Prior Authorization Review  
Panel MCO Policy Submission

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Type of Submission – Check all that apply:
- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

CPB 194 Spinal Cord Stimulation

This CPB is revised to state that dorsal root ganglion stimulators (e.g., Axium Neurostimulator System) are considered medically necessary for complex regional pain syndrome (CRPS) of the lower extremities, when general medical necessity criteria for spinal cord stimulators are met.

Name of Authorized Individual (Please type or print): Dr. Bernard Lewin, M.D.

Signature of Authorized Individual: [Signature]

www.aetnabetterhealth.com/pennsylvania  
Revised 08/01/2018
Policy

I. Aetna considers a trial of percutaneous dorsal column stimulation medically necessary to predict whether a dorsal column stimulator will induce significant pain relief in members with chronic pain due to any of the following indications when the criteria listed below are met:

A. Failed back surgery syndrome (FBSS) with low back pain and significant radicular pain; or
B. Complex regional pain syndrome (CRPS) (also known as reflex sympathetic dystrophy (RSD)); 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, 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 has undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation (Note: screening must include psychological as well as physical evaluations); and
2. Member does not have any untreated existing drug addiction problems (per American Society of Addiction Medicine (ASAM) guidelines), 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 implantation of a dorsal column stimulator (DCS) medically necessary for members who meet the above-listed criteria who have experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation.

III. Aetna considers the use of cervical dorsal column stimulation for the treatment of members with complex regional pain syndrome medically necessary when criteria in section I are met and the member has experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation.

IV. Aetna considers the use of cervical dorsal column stimulation experimental and investigational for the treatment of members with cervical trauma, disc herniation, failed cervical spine surgery syndrome presenting with arm pain,
neck pain, cervicogenic headache, gliomas, migraine, radiation-induced brain injury, stroke or any other indication (other than CRPS) because its effectiveness for these indications has not been established.

V. 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.

VI. 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), coccydynia, gait disorders including spinocerebellar ataxia, gastroparesis, irritable bowel syndrome, Parkinson's disease, peri-rectal pain, sleep disorders, Sphincter of Odi dysfunction, types of chronic non-malignant non-neuropathic pain not mentioned above, and ventricular fibrillation and ventricular tachycardia.

VII. Aetna considers high-frequency dorsal column stimulators (also known as BurstDR spinal cord stimulators) an equal effective alternative to standard dorsal column stimulators for the medically necessary indications listed above. Replacement of a functioning standard dorsal column stimulator with a high-frequency dorsal column stimulator is considered not medically necessary.

VIII. 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. Note:
Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life.

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

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

XI. Aetna considers up to 16 electrodes/contacts, 2 percutaneous leads, or 1 paddle lead medically necessary for a trial of a dorsal column stimulator. An additional 16 electrodes/contacts, 2 percutaneous leads, or 1 paddle lead are considered medically necessary for implantation of a dorsal column stimulator. Spinal cord stimulation using more than 16 electrodes/contacts or more than 2 percutaneous leads has not been proven more effective than standard spinal cord stimulation using up to 16 electrodes/contacts or 2 percutaneous leads.

XII. 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.

XIII. Aetna considers dorsal root ganglion stimulators (e.g., Axium Neurostimulator System) medically necessary for moderate to severe chronic intractable pain of the lower limbs in persons with complex regional pain syndrome (CRPS) types I and II, when general medical necessity criteria for spinal cord stimulators in Section I are met.
XIV. Aetna considers the concurrent use of 2 dorsal column stimulators for the treatment of complex regional pain syndrome or any other indications experimental and investigational because the effectiveness of this approach has not been established.

**Note:** A change in battery for spinal cord stimulator because of parasthesias is considered not medically necessary.

See CPB 0362 - Spasticity Management also ../300_399/0362.html.

**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.
Examples of DCS include, but may not be limited to, Eon, EonC, Eon Mini, Genesis IPG System, Itrel4, Precision Plus SCS System, Precision Spectra, Prime Advanced Neurostimulator, Protégé, Restore Advanced, Restore Prime, Restore Sensor and Restore Ultra. The Restore Sensor SureScan is an example of the first DCS that is approved by the US Food and Drug Administration (FDA) for use in a magnetic resonance imaging (MRI). The Senza HF-10 DCS is a bit different than the previously mentioned devices, as it utilizes high frequency stimulation, the first device to receive FDA approval to treat chronic pain without creating/causing paresthesia. The use of SCS is specifically contraindicated for individuals with cardiac pacemakers and/or defibrillators.

