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, 08/20/15, 10/20/16
(ARCHIVED: 03/21/13 - 06/19/14)

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- If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
- If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

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, cancer-related pain, heart failure, pelvic pain/pudendal neuralgia, abdominal pain, or cervical disease causing neck, upper extremity pain (presenting without other symptoms of CRPS) and/or headache.

V. Based upon our criteria and assessment of peer-reviewed literature, the use of a wirelessly powered, injectable spinal cord stimulation system has not been proven to be medically effective and is considered investigational.

VI. Based upon our criteria and assessment of peer-reviewed literature, the use of a high frequency spinal cord stimulation system has not been proven to be medically effective and is considered investigational.

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. Documentation must reflect an objective measure of a 50% reduction in pain scores with a temporarily implanted electrode in order 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 habitation that would negatively influence the outcome of the treatment.

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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.

A wireless, injectable spinal cord microchip system is under investigation. Potential advantages to this wireless device include the cheaper cost, MRI compatibility, injection of the device during a simple procedure, and the elimination of
complications that could arise from tunneling, lead migration and percutaneous trial leads. Potential disadvantages include the need for an externally worn transmitter, and its ability to deliver energy in a consistent and effective manner.

A spinal cord stimulation system capable of delivering stimulation frequencies up to 10 kHz has been developed. It delivers HF10™ SCS therapy, a therapy that uses proprietary waveform with stimulation frequencies up to 10 kHz. In contrast to other currently available systems that use frequencies in the range of 50 Hz (referred to as tonic spinal cord stimulation), this innovation does not require or produce paresthesia to achieve clinical efficacy. Potential proposed benefits of higher frequency stimulation include a lower incidence of paresthesias, which are a recognized side effect of SCS.

**RATIONALE:**

Totally implantable spinal cord stimulator systems are regulated by the FDA as class III pre-market-approval (PMA) devices. Several devices have received FDA PMA approval. Examples of these devices include, but are not limited to, 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, Axium Neurostimulator System (Spinal Modulation) and to Micronet Medical, Inc for its Axxess Spinal Cord Stimulation Lead. St. Jude Medical has also received FDA approval for its Protege MRI™ spinal cord stimulation system.

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
The FDA has approved an injectable microchip nerve-stimulation device for the relief of ongoing back and leg pain in December 2014 (predicate device approval). The Stimwave Technologies Incorporated (Stimwave) Freedom Spinal Cord SCS System is used for spinal column neural stimulation to provide therapeutic relief for chronic, intractable pain of the trunk and/or lower limbs including unilateral or bilateral pain. The therapy utilizes pulsed electrical current to create an electrical energy field that acts on nerves near the dorsal column of the spine. The System is comprised of an implantable stimulator (Freedom-4 Stimulator) and an externally worn transmitter (Wearable Antenna Assembly (WAA)) to power the device. The System is implanted only following a successful trial period with the Trial Freedom-4 Stimulator. Only one published clinical trial was found related to the investigations into the safety and efficacy of an injectable spinal cord stimulator system (Perryman, et al. 2012). There is currently an ongoing post-marketing study of the Freedom SCS system that is recruiting patients. Stimwave Technologies has also begun recruiting for a multi-center, randomized, double-blind, placebo-controlled clinical study of its wireless high frequency stimulator for the treatment of chronic, non-specific origin low back pain, the Tsunami study. The study is designed to compare a sham device to stimulation of spinal nerves at settings that are not perceived by the patient, thus allowing for a true, blinded patient experience. The study un-blinds the patients after 90 days, after which time the sham group devices are enabled to allow the sham participants to benefit from the therapy long-term. There is insufficient peer-reviewed evidence at this time to determine the efficacy of a wireless, injectable SCS system.

