



CIGNA MEDICAL COVERAGE POLICY

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Subject **Spinal Cord Stimulation**

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Coverage Policy

CIGNA covers a short-term trial of a lumbar or thoracic dorsal column spinal cord stimulator (SCS) for the treatment of chronic intractable pain of greater than six months' duration as medically necessary when BOTH of the following criteria are met:

- There is failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management.
- 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.

CIGNA covers permanent implantation of a lumbar or thoracic dorsal column spinal cord stimulator (SCS) for the treatment of chronic intractable pain of greater than six months' duration as medically necessary when ALL of the following criteria are met:

- There is failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management.
- 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.
- Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation.

CIGNA covers a short-term trial of a lumbar or thoracic dorsal column spinal cord stimulator (SCS) for the treatment of pain secondary to chronic stable angina pectoris as medically necessary in individuals with myocardial ischemia when ALL of the following criteria are met:

- Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see Appendix A).
- The individual has documented significant coronary artery disease (CAD) and is not a suitable candidate for revascularization procedures.
- 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.
- 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.

CIGNA covers permanent implantation of a lumbar or thoracic dorsal column spinal cord stimulator (SCS) for the treatment of pain secondary to chronic stable angina pectoris as medically necessary in individuals with myocardial ischemia when ALL of the following criteria are met:

- Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see Appendix A).
- The individual has documented significant coronary artery disease (CAD) and is not a suitable candidate for revascularization procedures.
- 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.
- 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.
- Pain relief from a temporarily implanted electrode has been demonstrated prior to permanent implantation.

CIGNA does not cover cervical placement of a dorsal column spinal cord stimulator (SCS) for any indication because it is considered experimental, investigational or unproven.

General Background

Dorsal column spinal cord stimulation (SCS), also called dorsal column stimulation or neurostimulation, is a neuromodulation therapy in which low voltage electrical signals are delivered to large afferent fibers in the dorsal columns of the spinal cord by neuroelectrodes placed in the epidural space in order to block sensations of pain. The stimulation overrides, or masks, the original pain sensation with paresthesia. The objectives of treatment are to minimize the frequency, intensity and duration of pain; enhance physical activity; and decrease the need for pain medication. While placement of a lumbar or thoracic dorsal column spinal cord stimulator is an established treatment modality for a subset of patients, cervical placement of a dorsal column spinal cord stimulator has not been established as safe and effective.

Lumbar or thoracic dorsal column SCS has been proposed for the treatment of chronic intractable pain and refractory chronic stable angina pectoris. Appropriate candidates for permanent lumbar or thoracic dorsal column SCS implantation include those for whom six months of conservative therapy has failed, surgical intervention has been unsuccessful, additional surgery is not indicated, no signs of drug dependency exist, and psychological clearance has been given. To determine if the paresthesia from SCS is more desirable to the patient than the pain, a short-term (e.g., 3–14 days) trial is conducted by using a temporarily implanted electrode and an external programmer. If at least 50% pain relief is achieved, the temporary system may be transitioned to a permanent system (Lee and Pilitsis, 2006; Doley, 2006; British Pain Society [BPS], 2005).

The subjective experience of pain is influenced by both physiological and psychological factors. Therefore, it is recommended that lumbar or thoracic dorsal column SCS candidates undergo psychiatric and psychosocial evaluation by a psychologist, psychiatrist or licensed mental health care provider prior to the temporary implantation of an SCS device. The purpose of the assessment is to evaluate the potential role that psychological factors (e.g., depression, anxiety, emotional state, underlying mental illness, drug and/or alcohol abuse) may play in mediating the pain response, and to offer appropriate recommendations with regard to psychological management before and after surgery. It is also important to assess the patient's support system for recovery following implantation. Chronic pain is multidimensional, and the relationship and influence of psychological factors can influence the success of SCS. According to the literature, a psychological/psychiatric evaluation for SCS candidates typically includes a face-to-face assessment and may include the analysis of data obtained from interviews, psychological questionnaires and/or psychological testing (e.g., Minnesota Multiphasic Personality inventory [MMPI], MMPI-2, Hamilton Psychiatric Rating Scale [HPRS], pain Coping Strategies Questionnaire [CSQ]) for depression). The assessment of readiness for change, coping skills, pain perception, expectations for pain alleviation, perceived disability, and acceptance of the disability may be useful in predicting the success of SCS. A loss of pain relief has been reported in up to 50% of patients one to two years postimplantation. It is speculated that this loss of efficacy may in part be due to psychological factors. Potential psychological contraindications to SCS reported in the literature include: drug and/or alcohol abuse, untreated or severe depression, psychosis, suicidal tendencies, mania, hypochondriasis, insufficient understanding of SCS, expectations of complete pain relief, lack of social support and a history of poor compliance to therapy (Sparkes, et al., 2010; North, et al., 2007; Doleys, 2006; Van Dorsten, 2006).

The permanent SCS system consists of a generator, electrode leads, and a programmer/transmitter. The leads are implanted in the dorsal epidural space, connected to the generator, and programmed through a wireless transmitter operated by the patient. The number and types of leads utilized depend on the nerve roots involved and the severity of pain. The internal generator receives signals from the programmer device resulting in either continuous or intermittent electrical stimuli (i.e., current flow) to the spinal cord. There are three types of generators. The conventional implantable pulse generator (IPG) has a nonrechargeable battery which requires a surgical procedure for battery replacement. A second type of generator has an internal battery with an external rechargeable battery device (rechargeable IPG systems). The third type of system is a radiofrequency system that uses external radiofrequency batteries. Some systems provide constant current while others provide constant voltage. The appropriate SCS system will depend on the underlying condition, the patient's pain patterns, the area of the body affected, and the amount and intensity of stimulation required. Following implantation of the device, the generator is secured in the abdominal, upper buttock, or subclavicular area (Markman and Philip, 2007; Mailis-Gagnon, et al., 2004).

Cervical SCS has been proposed for the treatment of a variety of conditions. In cervical SCS the leads are placed in the epidural space at the level of the cervical vertebrae (e.g., C2-C4) and connected to a generator for stimulation. It is hypothesized that cervical SCS increases cerebral blood flow leading to clinical improvement and/or better response to therapies. Concerns with cervical SCS include: cervical electrodes may more likely be dislodged compared to thoracic or lumbar placement and the mobility of the cervical spine and local anatomy may restrict effectiveness (British Pain Society, 2009; Simpson, et al., 2003). Evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of cervical SCS for any indication.

U.S. Food and Drug Administration (FDA)

SCS devices are approved for use "as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain" (FDA, 2004). They are not specifically approved for the treatment of chronic stable angina. Totally implantable SCS systems are regulated by the FDA as Class III premarket-

approval (PMA) devices. Examples of these devices include the PRECISION™ Plus SCS (Spinal Cord Stimulator) System (Boston Scientific, MA) and the Genesis™ IPG System (St. Jude Medical, Inc. previously Advanced Neuromodulation Systems, Inc.; Plano, TX). Systems with external transmitters (e.g., X-trel® Neurostimulation Systems [Medtronic, Inc., Minneapolis MN]) are regulated by the FDA as Class II 510(k) devices.

Lumbar or Thoracic Dorsal Column Spinal Cord Stimulation

Chronic Intractable Pain

Chronic intractable pain (e.g., neuropathic pain, noxious pain, inflammatory pain, sympathetic pain, oncologic pain) is typically pain that lasts for several months beyond the expected course of the condition or disease. Examples of chronic intractable pain conditions and diseases include: persistent or recurrent pain following back surgery (e.g., failed back surgery syndrome [FBSS] or postlaminectomy syndrome), complex regional pain syndrome (CRPS), peripheral neuropathy (e.g., diabetic neuropathy), phantom limb pain, critical limb ischemia (CLI), and trigeminal neuralgia. Conservative therapies used for the relief of chronic intractable pain include: topical agents, local or regional nerve blocks, acupuncture, transcutaneous electrical stimulation, physical therapy, behavioral therapy, and pharmacological agents. Surgical procedures may also be performed to relieve pain. Lumbar or thoracic dorsal column SCS is considered an established treatment option for chronic intractable pain not amendable to conventional medical and surgical interventions (Foletti, et al., 2007; Lee and Pilitsis, 2006; Kemler, et al., 2000).

Literature Review: The evidence in the published peer-reviewed scientific literature reporting 10–22 years of follow-up data supports lumbar or thoracic dorsal column SCS for chronic intractable pain. Diagnosis of subjects in the clinical trials included: CRPS types I and II (i.e., causalgia and reflex sympathetic dystrophy [RSD]), FBSS, peripheral neuropathy, bone and joint pain syndromes, spinal cord injury/lesion/cauda equina syndrome, nerve root compression, perirectal pain, postherpetic/intercostal neuralgia, chronic low back pain, CLI, and upper limb pain secondary to disc surgery. Following lumbar or thoracic dorsal column stimulation, significant pain relief (i.e., 50% or greater) requiring less analgesia and improvement in functional capacity including the ability to return to work were reported (Frey, et al., 2009; Klomp, et al., 2009; Simpson, et al., 2009; Kemler, et al., 2008; Kumar, et al., 2008; Ubbink, et al., 2005; Claeys, et al., 2007; Gersbach, et al., 2007; Kumar, et al., 2007; Pedrini and Magnoni, 2007; Brummer, et al., 2006; Kumar, et al., 2006; Taylor, et al., 2006; Taylor, 2006; Turner, et al., 2006; North, et al., 2005; Kemler, et al., 2004; Mailis-Gagnon, et al., 2004).

Sparkes et al. (2010) conducted a systematic review of the literature to “determine findings concerning the psychological characteristics observed and their impact on SCS efficacy for chronic pain.” Nine articles met inclusion criteria. Five of the studies were prospective with follow-ups ranging from three months to an average of 3.5 years. Four studies evaluated SCS efficacy by patient self-reports. Diverse questionnaires were used to identify possible psychological characteristics that would influence the outcome of SCS, with the Minnesota Multiphasic Personality Inventory (MMPI) or MMPI-2 being the most commonly used. Other studies used the Beck Depression Inventory (BDI), Hamilton Psychiatric Scale for depression (HPS), Pain Coping Strategies questionnaire (CSQ), Degoratis Affects Balance Scale (DABS), Hospital and Anxiety Depression Scale (HAD), or the Change Occurrence Scale (MHLC). One study used interview alone. Depression was considered as negatively impacting the efficacy of SCS in six studies and two studies reported significant improvement in depression with SCS. Other common psychological characteristics that were identified as having an impact on the efficacy of SCS included mania and hypochondriasis, but the results were “discrepant and inconclusive as predictors for SCS outcome.” Author-noted limitations of the review included the multiple methodologies used, different time points at which data were collected and the inconsistent manner in which depression was classified. Due to these variations, meta-analysis could not be performed. The authors suggested that “in-depth methods other than questionnaire assessment alone should be employed to limit false positives.” Though there was evidence that psychological factors did impact SCS efficacy, there is insufficient evidence to discern the specific impact of psychiatric illness on outcomes.

Technology Assessments: In their healthcare guidelines on the management of chronic pain, the Institute for Clinical Systems Improvement (ICSI) (2009) stated that lumbar or thoracic dorsal column SCS is a palliative intervention for “patients with lumbar and cervical radiculopathy who are not surgical candidates, patients with postlaminectomy syndrome, and patients with complex regional pain syndrome (CRPS) type 1 or RSD are the best candidates for SCS”.

In a technology appraisal, the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) (2008) recommended lumbar or thoracic dorsal column SCS for adults with chronic pain of neuropathic origin (e.g., failed back surgery syndrome, complex regional pain syndrome) with six months of continuous pain despite conventional medical management, who have had an assessment by a multidisciplinary team and a successful trial of dorsal stimulation.

Professional Societies/Organizations: In practice guidelines for the management of chronic pain, members of the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine (2010) agreed that lumbar or dorsal SCS should be used for persistent radicular pain, “postherpetic neuralgia, postamputation pain, peripheral neuropathic pain, spinal cord injury, CRPS, cauda equina syndrome, cervical root injury pain, peripheral vascular disease, and visceral pain”. It was strongly agreed that a trial of SCS should be performed prior to permanent implantation.

In their evidence-based guidelines for the management of chronic spinal pain (Manchikanti, et al., 2009), the American Society of Interventional Pain Physicians recommended lumbar or thoracic dorsal column SCS for the treatment of FBSS and CRPS. In the treatment algorithms they listed dorsal column stimulation as an option for chronic radicular back and neck pain nonresponsive to surgical interventions.

In practice parameters regarding the treatment of chronic neuropathic pain, the American Academy of Pain Medicine (North, et al., 2007) stated that lumbar or thoracic dorsal column SCS is recommended in the treatment of FBSS or lumbosacral root injury pain (also known as arachnoiditis), CRPS I (reflex sympathetic dystrophy) and CRPS II (causalgia). Recommended with uncertain validity are “peripheral neuropathic pain, phantom limb/postamputation syndrome, postherpetic neuralgia (PHN), root injury pain, spinal cord injury/lesion.”

The European Federation of Neurological Societies (EFNS) (Cruccu, et al., 2007) guidelines on neurostimulation therapy for neuropathic pain included a recommendation for lumbar or thoracic dorsal column SCS for the treatment of FBSS and CRPS I. Lumbar or thoracic dorsal column stimulation may also be useful in the management of “CRPS II, peripheral nerve injury, diabetic neuropathy, post-herpetic neuralgia, brachial plexus lesion, amputation (stump and phantom pains) and partial spinal cord injury,” but EFNS stated that additional comparative trials are needed before SCS can be “unreservedly recommended for these conditions”.

Chronic Stable Angina Pectoris

Chronic, intractable or refractory, stable angina pectoris, also known as end-stage coronary artery disease (CAD), is a chronic condition (i.e., duration of three months or more) characterized by the presence of angina that is unresponsive to medical and surgical interventions. Angina is a symptom of myocardial ischemia, a disorder that occurs as a result of insufficient blood flow to the myocardium due to atherosclerosis, coronary artery spasm, thrombosis, and a variety of other medical conditions (Deer and Raso, 2006; Mannheimer, et al., 2002).

There is a subset of patients with CAD who do not respond to conventional medical therapy, are not candidates for revascularization procedures, or have had previous revascularization surgery and have persistent anginal pain. Lumbar or thoracic dorsal column SCS is a treatment option for this subset of patients.

The scientific studies for lumbar or thoracic dorsal column SCS have typically included those patients who are categorized as Canadian Cardiovascular Society (CCS) class III or class IV. CCS is a modification of the New York Heart Association (NYHA) functional classification that allows patients to be categorized in more specific terms (Appendix A) (Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; CCS, 1976).

