

Case Number:	CM14-0213032		
Date Assigned:	12/30/2014	Date of Injury:	10/02/2001
Decision Date:	02/27/2015	UR Denial Date:	11/20/2014
Priority:	Standard	Application Received:	12/19/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
 State(s) of Licensure: Ohio, North Carolina, Virginia
 Certification(s)/Specialty: Family Practice

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 is a 43-year-old male with a date of injury of October 2, 2001. He fell downstairs resulting in a back and shoulder injury. He has undergone a number of surgeries for his back including a fusion involving L4-L5 and L5-S1 in 2004, hardware removal in 2010, and a fusion from L3-L4 later in 2010. Because of unremitting low back pain with radicular symptoms a spinal cord stimulator was placed in September 2012. Injured worker has generally been doing well with gradually reducing pain levels and need for opioid medication. The physical examination has revealed lower extremity strength at 5/5, lower extremity reflexes at bilaterally, coverage of pain corresponding to the left-sided L5 and S1 dermatome regions, with tenderness to palpation of the spinous processes of T 12, L1, and L2. The diagnoses include sacroiliac joint pain, lumbar neuralgia, failed back surgery syndrome, thoracic facet joint pain, opioid dependence, depression, and a right cited a rotator cuff tear. At issue is a prospective request for a [REDACTED] spinal cord stimulator reprogramming. This request has been repeatedly noncertified by utilization review because the record has consistently shown the spinal cord stimulator to be working well.

IMR ISSUES, DECISIONS AND RATIONALES

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

[REDACTED] spinal cord stimulator reprogramming: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic), Spinal Cord Stimulators

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back, Spinal cord stimulation (SCS).

Decision rationale: Spinal cord stimulation is recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated. See also the Pain Chapter for Indications for stimulator implantation. There is some evidence supporting the use of Spinal Cord Stimulation (SCS) for Failed Back Surgery Syndrome (FBSS) and other selected chronic pain conditions. Spinal Cord Stimulation is a treatment that has been used for more than 30 years, but only in recent 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. 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. Fair evidence supports the use of spinal cord stimulation in failed back surgery syndrome, those with persistent radiculopathy after surgery, according to the joint American College of Physicians/ American Pain Society guideline recommendations on surgery and interventional treatments. (Chou, 2008) The National Institute for Health and Clinical Excellence (NICE) of the UK 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 failed back surgery syndrome lasting at least 6 months despite appropriate conventional medical management. (NICE, 2008) 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) 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). In this instance, the clinic notes dated as recently as January 8, 2015 show that the spinal cord stimulator is working well. The referenced guidelines do not address prospectively authorizing spinal cord stimulator reprogramming in advance of a malfunction. Consequently, for [REDACTED] spinal cord stimulator reprogramming is not medically necessary per the referenced guidelines.