Nevro (Menlo Park, Calif) has gained FDA 510(k) clearance for its Senza spinal cord stimulation system intended for chronic pain treatment in May 2015. The device administers the company’s HF10 therapy in the trunk and/or limbs, which treats unilateral or bilateral pain related to failed back surgery, intractable low back pain and leg pain. The therapy is the only SCS therapy FDA-indicated to alleviate pain without paresthesia (a constant tingling sensation associated with traditional SCS techniques).

The evidence for high-frequency SCS in individuals who have treatment-refractory chronic pain of the trunk or limbs includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency to standard stimulation found a large and statistically significant benefit associated with high-frequency SCS. In contrast, a smaller study found no benefit for those receiving high-frequency stimulation compared with sham control. Given the uncertainty in these findings, additional trials are needed to corroborate the benefit of high-frequency stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

Perruchoud, et al. (2013) reported results of an RCT comparing active high-frequency SCS therapy at 5 kHz to sham stimulation in 40 patients with chronic, treatment-refractory back pain previously been treated with standard SCS. Patients were randomized to a 2-week sequence of high-frequency stimulation or sham stimulation after a 2-week period of standard stimulation; after that second 2-week period, all patients crossed over to the opposite treatment arm. Treatment was conducted with stimulator programmed to provide high-frequency (5 kHz) or standard stimulation. Results were available for 33 patients, all of whom received both modes of stimulation. For the study’s primary outcome (patient’s global impression of change), there was no statistically significant benefit from high-frequency treatment compared to sham stimulation, although the point estimate for proportion of patients responding was higher for high-frequency stimulation (42.4% for high-frequency vs 30.3% for sham, p=0.30).

In 2015, Kapural and colleagues reported results of a randomized, unblinded, active-controlled trial of high-frequency SCS therapy (HF10) compared to standard SCS therapy in patients with back and leg pain. Selected patients had chronic, intractable pain of the trunk and/or limbs refractory to a minimum of 3 months of conservative therapy, and had average pain intensity of at least 5 on a 10-cm VAS. Patients underwent a trial SCS phase, consisting of up to 14 days with an external stimulator; those with 40% or greater back pain reduction from baseline were eligible for permanent implantation. For those treated with traditional SCS, stimulation parameters were adjusted based on overlap between paresthesias and the pain location. Oral analgesics could be adjusted through the trial. The study prespecified a noninferiority design. A total of 198 subjects were randomized to HF10 therapy (n=101, of whom 97 were trialed with...
SCS with 90 implanted and included in 3-month primary and 12-month secondary analyses) or standard SCS therapy (n=97, of whom 92 received trial SCS and 81 with implanted and included in the primary and secondary analyses).

Patients had a variety of specific diagnoses, most frequently FBSS, radiculopathy, and degenerative disk disease. For the primary end point, a composite safety and efficacy (percentage of subjects who responded to SCS therapy for back pain with ≥50% reduction in pain on VAS without a stimulation-related neurologic deficit), 84.5% in the HF10 group met the end point for back pain compared with 43.8% in the standard SCS group (p<0.001 for inferiority and superiority). For leg pain, 83.1% in the HF10 group met the primary end point compared with 43.8% in the standard SCS group (p<0.001 for inferiority and superiority). Responder rates were sustained through 12 months. No patients in either group experienced stimulation-related neurologic deficits.

**CODES:**

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<tr>
<th>Number</th>
<th>Description</th>
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<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array; epidural</td>
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<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>
<td>63662</td>
<td>Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy when performed</td>
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<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s) including fluoroscopy, when performed</td>
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<td>Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
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<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<tr>
<td>63688</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
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<td>95970-95973</td>
<td>Neurostimulator programming and analysis (code range)</td>
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**HCPCS:**

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<tr>
<td>C1822 (E/I) if used in spinal cord stimulation</td>
<td>Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system</td>
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<td>L8679</td>
<td>Implantable neurostimulator pulse generator, any type</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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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.
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:


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* Key article

**KEY WORDS:**
Dorsal column, Neuromodulation, 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: