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Notice of Independent Review Decision

DATE OF REVIEW: NOVEMBER 5, 2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Spinal cord stimulator trial (CPT code 63650)

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

The physician providing this review is a Doctor of Medicine (M.D.). The reviewer is national board certified in Physical Medicine and Rehabilitation as well as Pain Medicine. The reviewer is a member of International Spinal Intervention Society and American Medical Association. The reviewer has been in active practice for ten years.

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 Spinal cord stimulator trial.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Health Care:

- Clinic notes (10/27/04 – 05/11/07)
- Radiodiagnostic studies (02/05/04)
- Electrodiagnostic studies (10/12/04)
- Utilization reviews (09/25/07 – 10/02/07)

Associates

- Clinic notes (12/02/04 – 05/11/07)

The ODG guidelines were provided with the rationales for denial of the disputed services.

PATIENT CLINICAL HISTORY [SUMMARY]:

This is a xx-year-old patient who injured his lower back on xx/xx/xx. He attempted to lift a pipe and apparently ruptured two discs with cracked vertebrae. He underwent multiple surgeries including fusion with hardware and subsequent hardware removal. He continued to have back pain radiating to the buttocks with numbness in both legs, worse on the right.

In 2004, magnetic resonance imaging (MRI) of the lumbar spine demonstrated extensive postoperative changes at L4-L5 and L5-S1 without convincing evidence of residual or recurrent disc disease that might impinge the exiting nerve roots or spinal canal. An electrodiagnostic evaluation was performed for back pain and numbness in both legs. It was noted that the patient was status post lumbar discectomy in 1994, fusion in 1994 and 1995, and hardware removal in 1996. He was also noted to have undergone a spinal cord stimulator (SCS) trial, implantation and revision x2, then removal in 2001 due to lack of stimulation. Ongoing medications consisted of Vicodin, Valium, Demerol, Nexium, MS Contin, and Levbid. The electrodiagnostic study revealed evidence of chronic L4 and L5 radiculopathy.

M.D., noted complaints of neck pain and headaches in addition to low back pain. Dr. reviewed additional information: *The patient had had nine surgeries in the past including fusion surgery with removal of instrumentation. An intrathecal morphine pump had been tried but had to be discontinued due to an allergic reaction. In addition, an SCS trial helped, but permanent SCS implant did not help and it was removed.* According to Dr., the patient was not a surgical candidate and referred him for spinal cord stimulation. M.D., noted the following: *The patient underwent multiple surgeries from 1994 through 1995. He returned back to work in 1996 and sustained a second injury causing neck pain and headache. He continued to work until April 1997 when he went on disability due to pain. He had some injection therapy early on as well as physical therapy (PT) but none since 1997. A morphine pump trial gave 90% pain relief but had to be discontinued because of an allergic reaction.* His ongoing medications were Vicodin, Valium, Nexium, MS Contin, Demerol, hyoscyamine, and Phenergan. Myelogram/CT of September 2004 revealed bilateral laminectomy defects at L5, narrowing at L5-S1, and mild effacement of the right lateral margin of the thecal sac at L4-L5 with poor filling from the mid body of L5 to L5-S1 disc space due to multiple surgeries. Dr. reviewed the 2004 MRI and noted degenerative disc height loss at L4-L5 and slightly greater degree at L5-S1 with degenerative end plate changes. Dr. assessed postlaminectomy syndrome, previous successful SCS trial with subsequent loss of stimulation, failed morphine pump trial, bilateral lumbar degenerative joint disease (DJD), and cervical spondylosis. He discussed an SCS retrial. Through 2005 and 2006, Dr. followed the patient's progress. He reviewed MRI of the cervical spine, which was normal.

In March 2007, in response to a denial for an SCS trial, Dr. stated that technology had changed. SCS devices could be placed in positions that would not be helpful, and then replaced and provide benefit. He opined that since the only thing that helped the patient in the past was his SCS trial, it should be attempted again. He suggested a lumbosacral orthotic (LSO) device or a thoracic/lumbar/sacral orthotic device. In May, Dr. noted diffuse tenderness in the lumbar paravertebral muscles bilaterally, decreased lumbar range of motion (ROM), and decreased sensation to pinprick in the mid calves. He diagnosed lumbar postlaminectomy syndrome and radicular syndrome of the lower limbs, stated that the patient was not a surgical candidate, and recommended an SCS trial.

On September 25, 2007, the request for the SCS trial was denied stating: *Records do not reflect the claimant's response to the initial SCS or why it was revised and removed. Based on the clinical information submitted for this review and using the evidenced-based, peer-reviewed guidelines (the ODG guidelines), the request was not indicated.*

On October 2, 2007, an appeal for reconsideration was denied stating: *based on the clinical information provided, the request for SCS trial is not medically necessary. This is an injury that occurred nearly 11 years ago. The patient previously had implantation of SCS, but the stimulator was ineffectual despite attempts at revision. Given the current clinical data and the failure of previous SCS, the request for another SCS trial was not recommended as medically necessary.*

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

THE PROPOSED TREATMENT HAS ALREADY BEEN DONE AND FAILED. THE NEW REQUEST IS FOR "NEW TECHNOLOGY". THE NEW TECHNOLOGY HAS NOT BEEN DESCRIBED AND THERE IS NO EVIDENCE THAT NEWER TECHNIQUES ARE MORE EFFICACIOUS THAN OLDER TECHNIQUES, GIVEN THE FACT THAT EACH PAPER DOES NOT DIFFERENTIATE THE TECHNIQUES. THE ODG PROVIDES SELECTION CRITERIA WHICH THIS ITEM DOES NOT MEET DUE TO A CASE-SPECIFIC FAILURE OF PREVIOUS SIMILAR OUTCOME.

The following references from ODG are cited. ([Sundaraj, 2005](#)) . ([Furlan-Cochrane, 2004](#)) (CM) ([Taylor, 2005](#)) ([Taylor, 2006](#)) ([North, 2005](#)). ([Kemler, 2000](#)) ([Harke, 2005](#))

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