Spinal cord stimulation requires a surgical procedure, conducted in two phases, to place an electrode into the epidural space of the spinal column. The electrode is then connected to a pulse generator (which contains the battery) that is surgically implanted. An electrical impulse generated by the device travels to the electrodes where it creates a "tingling" sensation (paresthesia) which is thought to alter the perception of pain by the patient.

In the first phase, a local anesthetic is given and an electrode is inserted with the assistance of fluoroscopy to guide the electrodes to the desired level in the spinal column. Over the next two to three days extensive testing with the temporary electrode is performed as an outpatient to measure the effectiveness and determine adequate positioning. If at least a 50% reduction in pain is reported, the patient returns for permanent electrodes and a generator device.

In the second phase, the patient is kept awake, though sedated, during the procedure to help guide electrode placement and ensure that the SCS
provides adequate parasthetic sensation over the affected area. Permanent electrodes are placed; a connector wire is tunneled under the skin and connected to an implantable pulse generator which is inserted into a surgically prepared pocket in the abdomen.

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. Harney 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 multivariate 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$15,395 (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 (interquartile 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).

**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.'"

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 (intra-thecal 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 all types of bias. The authors concluded that current evidence is insufficient to establish the role of SCS in treating refractory cancer-related pain. Moreover, they stated that future randomized studies should focus on the implantation of SCS in patients with cancer-related pain.

Cervical Spinal Cord Stimulation:
Cervical SCS has been used to treat patients with cervical trauma/disc herniation presenting with arm pain, neck pain, and/or cervicogenic headache. However, there is insufficient evidence that cervical SCS is effective for these indications.

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 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 Suijlekom In, 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 (2015) 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 (2015) 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 (2015) 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.

**Limb Ischemia:**

Abu Dabrh et al (2015) reviewed the existing evidence about various non-revascularization-based therapies used to treat patients with severe or critical limb ischemia (CLI) who are not candidates for surgical revascularization. These investigators searched multiple databases through November 2014 for controlled randomized and non-randomized studies comparing the effect of medical therapies (prostaglandin E1 and angiogenic growth factors) and devices (pumps and spinal cord stimulators). They reported odds ratios (ORs) and 95 % CIs of the
outcomes of interest pooling data across studies using the random effects model. These researchers included 19 studies that enrolled 2,779 patients. None of the non-revascularization-based treatments were associated with a significant effect on mortality. Intermittent pneumatic compression (OR, 0.14; 95% CI: 0.04 to 0.55) and spinal cord stimulators (OR, 0.53; 95% CI: 0.36 to 0.79) were associated with reduced risk of amputation. A priori established subgroup analyses (combined versus single therapy; randomized versus non-randomized) were not statistically significant. The authors concluded that very low-quality evidence, mainly due to imprecision and increased risk of bias, suggested that intermittent pneumatic compression and spinal cord stimulators may reduce the risk of amputations; evidence supporting other medical therapies is insufficient.

**Parkinson's Disease:**

dé Andrade et al (2016) stated that axial symptoms are a late-developing phenomenon in the course of Parkinson's disease (PD) and represent a therapeutic challenge given their poor response to levodopa therapy and deep brain stimulation. Spinal cord stimulation may be a new therapeutic approach for the alleviation of levodopa-resistant motor symptoms of PD. These investigators reviewed the effectiveness of SCS for the treatment of motor symptoms of PD and evaluated the technical and pathophysiological mechanisms that may influence the outcome efficacy of SCS. A comprehensive literature search was conducted using electronic databases for the period from January 1966 through April 2014. The methodology utilized in this work followed a review process derived from evidence-based systematic review and meta-analysis of randomized trials described in the PRISMA statement. Reports examining SCS for the treatment of PD are limited. A total of 8 studies with 24 patients were included in
this review. The overall motor score of the Unified Parkinson's Disease Rating Scale in the on/off-stimulation condition remained unchanged in 6 patients and improved in 18 patients after SCS. The authors concluded that SCS appeared to yield positive results for PD symptoms, especially for impairments in gait function and postural stability. However, they stated that the evidence is limited and long-term prospective studies are needed to identify the optimal candidates for SCS and the best parameters of stimulation and to fully characterize the effects of stimulation on motor and non-motor symptoms of PD.

