

Case Number:	CM13-0034881		
Date Assigned:	12/11/2013	Date of Injury:	11/20/1997
Decision Date:	10/29/2014	UR Denial Date:	10/01/2013
Priority:	Standard	Application Received:	10/15/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker had an original date of injury of November 20, 1997. The injured worker's diagnoses include lumbar post laminectomy syndrome, lumbar degenerative disc disease, and lumbar radiculopathy. MRI of the lumbar spine was obtained on May 14, 2013. This demonstrated neural foraminal narrowing at multiple levels and degenerative disc disease. Conservative therapies have been extensive including medication, physical therapy, and the patient continues on narcotic pain medications, muscle relaxant, and psychotropic medications. The disputed issue is a request for spinal cord stimulator trial. In a document dated October 1, 2013, the requesting provider appeals the utilization review determination. This supplemental report clarifies that the request is for a spinal cord stimulator trial with the use of 2 trial leads for a period of one week. The requesting provider states that at that time is anticipated the patient would have evaluation from a psychologist to obtain clearance prior to the trial.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

TRIAL SPINAL CORD STIMULATOR: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Spinal Cord Stimulator Page(s): 106-107.

Decision rationale: The Chronic Pain Medical Treatment Guidelines on pages 106-107 state the following regarding spinal cord stimulators (SCS): "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 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) 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 5 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. - 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)" In the case of this injured worker, there has been documentation of previous lumbar surgery in persistent pain despite conservative therapies. The patient has been treated with multiple pain medications including muscle relaxants, narcotic pain medications, and psychotropic medications to help with mood and pain. In the submitted medical documentation, there is no evidence of a psychologic clearance. The requesting provider had authored a document in October 2013 to clarify that the request is for spinal cord stimulator trial and psychologic evaluation for clearance. The psychologic evaluation clearance should be performed first and completed, before a spinal cord stimulator trial can be approved. This request is not medically necessary.