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Notice of Independent Review Decision

**November 19, 2014**

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Spinal cord stimulator lead revision

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

Pain Management Physician

**REVIEW OUTCOME:**

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

X 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.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male who sustained a work-related injury to the lower back on xx/xx/xx. The patient suffered pull/strain in the low back.

**xxxx – 2005:** No records are available.

**2006 – 2007:** On May 26, 2006, magnetic resonance imaging (MRI) of the lumbar spine was performed for complaints of low back pain radiating to left leg since two months. The findings revealed mild bilateral facet hypertrophy at L1-L2. At L2-L3, there was decreased disc signal intensity with decreased disc height consistent with degenerative disc disease. There was mild posterior bulge of the disc without evidence of herniated nucleus pulposus (HNP), spinal stenosis or neural foraminal encroachment. There was mild bilateral facet hypertrophy. At L3-L4, there was decreased disc signal intensity with normal disc height consistent with degenerative disc disease. There was a 2-3 mm broad-based

posterior bulge of the disc abutting the thecal sac and in conjunction with moderate bilateral ligamentous and facet hypertrophy causing bilateral neural foraminal encroachment. At L4-L5, there was decreased disc signal intensity with decreased disc height consistent with degenerative disc disease. There were post-surgical changes versus other irregular signal involving the posterior element of L4 with marked encroachment upon the left neural foramen. There was no definitive evidence of HNP or spinal stenosis. The patient apparently had hardware removed which was most likely accounting for abnormal signal on the left sacroiliac (SI) joint at this region. It was difficult to evaluate the neural foramina at this level due to the diffuse abnormal soft tissue. The right neural foramen was patent. At L5-S1, there was decreased disc signal intensity with decreased disc height consistent with degenerative disc disease. The patient again had abnormal signal arising from the left facet joint from hardware removal as diffuse soft tissue density in the left neural foramina. There was no evidence of HNP.

On December 13, 2007, electromyography/nerve conduction velocity (EMG/NCV) of the lower extremities revealed mild nonspecific reduction in recruitment pattern in right vastus lateralis, mild slow firing units in recruitment pattern in the left vastus lateralis and vastus medialis. There was limited voluntary effort on recruitment pattern in the left gastrocnemius.

**2008 – 2009:** No records are available.

**2010:** On April 26, 2010, x-rays of the lumbar spine were performed for complaints of low back pain. The findings revealed widespread degenerative disc disease (DDD) and facet arthrosis in the lumbar spine. There was hardware present at the L3 and L4 level consisting of pedicular screws and posterior side bars. There was evidence of interbody spinous fusion at this level. The lumbar lordotic curvature was straightened. There was no radiographic evidence of acute or destructive bony changes. The intervertebral discs were moderately decreased in height throughout. There was widespread posterior facet arthrosis.

On April 26, 2010, the patient underwent a fluoroscopic guided lumbar myelogram which revealed ventral epidural defect at the L2-L3 level. There were postsurgical changes including fusion at the L3-L4 level and interbody fusion device. There was filling defect on the ventral surface of the thecal sac at L2-L3 level.

On October 12, 2010, performed caudal epidural steroid injection (ESI) and left S1 transforaminal epidural steroid administration.

**2011:** No records are available.

**2012:** On June 1, 2012, performed percutaneous placement of Octrode spinal cord stimulator (SCS) lead with analysis and programming of SCS lead.

On December 7, 2012, performed placement of implant generator to the right gluteal region, analysis program with SCS lead and placement of laminotomy with SCS lead and placement of laminotomy lead.

On December 17, 2012, saw the patient for chronic low back pain due to lumbar post-laminectomy syndrome. The patient reported of some incisional pain, but was doing better since the implant. The pain score was 6/10. The urine drug screen (UDS) dated May 11, 2012, was compliant. diagnosed chronic low back pain due to lumbar post-laminectomy syndrome and recommended repeating UDS. The staples were removed and the SCS was programmed.

**2013:** On January 14, 2013, noted the patient was doing well, but had some programming issues. The current pain score was 4/10. The patient was utilizing hydrocodone and methocarbamol. maintained the current medications until reprogramming.

On March 6, 2013, the patient reported that the stimulator was helping his leg pain tremendously, but he was still having back pain. The pain score was 6/10 without medications and 4/10 with medications. The patient was utilizing hydrocodone and methocarbamol. renewed hydrocodone, Robaxin and Zonegran. UDS was done for compliancy testing.

On May 1, 2013, noted the patient was doing well with the current medications. He had minimal complaint and was to have a SCS rep. He rated the pain at 8/10 without medications and 6/10 with medications. added acetaminophen-hydrocodone.

On June 24, 2013, the patient continued to derive benefit from the medications. He stated he had back pain and some pressure. recommended trying a compound cream. Medications were refilled.

On November 11, 2013, evaluated the patient for low back pain and associated radicular leg pains. The patient reported that the generic hydrocodone was not effective as Vicodin. The patient stated that after the SCS placement in February 2013, his hair turned white and thinned out. He was told he might have had a reaction to anesthesia shots. He reported he had turned off the stimulator completely and the pain levels were better. He wanted to try to remove the stimulator all together. Examination revealed positive straight leg raise (SLR) on left side at 70 degrees, Kemp test was positive on the left side. Leg extension was weaker on left as compared to right. Foot dorsiflexion and planter flexion was weak on left compared to right. The gait was antalgic. He had difficulty sitting for the duration of the examination. Sitting SLR test showed weakness in the lower extremities as well as increased pain. Trunk flexion measured at 40 degrees. Lumbar palpation noted moderate tenderness and mild spasm of the lumbar paraspinal muscles. diagnosed lumbar disc disorder with myelopathy, lumbar post-fusion syndrome and lumbar radiculopathy. The patient wanted consultation about removing the stimulator.

**2014:** On May 2, 2014, noted the patient had spoken regarding removal of SCS. told the patient to have the technician look at it. After resetting the device, the patient noted the device malfunctioned and almost caused him to lose control of his car. He still wanted it removed. The L2-L3 and L3-L4 levels had herniations that had not been treated. Examination revealed positive left side SLR at 60 degrees. Kemp test was positive on left. Foot dorsiflexion and plantarflexion was weak on left. There was weakness in lower extremities with increased pain on sitting SLR. Trunk flexion was 40 degrees. There was moderate tenderness during palpation and mild spasm of lumbar paraspinal muscles. referred the patient for removal of SCS. The patient was also to be referred to orthopedic to determine surgical intervention to treat L2-L3 and L3-L4 discs.

On September 15, 2014, the patient stated the pain was tolerable with the medications. He was not working. He rated the pain at 6/10 with medications and 9/10 without medications. He was getting 30% pain relief from the medications. He continued to complain of shocking sensation and pain radiating laterally to his anterior abdomen region when the SCS was turned on. He was utilizing ciprofloxacin, doxycycline, Norco 5/500, ibuprofen and sulfamethoxazole-trimethoprim. diagnosed low back pain, degeneration of lumbar intervertebral disc, disorder of trunk, displacement of lumbar intervertebral disc without myelopathy and lumbar post-laminectomy syndrome. The patient was prescribed Norco 7.5/325, Robaxin 750 mg and Zonegran 100 mg.

On September 24, 2014, performed a peer review on the patient and opined: The patient was complaining of continued shocking sensation and pain which radiated laterally to the anterior abdominal region when the SCS was turned on. Per clinical notes, the pain was most likely due to lead fracture or a generator malfunction, especially since the patient experienced shocks and pain when the SCS was turned on. With the application of guidelines, the medical necessity was not established as guidelines did not address lead revision only battery replacement. Therefore, the request for SCS lead revision was not medically necessary.

Per utilization reviewed dated October 1, 2014, the request for spinal cord stimulator lead revision for the low back was denied with the following rationale: *"In my judgment, the clinical information provided does not establish the medical necessity of this request."*

On October 22, 2014, the patient returned for medication refill. The pain score was 6/10 with medications and 8/10 without medications. refilled Norco and Robaxin.

On October 27, 2014, request for reconsideration (appeal) was submitted.

Per a reconsideration reviewed dated October 29, 2014, the appeal for spinal cord stimulator lead revision for the low back was denied with the following rationale: *"In my judgment, the clinical information provided does not establish the medical necessity of this request. In this case, there is no clear documentation showing*

*why this revision would be necessary. The documentation states the patient reported 20% pain relief from this and medication. There is no documentation showing increase in function and no documentation showing why this procedure should be performed. Therefore, based on the evidence-based guidelines and medical evidence provided, this request has been determined to not be supported for medical necessity.”*

On October 31, 2014, request for IRO was submitted.

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

On the date of this review, the ODG provides the following with regard to spinal cord stimulation:

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See the Pain Chapter for *Indications for stimulator implantation*. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in the past five years has it met with widespread acceptance and recognition by the medical community. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the recently released joint American College of Physicians/American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008) The National Institute for Health and Clinical Excellence (NICE) of the UK just completed their Final Appraisal Determination (FAD) of the medical evidence on spinal cord stimulation (SCS), concluding that SCS is recommended as a treatment option for adults with failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management. (NICE, 2008)

Recent research: New 24-month data is available from a study randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone. At 24 months, the primary outcome was achieved by 37% randomized to SCS versus 2% to conventional medical management (CMM), and by 47% of patients who received SCS as final treatment versus 7% for CMM. All 100 patients in the study had undergone at least one previous anatomically successful spine surgery for a herniated disk but continued to experience moderate to severe pain in one or both legs, and to a lesser degree in the back, at least six months later. Conventional medical therapies included oral medications, nerve blocks, steroid injections, physical and psychological therapy and/or chiropractic care. (Kumar, 2008) There is fair evidence that spinal cord stimulation is moderately effective for failed back surgery syndrome with persistent radiculopathy, though device-related complications are common. (Chou3, 2009)

### **Pain chapter:**

Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, for specific conditions indicated below, and following a successful temporary trial. Although there is limited evidence in favor of Spinal Cord Stimulators (SCS) for Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type I, more trials are needed to confirm whether SCS is an effective treatment for certain types of chronic pain. (Mailis-Gagnon-Cochrane, 2004) (BlueCross BlueShield, 2004) See indications list below. This supporting evidence is

significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment.

**Indications for stimulator implantation:**

Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation and are not candidates for repeat surgery), when all of the following are present: (1) symptoms are primarily (sic) lower extremity radicular pain; there has been limited response to non-interventional care (e.g. neuroleptic agents, analgesics, injections, physical therapy, etc.); (2) psychological clearance indicates realistic expectations and clearance for the procedure; (3) there is no current evidence of substance abuse issues; (4) there are no contraindications to a trial; (5) Permanent placement requires evidence of 50% pain relief and medication reduction or functional improvement after temporary trial. Estimates are in the range of 40-60% success rate 5 years after surgery. Neurostimulation is generally considered to be ineffective in treating nociceptive pain.

Although the treating physician stated that he believes that a lead revision would now be effective, the medical evidence did not support this contention. In fact, the evidence reveals that when approached about this request the patient wanted the SCS removed because he received better relief from his medications than the SCS. In my opinion, a lead revision would most likely than not result in no further improved pain control. Thus upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be upheld.

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

**X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

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