Literature Review: The evidence in the published peer-reviewed scientific literature supports lumbar or thoracic dorsal column SCS as a well-established, safe treatment modality for patients with refractory, chronic stable angina (i.e., class III and class IV) unresponsive to medical and surgical intervention. Lumbar or thoracic dorsal column stimulation has been shown to be effective in this subgroup of patients in randomized controlled trials and prospective case series (N=25–104) with follow-ups of eight weeks to three years. Outcomes included: diminished episodes of angina; improved exercise capacity and quality of life; freedom from cardiac events (e.g., myocardial infarction and cardiac deaths); and a reduction in the use of short-acting nitrates, myocardial ischemia and hospitalizations (Andréll, et al., 2010; Taylor, et al., 2009; Bondesson, et al., 2008; Borjesson, et

al., 2008; Dyer, et al., 2008; de Vries, et al., 2007; Eddicks, et al., 2007; Lapenna, et al., 2006; McNab, et al., 2006; Diedrichs, et al., 2005).

Professional Societies/Organizations: In recommendations for best clinical practice using lumbar or thoracic dorsal column SCS for the management of pain, the British Pain Society (BPS, 2009) in consultation with the Society of British Neurological Surgeons stated that SCS is a well-established treatment for patients with refractory angina pectoris.

In their 2007 treatment guidelines for cardiovascular “Syndrome X” (i.e., “a syndrome of angina or angina-like discomfort with exercise, ST-segment depression on exercise testing or other objective signs of ischemia, and normal or nonobstructed coronary arteries on arteriography”), the American College of Cardiology/American Heart Association practice guidelines stated that lumbar or thoracic dorsal column SCS may be considered for highly symptomatic, refractory pain despite the implementation of medical therapy (i.e., nitrates, beta blockers, calcium channel blockers) and a reduction in risk factors (Anderson, et al., 2007).

The American College of Cardiology (ACC) and the American Heart Association (AHA) guidelines for the management of patients with chronic stable angina (Fraker and Fihn, 2007; Gibbons, et al., 2002) confirmed that lumbar or thoracic dorsal column SCS has been proposed as a method for providing analgesia for patients with chronic refractory angina pectoris since 1987. Results from clinical trials appeared promising, but there is still minimal data on the intermediate and long-term benefits of SCS devices. SCS should only be used in patients who cannot be managed adequately by medical therapy and who are not candidates for revascularization.

In the European Society of Cardiology (ESC) guidelines on management of stable angina pectoris (Fox, et al., 2006), the Society stated that lumbar or thoracic dorsal column SCS is a “well established method” used for the management of refractory angina. Patients experience a favorable analgesic effect and positive effects on symptoms when treated with SCS. A significant increase in the average exercise time has been demonstrated on treadmill testing. ESC also noted that the available clinical trials are small and long-term effects are unknown.

Cervical Spinal Cord Stimulation

Cervical SCS has been proposed for the treatment of numerous conditions including motor impairment from Parkinson’s disease, radiation induced brain injury, head trauma, cerebral vasospasm (e.g., following subarachnoid hemorrhage), facial pain, failed cervical fusion, stroke, Raynaud’s disease, high-grade gliomas, and head and neck cancers. The evidence in the published peer-reviewed scientific literature does not support the safety and efficacy of cervical SCS for any indication. Studies are primarily in the form of case reports and case series with small, heterogeneous patient populations and short-term follow-ups. Patient selection criteria and clinical applications have not been established.

Literature Review: Hayek et al. (2009) conducted a prospective case series (n=12) to evaluate if lower cervical spine stimulation (i.e., C3-C7) could produce paresthesia in patients with upper and lower limb pain that had not responded to medical management. Diagnosis included type 1 complex regional pain syndrome (CRPS), peripheral vascular disease, neuropathic pain persisting after cervical or lumbar laminectomy, chemotherapy-induced neuropathy, myelopathy status post cervical fusion, and multiple system atrophy. A 7–14 day trial period was conducted prior to permanent implantation. Eleven patients experienced paresthesia in all four extremities with cervical SCS. Five patients underwent permanent implantation. Two patients elected low thoracic implants. At the one-month follow-up, the five cervical SCS patients had a significant improvement in the visual analog scale scores ($p < 0.0065$) and the pain disability index scores ($p < 0.00045$).

Clavo et al. (2007) conducted a study to evaluate the effect of cervical SCS on blood flow in the middle cerebral artery (MCA) in 27 cancer patients with carotid artery-dependent tumor blood flow. Twelve patients had high-grade gliomas and 15 had advanced head and neck tumors. It was hypothesized that the proposed increased blood flow from cervical SCS at C2-C4 would lead to better results from chemoradiotherapy. Transcranial Doppler was used to evaluate cerebral blood flow prior to and following implantation on each patient’s tumor side compared to their healthy side. During the study cervical SCS was used as an adjuvant therapy to radiation and chemotherapy in the glioma patients. Following implantation, overall, there was a significant increase ($p < 0.001$) in the systolic and diastolic velocities in the MCA of the tumor and the healthy MCA cerebral hemispheres. In the glioma patients, the systolic velocity on the tumor side increased significantly by a mean

19% ($p=0.002$) and the diastolic velocity increased by 18% ($p=0.002$) compared to 30% ($p<0.001$) and 48% ($p<0.001$), respectively on the healthy side. In the head and neck patients, the systolic velocity on the tumor side increased significantly by a mean of 21% ($p=0.002$) and the diastolic velocity increased by 26% ($p=0.004$) compared to 24% ($p<0.001$) and 40% ($p<0.001$), respectively on the healthy side. Mean survival was 46 ± 15 months for grade III and 9 ± 2 months for grade IV tumors. Further studies are needed to validate the findings of this study and to establish the optimum stimulation schedule needed to obtain the maximal effect in blood flow.

Clavo et al. conducted additional studies to determine the effect of cervical SCS at C2-C4 on patients with high-grade gliomas or head and neck tumors (e.g., paranasal sinus, oropharynx, submandibular, supraglottis). The authors reported the effects of cervical SCS on brain glucose metabolism ($n=11$) (2006), common carotid artery (CCA) blood flow and tumor oxygenation ($n=16$) (2004), and locoregional blood flow ($n=15$) (2003). The SCS effect was recorded in tumor tissue and healthy tissue. Following cervical SCS, the basal glucose metabolism was significantly higher in the tumor than in the peritumoral areas ($p=0.048$), and there was a significant increase in glucose uptake in the tumor ($p=0.035$) and peritumoral ($p=0.001$) areas. The median tumor oxygenation significantly increased in two-thirds of the 11 patients who were tested ($p=0.023$) and the CCA blood flow significantly improved in 14 patients ($p<0.001$). A significant improvement was also seen in the diastolic ($p=0.003$) and systolic ($p=0.011$) velocities. Regarding locoregional blood flow, a significant increase was seen in tumor blood flow in 75% of the patients ($p=0.033$) and in systolic and diastolic blood flow velocities in tumor and healthy tissue ($p<0.002$). A mean increase in tumor and healthy tissue common carotid artery blood flow ($p<0.013$) was also reported. In the 2003 study, patient survival with grade III tumors was 28 ± 7 months and 9 ± 2 months with grade IV tumors. According to the authors, the survival rates appeared to be unaffected by SCS. Adverse events included occasional and transient upper limb paresthesia and electrode displacement.

Summary

The evidence in the scientific peer-reviewed published literature supports lumbar or thoracic dorsal column spinal cord stimulation (SCS) for the treatment of chronic intractable pain of greater than six months' duration which has been unresponsive to conventional medical management (e.g., pharmacotherapy, physical therapy) and surgical intervention. Patients eligible for lumbar or thoracic dorsal column SCS experience pain relief from a temporary trial of SCS and demonstrate a psychological profile that would be consistent with successful dorsal column stimulation.

Lumbar or thoracic dorsal column SCS is an established treatment modality for pain secondary to chronic stable angina pectoris with myocardial ischemia, refractory to pharmacotherapy and surgical intervention. Outcomes of clinical trials have shown that lumbar or thoracic dorsal column SCS is effective in alleviating refractory anginal pain in Canadian Cardiovascular Society class III and class IV patients.

There is insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of cervical placement of a dorsal column spinal cord stimulator for any indication. Studies are primarily in the form of case reports and case series with small, heterogeneous patient populations and short-term follow-ups. Patient selection criteria and clinical application have not been established.

Appendix A

New York Heart Association and Canadian Cardiovascular Society Functional Classifications

Class	New York Heart Association Functional Classification	Canadian Cardiovascular Society Functional Classification
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	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	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	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	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV	Patient with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.

(Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).

Coding/Billing Information

Covered when medically necessary when used to report a lumbar or thoracic dorsal column spinal cord stimulator:

CPT [®] * Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, autonomic nerve, neuromuscular)

	neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

HCPCS Codes	Description
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
L8680	Implantable neurostimulator electrode, each
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

ICD-9-CM Diagnosis Codes	Description
053.12	Postherpetic trigeminal neuralgia
053.13	Postherpetic polyneuropathy
250.60-250.63	Diabetes with neurological manifestations
337.20-337.29	Reflex sympathetic dystrophy
338.21-338.29	Other chronic pain
338.3	Neoplasm related chronic pain
338.4	Chronic pain syndrome
350.1	Trigeminal neuralgia
353.6	Phantom limb (syndrome)
353.8	Other nerve root and plexus disorders
354.4	Causalgia of upper limb
354.5	Mononeuritis multiplex
354.8	Other mononeuritis of upper limb
354.9	Mononeuritis of upper limb, unspecified
355.0	Lesion of sciatic nerve
355.71	Causalgia of lower limb
355.79	Other mononeuritis of lower limb
355.8	Mononeuritis of lower limb, unspecified
355.9	Mononeuritis of unspecified site
356.0	Hereditary peripheral neuropathy
356.9	Hereditary and idiopathic peripheral neuropathy, unspecified

413.0-413.9	Angina pectoris
414.00-414.9	Other forms of chronic ischemic heart disease
719.46	Pain in joint, lower leg
721.0	Cervical spondylosis without myelopathy
721.1	Cervical spondylosis with myelopathy
720.0	Ankylosing spondylitis
720.1	Spinal enthesopathy
721.2	Thoracic spondylosis without myelopathy
721.3	Lumbosacral spondylosis without myelopathy
721.41	Thoracic spondylosis with myelopathy
721.42	Lumbar spondylosis with myelopathy
722.0	Displacement of cervical intervertebral disc without myelopathy
722.10	Lumbar intervertebral disc displacement without myelopathy
722.11	Thoracic intervertebral disc displacement without myelopathy
722.2	Displacement of intervertebral disc, site unspecified, without myelopathy
722.4	Degeneration of cervical intervertebral disc
722.51	Degeneration of thoracic or thoracolumbar intervertebral disc
722.52	Degeneration of lumbar or lumbosacral intervertebral disc
722.6	Degeneration of intervertebral disc, site unspecified
722.70- 722.73	Intervertebral disc disorder with myelopathy
722.80- 722.83	Postlaminectomy syndrome
722.90- 722.93	Other and unspecified disc disorder
723.1	Cervicalgia
723.4	Brachial neuritis or radiculitis NOS
723.8	Other syndromes affecting cervical region
724.00	Spinal stenosis, unspecified region
724.01	Spinal stenosis, thoracic region
724.03	Spinal stenosis, lumbar region, with neurogenic claudication
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.9	Other unspecified back disorders
729.2	Neuralgia, neuritis, and radiculitis, unspecified
996.2	Mechanical complication of nervous system device, implant or graft
996.75	Other complications of internal (biological)(synthetic) prosthetic device, implant, and graft; due to nervous system device, implant or graft
	Multiple/varied

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	7/15/2008	0380	Spinal Cord Stimulation
Great-West Healthcare	11/20/06	95.244.05	Spinal Cord Stimulation (SCS)

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