The patient had groin pain and bilateral leg and foot pain. He needed lumbar decompression and fusion due to the stenosis, back and leg pain, failure of non-operative treatment all done within ODG. The patient stated that his back would hurt more than his neck at that time. He had failed non-operative treatment, decompression and fusion was indicated. Examination of the cervical spine showed decreased sensory in the upper extremities. Examination of the lumbar spine showed an antalgic gait. The patient was using a cane. The motor exam showed decreased strength in the quadriceps, anterior tibia, quadriceps, tibialis anterior, and extensor hallucis. Reflexes were decreased the in quadriceps, posterior tibialis and Achilles. Sensory examination was decreased in the right leg. Straight leg raising (SLR) was positive on the right. The patient had

undergone a medical evaluation who opined that the patient needed a cervical decompression and fusion and the request was within ODG. assessed solid cervical fusion at C5-C6, cervical stenosis with cord impingement at C6-C7, cervical stenosis at C3-C4 and C4-C5 and lumbar stenosis 6 mm canal diameter at L3-L4 and L4-L5 with back and bilateral leg radicular pain and myelopathy, failure of non-operative treatments, therapy and injections. He recommended continuing medications per and considering C6-C7 ACDF, L3-L4 laminectomy, TLIF at L3-L4 and L4-L5 and psychological evaluation for lumbar surgery prior to proceeding with precertification for surgery.

In April and May, noted two plus spasm, guarding and tenderness over the cervical spine, cervicodorsal trapezius and upper back. Spurling's was positive bilaterally. assessed cervical disc disease, postlaminectomy pain syndrome, cervical radiculopathy, chronic pain syndrome, low back pain and lumbar disc disease. He refilled OxyContin, Opana, amitriptyline, Ativan, Soma, Lyrica and Ambien and felt that the patient would benefit from a cervical epidural steroid injection (ESI).

On May 3, 2012, noted that the patient was seen by who had recommended more interventions to prepare him psychologically for surgery. Motor examination of the cervical spine showed decreased reflexes in left biceps, left triceps, and left brachioradialis. Sensory was decreased in bilateral upper extremities. There was numbness in the dorsal forearm bilaterally. Examination of the lumbar spine showed antalgic gait. Motor examination was decreased in quadriceps, tibialis anterior, and extensor hallucis longus. Reflexes were decreased in quadriceps on the right, tibialis posterior on the right and Achilles bilaterally. Sensory examination was decreased in the right leg. SLR was positive on the right. recommended cervical and lumbar surgery and psychological evaluation for lumbar surgery.

On May 11, 2012, a psychologist, noted that the patient was seen for health and behavioral therapy from March through May for a total of six sessions. The evaluation has showed severe psychological and behavioral risk factors for spine surgery but the patient had ongoing muscle wasting and so the surgery was necessary to prevent further loss. noted that the patient was in PRIDE many years ago but had never practiced them or mastered them. opined that the patient would benefit from an SSRI given his anxiety and depression and would hope this could be started prior to surgery since the improved mood and outlook would be helpful. diagnosed cognitive disorder, anxiety disorder, depressive disorder and psychological factors affecting medical conditions. He recommended six additional visits of psychotherapy.

From June through July, maintained the patient on Dilaudid, OxyContin, amitriptyline, Ativan, Soma, Lyrica, Ambien and Celexa. He recommended magnetic resonance imaging (MRI) of the cervical spine and spinal cord stimulator (SCS) trial.

On follow-up, noted that cervical MRI was denied. He refilled medications and gave a trial of generic Lunesta.

In June, noted that the patient's back was hurting more than his neck. He also noted that the patient was cleared for surgery after several therapy sessions. recommended cervical and lumbar surgery.

On August 16, 2012, noted that the surgery had been denied on the basis of smoking and no documentation of instability. He opined that these were not the valid indications for denial. The patient had greatly reduced his smoking. The patient had criteria for fusion on other indicators than the one cited for denial which made the denial completely invalid because it referenced conditions and criteria that did not apply to the patient. The indicators were identified pain generators which included the spinal stenosis at L3-L4 and L4-L5, failure of non-operative treatment including therapy and injections, psychological clearance, myopathic clinical findings that correlated to L5, L4 roots with weak quadriceps, anterior tibialis and hallucis longus, positive SLR that correlated and established clinical radiculopathy of the lumbar roots. With pain generators identified, radiculopathy established, and failure of all non-operative treatment the requested fusion and decompression at L3-L4 and L4-L5 was indicated by ODG. Smoking was not a contraindication for surgery and instability would not apply to this patient and was inappropriately utilized in determining his request for surgery. requested for a TLIF at L3-L4 and L4-L5 and post spinal fusion L3-L5 and spinal monitoring.

On August 22, 2012, noted that the patient had used only four of six approved sessions. He requested for four additional visits over the next ten weeks.

