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Notice of Independent Review Decision

DATE OF REVIEW: January 4, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Outpatient spinal cord stimulator trial and lead removal

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Fellow American Academy of Orthopaedic Surgeons

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

Insurance Company
- Operative notes (01/08/04, 01/10/07)
- Office visits (09/23/08 – 12/08/09)
- Utilization Reviews (11/06/09, 11/25/09)

Dr.
- Office notes (01/02/07 – 12/08/09)
- Operative notes (01/10/07)
- Diagnostic studies (01/10/07 – 07/28/09)
- Utilization Review (11-06-09 – 11/25/09)

TDI
- Utilization Reviews (11/06/09, 11/25/09)

ODG has been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who sustained a work-related low back injury in xx/xx/xx. He twisted his body as he worked on rebuilding a bulldozer engine.

The patient had sustained an on-the-job injury and had undergone extensive conservative treatment. He underwent a magnetic resonance imaging (MRI) scan that showed evidence of central disc protrusion at L5-S1 and nuclear desiccation at L4-L5 and L5-S1. A lumbar discography showed pain reproduction at the L4-L5 and L5-S1 levels. The L5-S1 level reproduced his pain. On January 8, 2004, M.D., performed complete anterior discectomy with decompression of anterior epidural space and lateral recesses at L4-L5 and L5-S1, anterior interbody fusion and internal fixation at L4-L5 and L5-S1. The postoperative diagnoses were central herniated nucleus pulposus (HNP) at L5-S1 with internal disc disruption at L4-L5 and L5-S1.

In January 2007, Dr. assessed painful hardware and performed removal of L4 and S1 pedical screws and rods as well as exploration of fusion mass.

M.D., a pain management physician, noted soreness and stiffness in the lower back and leg primarily over the left buttock area. Examination revealed some spasm in the left lumbosacral region and into the left gluteus. The patient was treated with Effexor, hydrocodone, Lyrica, and Robaxin.

However, in March 2007, the patient reported severe low back and left leg pain after he helped another employee lift an object weighing about 100 lbs. MRI of the lumbar spine showed grade I retrolisthesis of L5 upon S1, plugs within the L4-L5 and L5-S1 disc spaces, screws entering the anterior aspect of L5 and S1 vertebral bodies, prior screw tracks within the pedicle of L4 bilaterally and within both side of the sacrum, and a 3.9-cm cystic structure within the pelvis with slight shift to the right of the midline. Dr. treated him conservatively with medications to include muscle relaxant, anti-inflammatories, and analgesics. There was no improvement and the patient complained of a strong tingling sensation in his bilateral legs, left greater than right, with burning of his heels and severe right-sided low back pain. Examination revealed tenderness over the right L5-S1 facet and iliolumbar ligamentous area as well as slightly inferiorly into the superior sacroiliac (SI) area.

MRI of the lumbar spine showed mild retrolisthesis of L5 on S1, small central focal disc bulges at L4-L5 and L5-S1 unchanged from the previous studies. MRI of the pelvis showed metallic susceptibility artifact of the lower lumbar spine secondary to surgical fusion. Since there were no abnormalities on the MRIs, the patient was sent for pain management evaluation to Dr. who tried lumbar facet injections with no effect while the TPI performed actually worsened the patient's pain for about two weeks time. The medications were of no help. There was tenderness in the lower segments of the lumbar spine (right greater than left) with pain more in the center of the spine. Dr. believed the patient's pain was predominantly axial with some radiation into the posterior buttock and thigh. The patient declined conservative care type of injection such at TPI. Therefore, Dr. recommended a spinal cord stimulator (SCS) and referred him to a psychologist for SCS evaluation.

A single documented visit with M.D., on September 23, 2008, revealed unchanged chronic low back pain. Review of systems was positive for anxiety,

depression, feeling of stress and insomnia (back and legs kept him awake) and sleep only for three hours per night. Examination revealed pain with back flexion and extension and right lateral flexion. Dr. assessed chronic low back pain and referred him to a chronic pain specialist.

In 2009, the patient reported worsening of discomfort in his right, mid lumbar spine with pain radiating to the posterior thigh and left and right calf. He was utilizing Norco 10 mg five per day and was still working. He reported tingling in his right foot and right side of the back swelled sometimes to the size of a baseball. Examination of the back revealed edema and tenderness over the right lumbar paraspinal muscle, paresthesia over the bilateral lower extremities. Deep tendon reflexes were 2/4 left patellar, 0/4 right patellar, 1/4 left and right Achilles, and limited passive ROM with extension and left lateral bending. Dr. assessed low back pain and depression related to chronic illness and treated him with Cymbalta and Norco.

Dr. assessed chronic intractable back pain with radiation into the legs, failed back surgery syndrome, and history of two-level fusions with subsequent hardware removal. He suggested SCS therapy.

On July 28, 2009, MRI of the lumbar spine showed unchanged status from the previous MRI except for 1.4-cm benign hemangioma located in the vertebral body at L5.

An opinion on SCS was obtained from M.D., who reviewed the recent MRI report and found no compressive lesions in the lumbar spine responsible for the continuing lumbar and lower extremity radicular pain. He opined a trial of SCS would be reasonable. Depending upon the response to the trial, a permanent implantation of a dual-lead program rechargeable system would be considered.

