MEDICAL POLICY

SUBJECT: SPINAL CORD STIMULATION
POLICY NUMBER: 7.01.51
CATEGORY: Technology Assessment

EFFECTIVE DATE: 11/15/01
REVISED DATE: 09/19/02, 09/18/03, 07/15/04, 07/21/05, 05/18/06, 04/19/07, 06/19/08, 05/28/09,
04/22/10, 03/17/11, 03/15/12, 06/19/14, 09/15/15.
(ARCHIVED: 03/21/13-06/19/14)

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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
I. Based upon our criteria and assessment of the peer-reviewed literature, spinal cord stimulation has been medically proven to be effective and therefore, medically appropriate for treatment of patients with severe and chronic nonmalignant, neuropathic pain of the trunk and lower limbs that is refractory to all other pain therapies (please see guidelines).
II. Based upon our criteria and assessment of the peer-reviewed literature, spinal cord stimulation has been medically proven to be effective and therefore, medically appropriate for treatment of patients with complex regional pain syndrome (CRPS) of the upper extremities who have not responded to standard therapies (please see guidelines).
III. Based upon our criteria and assessment of peer-reviewed literature, spinal cord stimulation has not proven to be medically effective and is considered investigational for the treatment of patients experiencing chronic pain of ischemic origin, such as those patients with critical limb ischemia (when used as a technique to forestall amputation) or refractory angina pectoris.
IV. Based upon our criteria and assessment of the peer-reviewed literature, spinal cord stimulation has not been proven to be effective and is therefore considered investigational for the treatment of any other diseases or disorders, including but not limited to, cervical disease causing neck, upper extremity pain (presenting without other symptoms of CRPS) and/or headache.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia. In occipital nerve stimulation the neurostimulator delivers electrical impulses via insulated lead wires tunneled under the skin near the occipital nerves at the base of the head. Currently, there is no FDA approved device for this indication.

POLICY GUIDELINES:
I. The implantation of a spinal cord stimulator is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) need to have been tried and failed or have been judged unsuitable or contraindicated. Duration of refractory pain is six months or greater.
II. Demonstration of pain relief of at least 50% with a temporarily implanted electrode needs to precede permanent implantation.
III. Patients are to be carefully screened, evaluated, and diagnosed by a multidisciplinary team prior to application of these therapies. This evaluation may include a psychological evaluation to exclude any major mental disability or drug habituation that would negatively influence the outcome of the treatment.
IV. All the facilities, equipment, and professional and support personnel required for the diagnosis, treatment, and follow-up of the patient need to be available.
V. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
DESCRIPTION:

Spinal cord stimulation (SCS) is used to treat chronic back and extremity pain and consists of electrical stimulation of the dorsal columns by electrodes implanted in the epidural space. The neurophysiology of pain relief after spinal cord stimulation is uncertain, but may be related to either activation of an inhibitory system or blockage of facilitatory circuits. Spinal cord stimulation devices consist of implantable electrodes, a receiver/transducer and a programmable transmitter that may be worn externally or implanted. Implantation of the spinal cord stimulator is typically a two-step process. Initially the electrode(s) is temporarily implanted in the epidural space, allowing a trial period of stimulation. This trial period will typically last for a period of 3 to 7 days. Once treatment effectiveness has been established, the electrode(s) and receiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming to determine the optimum levels of stimulation to provide pain relief. There are two basic types of power source. In 1 type, the power source (battery) can be surgically implanted. In another, a radio-frequency receiver is implanted and the power source is worn externally with an antenna over the receiver. Totally implantable systems are most commonly used.

Spinal cord stimulation has been utilized in a variety of refractory neuropathic pain conditions, including pain associated with failed back syndrome, arachnoiditis, peripheral neuropathy and complex regional pain syndrome. Complex regional pain syndrome (CRPS) is a chronic pain condition most often affecting one of the limbs (arms, legs, hands, or feet), usually after an injury or trauma to that limb. CRPS is believed to be caused by damage to, or malfunction of, the peripheral and central nervous systems. The central nervous system is composed of the brain and spinal cord, and the peripheral nervous system involves nerve signaling from the brain and spinal cord to the rest of the body. CRPS is characterized by prolonged or excessive pain and mild or dramatic changes in skin color, temperature, and/or swelling in the affected area. There are two similar forms, called CRPS-I and CRPS-II, with the same symptoms and treatments. CRPS-II (previously called causalgia) is the term used for patients with confirmed nerve injuries. Individuals without confirmed nerve injury are classified as having CRPS-I (previously called reflex sympathetic dystrophy syndrome). People with CRPS also experience constant or intermittent changes in temperature, skin color, and swelling of the affected limb. This is due to abnormal microcirculation caused by damage to the nerves controlling blood flow and temperature. An affected arm or leg may feel warmer or cooler compared to the opposite limb. The skin on the affected limb may change color, becoming blotchy, blue, purple, pale, or red.

Spinal cord stimulation is generally not effective in treating nociceptive pain (pain resulting from irritation, as opposed to damage to the nerves) and central deafferentation pain (pain related to central nervous system damage from a stroke or spinal cord injury).

