

MATUTECH, INC.

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Notice of Independent Review Decision

DATE OF REVIEW: May 23, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Spinal cord stimulator (63650 and 63685); **63650:** Percutaneous implantation of neurostimulator electrode array, epidural; **63685:** Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

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 the Spinal cord stimulator (63650 and 63685); **63650:** Percutaneous implantation of neurostimulator electrode array, epidural; **63685:** Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Texas Department of Insurance

- Utilization reviews (03/26/08 – 04/18/08)

Healthcare Corporation

- Office notes (04/20/06 – 04/02/08)
- Utilization reviews (03/26/08 – 04/18/08)

Insurance Company

- Office notes (02/23/04– 04/02/08)
- Diagnostic studies (02/23/04 – 03/22/07)
- Therapy & Rehab notes (03/08/04 – 01/25/07)
- Procedure notes (05/19/05 - 07/05/07)
- Peer reviews (10/07/04 & 04/14/08)

- Utilization reviews for the request of SCS (02/22/07 – 04/18/08)

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male . On xx/xx/xx he was working in the parking lot and a car that he opened started to roll back. He tried to put on the brake and fell out and allegedly the door hit him along his left side. He initially complained of left shoulder and abdominal pain. Later, he also complained of lower back pain.

Following the injury, the patient was seen at an emergency room (ER) for left shoulder contusion and was treated with intramuscular injection of morphine sulfate and oral Vicodin. He then underwent extensive chiropractic therapy, aquatic therapy, and land-based physical therapy at Chiropractic for left shoulder, neck and low back complaints. History was significant for diabetes. Nerve conduction velocity (NCV) and evoked-potential studies of the lower extremities revealed bilateral peroneal and left tibial neuropathy; while NCV studies of the upper extremities revealed bilateral median sensory neuropathy at the wrists. Urine drug screening was positive for cocaine; however, the conclusion by various experts was that it was impossible to determine with any degree of certainty that the patient was indeed under the influence of cocaine at the time of the reported accident.

Magnetic resonance imaging (MRI) of the left shoulder revealed equivocal evidence of a partial-thickness tear of the supraspinatus tendon. MRI of the lumbar spine revealed a right paracentral disc extrusion with inferior extension at L5-S1 resulting in severe spinal canal stenosis and associated neural foraminal stenosis. M.D., an orthopedist, performed transforaminal lumbar ESIs x2 with very good improvement. With regards to the left shoulder, steroid injections were administered on two occasions with minimal effect. On November 3, 2005, M.D., performed left shoulder arthroscopic debridement, open acromioplasty, and rotator cuff repair with orthobiological graft. The patient underwent extensive postoperative rehabilitation as well as a few sessions of individual psychotherapy.

In January 2006, lumbar discogram-CT showed only some mild facet joint arthrosis from L3 through S1. Electromyography/nerve conduction velocity (EMG/NCV) study showed advanced peripheral neuropathy. Dr. felt that spinal cord stimulation (SCS) might be a better option. He provided prescription for transcutaneous electrical nerve stimulation (TENS) unit. In October 2006, he performed a lumbar ESI with improvement of about 90%. The patient was later placed into a chronic pain management program (CPMP) for four weeks. EMG/NCV studies of the left upper extremity revealed ulnar neuropathy with an entrapment site at the cubital tunnel and moderate-to-advance sensory motor left median neuropathy consistent with clinical diagnosis of the left carpal tunnel syndrome (CTS). Ph.D., cleared the patient psychologically for the SCS implantation.

In February 2007, Dr. reported that the patient was a perfect candidate for the SCS trial secondary to his failed back surgical syndrome and lumbar radiculopathy. On February 22, 2007, request for the SCS trial was denied with

rationale: *Records do not reflect that the claimant has had a psychological evaluation that was requested and approved in December 2006. In the absence of such information, this request is not indicated.*

In March 2007, Dr. obtained MRI of the left shoulder which revealed bicipital tenosynovitis. He administered steroid injection into the left shoulder without any benefit. On July 5, 2007, he performed arthroscopic release of adhesions and manipulation under anesthesia with open long head of biceps tenodesis and tenosynovectomy.