In a behavorial medicine evaluation, the patient was diagnosed with pain disorder associated with both psychological factor and a general medical condition and a very high stress level. The patient was unsure he wanted to have the surgery and was worried about lead migration. He scored 19 on CES-D indicating a high level of emotional distress and 50 of the Oswestry indicating severe disability due to spine-related pain. According to the psychologist, the patient utilized repression as a coping mechanism and could be bottling up a lot of anger and frustration. He may not have adequate means to express his emotion and had difficulty interacting at times. He might also be dealing with anger issues by working so many hours; this tendency towards overactivity was a red flag for surgery. The patient was kept on hold for surgery pending another meeting with Dr. to discuss his options and clarify ambivalence about surgery and define any activity restrictions related to SCS. Also, clear rehabilitation guidelines regarding self-care were recommended prior to a trial of SCS and a chronic pain management program should also be considered.

On October 29, 2009, Dr. noted the patient had pins and needles, burning and stabbing sensation across the back, right buttock and right posterior leg. With the presence of radicular complaint, the patient was scheduled for a trial.

On November 6, 2009, M.D., denied the outpatient lumbar SCS trial and lead removal with the following rationale: "*In the records dated 10/29/09 the patient is*

complaining of low back pain radiating to the bilateral legs, right worse than left. The records submitted did not provide a recent and complete physical examination of this patient to facilitate the review. In the behavior medicine evaluation performed on 10/07/09, it was stated that the patient belonged to the fair prognosis category and has moderate level of psychological and medical risk. Furthermore, it was stated that clear rehabilitation guidelines be given or have patient demonstrate better self-care prior to trial of SCS. There is no documentation that addresses the said issues. The records submitted did not provide clear rationale for the requested SCS trial. Moreover, there is no objective documentation regarding this patient's failure to conservative management such as physical therapy (PT), medications, and exercises. The medical necessity is not determined at this time."

On November 25, 2009, M.D., denied the appeal for lumbar SCS trial and lead removal with the following rationale: "*The patient is status post L4-S1 lumbar fusion with instrumentation and subsequent removal of hardware. The patient is noted to have tried TPIs as well as facet blocks in 2007, but there is no documentation of recent attempts at conservative care such as PT or other conservative measures. MRI lumbar spine done on 07/28/09 reported fusion lower lumbar spine with anterior screws extending into the vertebral bodies at L5 and S1. Pedicle screws have been removed from the L4 level. Disc spaces are present at L4-L5 and L5-S1 without interval change since the 08/03/07. A small focal disc protrusion at L4-L5 is noted abutting but not displacing the thecal sac, unchanged since 08/03/07. There is a minimal central disc bulge at L5-S1 with slight retrolisthesis of L5 on S1 unchanged. There is 1.4 cm benign hemangioma located in the vertebral body at L5. The patient is noted to have subjective complaints of low back pain radiating to the bilateral legs, right worse than left, but there is no detailed physical examination report. Objective findings on 10/29/09 reported the patient to have essentially normal gait pattern and remains independent with mobility. Balance and coordination were grossly normal. No neurological examination findings were reported. The patient underwent behavorial medicine evaluation/presurgical screen on 10/07/09 at which time it was noted that the patient is still not sure he wants to have surgery and wants to have lead migration with SCS placement. The patient reported he was very open to attempting psychotherapy which was recommended in 2007. Evaluation of the patient was in the fair prognosis category. Evaluation also stated that clear rehabilitation guidelines should be given or have patient demonstrate better self-care prior to SCS trial. As noted on previous review there is no documentation that this issue has been addressed. Given the current clinical data, the proposed SCS trial is not indicated as medically necessary at this time."*

On December 8, 2009, Dr. noted increased pain despite medication. It was difficult to work because of the radicular complaint. The patient was still taking hydrocodone 4 to 6 a day and was taking Cymbalta which was now denied. He reported episodes of right leg giving way at times and falling. Examination revealed an antalgic gait, decreased sensation to the entire right leg, and straight leg raise (SLR) reproducing pain in the right hamstring. Dr. diagnosed chronic lumbar pain with radiculopathy, chronic pain syndrome, and failed back surgery. He stated the patient ultimately was a candidate for SCS and resubmitted a request for this.

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

BASED ON ODG GUIDELINES, THE PATIENT DOES NOT MEET SEVERAL CRITERIA INCLUDING RESPONSE TO NEUROLITHIC AGENTS, RECENT INJECTIONS AND/OR PHYSICAL THERAPY. THE PATIENT ALSO HAS NOT HAD PSYCHOLOGICAL CLEARANCE AND ACCORDING TO THE EVALUATION FROM DIANE LOKAY-NICKELL CLEAR REHABILITATION GUIDELINES SHOULD BE GIVEN AND THE PATIENT SHOULD DEMONSTRATE BETTER CARE PRIOR TO TRIAL OF SPINAL CORD STIMULATOR. THERE IS NO DOCUMENTATION THAT THIS HAS BEEN DONE. THE PATIENT IS NOW INCREASING HIS NARCOTIC MEDICATION INTAKE AND THERE MAY BE SUBSTANCE ABUSE ISSUES. ALL THESE ISSUES NEED TO BE ADDRESSED.

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

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**