It is recommended that candidates for SCS undergo a psychological evaluation prior to surgery. The purpose of the evaluation is to assess the potential role that psychological factors (e.g., anxiety, depression, underlying mental illness) may have in influencing the success of surgery and to offer appropriate recommendations with regard to psychological management.

Spinal cord stimulation has also been investigated as a treatment for pain associated with cervical trauma or disc herniation, chronic refractory angina pectoris and critical limb ischemia in patients who are not candidates for revascularization procedures.

RATIONALE:

Totally implantable spinal cord stimulator systems are regulated by the FDA as class III pre-market-approval (PMA) devices. Examples of these devices include the Precision™ Spinal Cord Stimulator System, and the Genesis™ IPG System. Systems with external transmitters are regulated by the FDA as Class II 510(K) devices. The FDA gave 510 K approval for Advanced Neuromodulation systems to market their Renew spinal cord stimulator, to Medtronic for its Spinal Cord and Peripheral Nerve Stimulation Systems, X-trel®3 and Synergy®; Spinal Cord Stimulation Systems, and to Micronet Medical, Inc for its Axxxess Spinal Cord Stimulation Lead.
There is sufficient evidence in the peer-reviewed literature to permit conclusions that the technology provides significant and sustained relief of pain with minimal side effects in appropriately selected patients with chronic nonmalignant pain. Studies investigating the effectiveness of SCS as a treatment for patients with chronic back/extremity pain report successful management of pain, a substantial decrease in narcotic use and an improvement in the quality of life. Studies support the use of spinal cord stimulation for patients with CRPS in the upper extremities through outcomes that demonstrate reduction in pain intensity and increased quality of life (e.g., Harke, et al. 2005; Kemler, et al. 2006; Kumar, et al. 2011; Geurts, et al. 2013).

One essential step toward the effective use of SCS in potential patients is a trial of the system through percutaneous lead placement. This trial will determine the effectiveness in relieving pain (greater than 50% pain relief) and improving the quality of life in patients with refractory neuropathic pain.


Studies of spinal cord stimulation in patients with critical limb ischemia who are not suitable candidates for limb revascularization found similar outcomes in the rate of amputation and pain relief in patients undergoing SCS compared to patients receiving medical care. SCS did not improve amputation-free survival nor was the risk of major amputation significantly reduced.

Cervical spinal cord stimulation is being investigated as a treatment for patients with cervical disease presenting with chronic pain of the neck/upper extremities and/or headache. There is insufficient evidence that cervical spinal cord stimulation is an effective intervention (R Vallejo, et al. 2007, BA Simpson, et al. 2003). The clinical value of cervical SCS for cervical symptoms needs further investigation with well-designed studies.

A technology appraisal guidance on spinal cord stimulation for chronic pain of ischemic origin (e.g., critical leg ischemia, refractory angina) from the National Institute for Health and Clinical Excellence (NICE) was published in October 2008. In their review, they found that no studies had demonstrated statistically significant differences for pain outcomes, but that for refractory angina the effect of SCS had been shown to be comparable to other treatments, such as CABG and PCI (percutaneous coronary intervention), for functional outcomes. NICE concluded that “SCS is not recommended as a treatment option for adults with chronic pain of ischemic origin except in the context of research as part of a clinical trial”. Overall, the available literature addressing the use of SCS for the treatment of angina consists of case series and small controlled trials with methodological limitations and limited follow-up. The evidence is not sufficient to conclude that SCS improves health outcomes for patients with refractory angina pectoris.

**CODES:**

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<td>63650</td>
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<tr>
<td>63655</td>
<td>Laminectomy for implantation neurostimulator electrode plate/paddle; epidural</td>
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<tr>
<td>63661</td>
<td>Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<tr>
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Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:**

63650  Percutaneous implantation of neurostimulator electrode array; epidural
63655  Laminectomy for implantation neurostimulator electrode plate/paddle; epidural
63661  Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662  Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy when performed
63663  Revision including replacement, when performed, of spinal neurostimulator electrode
percutaneous array(s) including fluoroscopy, when performed

63664  Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed

63685  Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

63688  Revision or removal of implanted spinal neurostimulator pulse generator or receiver

95970-95973 Neurostimulator programming and analysis (code range)

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HCPCS:

L8679  Implantable neurostimulator pulse generator, any type
L8680  Implantable neurostimulator electrode, each
L8681  Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682  Implantable neurostimulator radiofrequency receiver
L8683  Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685  Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686  Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689  External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695  External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD9:  Refer to “Pain” in ICD-9 diagnosis index

ICD10:  Multiple diagnosis codes

REFERENCES:


Proprietary Information of YourCare Health Plan


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* Key article

**Key Words:**
Dorsal column, Neurostimulation.

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**CMS Coverage for Medicare Product Members**

There is currently a National Coverage Determination (NCD) for electrical nerve stimulators that includes dorsal column stimulators. Please refer to the following NCD website for Medicare Members: