



# Lumetra

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## Notice of Independent Review Decision

**DATE OF REVIEW:** 4/20/09

**IRO CASE #:**

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

Spinal Cord Stimulator Placement

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

Certified by the American Board of Physical Medicine & Rehabilitation and fellowship trained in Pain Management

### **REVIEW OUTCOME**

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

| Injury date | Claim # | Review Type | ICD-9 DSMV | HCPCS/<br>NDC | Upheld/<br>Overturned |
|-------------|---------|-------------|------------|---------------|-----------------------|
|             |         | Prospective | 337.22     | 95972         | Upheld                |
|             |         | Prospective | 337.22     | 63685         | Upheld                |
|             |         | Prospective | 337.22     | 63650         | Upheld                |

### **INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Correspondence throughout appeal process, including first and second level decision letters, reviews, letters and requests for reconsideration, and request for review by an independent review organization.

Designated Doctor report dated 9/29/08

Clinical records 1/30/08 to 4/6/09

Operative Note dated 2/20/09

Procedure and office note dated 3/23/09

Psychological Evaluation dated 4/2/09

Official Disability Guidelines cited but not provided-Lower Extremity Treatment Guidelines

## **PATIENT CLINICAL HISTORY:**

This xx-year-old claimant sustained an injury to the left foot on xx/xx/xx, when a car ran over her left foot while working as a . The claimant has been treated with oral medications to include long term use of narcotics and has completed courses of physical therapy with only slight improvement in range of motion. The claimant was subsequently evaluated and diagnosed with Chronic Regional Pain Syndrome (CRPS). The claimant underwent a series of stellate blocks with no significant improvement in her condition. The 9/29/08 evaluation noted that the claimant has been treated with oral medications which included Kadian, Norco, Lyrica, Neurontin, and Zanaflex. She has pain at the distal left lower extremity that is reported to be severe. On physical examination the outer portion of the ball of the left foot was swollen. It had suffused appearance not seen elsewhere. Surface temperature of the proximal mid foot was clearly less on the right side. There were early dystrophic changes of the skin. Passive range of motion is diminished. The claimant is reported to shave her legs and cuts her toenails frequently. It is not possible to tell if she has or has not accelerated hair growth or nail growth. Radiographs and triple phase bone scan are recommended to evaluate for regional osteopenia and it is noted that the claimant is a candidate for a trial of a spinal cord stimulator. This trial was subsequently performed on 2/20/09 without complications. The claimant reports 60 percent improvement in analgesia in her lower extremity. She is reported to be tolerating activities a whole lot better and her ambulation has improved. She is diagnosed with reflex sympathetic dystrophy of the lower extremity and is status post spinal cord stimulator percutaneous trial reported to be successful. Psychological evaluation dated 4/2/09 notes that the claimant has a clear preoccupation with somatic complaints consistent with a chronic physical condition. Other multi dimensional tests are reported to be normal. The claimant is reported to be psychologically stable and understands the risks and benefits of the proposed procedures. She appears to have appropriate goals to minimize use of medications and improve functional status, and be a reasonable candidate for implantation of a spinal cord stimulator.

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

In the Reviewer's opinion, the request for permanent implantation of a spinal cord stimulator is not supported by the submitted clinical information. The medical record as submitted does not provide clear documentation that the patient has CRPS. A single note suggests that the patient has physical findings that can be associated with CRPS and she is noted to have undergone stellate ganglion blocks with only a limited response. The patient was approved for a trial of a spinal cord stimulator and is reported to have achieved 60 percent relief. However, the submitted clinical records do not fully quantify the patient's response. The record does not provide objective documentation to establish that the patient had improvement with this trial. There are no submitted documents to establish improved function nor is there documentation of concomitant reduction in oral medications.

## **REFERENCES:**

The Official Disability Guidelines, 13th edition, The Work Loss Data Institute.  
Spinal Cord Stimulation:

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](#)) These implantable devices have a very high initial cost relative to conventional medical management (CMM); however, over the lifetime of the carefully selected patient, SCS may lead to cost-saving and more health gain relative to CMM for FBSS and CRPS. ([Taylor, 2005](#)) ([Taylor, 2006](#)) SCS for treatment of chronic nonmalignant pain, including FBSS, has demonstrated a 74% long-term success rate ([Kumar, 2006](#)). SCS for treatment of failed back surgery syndrome (FBSS) reported better effectiveness compared to reoperation ([North, 2005](#)). A cost utility analysis of SCS versus reoperation for FBSS based on this RCT concluded that SCS was less expensive and more effective than reoperation, and should be the initial therapy of choice. Should SCS fail, reoperation is unlikely to succeed. ([North, 2007](#)) CRPS patients implanted with SCS reported pain relief of at least 50% over a median follow-up period of 33 months. ([Taylor, 2006](#)) SCS appears to be an effective therapy in the management of patients with CRPS. ([Kemler, 2004](#)) ([Kemler, 2000](#)) Recently published 5-year data from this study showed that change in pain intensity was not significantly different between the SCS plus PT group and the PT alone group, but in the subgroup analysis of implanted SCS patients, the change in pain intensity between the two groups approached statistical significance in favor of SCS, and 95% of patients with an implant would repeat the treatment for the same result. 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](#)) Permanent pain relief in CRPS-I can be attained under long-term SCS therapy combined with physical therapy. ([Harke, 2005](#)) Neuromodulation may be successfully applied in the treatment of visceral pain, a common form of pain when internal organs are damaged or injured, if more traditional analgesic treatments have been unsuccessful. ([Kapural, 2006](#)) ([Prager, 2007](#)) A recent RCT of 100 failed back surgery syndrome (FBSS) patients randomized to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group), found that 48% of SCS patients versus 9% of CMM patients achieved the primary outcome of 50% or more pain relief at 6 months. This study, funded by Medtronic, suggested that FBSS patients randomized to spinal cord stimulation had 9 times the odds of achieving the primary end point. ([Kumar, 2007](#)) According to the European Federation

of Neurological Societies (EFNS), spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS) type I (level B recommendation). ([Cruccu, 2007](#)) 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 chronic neuropathic pain lasting at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation. Recommended conditions include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). ([NICE, 2008](#)) See also Psychological evaluations (SCS) in the [Stress & Other Mental Conditions Chapter](#).

*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](#))

#### **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
- Post herpetic neuralgia, 90% success rate
- 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](#))

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- INTERQUAL CRITERIA**
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- MILLIMAN CARE GUIDELINES**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**