On June 7, 2007, request for the SCS trial was again denied with rationale: *There was no psychological assessment of his fitness for the use of a SCS. His EMG/NCV was positive for peripheral neuropathy and not radiculopathy. His neurological exam per Dr. showed normal strength, sensation, and reflexes. There was no operative report forwarded. The medication trial had included Neurontin but its effectiveness is not clearly described. The benefit to be gained from an SCS would appear marginal. The patient should have had a designated doctor exam.*

On July 9, 2007, request for the SCS was again denied with rationale: *The patient has achieved adequate control on oral medications and at the time of the initial request for this device the patient was reported to have improvement in his symptoms via the use of oral medications. However, the records do not include a detailed psychiatric evaluation as required by current evidence based medicine.*

On July 13, 2007, Dr. provided a letter of medical necessity for the SCS trial stating: *The patient has been on long-term pain medications for more than three years now, with good pain relief at some point, 60-70%, but lately escalation has been needed, for which I would rather try an SCS that will decrease the amount of medications that the patient is taking before we escalate into any stronger pain medications. Later, Dr. prescribed Lyrica, OxyContin, hydrocodone, and Dilaudid.*

On March 26, 2008, a request for the SCS was denied with the following rationale: *Indications for stimulator implantation: failed back syndrome (persistent pain in patients who have undergone at least one previous back operation), more helpful for lower extremity than low back pain, although both stand to benefit, 40-60% success rate five years after surgery. It works best for neuropathic pain. Neurostimulation is generally considered to be ineffective in treating nociceptive pain. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar.*

On April 2, 2008, Dr. stated: *"It is still my intention to do the SCS trial on this patient. He requires this, as medications are not helping his pain and an interventional procedure such as this one would be better than having him take medications for the rest of his life. This will be a cheaper option for the insurance company than heavy medications prescribed on a monthly basis, which are very expensive when it comes to narcotics.*

On April 14, 2008, D.O., performed a peer review and rendered the following opinions: (1) there was no evidence that the use of opiates had resulted in significant relief of pain. Despite being on opiates, the doctors had continued to recommend injections and neurostimulation. This would all attest to the virtual failure of the opiates to provide acceptable efficacy. (2) Continued use of opiates would certainly be questionable for this individual. A medically supervised detoxification program was strongly recommended. (3) Use of non-opiate analgesics and tricyclic antidepressant such as Cymbalta would be supported.

On April 18, 2008, appeal for the SCS was denied with the following rationale: *The request for a trial of a SCS is not supported by the submitted medical documentation. The patient has a long-standing history of intractable pain and is reported to have escalating use of oral medications. The patient does not have clinical evidence of lumbar radiculopathy on multiple examinations. He is further noted to have no evidence of radiculopathy on electrodiagnostic studies, but did have advanced diabetic peripheral neuropathy. The patient was referred for psychological evaluation and a one paragraph note is not sufficient to establish the patient's psychological state and clearance for an SCS. Current evidence based guidelines only support the implantation of an SCS in chronic pain patients when there is clear evidence of a lower extremity radiculopathy, which is clearly not the case with this particular patient. Further clinical information may establish the medical necessity of this request.*

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

PATIENT WITH HISTORY OF SUBSTANCE ABUSE, CO MORBIDITIES INCLUDING NEUROPATHY DUE TO DIABETES. HE DOES NOT MEET ENTRY CRITERIA FOR SPINAL CORD STIMULATION WHICH ARE HIGHLY SELECTIVE CRITERIA 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. See [Complete list of SCS References](#). 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. ([Sundaraj, 2005](#)) 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. In the first decade after its introduction, SCS was extensively practiced and applied to a wide spectrum of pain diagnoses, probably indiscriminately. The results at follow-up were poor and the method soon fell in disrepute. In the last decade there has been growing awareness that SCS is a reasonably effective therapy for many patients suffering from neuropathic pain for which there is no alternative therapy. There are several reasons for this development, the principal one being that the indications have been more clearly identified. The enhanced design of electrodes, leads, and receivers/stimulators has substantially decreased the incidence of re-operations for device failure. Further, the introduction of the percutaneous electrode implantation has enabled trial stimulation, which is now commonly recognized as an indispensable step in assessing whether the treatment is appropriate for individual patients. ([Furlan-Cochrane, 2004](#)). A thorough understanding of these results including the merits of intention-to-treat and as-treated forms of analysis as they relate to this therapy (where trial stimulation may result in a large drop-out rate) should be undertaken prior to definitive conclusions being made. ([Kemler, 2008](#))

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

**DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR
GUIDELINES**

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