Sphincter of Oddi Dysfunction:

Lee and colleagues (2015) noted that sphincter of Oddi dysfunction (SOD) is a syndrome of chronic biliary pain or recurrent pancreatitis due to the functional obstruction of the pancreaticobiliary flow. These investigators reported a case of spinal cord stimulation (SCS) for chronic abdominal pain due to SOD. The patient had a history of cholecystectomy and had suffered from chronic right upper quadrant abdominal pain. The patient had been diagnosed as having SOD. The patient was treated with opioid analgesics and nerve blocks, including a splanchnic nerve block. However, 2 years later, the pain became intractable. These researchers implanted percutaneous SCS at the T5 to T7 level for this patient. Visual analog scale (VAS) scores for pain and the amount of opioid intake decreased. The patient was tracked for more than 6 months without significant complications. The authors concluded that from this clinical case, SCS is an effective and alternative treatment option for SOD. Moreover, they stated that further studies and long-term follow-up are needed to understand the effectiveness and the limitations of SCS on SOD.
**Coccydynia:**

Hope and Gruber (2012) noted that only 1 case report was found that discussed SCS for treatment of coccygodynia after a coccygeal fracture. The majority of pain that the sacral neuromodulation has previously treated has been chronic pelvic pain that is refractory to other therapies, which often coexists with urinary incontinence or refractory interstitial cystitis. For these 2 indications, it appears that the sacral neuromodulation has a significant improvement in pain. No citations were found that described the use of sacral neuromodulation in terms of coccygeal pain; only SCS has previously been used. The authors concluded that sacral neuromodulation has the potential for treatment of coccygeal pain.

**High-Frequency Spinal Cord Stimulation:**

In a prospective, multi-center, open-label, pilot trial, Tiede et al (2013) examined the feasibility of novel high-frequency spinal cord stimulation therapy in a cohort of patients with chronic predominant back pain during a 4-day, percutaneous trial. A total of 24 patients with back pain greater than leg pain who were candidates for spinal cord stimulation (SCS) were trialed at 5 U.S. centers. Patients completed a percutaneous trial with a commercially available spinal cord stimulator. The implanted leads were then connected to the novel external stimulation device and patients were trialed for an additional 4 days. Outcome measures included pain intensity ratings, subjective descriptions, and patients' preference. There was significant improvement from baseline in overall pain scores (8.68 to 2.03, \[p < 0.001\]) and back pain scores (8.12 to 1.88, \[p < 0.001\]) with the investigational stimulation. The investigational stimulation was preferred to the commercially available systems in 21 of 24 patients (88%). The authors concluded that patients with
predominant back pain reported a substantial reduction in overall pain and back pain when trialed with high-frequency SCS therapy.

In a prospective, multi-center, observational study, Al-Kaisy et al (2014) examined the long-term safety and effectiveness of paresthesia-free high-frequency SCS (HF10 SCS) for the treatment of chronic, intractable pain of the low back and legs. Patients with significant chronic low back pain (LBP) underwent implantation of a spinal cord stimulator capable of HF10 SCS. Patients’ pain ratings, disability, sleep disturbances, opioid use, satisfaction, and adverse events were assessed for 24 months. After a trial period, 88% (72 of 82) of patients reported a significant improvement in pain scores and underwent the permanent implantation of the system; 90% (65 of 72) of patients attended a 24-month follow-up visit. Mean back pain was reduced from 8.4 ± 0.1 at baseline to 3.3 ± 0.3 at 24 months (p < 0.001), and mean leg pain from 5.4 ± 0.4 to 2.3 ± 0.3 (p < 0.001). Concomitantly to the pain relief, there were significant decreases in opioid use, Oswestry Disability Index score, and sleep disturbances. Patients’ satisfaction and recommendation ratings were high. Adverse Events were similar in type and frequency to those observed with traditional SCS systems.

In a randomized, parallel-arm, non-inferiority study, Kapural et al (2015) compared long-term safety and effectiveness of SCS therapies in patients with back and leg pain. A total of 198 subjects with both back and leg pain were randomized in a 1:1 ratio to a treatment group across 10 comprehensive pain treatment centers. Of these, 171 passed a temporary trial and were implanted with an SCS system. Responders (the primary outcome) were defined as having 50% or greater back pain reduction with no stimulation-related neurological deficit. At 3 months, 84.5% of implanted HF10 therapy subjects were
responders for back pain and 83.1 % for leg pain, and 43.8 % of traditional SCS subjects were responders for back pain and 55.5 % for leg pain (p < 0.001 for both back and leg pain comparisons). The relative ratio for responders was 1.9 (95 % confidence interval [CI]: 1.4 to 2.5) for back pain and 1.5 (95 % CI: 1.2 to 1.9) for leg pain. The superiority of HF10 therapy over traditional SCS for leg and back pain was sustained through 12 months (p < 0.001). HF10 therapy subjects did not experience paresthesias. The authors concluded that HF10 therapy promised to substantially impact the management of back and leg pain.

Rapcan et al (2015) presented their clinical experience with HF-SCS for failed back surgery syndrome (FBSS) in patients with predominant LBP. After a trial period, 100 % (21 out of 21) of patients with FBSS with predominant LBP reported a significant improvement in visual analog scale (VAS) pain score and underwent permanent implantation of the HF-SCS system; SCS trials lasted 7 to 14 days (median of 9 days); SCS leads were mostly positioned at the T8 to T10 or T8 to T12 vertebral levels. These researchers used both single and dual lead placement; VAS, patient satisfaction, patient performance status, opioid consumption and complication rate were assessed for the period of 12 months. The mean VAS score before implantation (8.7) compared to VAS 12 months after implantation (4.0) was significantly lower (95 % CI: 3.9 to 5.4, p < 0.001). There was a significant improvement in performance status when comparing PS before implantation (3.0) and 12 months after implantation (1.8) (95 % CI: 0.9 to 1.6, p < 0.001). The mean patient satisfaction scores (PSS) did not differ throughout the whole 1-year follow-up period. The authors concluded that this group of 21 patients with implanted HF-SCS systems reported significant LBP and leg pain relief within the period of 12 months as well as significant improvement in their performance.
status. There was a special subgroup of 5 patients with regular change of frequencies between high frequency and conventional frequency (with paresthesia) also with significant leg and LBP relief.

Russo and Van Buyten (2015) stated that chronic pain remains a serious public health problem worldwide. A SCS therapy called HF10 SCS uses 10-kHz high-frequency stimulation to provide pain relief without paresthesia. These investigators described the therapy, device, and the methods of implant and then reviewed the safety and effectiveness data for this therapy. HF10 SCS uses a charge-balanced stimulation waveform that has been shown to be safe in both animal and human studies. Data from a multi-center, prospective clinical trial showed that the therapy provided substantial back and leg pain relief. Numerous additional reports suggested improved pain relief in other body areas and for complex pain patterns, even for patients who have previously failed other neuromodulation therapies. The authors concluded that the clinical experience reported in this article supported the effectiveness and pain relief provided by HF10 SCS therapy. Clinical studies have also concluded that HF10 SCS did not generate paresthesia nor was it necessary to provide adequate coverage for pain relief. As clinical evidence accumulates and technological innovation improves patient outcomes, neuromodulatory techniques will be sought earlier in the treatment continuum to reduce the suffering for the many with otherwise intractable chronic pain.

**Spinal Cord Stimulators with Extra Contacts/leads:**

Standard spinal cord stimulators use up to 16 contacts/electrodes or up to 2 leads. Nuvestra Medical's Algovita spinal cord stimulator has the capability for up to three leads with a lead portfolio.
of both 8 and 12 contact leads. Stimwave spinal cord stimulator has the ability for physicians to utilize a configuration of up to 64 contacts.

Boston Scientific is currently developing a 4-lead, 32 electrode spinal cord stimulator (the Precision Spectra System) to increase the effectiveness of dorsal column stimulation. In 2013, the manufacturer initiated the LUMINA study to test the hypothesis that the 4-lead, 32 contact Precision Spectrum System can provide effective low back pain relief. Preliminary results of this study have been presented in abstract form (Hayek, et al., 2015), and study results have been published.

In a multi-center, open-label, observational study with an observational arm and retrospective analysis of a matched cohort, Veizi and colleagues (2017) examined if SCS using 3D neural targeting provided sustained overall and LBP relief in a broad routine clinical practice population. After implantable pulse generator (IPG) implantation, programming was carried out using a patient-specific, model-based algorithm to adjust for lead position (3D neural targeting) or previous generation software (traditional). Demographics, medical histories, SCS parameters, pain locations, pain intensities, disabilities, and safety data were collected for all participants. A total of 213 patients using 3D neural targeting were included, with a trial-to-implant ratio of 86%. Patients used 7 different lead configurations, with 62% receiving 24 to 32 contacts, and a broad range of stimulation parameters utilizing a mean of 14.3 (± 6.1) contacts. At 24 months post-implant, pain intensity decreased significantly from baseline (ΔNRS = 4.2, n = 169, p < 0.0001) and even more in in the severe pain subgroup (ΔNRS = 5.3, n = 91, p < 0.0001). Axial LBP also decreased significantly from baseline to 24 months (ΔNRS = 4.1, n = 70, p < 0.0001, on the overall cohort and ΔNRS = 5.6, n = 38, on the severe subgroup).
comparison with 213 patients treated with traditional SCS at the same centers showed overall pain responder rates of 51% (traditional SCS) and 74% (neural targeting SCS) and axial LBP responder rates of 41% and 71% in the traditional SCS and neural targeting SCS cohorts, respectively. Lastly, complications occurred in a total of 33 of the 213 patients, with a 1.6% lead replacement rate and a 1.6% explant rate. The authors concluded that these findings suggested that 3D neural targeting SCS and its associated hardware flexibility provided effective treatment for both chronic leg and chronic axial LBP that was significantly superior to traditional SCS.

The authors noted that this study had several drawbacks: (i) the combination of an observational design with statistical cohort matching is a powerful way of achieving valid comparisons between the 2 treatment groups without compromising the pragmatic generalizability of the study results. However, it is important to recognize that unknown confounding variables may exist and this comparison method in this study did not incorporate prospective randomization, (ii) the measurement of LBP relied only on the axial LBP patients in this study, not patients with both LBP and leg pain. These researchers chose this approach because these patients provided the cleanest signal of LBP improvement, without the confounding matters of additional pain areas. Additionally, axial LBP patients have historically been the most challenging. Consequently, measuring LBP outcomes in these patients is conservative and may mark the minimal expected improvement with this 3D neural targeting for LBP, (iii) the study's inclusion and exclusion criteria were purposefully left almost entirely open, with the exception of age and on-label treatment, in order to best mirror real world clinical practice. While the authors believed that this generalizability is critical to the objective of the study, it did inherently result in patient heterogeneity. In fact, it was
precisely this heterogeneity that these researchers sought to capture, (iv) a limitation of the study was that the outcomes reflect mean improvements, some of which may be different among different patient subgroups and etiologies, and (v) this study did not attempt to differentiate the pain types and the phenotype(s) that is (are) responsive to SCS (nature of chronic pain may be nociceptive, neuropathic, or mixed).

Dorsal Root Ganglion Stimulation:

A technique with a different neural target than dorsal column stimulation is dorsal root ganglion stimulation (Thompson, 2016). Electrodes are placed through the intraspinal epidural space in contact with the sensory dorsal root ganglia. Electrical fields are generated that can selectively stimulate different parts of the dorsal root ganglia. This is intended to allow focusing of stimulation onto specific nerve roots or parts of nerve roots.

In a pilot and feasibility 2-phase study, Weiner et al (2016) tested a miniaturized neurostimulator transforaminally placed at the dorsal root ganglion (DRG) and evaluated the device's safety and effectiveness in treating failed back surgery syndrome (FBSS) low back pain (LBP). A total of 11 subjects with chronic intractable neuropathic trunk and/or lower limbs pain were included. The system consisted of an implantable, miniaturized stimulator, provided by Stimwave Technologies (Freedom-4) and an external transmitter. Only 1 stimulator per subject was implanted unilaterally and transforaminally at L1 to L5 levels. During phase 1 of the study, the stimulators were not anchored. In phase 2, the stimulators were anchored. Subjects were treated during 45 days after which the stimulator was removed. Pain reduction, implant duration, and stimulator migration were registered. Overall pain reduction was 59.9 %, with only 1 device
placed at 1 location, covering only a portion of the painful areas in the majority of the subjects. In phase 1, the non-anchored stimulators migrated a mean of 8.80 mm and in phase 2 a mean of 1.83 mm. Stimulator migration did not correlate with changes in pain relief. Mean time-to-implant duration was 10 minutes and no adverse events were reported during implant, follow-up period, or after explant. The authors concluded that the pain reduction results indicated that the Freedom-4 spinal cord stimulation (SCS) Wireless System is a viable treatment of LBP through stimulation of the DRG, and better overall pain reduction may be achieved by implanting multiple devices. They stated that with short percutaneous implant times and excellent safety profile, this new system may offer health cost savings. This was a small (n = 11) study with short duration (45 days). The findings of this pilot and feasibility study need to be validated by well-designed studies.

A commercially sponsored uncontrolled trial reported on outcomes of DRG stimulation in complex regional pain syndrome (Liem, et al., 2015). Subjects with intractable pain in the back and/or lower limbs were implanted with an active neurostimulator device. Up to four percutaneous leads were placed epidurally near DRGs. Subjects were tracked prospectively for 12 months. The investigators reported that, overall, pain was reduced by 56% at 12 months post-implantation, and 60% of subjects reported greater than 50% improvement in their pain. Pain localized to the back, legs, and feet was reduced by 42%, 62%, and 80%, respectively. Measures of quality of life and mood were also improved over the course of the study, and subjects reported high levels of satisfaction. Importantly, excellent pain-paresthesia overlap was reported, remaining stable through 12 months.
Schu et al (2015) reported on a retrospective study of DRG in patients with groin pain of various etiologies. Data from 29 patients with neuropathic groin pain were reviewed. Patients underwent trial therapy where specifically designed leads were implanted at the target DRGs between T12 and L4. Patients who had a successful trial (> 50% improvement) received the fully implantable neuromodulation system. Pain scores were captured on a visual analog scale (VAS) at baseline and at regular follow-up visits. Twenty-five patients (86.2%) received fully implantable neurostimulators, and the average follow-up period was 27.8 ± 4.3 (standard error of the mean, SEM) weeks. The average pain reduction was 71.4 ± 5.6%, and 82.6% (19/23) of patients experienced a > 50% reduction in their pain at the latest follow-up. Individual cases showed improvement with a variety of etiologies and pain distributions; a subanalysis of post-herniorrhaphy cohort also showed significant improvement.

Eldabe et al (2015) reported on outcomes of DRG in phantom limb pain (PLP). Patients trialed a DRG neurostimulation system for their PLP and were subsequently implanted if results were positive. Retrospective chart review was completed, including pain ratings on a 100-mm visual analogue scale (VAS) and patient-reported outcomes. Across eight patients, the average baseline pain rating was 85.5 mm. At follow-up (mean of 14.4 months), pain was rated at 43.5 mm. Subjective ratings of quality of life and functional capacity improved. Some patients reduced or eliminated pain medications. Patients reported precise concordance of the paresthesia with painful regions, including in their phantom limbs; in one case, stimulation eliminated PLP as well as nonpainful phantom sensations. Three patients experienced a diminution of pain relief, despite good initial outcomes.
van Buyten et al (2015) reported on a prospective case series of DRG in complex regional pain syndrome. Eleven subjects diagnosed with uni- or bilateral lower-extremity CRPS were recruited as part of a larger study involving chronic pain of heterogeneous etiologies. Quadripolar epidural leads of a neurostimulation system were placed near lumbar DRGs using conventional percutaneous techniques. The neurostimulators were trialed; 8 were successful and permanently implanted and programed to achieve optimal pain-paresthesia overlap. The investigators reported that all 8 subjects experienced some degree of pain relief and subjective improvement in function, as measured by multiple metrics. One month after implantation of the neurostimulator, there was significant reduction in average self-reported pain to 62% relative to baseline values. Pain relief persisted through 12 months in most subjects.

Rowland et al (2016) reported the 1st case of successful implantation of a DRG stimulator at L1 and L2 for sustained improvement in chronic pelvic girdle pain. Additional case reports have been published on DRG in upper extremity complex regional pain syndrome (Garg and Danesh, 2015), and in complex regional pain syndrome of the knee (van Bussel, et al, 2015).

Deer and colleagues (2017) stated that animal and human studies indicated that electrical stimulation of DRG neurons may modulate neuropathic pain signals. ACCURATE, a pivotal, prospective, multi-center, randomized-comparative effectiveness trial, was conducted in 152 subjects diagnosed with CRPS or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or DCS. The primary end-point was a composite of safety and effectiveness at 3 months and subjects were assessed through 12 months for long-term outcomes and adverse events (AEs). The pre-defined primary
composite end-point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in VAS from pre-implant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving greater than or equal to 50% pain relief and treatment success was greater in the DRG arm (81.2%) versus the DCS arm (55.7%, p < 0.001) at 3 months. Device-related and serious AEs were not different between the 2 groups; DRG stimulation also demonstrated greater improvements in quality of life and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia (p < 0.001) and reduced extraneous stimulation in non-painful areas (p = 0.014), indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. The authors concluded that as the largest prospective, randomized comparative effectiveness trial to date, the results showed DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS. These encouraging findings need to be validated by well-designed RCTs.

This unblinded study had several drawbacks that may affect the interpretation of the results. The calculated success rate was contingent upon subjects not only achieving 50% pain relief but also continuing in the study (drop-outs were counted as failures). Therefore, the success rate could be influenced by factors associated with the lack of blinded treatments (e.g., spinal cord stimulation (SCS) subjects were less motivated to stay in the trial, uncontrolled differences in health care provider interactions). In addition, subjects were required to maintain a stable regimen of pain medications through 3 months only, and the long-term results after 3 months may be affected by medication changes. The SCS device also had limitations placed on the programming of the device.
so that the comparison between the devices was not confounded by unique SCS device programming features. In particular, the accelerometer function in the SCS device was disabled. If the accelerometer was enabled, the SCS group may have had less postural changes in perceived paresthesia intensity. In addition, the analysis of subjects who did and did not experience paresthesia when stimulation was on was confounded by the fact that the SCS device instruction for use requires the device to be programmed for subjects to receive paresthesia. In addition, the number of subjects who did not have paresthesia was very small, and this end-point was not adequately powered to detect the difference in pain relief for subjects who reported feeling versus not feeling paresthesia.

Maino et al (2017) noted that small fiber neuropathy is a disorder of the peripheral nerves with typical symptoms of burning, sharp, and shooting pain and sensory disturbances in the feet. Pain treatment depends principally on the underlying etiology with concurrent administration of anti-depressants, anti-convulsants, opioids, and topical treatments like capsaicin and local anesthetics. However, treatments for pain relief in these patients frequently fail. These investigators described the first case of intractable painful small fiber neuropathy of the foot successfully treated with SCS of the left L5 DRG. A 74-year old man presented at the authors’ clinic with severe intractable pain, dysesthesia, and allodynia of the left foot caused by idiopathic small fiber neuropathy, confirmed by skin biopsy. His pain score was 8 on a standard 0 to 10 numeric rating scale. As the pain was not satisfactorily controlled by conventional therapy, DRG stimulation was proposed to the
patient and, after informed consent, a specifically
designed percutaneous stimulation lead was placed
over the left L5 DRG and connected to an external
neuro-stimulator. After a positive trial of 10 days, a
permanent neuro-stimulator was implanted. Twenty
months post-implantation the patient continued to
experience stimulation-induced paresthesia covering
the entire pain area and reported a pain rating of 4.
The authors concluded that results from the case
report demonstrated that the DRG is a promising
neural stimulation target to treat neuropathic pain
due to intractable small fiber neuropathy. Moreover,
they stated that prospective controlled studies are
needed to confirm the effectiveness of this treatment
as an option for the afore-mentioned condition.

