

---

**ReviewTex. Inc.**  
1818 Mountjoy Drive  
San Antonio, TX 78232  
(phone) 210-598-9381 (fax) 210-598-9382  
reviewtex@hotmail.com

**Notice of Independent Review Decision**

**Date notice sent to all parties:**

January 7, 2013

**IRO CASE #:**

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

Appeal Trial Dorsal Column Stimulator – Back.

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

Board Certified PM&R; Board Certified Pain Medicine

**REVIEW OUTCOME:**

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

Upheld (Agree)

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:**

Clinical notes dated 04/19/11 and 05/31/11  
Chest x-rays dated 07/26/11  
Laboratory reports dated 07/27/11  
Anesthesia record dated 07/27/11  
Radiographs lumbar spine dated 07/28/11

Undated letter, handwritten  
Multiple prior reviews  
Operative reports dated 07/27/11 and 10/22/11  
Clinical notes dated 01/26/12 – 06/27/12  
Clinical note dated 07/13/12  
Mental health evaluation dated 07/16/12  
Clinical note dated 07/17/12  
Clinical note dated 07/25/12  
Clinical note dated 07/27/12  
Clinical note dated 08/03/12  
Clinical note dated 08/07/12  
Occupational therapy progress reports dated 08/07/12 and 08/10/12  
Electrodiagnostic study dated 08/17/12  
Procedure report dated 08/31/12  
Clinical note dated 09/07/12  
Behavioral Health Assessment Feedback Form 10/16/12  
Clinical note dated 10/19/12 and 11/07/12  
Prior reviews dated 10/31/12 and 11/27/12  
Clinical note dated 12/07/12  
Cover sheet and working documents

### **PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male who is status post posterior lumbar interbody and posterolateral fusion at L5-S1 on 07/27/11. The patient is also status post hardware removal and revision laminectomy with fusion exploration on 10/22/11. The patient continued to have ongoing chronic low back pain consistent with failed back surgery syndrome. The patient was maintained on chronic narcotics throughout 2012. There were questions regarding non-compliance with narcotic medications. The patient was noted to have been recommended for an interdisciplinary pain management program and a mental health evaluation completed on 07/16/12 did approve a chronic pain management program. It does appear that the patient attended a pain management program, although no significant progress reports from this program were provided for review. Electrodiagnostic studies completed on 08/17/12 revealed evidence of a chronic right L5 radiculopathy. The patient did undergo a transforaminal epidural steroid injection on 08/31/12. The patient was recommended for a psychological evaluation by on 09/07/12 to determine the appropriateness of a spinal cord stimulator trial. The patient did complete 11 sessions of a functional restoration program but continued to complain of severe pain in the low back with radiation into the right lower extremity. Clinical note on 09/07/12 indicated that the patient had no relief with the 08/31/12 epidural steroid injection. The patient was recommended for a spinal cord stimulator trial. The clinical report on 11/07/12

indicated that the patient was cleared from a psychological perspective for a spinal cord stimulator trial. However, this report was not provided for review.

The request for a spinal cord stimulator trial was denied by utilization review on 10/31/12 as there was no documentation of a complete physical examination as of 09/07/12. Further, there was no objective elaboration of a mental health evaluation by a qualified specialist indicating realistic expectations for the spinal cord stimulator trial.

The request was again denied by utilization review on 11/27/12 as there was no psychological interview available for review.

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

The requested trial of a dorsal column stimulator is not supported as medically necessary based on the clinical documentation provided for review. The clinical documentation establishes that the patient has ongoing complaints of low back pain radiating to the lower extremities consistent with failed back surgery syndrome. The patient has completed tertiary levels of care to include a chronic pain management program as well as epidural steroid injections and medications which have ultimately not improved the patient's clinical status. Although the patient is reported to have received psychological clearance for a spinal cord stimulator trial, the psychological evaluation was not provided for review. Additionally, there have been no updated exam findings for the patient since September of 2012. Without clinical documentation establishing that the patient has realistic expectations for the spinal cord stimulator trial and without objective findings consistent with neuropathic or radicular symptoms in the lower extremities that would reasonably be addressed with a spinal cord stimulator, medical

The requested trial of a dorsal column stimulator is not supported as medically necessary based on the clinical documentation provided for review. The clinical documentation establishes that the patient has ongoing complaints of low back pain radiating to the lower extremities consistent with failed back surgery syndrome. The patient has completed tertiary levels of care to include a chronic pain management program as well as epidural steroid injections and medications which have ultimately not improved the patient's clinical status. Although the patient is reported to have received psychological clearance for a spinal cord stimulator trial, there was no actual psychological evaluation provided for review. Included was a behavioral assessment feedback form for an implanted medical device dated 10/16/12. This form contained a series of check marks for risk factors which identified moderate risks due to fear of pain/re-injury and a lack of understanding regarding procedures. Recommended interventions included follow up at pain management with medications after the implant. The provided assessment form lacked any in-depth evaluation or testing that reasonably ascertained that the claimant was an appropriate candidate for a spinal cord stimulator trial. There was indication that the claimant lacked understanding regarding the procedure and no validity testing was provided.

Additionally, there have been no updated exam findings for the patient since September of 2012. Without sufficient clinical documentation establishing that the patient has realistic expectations for the spinal cord stimulator trial and without objective findings consistent with neuropathic or radicular symptoms in the lower extremities that would reasonably be addressed with a spinal cord stimulator, medical necessity cannot be established at this time.

---

## IRO REVIEWER REPORT TEMPLATE -WC

---

### 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**

#### **ODG**

##### **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 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. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar due to potential complications and limited literature evidence.
- Complex Regional Pain Syndrome (CRPS)/Reflex sympathetic dystrophy (RSD), 70-90% success rate, at 14 to 41 months after surgery. (Note: This is a controversial diagnosis.)
- Post amputation pain (phantom limb pain), 68% success rate ([Deer, 2001](#))
- Post herpetic neuralgia, 90% success rate ([Deer, 2001](#))
- Spinal cord injury dysesthesias (pain in lower extremities associated with spinal cord injury)
- Pain associated with multiple sclerosis
- Peripheral vascular disease (insufficient blood flow to the lower extremity, causing pain and placing it at risk for amputation), 80% success at avoiding the need for amputation when the initial implant trial was successful. The data is also very strong for angina. ([Flotte, 2004](#))