Clinical Policy Bulletin:  
Dorsal Column Stimulation

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Policy

I. Aetna considers dorsal column stimulators (DCS) medically necessary durable medical equipment (DME) for the management of members with chronic pain due to any of the following indications when the criteria listed below are met:

A. Failed back surgery syndrome with low back pain and significant radicular pain; or  
B. Complex regional pain syndrome (also known as reflex sympathetic dystrophy); or  
C. Inoperable chronic ischemic limb pain secondary to peripheral vascular disease; or  
D. Last resort treatment of moderate to severe (5 or more on a 10-point VAS scale) chronic neuropathic pain of certain origins (i.e., lumbosacral arachnoiditis and radiculopathies, phantom limb/stump pain, peripheral neuropathy, post-herpetic neuralgia, intercostal neuralgia, cauda equina injury, incomplete spinal cord injury, or plexopathy) that is refractory to 12 or more months of standard therapy (including non-steroidal anti-inflammatory drugs, tricyclic antidepressants, and anticonvulsants).

The member must meet all of the following criteria:

1. Member does not have any untreated existing drug addiction problems (per American Society of Addiction Medicine (ASAM) guidelines), and  
2. Member experienced significant pain reduction (50 % or more) with a 3- to 7-day trial of percutaneous spinal stimulation. (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet the above-listed criteria, in order to predict whether a dorsal column stimulator will induce significant pain relief), and  
3. Member has obtained clearance from a psychiatrist or psychologist, and  
4. Other more conservative methods of pain management have been tried and failed, and  
5. There is documented pathology, i.e., an objective basis for the pain complaint.

II. Aetna considers the use of cervical spinal cord stimulation for the treatment of members with complex regional pain syndrome medically necessary when criteria in section I are met.
Ill. Aetna considers the use of cervical spinal cord stimulation for the treatment of members with cervical trauma, disc herniation, failed cervical spine surgery syndrome presenting with arm pain, neck pain, and/or cervicogenic headache, gliomas, migraine, radiation-induced brain injury, or stroke experimental and investigational because its effectiveness for these indications has not been established.

IV. Aetna considers DCS medically necessary DME for the management of intractable angina in members who are not surgical candidates and whose pain is unresponsive to all standard therapies when all of the following criteria are met:

A. Member experienced significant pain reduction (50 % or more) with a 3- to 7-day trial of percutaneous spinal stimulation. (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet the above-listed criteria, in order to predict whether a dorsal column stimulator will induce significant pain relief), and

B. Member has angiographically documented significant coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA), and

C. Member has had optimal pharmacotherapy for at least one month. Optimal pharmacotherapy includes the maximal tolerated dosages of at least 2 of the following anti-anginal medications: long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists; and

D. Member's angina pectoris is New York Heart Association (NYHA) Functional Class III (patients are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain) or Class IV (symptoms of cardiac insufficiency or angina are present at rest; symptoms are increased with physical activity), and

E. Reversible ischemia is documented by symptom-limited treadmill exercise test.

Contraindications to dorsal column stimulation for intractable angina are presented in an Appendix to the Background section of this CPB.

V. Aetna considers dorsal column stimulation experimental and investigational for all other indications not mentioned above because its effectiveness for other indications has not been established. This includes treatment of persons in a chronic vegetative or minimally conscious state, chronic malignant pain, chronic pelvic pain (chronic abdominal pain, chronic visceral pain), gait disorders including spinocerebellar ataxia, irritable bowel syndrome, sleep disorders, types of chronic non-malignant non-neuropathic pain not mentioned above, and ventricular fibrillation and ventricular tachycardia.

VI. Aetna considers replacement of a cervical, lumbar or thoracic dorsal column stimulator or battery/generator medically necessary for individuals who meet medical necessity criteria for dorsal column stimulation and the existing stimulator or battery/generator are no longer under warranty and cannot be repaired.

VII. Aetna considers removal of dorsal column stimulator medically necessary even where installation would not have been indicated.

VIII. Aetna considers a spinal cord stimulator patient programmer medically necessary for members who meet criteria for a dorsal column stimulator.

IX. Aetna considers the use of intra-operative motor evoked potentials (MEP) and somatosensory evoked potentials (SSEP) experimental and investigational for implantation of spinal cord stimulators.

See also CPB 0362 - Spasticity Management.

Background

Dorsal Column Stimulation for Chronic Pain:

Dorsal column stimulators (DCS), also known as spinal cord stimulators, are most commonly used for the management of failed back surgery syndrome. The use of DCS for controlling chronic low back pain (LBP) is a non-destructive, reversible procedure, thus, it is an attractive alternative for patients who may be facing or have already experienced neuroablative procedures, or habituating opioid medications. The failure in earlier trials of spinal stimulation pointed to the importance of carefully selected patients in the success of this procedure. Today, a patient should meet the following criteria (Kumar et al, 1986) before permanent implantation of a DCS is considered: (i) other more conservative methods of pain management have been tried and failed; (ii) the patient has exhausted all surgical options; (iii) the patient has predominantly radiating extremity pain; and (iv) the patient experienced significant pain reduction with trial percutaneous spinal stimulation.

Dorsal column stimulation is a therapy for chronic pain with organic origins and has not been shown to benefit problems which are largely behavioral or psychiatric. There is evidence that outcomes of DCS are improved if candidates are subject to psychological clearance to exclude from surgery persons with serious mental disabilities, psychiatric disturbances, or poor personality factors that are associated with poor outcomes. The literature supporting pre-surgical psychological clearance for DCS has been reviewed by a number of authors (Heckler et al, 2007; van Dorsten, 2006).

There is sufficient evidence of the effectiveness of dorsal column stimulation in failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). North et al (1991b) reviewed the long-term results of 50 patients with FBSS who had received implantable DCS. Successful outcome, as judged by at least 50 % sustained analgesia and patient satisfaction with the result, was recorded in 53 % of patients at 2.2 years and 47 % of patients at 5.0 years. Eighty three percent of the subjects continued to use their stimulators at the 5-year follow-up. At the time of follow-up, only 12 % of patients were using analgesic medications with half of them at reduced dosage, compared with 74 % before the commencement of DCS therapy. Moreover, most patients reported an improvement in ability to perform daily activities. In another report that examined 5-year follow-up in 102 patients with FBSS undergoing repeated operation, North et al (1991a) found that most of these patients reported no change in their abilities to carry out activities of daily living.

Bell et al (1997) as well as Devulder et al (1997) reported that spinal cord stimulation is cost-effective in treating patients with chronic FBSS.

Turner et al (2004) conducted a systematic review on the effectiveness of DCS in relieving pain and improving functioning for patients with FBSS and CRPS. These authors concluded with suggestions for methodologically stronger studies to provide more definitive data regarding the effectiveness of DCS in relieving pain and improving functioning, short-term and long-term, among patients with chronic pain syndromes. Taylor et al (2005) assessed the safety and effectiveness of DCS for the treatment of chronic back and leg pain and FBSS and concluded that there is moderate evidence for the effectiveness of DCS for these indications. Furthermore, a recent Cochrane review (Mailis-Gagnon et al, 2004) concluded that although there is limited evidence in favor of DCS for FBSS and CRPS, more research is needed to confirm whether DCS is an effective treatment for certain types of chronic pain. This is in agreement with the findings of a recent assessment on spinal cord stimulation for the management of neuropathic pain by the Ontario Ministry of Health and Long Term Care (2005). This report stated that FBSS and CRPS are the 2 most common indications for DCS. North et al (2005) also reported that DCS provided adequate pain relief in patients with FBSS with predominant LBP and secondary radicular pain. Hanney et al (2005) stated that there is now a significant body of evidence to support the utilization of DCS in the management of CRPS.

The National Institute for Health and Clinical Excellence (NICE)’s guideline on spinal cord stimulation for chronic neuropathic or ischemic pain (2008) recommended DCS for patients who continue to experience chronic neuropathic pain (e.g. FBSS after lumbar spine surgery and CRPS) for at least 6 months despite trying conventional approaches to pain management. Patients should have had a successful trial of the therapy before a spinal cord stimulator is implanted.
Kumar and co-workers (2008) reported that after randomizing 100 FBSS patients to receive DCS plus conventional medical management (CMM) or CMM alone, the results of the 6-month Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation (i.e., PROCESS) showed that DCS offered superior pain relief, health-related quality of life (HRQoL), and functional capacity. Because the rate of cross-over favoring DCS beyond 6 months would bias a long-term randomized group comparison, these investigators presented all outcomes in patients who continued DCS from randomization to 24 months and, for illustrative purposes, the primary outcome (greater than 50% leg pain relief) per randomization and final treatment. Patients provided data on pain, quality of life, function, pain medication use, treatment satisfaction, and employment status. Investigators documented adverse events. Data analysis included inferential comparisons and multi-variate regression analyses. The 42 patients continuing DCS (of 52 randomized to DCS) reported significantly improved leg pain relief ($p < 0.0001$), quality of life ($p < 0.01$), and functional capacity ($p = 0.0002$); and 13 patients (31%) required a device-related surgical revision. At 24 months, of 46 of 52 patients randomized to DCS and 41 of 48 randomized to CMM who were available, the primary outcome was achieved by 17 (37%) randomized to DCS versus 1 (2%) to CMM ($p = 0.003$) and by 34 (47%) of 72 patients who received DCS as final treatment versus 1 (7%) of 15 for CMM ($p = 0.02$). The authors concluded that at 24 months of DCS treatment, selected FBSS patients reported sustained pain relief, clinically important improvements in functional capacity and HRQoL, and satisfaction with treatment.

Manca and associates (2008) assessed HRQoL as well as cost implications of DCS plus non-surgical CMM (DCS group) versus non-surgical CMM alone (CMM group) in the management of neuropathic pain in patients with FBSS. A total of 100 patients were randomized to either the DCS or CMM group. Healthcare resource consumption data relating to screening, the use of the implantable generator in DCS patients, hospital stay, and drug and non-drug pain-related treatment were collected prospectively. Resource consumption was costed using UK and Canadian 2005 to 2006 national figures. Health-related quality of life was assessed using the EuroQol-5D (EQ-5D) questionnaire. Costs and outcomes were assessed for each patient over their first 6-months of the trial. The 6-month mean total healthcare cost in the DCS group (CAN$19,486; 12,653 Euros) was significantly higher than in the CMM group (CAN$3,994; 2,594 Euros), with a mean adjusted difference of CAN$15,995 (9,997 Euros) ($p < 0.001$). However, the gain in HRQoL with DCS over the same period of time was markedly greater in the DCS group, with a mean EQ-5D score difference of 0.25 [$p < 0.001$] and 0.21 [$p < 0.001$], respectively at 3- and 6-months after adjusting for baseline variables. The authors concluded that the addition of DCS to CMM in patients with neuropathic leg and back pain results in higher costs to health systems but also generates important improvements in patients' EQ-5D over the same period.

In a randomized controlled study, Kemler et al (2008) evaluated the effectiveness of DCS in reducing pain due to CRPS-I at the 5-year follow-up. These researchers carried out a randomized trial in a 2:1 ratio in which 36 patients with CRPS-I were allocated to receive DCS and physical therapy (PT) and 18 patients to receive PT alone. Twenty-four patients who received DCS+PT also underwent placement of a permanent spinal cord stimulator after successful test stimulation; the remaining 12 patients did not receive a permanent stimulator. These investigators assessed pain intensity, global perceived effect, treatment satisfaction, and health-related quality of life. Patients were examined before randomization, before implantation, and every year until 5 years thereafter. A total of 10 patients were excluded from the final analysis. At 5 years post-treatment, DCS+PT produced results similar to those following PT for pain relief and all other measured variables. In a sub-group analysis, the results with regard to global perceived effect ($p = 0.02$) and pain relief ($p = 0.06$) in 20 patients with an implant exceeded those in 13 patients who received PT. The authors concluded that despite the diminishing effectiveness of DCS over time, 95% of patients with an implant would repeat the treatment for the same result.

A Cochrane review (Ubbink and Vermeulen, 2003) stated that there is evidence to favor DCS over standard conservative treatment to improve limb salvage and clinical situation in patients with inoperable chronic critical leg ischemia. This is in agreement with the findings of Carter (2004) who noted that though limited in quantity and quality, better evidence exists for the use of DCS in
neuropathic pain, CRPS, angina pectoris and critical limb ischemia, as well as Cameron (2004) who stated that DCS had a positive, symptomatic, long-term effect in cases of refractory angina pain, severe ischemic limb pain secondary to peripheral vascular disease, peripheral neuropathic pain, and chronic LBP.

Ohnmeiss et al (1996) concluded that spinal cord stimulation can result in improved physical function and reduced pain in selected patients with intractable leg pain. Shatin et al (1986) published the findings of a multi-center clinical study of DCS for treatment of chronic, intractable pain of the low back and/or legs. Ninety patients were available for follow-up which averaged 14.5 months. Seventy percent of the subjects experienced excellent (75 to 100%) or good (50 to 74%) analgesia. In addition, 28% of all subjects at last follow-up used opioid medications, compared to 40% of all subjects before implantation of the DCS.

In a review of the evidence for non-surgical interventional therapies for LBP for the American Pain Society, Chou and colleagues (2009) concluded that there is fair evidence that spinal cord stimulation (SCS) is moderately effective for FBSS with persistent radiculopathy though device-related complications are common.

Simpson et al (2009) examined the clinical and cost-effectiveness of SCS in the management of chronic neuropathic or ischemic pain. A total of 13 electronic databases including MEDLINE (1950 to 2007), EMBASE (1980 to 2007) and the Cochrane Library (1991 to 2007) were searched from inception; relevant journals were hand-searched; and appropriate websites for specific conditions causing chronic neuropathic/ischemic pain were browsed. Literature searches were conducted from August 2007 to September 2007. A systematic review of the literature sought clinical and cost-effectiveness data for SCS in adults with chronic neuropathic or ischemic pain with inadequate response to medical or surgical treatment other than SCS. Economic analyses were performed to model the cost-effectiveness and cost-utility of SCS in patients with neuropathic or ischemic pain. From approximately 6,000 citations identified, 11 randomized controlled trials (RCTs) were included in the clinical effectiveness review: 3 of neuropathic pain and 8 of ischemic pain. Trials were available for the neuropathic conditions FBSS and CRPS type I, and they suggested that SCS was more effective than conventional medical management (CMM) or re-operation in reducing pain.

The ischemic pain trials had small sample sizes, meaning that most may not have been adequately powered to detect clinically meaningful differences. Trial evidence failed to demonstrate that pain relief in critical limb ischemia (CLI) was better for SCS than for CMM; however, it suggested that SCS was effective in delaying refractory angina pain onset during exercise at short-term follow-up, although not more so than coronary artery bypass grafting (CABG) for those patients eligible for that surgery. The results for the neuropathic pain model suggested that the cost-effectiveness estimates for SCS in patients with FBSS who had inadequate responses to medical or surgical treatment were below 20,000 pounds per quality-adjusted life-year (QALY) gained. In patients with CRPS who had had an inadequate response to medical treatment the incremental cost-effectiveness ratio (ICER) was 25,095 pounds per QALY gained. When the SCS device costs varied from 5,000 pounds to 15,000 pounds, the ICERs ranged from 2,563 pounds per QALY to 22,356 pounds per QALY for FBSS when compared with CMM and from 2,283 pounds per QALY to 19,624 pounds per QALY for FBSS compared with re-operation. For CRPS the ICERs ranged from 9,374 pounds per QALY to 66,646 pounds per QALY. If device longevity (1 to 14 years) and device average price (5,000 pounds to 15,000 pounds) were varied simultaneously, ICERs were below or very close to 30,000 pounds per QALY when device longevity was 3 years and below or very close to 20,000 pounds per QALY when device longevity was 4 years. Sensitivity analyses were performed varying the costs of CMM, device longevity and average device cost, showing that ICERs for CRPS were higher. In the ischemic model, it was difficult to determine whether SCS represented value for money when there was insufficient evidence to demonstrate its comparative efficacy. The threshold analysis suggested that the most favorable economic profiles for treatment with SCS were when compared to CABG in patients eligible for percutaneous coronary intervention (PCI), and in patients eligible for CABG and PCI. In these 2 cases, SCS dominated (it cost less and accrued more survival benefits) over CABG. The authors concluded that the evidence suggested that SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I. For ischemic pain, there may need to be selection criteria developed for CLI, and SCS may have clinical benefit for refractory
angina short-term. They stated that further trials of other types of neuropathic pain or subgroups of ischemic pain may be useful.

The review by Simpson et al (2009) did not address chronic painful diabetic neuropathy (CPDN), and there is inadequate evidence to support the use of SCS for this indication.

Daousi and colleagues (2005) assessed the efficacy and complication rate of SCS at least 7 years previously in 8 patients. After a trial period of percutaneous stimulation, 8 male patients had been implanted with a permanent system. Mean age at implantation was 53.5 years and all patients were insulin-treated with stage 3 severe disabling CPDN of at least 1 year’s duration.

The stimulator was removed from 1 patient at 4 months because of system failure and 1 patient died 2 months after implantation from a myocardial infarction. Thus, a total of 6 patients were reviewed a mean of 3.3 years post-implantation. With the stimulator off, McGill pain questionnaire (MPQ) scores (a measure of the quality and severity of pain) were similar to MPQ scores prior to insertion of the stimulator. Visual analog scale (VAS) were measured with the stimulator off and on, respectively: background pain [74.5 (63 to 79) mm versus 25 (17 to 33) mm, median (inter-quartile range), p = 0.03), peak pain (85 (80 to 92) mm versus 19 (11 to 47) mm, p = 0.03]. There were 2 further cardiovascular deaths (these patients had continued pain relief) and the 4 surviving patients were re-assessed at 7.5 (range of 7 to 8.5) years: background pain [73 (65 to 77) mm versus 33 (28 to 36) mm, median (inter-quartile range)], peak pain [86 (81 to 94) mm versus 42 (31 to 53) mm]. Late complications (greater than 6 months post-insertion) occurred in 2 patients; electrode damage secondary to trauma requiring replacement (n = 1), and skin peeling under the transmitter site (n = 1). One patient had a second electrode implanted in the cervical region which relieved typical neuropathic hand pains. The authors concluded that SCS can continue to provide significant pain relief over a prolonged period of time with little associated morbidity.

In a prospective, open-label study, de Vos et al (2009) evaluated the safety and effectiveness of SCS for the treatment of pain and the effects on microcirculatory blood flow in the affected areas in patients with refractory peripheral diabetic neuropathy. Data were collected during screening, at implant and at regular intervals, after initiation of therapy. A total of 11 diabetic patients with chronic pain in their lower limbs and no response to conventional treatment were studied. The SCS electrode was implanted in the thoracic epidural space. Neuropathic pain relief was assessed by VAS and microcirculatory skin perfusion was measured with laser Doppler flowmetry. Nine subjects had significant pain relief with the percutaneous electrical stimulator. Average pain score for all 9 patients was 77 at baseline and 34 at 6 months after implantation. At the end of the study, 8 of 9 patients continued to experience significant pain relief and have been able to significantly reduce their pain medication. For 6 of them, the stimulator was the sole treatment for their neuropathic pain. No significant changes in microcirculatory perfusion were recorded.

Findings from the studies by Daousi et al (2005) as well as de Vos et al (2009) need to be validated by well-designed RCTs.

Kapural and colleagues (2010) noted that a few recent reports suggested that SCS effectively suppresses chronic abdominal pain. However, there is no consensus on patient selection or technical aspects of SCS for such pain. Thus, these researchers conducted national survey and collected 76 case reports. There were 6 incompletely filled reports, so 70 cases were analyzed. There were 43 female and 27 male patients. Spinal cord stimulation was trialed in an average of 4.7 days (median of 4 days). In most patients, the leads were positioned for the SCS trial with their tips at the level of the T5 vertebral body (n = 26) or T6 vertebral body (n = 15). Four patients failed SCS trial: their average baseline VAS pain score was 7 +/- 2.4 cm and did not improve at the conclusion of the trial (6.5 +/- 1.9 cm; p = 0.759). Pain relief exceeded 50 % in 66 of 70 patients reported. Among those, VAS pain score before the trial averaged 7.9 +/- 1.8 cm. During the trial VAS pain scores decreased to 2.45 +/- 1.45 cm (p < 0.001). The opioid use decreased from 128 +/- 159 mg of morphine sulfate equivalents a day to 79 +/- 112 mg (p < 0.017). During permanent implantation most of the physicians used 2 octrode leads and were positioned mid-line at T5 to T6 levels. The average patient follow-up was 84 weeks. Pain scores (VAS) before an implant were 8 +/- 1.9 cm, while after the implant 2.49 +/- 1.9 cm. The opioid use before an implant was 158 +/-
160 mg and at the last office visit after the implant 36 +/- 49 mg. The authors concluded that it seems that the SCS for the treatment of the abdominal visceral pain may provide a positive patient long-term experience, significant improvements in pain scores and a decrease in opioid use. The findings of this study needs to be validated by well-designed studies (RCTs).

In an evidence-based guideline on "Neuropathic pain interventional treatments", Mailis and Taenzer (2012) provided the following recommendations:

Failed back surgery syndrome and complex regional pain syndrome: In patients with FBSS and CRPS I or II, who are not candidates for corrective surgery and have failed more conservative evidence-based treatment, clinicians should consider offering a trial of SCS. Evidence quality: Good; Certainty: Moderate; Strength of recommendation: Grade B (Recommend: High certainty with moderate effect or moderate certainty with moderate to substantial effect.

Traumatic neuropathy and brachial plexopathy: In patients with traumatic neuropathy and brachial plexopathy, who are not candidates for corrective surgery and who have failed more conservative evidence-based treatment, clinicians may consider offering a trial of SCS. Evidence quality: Fair; Certainty: Moderate; Strength of recommendation: Grade C (May recommend depending on circumstances. At least moderate certainty with small net benefit).

Other neuropathic pain syndromes: In patients with other (than the above) neuropathic pain syndromes, there is insufficient evidence to recommend a trial of SCS. Evidence quality: Poor; Certainty: Low; Strength of recommendation: Grade I (Current evidence is insufficient to make a recommendation for or against using the intervention (poor quality of evidence, conflicting evidence, or benefits and harms cannot be determined).

In a Cochrane review, Lihua and colleagues (2013) evaluated the effectiveness of SCS for cancer-related pain compared with standard care using conventional analgesic medication. These investigators also appraised risk and potential adverse events associated with the use of SCS. They searched the following bibliographic databases in order to identify relevant studies: the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library (from inception to 2012, Issue 6); MEDLINE; EMBASE; and CBM (Chinese Biomedical Database) (from inception to July, 2012); they also hand-searched relevant journals. These researchers planned to include RCTs that directly compared SCS with other interventions with regards to the effectiveness of pain management. They also planned to include cross-over trials that compared SCS with another treatment. They planned to identify non-RCTs but these would only be included if no RCTs could be found. The initial search strategy yielded 430 articles. By scrutinizing titles and abstracts, these investigators found 412 articles irrelevant to the analytical purpose of this systematic review due to different scopes of diseases or different methods of intervention (intrathecal infusion system; oral medication) or aims other than pain control (spinal cord function monitoring, bladder function restoration or amelioration of organ metabolism). The remaining 18 trials were reviewed as full manuscripts. No RCTs were identified; 14 sporadic case reports and review articles were excluded and 4 before-and-after case-series studies (92 participants) were included. Two review authors independently selected the studies to be included in the review according to the pre-specified eligibility criteria. A check-list for methodological quality of non-RCTs was used (STROBE check-list) and all review authors discussed and agreed on the inclusion of trials and the results of the quality assessment. Four before-and-after case-series studies (a total of 92 participants) met inclusion criteria. All included trials adopted a VAS to evaluate pain relief. Heterogeneity existed in terms of baseline characteristics, electrode and stimulator parameters, level of implantation and route of implantation; data reporting was different among all trials. In 2 trials, pain relief was achieved in 76 % (48/63) of patients at the end of the follow-up period. In the 3rd trial, pre-procedure VAS was 6 to 9 (mean of 7.43); the 1-month post-implant VAS was 2 to 4 (mean of 3.07); the 12-month post-implant VAS was 1 to 3 (mean of 2.67). In the 4th trial, the pre-procedure VAS was 6 to 9 (mean of 7.07); 1 to 4 (mean of 2.67) at 1-month; 1 to 4 (mean of 1.87) at 12 months. Analgesic use was largely reduced. The main adverse events were infection of sites of implantation, cerebrospinal fluid (CSF) leakage, pain at the sites of electrodes, dislodgement of the electrodes and system failure, however, the incidence in patients with cancer could not be calculated. Since all trials were non-RCTs, they carried risk of
Dorsal Column Stimulation for Angina Pectoris:

Dorsal column stimulators have also been shown to be effective in the treatment of patients with angina pectoris patients who fail to respond to standard pharmacotherapies and are not candidates for surgical interventions. Patients should undergo a screening trial of percutaneous DCS of 3 to 7 days. If they achieve significant pain reduction (more than 50%), the system is then implanted permanently. For this procedure, epidural electrodes are generally placed at an upper thoracic or lower cervical spinal level. Although the exact mode of action of DCS in alleviating anginal pain is unclear, it has been suggested that its beneficial effects are achieved through an increase in oxygen supply to the myocardium in addition to its analgesic effect.

Gonzalez-Dader et al (1991) reported their findings of DCS on 12 patients with established angina at rest or with minimum effort, who are unresponsive to the maximum tolerable pharmacotherapies, and there was a contraindication for re-vascularization surgery or intraluminal angioplasty. After a mean follow-up of 9.8 months, there was a significant decrease in the number of angina attacks (30.9 to 9.6 attacks per week) and a significant improvement in the treadmill ergometric test. The authors concluded that DCS is a very low-risk technique that significantly enhances the quality of life of patients with unstable angina. Similarly, Sanderson et al (1992) noted that in 14 patients with severe intractable angina pectoris unresponsive to conventional therapies including bypass grafting, DCS resulted in a significant improvement of symptoms and a marked decrease in glycerol trinitrate consumption. These benefits persisted in some patients for over 2 years without any apparent adverse sequelae. It was concluded that DCS is a useful technique for patients with severe intractable angina who have failed to respond to standard therapies.

In a RCT with a 1-year follow-up (n = 22), de Jongste and Staal (1993) found that DCS improved both the quality of life and cardiac parameters of patients with refractory angina pectoris. Mannheimer et al (1993) examined the effects of DCS on myocardial ischemia, coronary blood flow, and myocardial oxygen consumption in angina pectoris induced by atrial pacing (n = 20). Fifteen subjects had recurrent angina following a previous coronary bypass procedure and 5 subjects were considered unsuitable for bypass surgery. It was concluded that DCS has an anti-anginal and an anti-ischemic effect in severe coronary artery disease. Moreover, myocardial ischemia during treatment (SCS) results in anginal pain. Thus, DCS does not deprive these patients of a warning signal. This observation was supported by the findings of Anderson et al (1994) as well as Eliasson et al (1994). In a prospective study (n = 50), Anderson and co-workers investigated whether DCS employed for relief of refractory angina can mask acute myocardial infarction. These investigators found no evidence that DCS concealed acute myocardial infarction. Eliasson and colleagues evaluated the safety aspects of DCS in patients (n = 19) with severe angina pectoris by means of repeated long-term electrocardiograph recordings. There were no increases in the frequency of ischemic attacks, the total ischemic burden, or the number of arrhythmic episodes during treatment with DCS.

In a prospective RCT, de Jongste et al (1994) studied the effects of DCS on quality of life and exercise capacity in patients with intractable angina. Patient inclusion criteria were as follows: (i) angiographically documented significant coronary artery disease not suitable for revascularization procedures such as CABG or PTCA, (ii) New York Heart Association Functional Class III or IV angina pectoris, (iii) reversible ischemia documented at least by a symptom-limited treadmill exercise test, and (iv) pharmacologically optimal drug treatment for at least 1 month. Optimal pharmacotherapy included the maximal tolerated dosages of at least 2 of the following anti-anginal medications -- long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists. Exclusion criteria included myocardial infarction or unstable angina in the last 3 months; significant valve abnormalities as demonstrated by echocardiography; and somatic disorders of the spine leading to insurmountable technical problems in treatment. Seventeen patients were randomly assigned to one of the two groups: (i) treatment (implantation within 2 weeks, n = 8), and (ii)
control (implantation after 8 weeks, n = 9). Quality of life was assessed by daily and social activity scores and recording sublingual glyceryl trinitrate consumption and angina pectoris episodes in a diary. Exercise capacity was evaluated by means of treadmill exercise testing. All subjects were followed up for 1 year. The authors found that DCS significantly improved quality of life and exercise capacity in these patients and that the beneficial effects of DCS may be mediated via an improvement of oxygen supply to the heart in addition to an analgesic effect.

Sanderson et al (1994) reported the long-term clinical outcome of 23 patients with intractable angina treated with DCS. They were followed-up for 21 to 62 months. Three patients died during the course of the study. None of the deaths was sudden or unexplained; and this mortality rate was acceptable for such patients. Two subjects had a myocardial infarction which was associated with typical pain, and not concealed by DCS. The authors concluded that DCS is an effective and safe treatment for patients whose angina is unresponsive to conventional therapies.

Dorsal Column Stimulation for Cancer Pain:

An AHRQ evidence-based guideline on management of cancer pain concluded that dorsal column stimulators have not been shown to be effective for treatment of refractory cancer pain. The assessment states: "Percutaneous electrical stimulation for the relief of otherwise refractory cancer pain has likewise not yet been evaluated in controlled trials. Case reports -- limited essentially to the percutaneous insertion of spinal cord electrodes for dorsal column stimulation -- tend to focus on details of the method, to use non-uniform patient selection criteria, and to use heterogeneous pain assessment methods and follow-up duration. Not all experience is favorable. Hence, as Miles and colleagues wrote nearly 20 years ago, 'At this stage it seems sensible to concentrate effort on evaluating the method rather than on encouraging widespread and possibly indiscriminate use of what is an expensive use and relatively unproven technique.'"

Cervical Spinal Cord Stimulation:

Garcia-March et al (1987) reported the use of SCS in 6 patients with total or partial brachial plexus avulsion. Two patients had had amputation of the arm and suffered from phantom limb and stump pain. After a mean follow-up of 14 months, 2 patients were pain-free, 1 had partial relief and required analgesics, and in 3 patients there was no effect. Robaina et al (1989) studied the use of SCS for relief of chronic pain in vasospastic disorders of the upper limbs. A total of 11 patients with chronic pain due to severe vasospastic disorders in the upper limbs were treated with cervical SCS. In 8 patients the pain was due to reflex sympathetic dystrophy (RSD) in the late stage of the disease, and 3 patients had severe idiopathic Raynaud's disease. The mean follow-up for both groups was 27 months. A total of 10 patients (91 %) had good or excellent results. In the RSD group, the amount of pain relief achieved enabled most patients to undergo subsequent physiotherapy and rehabilitation. These investigators concluded that in severe cases of RSD and idiopathic Raynaud's disease, SCS is an alternative treatment that can be used as primary therapy or as secondary therapy after unsuccessful sympathectomy or sympathetic blocks.

Forouzanfar et al (2004) noted that SCS has been used since 1967 for the treatment of patients with chronic pain. However, long-term effects of this treatment have not been reported. The present study investigated the long-term effects of cervical and lumbar SCS in patients with CRPS type I (CRPS I). A total of 36 patients with a definitive implant were included in this study. A pain diary was obtained from all patients before treatment and 6 months and 1 and 2 years after implantation. All patients were asked to complete a seven-point Global Perceived Effect (GPE) scale and the Euroqol-5D (EQ-5D) at each post-implant assessment point. The pain intensity was reduced at 6 months, 1 and 2 years after implantation (p < 0.05). However, the repeated measures ANOVA showed a statistically significant, linear increase in the visual analog scale (VAS) score (p = 0.03). According to the GPE, at least 42 % of the cervical SCS patients and 47 % of the lumbar SCS patients reported at least "much improvement". The health status of the patients, as measured on the EQ-5D, was improved after treatment (p < 0.05). This improvement
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was noted both from the social and from the patients' perspective. Complications and adverse effects occurred in 64% of the patients and consisted mainly of technical defects. There were no differences between cervical and lumbar groups with regard to outcome measures. The authors concluded that SCS reduced the pain intensity and improves health status in the majority of the CRPS I patients in this study. There was no difference in pain relief and complications between cervical and lumbar SCS.

De Andres et al (2007) stated that SCS is used in the treatment of chronic pain, ischemia because of obstructive arterial disease, and anginal pain. Recently, a number of studies have described the effects of the high cervical SCS, including increased cerebral blood flow, although the underlying mechanisms are unknown. The authors presented the case of a patient with a severe complex ischemic condition affecting both cerebral and upper limb blood flow with an associated CRPS in upper limb. While all previous clinical treatments proved ineffective, cervical SCS afforded satisfactory results.

Canlas et al (2010) reported a case of a severe form of a rapidly progressive CRPS I developing after a right shoulder injury managed with SCS. After failed conservative treatments, a rechargeable SCS system was implanted in the cervical spine. Allodynia and dystonia improved but the patient subsequently developed similar symptoms in lower right extremity followed by her lower left extremity. The patient became wheelchair bound. A second rechargeable SCS with a paddle electrode was implanted for the lower extremity coverage. The patient's allodynia and skin lesions improved significantly. However, over time, her initial symptoms re-appeared which included skin breakdown. Due to the need for frequent recharging, the system was removed. During explantation of the surgical paddle lead, it was noted by the neurosurgeon that the contacts of the paddle lead were detached from the lead. After successful implantation of another SCS system, the patient was able to reduce her medications and is now able to ambulate with the use of a left elbow crutch.

Simpson et al (2003) reported on the use of cervical SCS for the management of patients with chronic pain syndromes affecting the upper limb and face (n = 41). Follow-up ranged from 5 months to 11 years and 3 months (median of 4 years and 7 months). Overall, 68% obtained sustained pain relief, rated as significant in 51% of total. Patients with facial pain did not respond, while those with ischemic syndromes responded well. The major drawback of this study was that it was a retrospective uncontrolled study.

In a review on the treatment of cervicogenic headache (Martelletti and van SuijlekomIn, 2004), cervical SCS was not listed as one of the therapeutic approaches that include drug-based therapies (e.g., paracetamol and non-steroidal anti-inflammatory drugs), manual modalities, transcutaneous electrical nerve stimulation, local injection of anesthetic or corticosteroids, and invasive surgical therapies. In addition, in a review on the safety and effectiveness of SCS for the treatment of chronic pain, Cameron (2004) stated that SCS had a positive, symptomatic, long-term effect in cases of refractory angina pain, severe ischemic limb pain secondary to peripheral vascular disease, peripheral neuropathic pain, and chronic low-back pain. Spinal cord stimulation for the treatment of cervical trauma with disc herniation presenting with arm pain, neck pain, and/or cervicogenic headache was not discussed in the review. The clinical value of cervical SCS for these indications needs to be investigated by well-designed RCTs.

Clavo and colleagues (2008) stated that syndromes resulting from decreased cerebral blood flow and metabolic activity have significant clinical and social repercussion. However, treatment options are limited. These investigators examined the effect of cervical SCS on cerebral glucose metabolism. Between April 2000 and December 2005, a total of 16 patients with brain tumors were assessed. Before and during SCS, they had cerebral glucose metabolism evaluated using 18fluoro-2-deoxyglucose positron emission tomography (18FDG-PET) in the healthy cerebral hemisphere contralateral to the lesion area. Following cervical SCS, there was a significant (p < 0.001) increase in glucose metabolism in healthy cerebral hemisphere. The measured increase was 37.7%, with an estimated potential maximal contribution of the first 18FDG injection to the quantification of the second PET study (carry-over effect) less than or equal to 16.6%. The authors concluded that cervical SCS can increase cerebral glucose metabolism. This result
supports the potential usefulness of this neurosurgical technique as an adjuvant treatment in stroke and brain disorders that result from decreased blood flow and metabolism.

In a preliminary study, Clavo et al (2009) examined the effect of cervical SCS on radiation-induced brain injury (RBI)-tissue metabolism, as indexed by FDG-PET. Devices for cervical SCS were inserted in 8 patients with diagnosis of potential RBI in previously irradiated areas. While the SCS device was de-activated, each patient underwent an initial FDG-PET study to evaluate the clinical status. A second FDG-PET study was performed later the same day while the SCS device was activated in order to evaluate the effect of cervical SCS on glucose metabolism. Basal glucose metabolism in RBI areas was 31 % lower than peri-RBI areas (p = 0.009) and 32 % lower than healthy contra-lateral areas (p = 0.020). There was a significant increase in glucose uptake during SCS in both the RBI (p = 0.005) and the peri-RBI (p = 0.004) areas, with measured increases of 38 % and 42 %, respectively. The estimated potential maximal residual activity of the first FDG dose's contribution to the activity on the second scan was less than or equal to 14.3 +/- 4.6 %. The authors concluded that in this study using PET, SCS increased glucose metabolism in RBI and peri-RBI areas. They stated that these findings warrant further clinical investigation to elucidate more fully the clinical usefulness of SCS in these patients.

Dorsal Column Stimulation for Other Conditions:

Georgiopoulos and colleagues (2010) performed a systematic review of the proposed medical or surgical treatments in patients in chronic vegetative state (VS) or minimally conscious state (MCS), as well as of their mechanisms of action and limitations. These investigators have agreed to include patients in VS or MCS having persisted for over 6 months in post-traumatic cases, and over 3 months in non-traumatic cases, before the time of intervention. Searches were independently conducted by 2 investigators between May 2009 and September 2009 in the following databases: Medline, Web of Science and the Cochrane Library. The electronic search was complemented by cross-checking the references of all relevant articles. Overall, 16 papers were eligible for this systematic review. According to the 16 eligible studies, medical management by dopaminergic agents (levodopa, amantadine), zolpidem and median nerve stimulation, or surgical management by deep brain stimulation, extra-dural cortical stimulation, SCS and intra-thecal baclofen have shown to improve the level of consciousness in certain cases. The authors concluded that treatments proposed for disorders of consciousness have not yet gained the level of “evidence-based treatments”; moreover, the studies to date have led to inconclusiveness. The published therapeutic responses must be substantiated by further clinical studies of sound methodology.

In a case report, Rana and Knezevic (2013) described the use of transverse tripolar DCS in a patient with a history of irritable bowel syndrome (IBS) associated with abdominal pain resistant to conservative treatments. These researchers reported a 36-year old man who presented to the pain clinic with an 8-year history of IBS (constipation predominant with occasional diarrheal episodes), with "crampy and sharp" abdominal pain. He also had non-radicular thoracic spine pain due to thoracic scoliosis. Both pains were affecting his ability to function as an attorney. Prior conservative therapy, including psychologic treatment, anti-depressants, and opioids, was without any benefits. The use of a SCS was discussed with the patient. The procedure was performed after Institutional Review Board approval. A tripolar SCS was implanted at the T8 level using one-eight contact and two-four contact percutaneous leads based on paresthesia reproduction of patient's areas of discomfort. This tripolar SCS provided relief of abdominal and thoracic pain, and better management of gastro-intestinal symptoms. The patient was followed-up for 1 year, and his quality of life also was improved via the IBS-Severity Scoring System quality of life tool. The authors concluded that the use of the tripolar SCS in this patient provided relief of abdominal and thoracic spine pain, regulated bowel habits, and improved the patient's quality of life. They believe that the use of SCS should be considered as a treatment option in patients with IBS when all conservative treatments failed. The findings of this case study need to be validated by well-designed randomized, controlled trials.

Hunter et al (2013) stated that chronic pelvic pain (CPP) is complex and often resistant to treatment. While the exact pathophysiology is unknown, the pain states resultant from conditions
such as interstitial cystitis and the like yield patients with a presentation that bears a striking similarity to neuropathic syndromes that are known to respond to neuromodulation. In this study, 5 cases of CPP were presented. All 5 cases were different in presentation (vulvar, rectal, low abdominal pain) and required different “sweet spots” with a broad stimulation field; in 4 of 5 cases, 2 octapolar leads were used. The optimal positioning of the electrode is of major importance to the success of the treatment, but there is limited information available to-date regarding neuromodulation in visceral pain syndromes generally. While there has been past success using the sacral region as a target for SCS to treat these patients, there remains to be a consensus on the optimal location for lead placement. In an editorial that accompanied the afore-mentioned article, Puylaert (2013) noted that SCS is a potential treatment option for refractory visceral pain syndromes. In the era of evidence-based medicine, RCTs should be performed, but as visceral pain syndromes are so different in nature and expression, it is very difficult to select patient groups properly.

The American College of Obstetricians and Gynecologists’ clinical practice guideline on “Chronic pelvic pain” (ACOG, 2008) and the Royal College of Obstetricians and Gynaecologists’ clinical practice guideline on “The initial management of chronic pelvic pain” (RCOG, 2012) did not mention SCS as a management tool. Also, the European Association of Urology’s clinical guideline on “General treatment of chronic pelvic pain” (Engeler et al, 2012) rendered a “C” grade (made despite the absence of directly applicable clinical studies of good quality) of recommendation on the use of neuromodulation for chronic pelvic pain. The guideline noted that the role of neuromodulation is developing with increasing research.

Furthermore, an UpToDate review on “Treatment of chronic pelvic pain in women” (Howard, 2013) states that “In general, neuromodulation for CPP has not been well-studied. Sacral nerve root neuromodulation for bladder related symptoms and pain is the best studied technique, but all trials are observational. A review of published case series suggests a 40 to 60 percent rate of improvement in pelvic pain symptoms after placement of either unilateral or bilateral lead placement. Follow-up has been up to three years in some series”. This review discusses sacral nerve stimulation; but it does not mention the use of SCS as a therapeutic option.

Baranidharan et al (2014) described a retrospective series of 26 patients with visceral neuropathic pain who were treated with neuromodulation. Patients with either dermatomal hyper-algesia or sympathetically mediated neuropathic abdominal pain who had been treated with SCS were assessed. An independent observer conducted a face-to-face interview with each patient to collect data including demography, electrode placement, electrode mapping, and outcomes. There was significant reduction in VAS from a median 9 at baseline to 4 at 26 months (p ≤ 0.05). Reduction in opioid consumption was very significant from a baseline median oral morphine equivalent of 160 mg to 26 mg (p < 0.001). In addition, quality of life, activities of daily living, and patient global impression of change improved. The authors concluded that there is a need to further investigate the use of ventral stimulation for visceral pain syndromes. This would need multi-center trials to collect adequate numbers of patients to allow hypothesis testing to underpin recommendations for future evidence-based therapies.

Clavo et al (2014) noted that relapsed high-grade gliomas (HGGs) have poor prognoses and there is no standard treatment. High-grade gliomas have ischemia/hypoxia associated and, as such, drugs and oxygen have low access, with increased resistance to chemotherapy and radiotherapy. Tumor hypoxia modification can improve outcomes and overall survival in some patients with these tumors. In previous works, these researchers have described that cervical SCS can modify tumor microenvironment in HGG by increasing tumor blood flow, oxygenation, and metabolism. The aim of this preliminary, non-randomized, study was to assess the clinical effect of SCS during brain re-irradiation and chemotherapy deployed for the treatment of recurrent HGG; the hypothesis being that an improvement in oxygenated blood supply would facilitate enhanced delivery of the scheduled therapy. A total of 7 patients had SCS applied during the scheduled re-irradiation and chemotherapy for the treatment of recurrent HGG (6 anaplastic gliomas and 1 glioblastoma). Median dose of previous irradiation was 60 Gy (range of 56 to 72 Gy) and median dose of re-irradiation was 46 Gy (range of 40 to 46 Gy). Primary end-point of the study was overall survival (OS) following confirmation of HGG relapse. From the time of diagnosis of last tumor relapse
before re-irradiation, median OS was 39 months (95% confidence intervals [CI]: 0 to 93) for the overall study group: 39 months (95% CI: 9 to 69) for those with anaplastic gliomas and 16 months for the patient with glioblastoma. Post-treatment, doses of corticosteroids was significantly decreased (p = 0.026) and performance status significantly improved (p = 0.046). The authors concluded that SCS during re-irradiation and chemotherapy is feasible and well-tolerated. In this study, SCS was associated with clinical improvement and longer survival than previously reported in recurrent anaplastic gliomas. They stated that SCS as adjuvant during chemotherapy and re-irradiation in relapsed HGGs merits further research.

De Agostino et al (2014) stated that high-cervical SCS is a promising neurostimulation method for the control of chronic pain, including chronic cluster headache. The effects of high-cervical SCS in patients with intractable chronic migraine pain are unknown. This study was a retrospective survey of a cohort of 17 consecutive patients with medically intractable chronic migraine pain implanted with a high-cervical SCS device between 2007 and 2011. After a median of 15 months (range of 2 to 48) since implantation, mean pain intensity was significantly reduced by 60% (p < 0.0001), with 71% of the patients experiencing a decrease of 50% or more. The median number of days with migraine decreased from 28 (range of 12 to 28) to 9.0 (range of 0 to 28) days (p = 0.0313). Quality of life was significantly improved (p = 0.0006), and the proportion of patients not requiring pain medication increased from 0.0% to 37.5% (p = 0.0313). Use of pharmacological and non-pharmacological treatments of migraine was decreased. Working capacity was not significantly improved. Complications were infrequent: 3 infections (13.0% of all implanted) and 3 lead dislocations (17.6% of all included). The authors concluded that in patients with intractable chronic migraine treated with high-cervical SCS, pain and quality of life significantly improved, warranting further research.

Sidiropoulos et al (2014) reported on the clinical effectiveness of epidural thoracic SCS on gait and balance in a 39-year old man with genetically confirmed spinocerebellar ataxia 7. A RESUME Medtronic electrode was placed at the epidural T-11 level. Spatiotemporal gait assessment using an electronic walkway and static posturography were obtained and analyzed in a blinded manner with and without stimulation. The Tinetti Mobility Test was also performed in the 2 conditions. At 11 months after surgery, there was a 3-point improvement in the Tinetti Mobility Test in the on stimulation condition, although there was no statistically significant difference in spatiotemporal gait parameters. Static posturography did not demonstrate a significant improvement in stability measures between the 2 conditions in a stochastic way. The authors concluded that thoracic epidural SCS had a mild but clinically meaningful beneficial effect in improving gait and balance in a patient with SCA-7. They stated that the underlying pathophysiologic mechanisms remain to be elucidated; further experience with SCS in refractory gait disorders is needed.

Walega and Rosenow (2014) observed the effect of thoracic SCS with dual octi-polar epidural electrodes on episodes of ventricular tachycardia (VT) and ventricular fibrillation (VF) in a patient with non-ischemic familial cardiomyopathy and severe electrical storm refractory to conventional medical treatment. Following implantation of temporary bilateral octi-polar thoracic epidural electrodes and constant low-grade stimulation, episodes of VT and VF were eradicated, and a permanent system was surgically implanted uneventfully. Electrical storm ceased thereafter, though ventricular function from progressive cardiomyopathy worsened, requiring heart transplantation several months later. The authors concluded that SCS may play an important therapeutic role in the treatment of refractory electrical storm when conventional medical treatments have failed. The mechanism by which stimulation of the spinal cord confers a therapeutic effect is not completely understood, although direct modulation of sympathetic and parasympathetic tone in the cardiac conduction system is most likely, based on animal models of ischemia-induced VT.

Obuchi et al (2014) stated that although sleep disorder is one of the most serious co-morbidities of refractory chronic pain, it is usually assessed only from the patients’ subjective point of view. These investigators evaluated the sleep efficiency of patients with chronic pain. Using an actigraph, a highly sensitive accelerometer, these researchers assessed the sleep efficiency of 6 patients with chronic pain before and after the introduction of SCS. While pain improved in only 5 out of 6 patients after SCS, sleep efficiency improved in all cases. Interestingly, in 1 case, sleep
efficiency improved even though pain intensity remained unchanged. The authors concluded that with the use of an actigraph, improvements in sleep of patients with chronic pain undergoing SCS were demonstrated. One case showing improvement in sleep despite pain palliation may suggest that SCS might have independently affected the sleep system, although further studies are needed.

Appendix

DCS for intractable angina pectoris is contraindicated in any of the following conditions:

- Myocardial infarction or unstable angina in the previous 3 months, or
- Significant valve abnormalities as demonstrated by echocardiography, or
- Somatic disorders of the spine leading to insurmountable technical problems in treatment with DCS.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

- 63650 Percutaneous implantation of neurostimulator electrode array, epidural
- 63655 Laminectomy for implantation of neurostimulator electrodes, 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

Other CPT codes related to the CPB:

- 95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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 (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971 simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972 complex spinal cord, or peripheral (i.e, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse
generator/transmitter, with intraoperative or subsequent programming, up to 1 hour

+ 95973 complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (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 covered if selection criteria are met:**

A4290 Sacral nerve stimulation test lead, each
C1767 Generator, neurostimulator (implantable), nonrechargeable
C1778 Lead, neurostimulator (implantable)
C1816 Receiver and/or transmitter, neurostimulator (implantable)
C1820 Generator, neurostimulator [implantable], with rechargeable battery and charging system
C1883 Adaptor/extension, pacing lead or neurostimulator lead (implantable)
E0745 Neuromuscular stimulator, electronic shock unit
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
L8684 Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
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

**ICD-9 codes covered if selection criteria are met:**

053.10 Herpes zoster with unspecified nervous system complication
053.12 Postherpetic trigeminal neuralgia
053.13 Postherpetic polyneuropathy

053.19 Herpes zoster with other nervous system complications

322.0 - 322.9 Meningitis, unspecified [lumbar arachnoiditis]

337.20 - 337.29 Reflex sympathetic dystrophy [complex regional pain syndrome] [see criteria]

353.6 Phantom limb (syndrome)

353.8 Other nerve root and plexus disorders [intercostal neuralgia]

354.0 - 356.9 Mononeuritis of upper and lower limb; hereditary and idiopathic peripheral neuropathy

413.0 - 413.9 Angina pectoris [intractable angina in members who are not surgical candidates and whose pain is unresponsive to all standard therapies - see additional criteria]

443.0 - 443.9 Other peripheral vascular disease [with chronic ischemic limb pain] [see criteria]

722.10 - 722.11 Displacement of thoracic or lumbar intervertebral disc without myelopathy

722.2 Displacement of intervertebral disc, site unspecified, without myelopathy

722.30, 722.39 Schmorl's nodes, unspecified and other region

722.39

722.70 Intervertebral disc disorder with myelopathy; unspecified region

722.72 thoracic region

722.73 lumbar region

722.82 Postaminectomy syndrome, thoracic region [failed back surgery syndrome] [see criteria]

722.83 Postaminectomy syndrome, lumbar region [failed back surgery syndrome] [see criteria]

723.4 Brachia neuritis or radiculitis NOS

806.20 - 806.79 Fracture of dorsal (thoracic) and lumbar vertebra, sacrum and coccyx, with spinal cord injury [incomplete spinal cord injury]

839.20 - 839.59 Dislocation of thoracic and lumbar vertebra, sacrum, and coccyx [incomplete spinal cord injury]

952.10 - 952.9 Dorsal, lumbar, sacral, and cauda equina spinal cord injury without evidence of spinal bone injury [incomplete spinal cord injury]

**ICD-9 codes not covered for indications listed in the CPB:**

140.0 - 209.79 Malignant neoplasm

230.0 - 234.9 Carcinoma in situ

338.21 - 338.29 Chronic pain

350.1 Trigeminal neuralgia
357.2 Polyneuropathy in diabetes
564.1 Irritable bowel syndrome
625.8 - 625.9 Other and unspecified symptoms associated with female genital organs [inguinal pain - female] [chronic pelvic pain]
722.0 Displacement of cervical intervertebral disc without myelopathy
722.71 Intervertebral disc disorder with myelopathy, cervical region
722.81 Postlaminectomy syndrome, cervical region [failed cervical spine surgery syndrome] [see criteria]
723.1 Cervicalgia
723.8 Other syndromes affecting cervical region
723.9 Unspecified musculoskeletal disorders and symptoms referable to neck
724.8 Other symptoms referable to back [spasticity of back muscle]
728.85 Spasm of muscle [spasticity of muscle]
780.01 - 780.09 Alteration of consciousness
781.0 Abnormal involuntary movements [spasticity]
784.0 Headache
789.00 - 789.09 Abdominal pain [inguinal pain - male] [chronic visceral] [chronic pelvic pain]
805.00 - 805.18 Fracture of vertebral column without mention of spinal cord injury, cervical
806.00 - 806.19 Fracture of vertebral column with spinal cord injury, cervical
839.00 - 839.18 Dislocation of cervical vertebra
847.0 Sprain and strain of neck
851.00 - 854.19 Intracranial injury [radiation-induced brain injury]
909.2 Late effect of radiation [radiation-induced brain injury or stroke]
952.00 - 952.09 Spinal cord injury without evidence of spinal bone injury, cervical
953.0 Injury to cervical root
954.0 Injury to cervical sympathetic nerve
959.09 Injury other and unspecified of face and neck
990 Effects of radiation, unspecified [radiation-induced brain injury or stroke]

Other ICD-9 codes related to the CPB:

290.0 - 316 Mental disorders
414.00 - 414.9 Other forms of chronic ischemic heart disease [angiographically documented significant coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA)]
Dorsal Column Stimulation

724.2 Lumbago
724.3 Sciatica
724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified
729.2 Neuralgia, neuritis, and radiculitis [radicular pain]
729.5 Pain in limb [chronic ischemic limb pain] [radiating extremity pain]
780.79 Other malaise and fatigue
785.1 Palpitations
786.09 Other dyspnea and respiratory abnormalities

ICD-9 codes contraindicated for this CPB:

- 300.81 - 300.89 Somatoform disorders
- 394.0 - 397.9 Diseases of mitral valve, aortic valve, mitral and aortic valve, and other endocardial structures
- 410.00 - 412 Myocardial infarction
- 420.0 - 424.99 Acute pericarditis, acute and subacute endocarditis, acute myocarditis, other diseases of pericardium, and other diseases of endocardium

The above policy is based on the following references:

Dorsal Column Stimulator for Chronic Pain


Dorsal Column Stimulator for Angina Pectoris


Cervical Spinal Cord Stimulation

Dorsal Column Stimulator for Other Conditions

9. Howard F. Treatment of chronic pelvic pain in women. UpToDate [serial online], Waltham, MA: UpToDate; reviewed November 2013.