

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	SPINAL CORD STIMULATION/DORSAL COLUMN STIMULATION
Policy Number	7.01.51
Category	Technology Assessment
Effective Date	11/15/01
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Archived Date	(03/21/13-06/19/14)
Product Disclaimer	<ul style="list-style-type: none"> • 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) or a Medicaid 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 peer-reviewed literature, implantation of a spinal cord stimulator (i.e. *non-high frequency or high frequency*) has been medically proven to be effective and therefore, **medically appropriate** for treatment of patients with *failed back surgery syndrome (FBSS) with intractable neuropathic leg pain* for the following:
- A. A short term trial (e.g., greater than 48 hours) of spinal cord stimulation (i.e. *non high frequency or high frequency (HF 10 SCS)*) when ALL of the following criteria are met:
 1. Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
 2. Surgical intervention is not indicated or patients do not wish to proceed with spinal surgery; and
 3. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device.
 - B. Permanent implantation of a spinal cord stimulator (i.e. *non-high frequency or high frequency (HF 10 SCS)*) when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.
- II. Based upon our criteria and assessment of peer-reviewed literature, use of a *non-high frequency* dorsal column spinal cord stimulator has been medically proven to be effective and therefore, **medically appropriate** for treatment of patients with *complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)* for the following:
- A. A short-term trial (e.g., greater than 48 hours) of a *non-high frequency* spinal cord stimulator (SCS) when all of the following criteria are met:
 1. Diagnosis of complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) as evidenced by ALL of the following:
 - a. Continuing pain that is disproportionate to any inciting event;
 - b. Must report at least one (1) of the symptoms in the following categories:
 - i. Sensory: reports of hyperesthesia,
 - ii. Vasomotor: reports of temperature asymmetry, skin color changes, and/or skin color asymmetry,
 - iii. Sudomotor/edema: reports of edema, sweating changes, and/or sweating asymmetry, or
 - iv. Motor/trophic: reports of decreased range of motion, motor dysfunction (weakness, tremor, dystonia), and/or trophic changes (hair, nail, skin).
 - c. Must display at least one (1) of the signs on physical examination in two (2) or more of the following categories:
 - i. Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch),

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- ii. Vasomotor: evidence of temperature asymmetry, skin color changes, and/or asymmetry,
 - iii. Sudomotor/edema: evidence of edema, sweating changes, and/or sweating asymmetry,
 - iv. Motor/trophic: evidence of decreased range of motion, motor dysfunction (weakness, tremor, dystonia). and/or trophic changes (hair, nail, skin).
 2. Failure of at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
 3. Surgical intervention is not indicated;
 4. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate its placement.
 - B. Permanent implantation of a *non-high frequency* dorsal column spinal cord stimulator when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.
- III. Based upon our criteria and assessment of peer-reviewed literature, use of a *non-high frequency* dorsal column spinal cord stimulator (SCS) has been medically proven to be effective and therefore, **medically appropriate** for treatment of patients with chronic, intractable pain secondary to *chronic critical limb ischemia (CLI)* for the following:
- A. A short-term trial (e.g., greater than 48 hours) of a *non-high frequency* dorsal column spinal cord stimulator (SCS) when both of the following criteria are met:
 1. Failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management (e.g., revascularization); and
 2. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement.
 - B. Permanent implantation of a *non-high frequency* dorsal column spinal cord stimulator when a beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.
- IV. Based upon our criteria and assessment of peer-reviewed literature, use of a *non-high frequency* dorsal column spinal cord stimulator has been medically proven to be effective and therefore, **medically appropriate** for treatment of patients with chronic, intractable pain secondary to *chronic stable angina pectoris or myocardial ischemia* for the following:
- A. A short-term trial (e.g., greater than 48 hours) of a *non-high frequency* dorsal column spinal cord stimulator (SCS) when all of the following criteria are met:
 1. Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV;
 2. An attestation from the Individual's treating cardiologist confirming that the individual has coronary artery disease (CAD) and is not a suitable candidate for a revascularization procedure;
 3. Optimal pharmacological treatment using anti-anginal medications (e.g., long-acting nitrates, beta-adrenergic blockers, or calcium-channel antagonists) has failed to adequately improve anginal symptoms; and
 4. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate its placement of the device.
 - B. Permanent implantation of a *non-high frequency* dorsal column spinal cord stimulator (SCS) when a beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.
- V. Based upon our criteria and assessment of peer-reviewed literature, the *replacement of an existing high frequency or non-high frequency* dorsal column spinal cord stimulator (SCS) and/or battery/generator is considered **medically necessary** for an individual when the existing stimulator and/or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.

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- VI. Based upon our criteria and assessment of peer-reviewed literature, replacement of a functioning *non-high frequency* dorsal column spinal cord stimulator with a high frequency spinal cord stimulator is considered **not medically necessary**.
- VII. Based upon our criteria and assessment of peer-reviewed literature, implantation of a *non-high frequency* dorsal column spinal cord stimulator (SCS) has not been medically proven to be effective and is considered **investigational**, for all other indications, including but not limited to:
- A. Post-amputation pain (phantom limb pain)
 - B. Post-herpetic neuralgia
 - C. Peripheral neuropathy
 - D. Dysesthesias involving the lower extremities secondary to spinal cord injury.
- VIII. Based upon our criteria and assessment of peer-reviewed literature, implantation of a *high frequency* spinal cord stimulator has not been medically proven to be effective and is considered **investigational** for all other indications, including CRPS/RSD.
- IX. Based upon our criteria and assessment of peer-reviewed literature, *dorsal root ganglion (DRG) stimulation* is considered **investigational** for all indications.
- X. Based upon our criteria and assessment of peer-reviewed literature, generator modes other than tonic low and high frequency (i.e. *burst stimulation*) is considered **investigational**.
- XI. Based upon our criteria and assessment of peer-reviewed literature, *peripheral nerve field stimulation*, is considered **investigational** for treatment of acute or chronic pain conditions, including treatment of the following;
- A. Failed back surgery syndrome (FBSS) with intractable neuropathic leg pain
 - B. Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)
 - C. Chronic Critical Limb Ischemia (CLI)
 - D. Chronic Stable Angina Pectoris
 - E. Post-amputation pain (phantom limb pain)
 - F. Post-herpetic neuralgia
 - G. Peripheral neuropathy; and
 - H. Dysesthesias involving the lower extremities secondary to spinal cord injury

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 habituation that would negatively influence the outcome of the treatment. *Please to Refer to Corporate Medical Policy #3.01.02 regarding Psychological Testing.*
- IV. 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.

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DESCRIPTION

Spinal cord stimulation (SCS), also known as dorsal column stimulation or neuromodulation, 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 SCS is uncertain, but may be related to either activation of an inhibitory system or blockage of facilitatory circuits. SCS 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 SCS 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.

SCS 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.

SCS 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.

SCS 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.

High frequency spinal cord stimulation, also referred to as kilohertz frequency SCS or HF10, is a type of SCS providing a higher frequency than traditional spinal cord stimulator systems. The HF10 SCS uses low amplitude, high frequency, and short duration pulses. HF10 SCS does not generate paresthesia and operates at a frequency of 10,000 Hz to provide pain relief in comparison to traditional SCS systems, which operate at a frequency in the range of 40-60 Hz and do generate paresthesia. As an alternative to traditional dorsal spinal column stimulation, HF 10 SCS is proven safe and effective for treatment of chronic, intractable low back and leg pain in patients with failed back surgery syndrome.

Peripheral nerve stimulation involves implantation of electrodes near or on a peripheral nerve to reduce pain. Peripheral nerve field stimulation is a technology that involves placement of electrodes subcutaneously within an area of maximal pain, with the objective of stimulating a region of affected nerves to reduce pain. Depending on the targeted nerve, leads may be placed percutaneously just under the skin or via an open approach for larger deeper peripheral nerves. Similar to SCS, a short-term trial is required prior to permanent implantation of a generator. The use of these technologies, used alone or in combination with SCS for the treatment of pain conditions, is under investigation.

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Canadian Cardiovascular Society Functional Classifications

- I. Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous or rapid or prolonged exertion at work or recreation.
- II. Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
- III. Marked limitation of ordinary physical activity. Walking one (1) to two (2) blocks on the level and climbing one flight in normal conditions and at a normal pace.
- IV. Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.

RATIONALE

Traditional stimulation

Totally implantable spinal cord (dorsal column) 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, 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 SCS 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.

Literature exists to support the value of a presurgical psychological evaluation to identify factors that may adversely impact functional outcomes after SCS (DM Doleys 2006, B Van Dorsten 2006, DR Heckler, et al. 2007, J Celestin, et al. 2009).

There is evidence to favor SCS over standard conservative treatment to improve limb salvage and clinical situation in patients with inoperable chronic critical leg ischemia.

Studies found that SCS improved both the quality of life and cardiac parameters of patients with refractory angina pectoris.

High-frequency stimulation

Nevro (Menlo Park, Calif) has gained FDA 510(k) clearance for its Senza SCS 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).

Dorsal root ganglion stimulation

Dorsal root ganglion (DRG) stimulation is an emerging method of treatment for neuropathic pain. With DRG stimulation leads are placed percutaneously into the epidural space under fluoroscopic guidance directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine. Similar to spinal cord stimulation, a short-term trial (i.e., greater

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than 48 hours) is recommended using an external pulse generator; upon success of the trial a permanent pulse generator may then be implanted. At this time, the evidence in the peer-reviewed scientific literature is insufficient to support long-term safety and efficacy. The use of this technology for treatment of pain conditions remains under investigation.

CODES

- *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 Codes

Code	Description
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
95970-95972	Neurostimulator programming and analysis (code range)

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HCPCS Codes

Code	Description
C1820	Generator, neurostimulator (implantable), non-high frequency with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
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

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Code	Description
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

ICD10 Codes

Code	Description
Multiple diagnosis codes	

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*Key Article

KEY WORDS

Burst stimulation, Dorsal column, Dorsal root ganglion, High-frequency neurostimulation, Neuromodulation, Neurostimulation, Wireless neurostimulation.

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: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>.