Cigna Medical Coverage Policy

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Subject **Spinal Cord Stimulation**

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Coverage Policy

Cigna covers up to a 16-contact/electrode dorsal column spinal cord stimulator (SCS) when any of the following criteria outlined below are met.

Failed Back Syndrome (FBS)/Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)

Cigna covers a short-term trial of a dorsal column spinal cord stimulator (SCS) as medically necessary for the treatment of chronic, intractable pain secondary to EITHER of the following indications:

- failed back syndrome (FBS)
- complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)

when ALL of the following criteria are met:

- failure of at least six consecutive months of physician-supervised conservative medical management including pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification
- surgical intervention is not indicated
- 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 dorsal column spinal cord stimulator (SCS) as medically necessary for the treatment of chronic, intractable pain secondary to EITHER of the following indications:

- failed back syndrome (FBS)
- complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)

when ALL of the following criteria are met:

- failure of at least six consecutive months of physician-supervised conservative medical management including pharmacotherapy, physical therapy, cognitive therapy, activity lifestyle modification
- surgical intervention is not indicated
- 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
- beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation

Chronic Critical Limb Ischemia (CLI)

Cigna covers a short-term trial of a dorsal column spinal cord stimulator (SCS) for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI) as medically necessary when all of the following criteria are met:

- failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management (e.g., revascularization)
- 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 dorsal column spinal cord stimulator (SCS) for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI) as medically necessary when all of the following criteria are met:

- failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management (e.g., revascularization)
- 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
- beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation

Chronic Stable Angina Pectoris

Cigna covers a short-term trial of a dorsal column spinal cord stimulator (SCS) for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris as medically necessary for 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)
- individual has documented significant coronary artery disease (CAD) and is not a suitable candidate for a revascularization procedure
- 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 dorsal column spinal cord stimulator (SCS) for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris as medically necessary for 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 a revascularization procedure
- 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
- beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation

Dorsal Column Spinal Cord Stimulator Replacement

Cigna covers the replacement of a dorsal column spinal cord stimulator (SCS) and/or battery/generator replacement, as medically necessary for an individual who meets ALL of the above criteria and the existing stimulator and/or battery/generator replacement are/is no longer under warranty and cannot be repaired.

Not Covered Services

Cigna does not cover implantation of up to a 16-contact/electrode dorsal column spinal cord stimulator (SCS) for any other indication because it is considered experimental, investigational or unproven.

Cigna does not cover implantation of a spinal cord stimulator (SCS) with more than 16 contacts/electrodes 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.

Dorsal column SCS with up to 16 contacts/electrodes is an established treatment option patients with chronic, intractable pain secondary to failed back syndrome (FBS), also called failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD), chronic critical leg ischemia (CLI) and refractory chronic stable angina pectoris. In general, SCS candidates have experienced at least six consecutive months of persistent pain and have failed or cannot tolerate medical management (e.g., pharmacotherapy, exercise, physical therapy, behavior modification, lifestyle changes, psychological therapy) or the treatment is contraindicated. Initial or repeat surgical management (e.g., laminectomy, discectomy, revascularization) is also not tolerated, contraindicated or has failed. Candidates for SCS with chronic stable angina have Canadian Cardiovascular Society (CCS) functional class III or class IV (see Appendix A) angina pectoris and significant coronary artery disease (CAD) not suitable for revascularization. There should be no signs of drug dependency 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 trial (e.g., 3–14 days) 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; Doleys, 2006; British Pain Society [BPS], 2009).

The subjective experience of pain is influenced by both physiological and psychological factors. Therefore, it is recommended that SCS candidates undergo a face-to-face psychiatric and psychosocial evaluation by a psychologist, psychiatrist or licensed mental health care provider prior to the temporary implantation of an SCS device. A self-report computer analysis (e.g., Battery for Health Improvement 2 [BHI™ 2] is not sufficient. 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 with up to 16 contacts/electrodes systems typically include: an implantable, single or dual output pulse generator (IPG) (neurostimulator) with a rechargeable or a non-rechargeable battery; percutaneous permanent lead kit and leads; lead extensions; percutaneous trial lead kit and an external patient programmer/transmitter. The leads come in various lengths (e.g., 30, 50 and 70 cm). The distal (paddle) end of the lead has two columns of evenly spaced plantar electrodes (e.g., 4–16 electrodes). The number of electrodes needed will be determined by the pain pattern with more electrodes needed for more complex pain patterns (e.g., bilateral pain, pain radiating into limbs). Lead extensions may be added to a lead to externalize the lead for the trial procedure or to internally extend a lead. Multiple leads can be connected to a generator and a lead splitter may be used. One or more leads are implanted in the dorsal epidural space, connected to the generator, and programmed by the physician through a wireless transmitter operated by the patient. 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 with up to 16 contacts/electrodes 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. Reoperation may be necessary to replace the battery if the patient has a non-rechargeable system, reposition the lead or generator or to address problems with the device. The longevity of the system and batteries depends on the patient pain patterns, the level of simulation used and the type of system (Markman and Philip, 2007; Mailis-Gagnon, et al., 2004).

It is being proposed that SCS with a device with more than 16 contacts/electrodes can provide wider coverage of the spinal cord and therefore result in better pain relief. There is insufficient evidence to support the effectiveness of these newer devices.

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 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). Rechargeable systems include the Eon® Neurostimulation System (St. Jude Medical, St. Paul, MN) and the Restore™ Rechargeable Neurostimulation System (Medtronic, Inc., Minneapolis, MN). Programmers, leads and other accessories are regulated by the FDA as Class II 510(k) devices. The IPG in these systems have two lead ports and can be connected to a single 8-contact lead or dual 8-contact leads with 16 contacts/electrodes.

In 2012, the Precision Spectra™ Spinal Cord Stimulator (SCS) System with IIllumin 3D™ software (Boston Scientific, MA) received premarket approval (PMA) as a supplemental device to the original Precision Device that was approved in 2004. This device has four lead ports and can be connected to up to four leads providing 32 contacts.

<u>Dorsal Column Spinal Cord Stimulation</u>

SCS with up to 16 contacts/electrodes is an established treatment option for a carefully selected subset of patients with failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD), and chronic critical limb ischemia (CLI).

Failed Back Syndrome (FBS)
Failed back syndrome (FBS), also known as failed back surgery syndrome (FBSS), is a term used to describe the condition of patients who have had back surgery and continue to experience or have recurrent neuropathic and nociceptive low back and/or leg pain following the surgery. Following surgery, persistent pain may be due to recurrence of the original problem, failure of the surgery or of an implanted device, scar tissue, improper healing, abscess, loss of spinal stability, herniation or spinal stenosis. Treatment includes pharmacotherapy, physical therapy, exercise, cognitive therapy, and activity lifestyle modifications. In some cases, a second corrective surgery may be needed (Jeon and Huh, 2009; Ragab and deShazo, 2008). SCS with up to 16 contacts/electrodes is indicated in a carefully selected subgroup of patients with FBS who have had persistent pain for at least six consecutive months under physician supervised medical management, have not responded to medical interventions and surgery is not indicated.

Literature Review: Systematic reviews, randomized controlled trials and case series support SCS with up to 16 contacts/electrodes for the treatment of FBS. Studies with up to ten years of follow-up reported that SCS was significantly more successful in relieving pain compared to other treatment modalities (e.g., physical therapy, analgesia) (Slavin, et al., 2013; Taylor, et al., 2013; Kelly, et al., 2012; Frey, et al., 2009; Simpson, et al., 2009; Kumar, et al., 2008; Taylor, et al., 2006; North, et al., 2005; Mailis-Gagnon, et al., 2004).

Complex Regional Pain Syndrome (CRPS)
Complex regional pain syndrome (CRPS), formerly known as reflex sympathetic dystrophy (RSD) or causalgia, is a neuropathic pain disorder characterized by intractable burning pain that can be exacerbated by emotional distress, light touch, movement, and changes in temperature. The pain can affect any area of the body, but most often affects an arm or leg. CRPS has two forms. CRPS type I corresponds to what was previously referred to as RSD and is a chronic nerve disorder typically in the arms or legs following an injury. CRPS type II

corresponds to the condition previously known as causalgia and is caused by a nerve injury. CRPS treatment includes pharmacotherapy, physiotherapy, psychological therapy (e.g., cognitive-behavioral therapy, pain coping skills) and/or regional anesthetic nerve blocks (e.g., sympathetic nerve block, intravenous regional block). If there is an inadequate or partial response, or a failure to progress in rehabilitation, more invasive procedures such as epidural block, injectable and/or intravenous drug therapy, intrathecal drug therapy and/or sympathectomy may be indicated (de Mos, et al., 2009; Foletti, et al., 2007; Stanton-Hicks, et al., 2002). SCS with up to 16 contacts/electrodes may be indicated when medical therapies fail and surgical intervention is contraindicated.

Literature Review: Systematic reviews, randomized controlled trials and case series have investigated SCS with up to 16 contacts/electrodes for the treatment of CRPS and reported significant pain relief compared to medical management without SCS (e.g., physical therapy). Greater than 50% pain relief was reported in patients for up to two years (Slavin, et al., 2013; Simpson, et al., 2009; Kemler, et al., 2008; Taylor, et al., 2006; Mailis-Gagnon, et al., 2004; Kemler, et al., 2004; Kemler, et al., 2000).

Chronic Critical Limb Ischemia (CLI)
Chronic critical limb ischemia (CLI) is a condition in which the patient experiences chronic, severe ischemic rest pain, nonhealing ulcers and gangrene caused by inadequate blood flow or arterial occlusion. The ischemic pain is typically a burning pain in the arch or distal foot when the patient is recumbent, has been persistent for two weeks and requires regular pain medication. CLI differs from acute leg ischemia which is a sudden decrease in limb perfusion typically due to arterial thrombosis or peripheral thromboembolism. The care of a patient with CLI frequently involves a multidisciplinary team approach. The mainstay of therapy is revascularization. If revascularization is not feasible, conservative treatment includes analgesics, vasodilators, and/or anticoagulants along with appropriate wound care for ulcerations. Amputation may ultimately become necessary in patients with extensive tissue necrosis, life-threatening infection or lesions not amenable to revascularization (Ubbink and Vermeulen, 2013; Powell, 2008; Slovut and Sullivan, 2008). SCS with up to 16 contacts/electrodes is a recognized treatment option in patients with critical limb ischemia who are not candidates for surgical intervention and are nonresponsive to medical management.

Literature Review: Many studies investigating SCS with up to 16 contacts/electrodes for CLI were reported prior to 2000. Current systematic reviews, randomized controlled trials and prospective case series, reported more significant pain relief with CLI patients compared to medical management (e.g., pharmacotherapy) (Simpson, et al., 2009; Ubbink, et al., 2008).

Technology Assessments: In a technology appraisal, the National Institute for Health and Clinical Excellence (NICE) (United Kingdom) (2008) recommended 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: Following a systematic review of the literature, the Special Interest Group of the Canadian Pain Society published evidence-based guidelines for the treatment of neuropathic pain. The Work Group recommended SCS for failed back surgery syndrome and complex regional pain syndrome (CRPS) I or II in patients who are not candidates for corrective surgery and have failed more conservative treatment (recommendation B: high certainty with moderate effect or moderate certainty with moderate to substantial effect). They also stated that a trial of SCS could be offered to patients with traumatic neuropathy and brachial plexopathy who are not candidates for corrective surgery and who have failed more conservative therapies (recommendation C: may recommend depending on circumstances; at least moderate certainty with small net benefit). There was insufficient evidence to support SCS for all other neuropathic pain syndromes (Mailis and Taenzer, 2012).

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 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 recommendations for best clinical practice using 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 clinical evidence from randomized controlled trials support SCS for the treatment of pain from failed back surgical syndrome (FBSS), complex regional pain syndrome, (CRPS) and neuropathic pain. Patients with refractory angina pectoris are likely to respond to SCS. BPS noted that not all patients are suited for SCS and individuals should be assessed by multidisciplinary team of healthcare professionals experienced in SCS treatment.

In their evidence-based guidelines for the management of chronic spinal pain (Manchikanti, et al., 2009), the American Society of Interventional Pain Physicians recommended 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 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.”

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. Dorsal column SCS with up to 16 contacts/electrodes is a treatment option for this subset of patients.

The scientific studies for dorsal column SCS with up to 16 contacts/electrodes 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], 2002; Gibbons, et al., 2002; American Heart Association [AHA], 1994; CCS, 1976).

Literature Review: Randomized controlled trials and prospective case series support dorsal column SCS with up to 16 contacts/leads 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. 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 (Lanza, et al., 2012; 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: The 2013 American Society of Interventional Pain Physicians’ (ASIPP) guidance and recommendations for chronic spinal pain states that SCS is primarily implanted for failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). Based on a systematic review of the evidence, ASIPP states that there is “fair” evidence for SCS for long-term pain relief for the treatment of FBSS when multiple conservative and interventional modalities have been exhausted. SCS for the management of chronic intractable neck pain has not been evaluated. According to ASIPP there is “no evidence” to support SCS for the treatment of thoracic spinal pain (Manchikanti, et al., 2013).

The American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of

Thoracic Surgeons published a 2012 guideline for the diagnosis and management of stable ischemic heart disease. The guideline included two randomized controlled trials that reported better outcomes with SCS. The authors concluded that the studies suggested that SCS might have some use as a method to relieve angina in patients with symptoms that are refractory to standard medical therapy and revascularization. However, there is a paucity of data on the mechanisms and long-term risks and benefits of this therapeutic approach (Fihn, et al., 2012).

In recommendations for best clinical practice using 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 patients with refractory angina pectoris are likely to respond to SCS. BPS noted that not all patients are suited for SCS and individuals should be assessed by multidisciplinary team of healthcare professionals experienced in SCS treatment.

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 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).

In the European Society of Cardiology (ESC) guidelines on management of stable angina pectoris (Fox, et al., 2006), the Society stated that 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.

Other Indications
SCS has been proposed for the treatment of multiple other conditions including Parkinson's disease, akinesia, central poststroke pain, degenerative joint disease, gliomas, irritable bowl syndrome, diabetic neuropathy, peripheral neuropathy, paraplegia, neuropathic cancer pain, peripheral vascular disease, vegetative state, visceral pain (e.g., chest, abdomen and pelvis), spinal cord injury, cauda equina syndrome, perirectal pain, and postherpetic/intercostal neuralgia. Studies are primarily in the form of case reports, case series with small patient populations (n=2–30) and retrospective reviews with conflicting and various outcomes. SCS was reported not clinically beneficial for some conditions (Compton, et al., 2012; Thevathasan, et al., 2010; Jeon and Huh, 2009; Robaina and Clavo, 2007a; Robaina and Clavo, 2007b). There is insufficient evidence in the published peer-reviewed literature to support SCS for these other indications.

Lihua et al. (2013) conducted a systematic review to evaluate the effectiveness of SCS for the treatment of cancer-related pain. No randomized controlled trials were found. Four case series (n=92) were included in the analysis. Limitations of the studies included heterogeneity of baseline characteristics, electrode and stimulator parameters, and level and route of implantation. Data reporting was different among all trials and the risk of bias was high. There is insufficient evidence to support SCS for the treatment of cancer-related pain.

Della Pepa et al. (2013) conducted a systematic review to evaluate SCS for the treatment of vegetative state (VS). Ten case series and case reports (n=308)) met inclusion criteria. A clinical response was reported in 159 patients. Patients were in VS secondary to trauma, stroke or anoxia. Limitations of the studies included the small patient populations, heterogeneity of patient characteristics and brain injuries (location, distribution and duration), lack of a comparator and inability to determine if recovery was spontaneous or due to SCS. The available data do not support the efficacy of SCS for the treatment of VS.

Spinal Cord Stimulator (SCS) Systems with More than 16 Contacts/Electrodes
It is being proposed that SCS systems with more than 16-contacts/electrodes can provide more flexibility in spinal cord coverage resulting in improved pain control. Boston Scientific Corporation has recently received FDA approval for the Precision Spectra™ Spinal Cord Stimulator (SCS) System with IIllumin 3D™ software. The device provides 32 contacts and four lead ports, twice that of current systems with 16 contacts and two lead ports. Each port allows the placement of one lead. The software is based on a "proprietary" computer model that is proposed to allow the physician to select a desired location on the spinal cord and then program the software to create a customized stimulation (Boston Scientific, 2013). There is ongoing controversy as to whether

additional contacts/electrodes and leads improve the clinical utility of SCS. There is insufficient evidence to support the effectiveness of a SCS system with more than 16 contacts/electrodes. Studies comparing SCS systems with up to 16 contacts/electrodes to systems with more than 16 contacts/electrodes are lacking.

Summary
The evidence in the scientific, peer-reviewed published literature supports dorsal column spinal cord stimulation (SCS) with up to 16 contacts/electrodes for the treatment of a carefully selected subgroup of patients with chronic, intractable pain secondary to failed back syndrome (FBS), complex regional pain syndrome (CRPS), or chronic critical limb ischemia (CLI) who are unresponsive to conventional medical management and surgical intervention is not indicated. Patients eligible for dorsal column SCS with up to 16 contacts/electrodes experience pain relief from a temporary trial of SCS and demonstrate a psychological profile that would be consistent with successful dorsal column stimulation.

Dorsal column SCS with up to 16 contacts/electrodes is an established treatment modality for chronic, intractable pain secondary to chronic stable angina pectoris with myocardial ischemia, refractory to pharmacotherapy and surgical intervention. Outcomes of clinical trials have shown that dorsal column SCS with up to 16 contacts/electrodes is effective in alleviating refractory anginal pain in Canadian Cardiovascular Society class III and class IV patients.

Dorsal column SCS has been proposed for the treatment of numerous other conditions (e.g., diabetic neuropathies, phantom limb pain). However there is insufficient evidence to support SCS for these conditions. Studies investigating SCS for various other conditions are limited in number and consist of case reports, small case series and retrospective reviews. Outcomes have been conflicting or have reported no significant improvement with SCS.

A spinal cord stimulator system with more than 16 contacts/electrodes has been proposed for the treatment of patients with chronic pain. Data comparing the clinical effectiveness of these new devices to the established 16 contact/electrode devices are lacking.

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	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.

Class	New York Heart Association Functional Classification	Canadian Cardiovascular Society Functional Classification
	of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	
(Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Short-Term Trial of Dorsal Column Spinal Cord Stimulator

Covered when medically necessary when used to report a spinal cord stimulator with 16 or less contacts/electrodes:

CPT®* Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
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
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
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

Permanent Implantation of a Dorsal Column Spinal Cord Stimulator

Covered when medically necessary when used to report a spinal cord stimulator with 16 or less contacts/electrodes:

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
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
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

Replacement of a Dorsal Column Spinal Cord Stimulator

Covered when medically necessary when used to report a spinal cord stimulator with 16 or less contacts/electrodes:

CPT®* Codes	**Description**
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

HCPCS Codes	**Description**
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
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

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