Per utilization review dated August 30, 2012, the request for implant neuro-electrodes, simple and complex neurostimulator, and implantation of neurostimulator electronic and SCS trial was denied with the following rationale: *"As per latest medical report dated July 31, 2012, the patient returned with persistent neck and low back pain. No recent clinical objective findings on the cervical and lumbar spine were provided for review. Physical examination dated May 8, 2012, showed cervical spasm and tenderness, Spurling's test was positive. DTRs were decreased with intact pin sensation to the middle fingers. There were no objective findings on the lumbar spine. This is a request for SCS trial, lower extremity radicular pain was not demonstrated. There was no documentation of previous attempts to elevate symptoms with injection or PT. Unresponsiveness to oral medications was not documented. Furthermore, it was not specified whether the SCS trial will address the cervical or the lumbar problem. Hence this medical necessity of the request has not been established."*

Per reconsideration review dated September 12, 2012, an appeal for spinal monitoring, L3-L4 laminectomy, transforaminal lumbar interbody fusion L3-L4, L4-L5 and five-day inpatient stay was denied with the following rationale: *"The previous non-certification from June 15, 2012, by was due to a lack of documentation of meeting the guidelines requirements of smoking cessation on*

the claimant's part and demonstration of instability on the diagnostic imaging. Additional medical records in the form of letter prepared on August 16, 2012, were reviewed. This letter states that the reasons for non-certification including no documentation of smoking cessation and lack of documentation of demonstration of instability are not valid indications for the non-certification. The ODG clearly state that smoking cessation for at six least weeks prior to surgery and during the period of fusion healing is recommended. The guidelines also state that x-rays demonstrating instability with diagnostic imaging and discography demonstrating disc pathology correlated with symptoms and examination findings must be documented. The radiologist's interpretation of x-rays demonstrating instability was noted. A CT myelogram of the lumbar spine notes central canal stenosis but no definitive mention of neural foraminal stenosis was made. This does not support the guideline recommend of imaging correlation with symptoms and examination findings. Based on the failure to meet these criteria, this previous non-certification is supported. The request for transforaminal lumbar interbody fusion at L3-L4 – L4-L5, and L3-L4 laminectomy with spinal monitoring with five-day inpatient stay is not certified."

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

The concomitant request both for a spinal cord stimulator and a two level lumbar fusion is somewhat confusing. In general, patients undergo spinal cord stimulator placement for specific reasons including failed lumbar fusion or sometimes complex regional pain syndrome. Accordingly, the request for both surgeries at the same time would be atypical and most practitioners would request one or the other.

With respect to the spinal cord stimulator, the spinal cord stimulator cannot be recommended as medically necessary. The patient does not meet Official Disability Guidelines for stimulator implantation. Specifically, the patient does not fulfil the criteria of failed back syndrome (persistent pain in patients who have undergone at least one previous back operation) or complex regional pain syndrome. Spinal cord stimulator therefore cannot be deemed medically necessary.

With respect to the requested two level fusion, this also cannot be recommended as medically necessary. The claimant does not clearly have focal radicular complaints or myelopathic complaints related to lumbar spinal stenosis. It is not clear if the patient has neurogenic claudication type symptoms. The patient has lumbar stenosis, but this results primarily from the patient's epidural lipomatosis rather than severe disc pathology according to the patient's CT myelogram. The patient's exam has been rather nonspecific with reports of weakness in multiple muscle groups, diffuse decreased sensory findings for the right leg and diminished reflexes in multiple areas. It is difficult to correlate the diffuse changes with the pathology noted on the CT myelogram. However, there may be sufficient pathology to warrant lumbar decompression with the failure of conservative care.

The request for the associated fusion, however, remains unclear. Records do not indicate that the patient has dynamic instability as a component of the lumbar stenosis and the patient has only mild facet hypertrophy below the most stenotic level at L5-S1. In the absence of instability, it appears the treating practitioner has requested a lumbar fusion to treat the patient back pain symptoms. Guidelines generally require psychological clearance before fusion in patients who lack instability and have a suspected discogenic pain component. This patient has not clearly met the criteria to pass a psychological evaluation. Rather, the patient was noted to have severe psychological and behavioral risk factors for poor outcome from spine surgery after an evaluation in February of 2012. The patient again was noted to have severe psychological and behavioral risk factors in May of 2012. Though the patient was thought to have muscle wasting to justify surgery even in the presence of negative psychological factors, the patient is not clearly myelopathic and the rationale for fusion has not been justified. It remains unclear why the treating physician has requested to proceed with the fusion rather than a lumbar decompression to treat the stenosis. A lumbar fusion procedure is more often performed for patients with instability and there is significant increased morbidity along with the risk factors with smoking as indicated in prior reviews.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES