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**Notice of Independent Review Decision**

**DATE OF REVIEW:** 05/22/2012

**IRO CASE #:**

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

63650 Percutaneous implantation neurostimulator ele  
L8680 Implantable neurostimulator el  
95970 Elec alys nstim pls gen brn/sc/per

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

Board Certified Neurosurgeon

**REVIEW OUTCOME:**

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

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

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

Required medical examination dated 03/01/11  
Clinical records dated 11/30/11  
Clinical records 12/20/11  
Medical assistant office note dated 10/27/11  
Clinic note dated 01/27/12  
Clinic note dated 02/12/12  
Utilization review determination dated 03/27/12  
Utilization review determination dated 04/11/12

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

The claimant is a male who is reported to have sustained work related injuries to his left knee on xx/xx/xx. On this date he was diagnosed with left knee strain after hyper extending his knee when he slipped on wet floor. The claimant has a longstanding history of bilateral knee problems including left knee ACL instability and arthritis. He is reported to have had multiple surgeries on both knees and had a total of 13 surgeries to left knee. It is reported 5 months post date of injury he underwent left knee replacement with subsequently problems including hair line fracture in tibia necessitating a second surgery. Since surgery it is reported knee pain has been worse than before. He has been given diagnosis of CRPS. The claimant is reported to have undergone sympathetic blocks with good relief. There has been conscious effort to attempt weaning claimant off multiple narcotics. Electrodiagnostic studies performed on 02/22/11 demonstrated evidence of left peroneal nerve axonopathy and mild tibial axonopathy with acute and chronic changes. On required medical examination dated 03/01/11 he has complaints of continued pain in left leg, increased skins sensitivity and numbness. Walking or standing for prolonged periods makes it worse. Current medications include Motrin and Norco 7.5/325. On physical examination he is hypertensive. He has mildly tender 20 cm keloid surgical scar over left knee which is noted to have patch of scaly skin over patella. Most of knee area is numb to touch. Bilateral lower extremities have symmetric and equal hair distribution with hair noted on toes. There is no skin mottling or skin discoloration. There is no edema present. Both legs were symmetrically warm to touch. The toes of left foot were slightly cooler to touch than those on right. Both extremities were dry without sweating. His nails were normal on both feet. There is some atrophy of VMO on left when compared to right but has good contraction of both quadriceps. He has minimally antalgic gait. He is noted to have mild left weakness of heel walking. Toe walking is normal. He has hypersensitivity to touch over left foreleg in nonspecific pattern. The bottoms of both feet were inspected and significant. Pressure was applied to dorsum and he did not experience any pain or discomfort. He is opined to be status post left knee replacement surgery with no evidence of left leg peroneal neuropathy secondary to surgery and no evidence of chronic regional pain syndrome. Records indicate the claimant ultimately was approved for trial of spinal cord stimulation which was performed on 12/20/11. Post procedurally on 12/27/11 the claimant reported he had 10-25% relief and would like to proceed with implant. A subsequent clinic note dated 01/27/11 reports the claimant had 50% pain relief and he was recommended to undergo permanent implantation.

The initial review was performed by on 03/27/12. notes the Official Disability Guidelines would not support specific request to be one of medically necessary. He notes records available for review do not clearly indicate there was definitive significant resolution in pain symptoms with respect to previous attempt at spinal cord stimulator trial. He therefore finds the request was not medically necessary.

The subsequent appeal request was reviewed by on 04/11/12. non-certified the request noting physical examination is without objectified diagnosis of complex

regional pain syndrome. It is noted with previous trial the claimant received 10-25% relief and would not meet requirements for permanent placement.

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

The request for permanent percutaneous implantation neurostimulator electrode array and pulse generator is not supported as medically necessary and prior utilization review determinations are upheld. The submitted clinical records indicate the claimant sustained an injury to his right knee as result of slip and fall. He has history of multiple surgeries to bilateral knees and degenerative joint disease. He was ultimately taken to surgery and underwent a total knee arthroplasty which was subsequently complicated by fracture and required revision surgery. He has subjective complaints of continued pain and dysfunction in left knee and is reported to have diagnosis of CRPS which does not appear to be validated on independent medical examination. It would further be noted despite lack of definitive diagnosis, the claimant underwent trial of dorsal column stimulation. Post procedurally the claimant reported 10-25% relief during trial. He therefore would not have met criteria per Official Disability Guidelines as he does not have definitive diagnosis of CRPS and response to trial was less than 50% required to consider permanent implantation.

**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**

The 2012 Official Disability Guidelines, 17th edition, The Work Loss Data Institute. Online edition.

*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 (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.

Battery Life for SCS: As batteries for both rechargeable and nonrechargeable systems are nearing end of life, there are both early replacement indicators and end of service notifications. Typical life may be 8-9 years for rechargeable batteries, but this depends on the unit. In addition, the physician programmer can be used to interrogate the implanted device and determine the estimated remaining battery life. (Restore, 2011)

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) (Frey, 2009) A nonrandomized, prospective cohort study in workers comp patients with chronic back and leg pain after spine surgery, ie failed back surgery syndrome (FBSS), found no significant difference in pain, disability, or opioid use between patients that received (at least a trial of) SCS, care at a pain clinic, or neither (usual care) at 12 and 24 months. Only 25% of SCS patients in this study received psychological screening prior to the trial, whereas ODG recommends psychological screening prior to all SCS implantations. Because few patients in any group in this study achieved success at any follow-up, the authors suggested that no treatment has a substantial impact on average in this patient group. (Turner, 2010)

**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)

For average hospital LOS if criteria are met, see Hospital length of stay (LOS).