Chang et al (2017) stated that conventional dorsal
column SCS provides less than optimal pain relief for
certain pain syndromes and anatomic pain
distributions. Practitioners have sought to treat
these challenging therapeutic areas with stimulation
of alternate intra-spinal targets. These investigators
systematically reviewed the evidence for the value
neuro-modulating specific neuronal targets within
the spinal canal to achieve relief of chronic pain.
They performed a systematic literature search using
PubMed for clinical trials published from 1966 to
March 1, 2015 to identify neuro-stimulation studies
that employed non-dorsal column intra-spinal
stimulation to achieve pain relief. Identified studies
on such targeted intra-spinal stimulation were
reviewed and graded using Evidence Based
Interventional Pain Medicine criteria. These
researchers found a total of 13 articles that satisfied
the search criteria on targeted, non-dorsal column
intra-spinal stimulation for pain. They identified 5
studies on neuro-stimulation of the cervico-medullary
junction, 6 studies on neuro-stimulation of the DRG, 2
studies on the neuro-stimulation of the conus
medullaris, unfortunately none was found on intra-
spinal nerve root stimulation. The authors concluded
that clinical use of intra-spinal neuro-stimulation is expanding at a very fast pace. Intra-spinal stimulation of non-dorsal column targets may well be the future of neuro-stimulation as it provides new clinically significant neuro-modulation of specific therapeutic targets that are not well or not easily addressed with conventional dorsal column SCS. In addition, they may avoid undesired stimulation-induced paresthesia, particularly in non-painful areas of the body. The limitations of this review included the relative paucity of well-designed prospective studies on targeted SCS.

Huygen et al (2017) noted that chronic low back pain (LBP) affects millions of people worldwide and can arise through a variety of clinical origins. In the case of failed back surgery syndrome (FBSS), previous surgical procedures can contribute to LBP that is often unresponsive to intervention. Although SCS can be an effective treatment modality, it does not provide sufficient pain relief for some intractable cases. Recently, alternative neuro-modulation options have been developed, including DRG stimulation. These researchers further examined these clinical observations. A total of 12 patients with significant chronic discogenic LBP due to FBSS were included. All subjects were implanted with DRG stimulation systems that had at least 1 lead placed at L2 or L3. Subjects' pain ratings, mood, and QOL was tracked prospectively for up to 12 months. More than 50 % of subjects reported 50 % or better pain relief in the low back, and the average LBP relief was 45.5 % at 12 months. Concomitant reductions in overall pain, leg pain, pain interference, mood, and QOL were also found. The authors concluded that for the studied population, DRG stimulation at the L2 to L3 levels was effective at relieving LBP. These reductions in pain were associated with improvements in QOL. Thus, DRG stimulation at these levels may be effective for LBP by recruiting both segmental and non-segmental neural pathways.
that are not otherwise accessible via traditional SCS. This was a small study (n = 12) with moderate follow-up (up to 12 months). These findings need to be validated by well-designed studies.

Vuka and colleagues (2017) stated that DRG has recently emerged as an attractive target for neuromodulation therapy since primary sensory neurons and their soma in DRGs are important sites for pathophysiologic changes that lead to neuropathic pain. These investigators created evidence synthesis regarding the effects of electrical stimulation of DRG in the context of pain from in-vitro and in-vivo animal models, analyzed methodology and quality of studies in the field. For conducting systematic review the researchers searched 3 data bases: Medline, Embase and Web of Science. The quality of included studies was assessed with the Systematic Review Centre for Laboratory Animal Experimentation risk of bias tool for animal studies. The study was registered in the Collaborative Approach to Meta-Analysis and Review of Animal Data from Experimental Studies data base. They included 6 in-vitro and 8 in-vivo animal studies. All included in-vitro studies combined neurostimulation with substances or drugs and reported an improvement in pain-related parameters due to neurostimulation. Among in-vivo studies, 6 used pulsed radiofrequency, while 2 used electrical field stimulation. All in-vivo studies reported improvement in pain-related behavior following stimulation. Meta-analysis was not possible because of heterogeneity and missing data. The quality of included studies was sub-optimal since all had an unclear risk of bias in multiple domains. The authors concluded that limited data from in-vitro and in-vivo animal studies indicated that electrical stimulation of DRG has a positive therapeutic effect in the context of pain-related outcomes. Moreover, they stated that further studies with a standardized methodological
approach and outcomes will provide useful information about electrical stimulation of DRG in animal models.

Additional well-controlled clinical trials are necessary to assess the effectiveness of DRG in complex regional pain syndrome and in neuropathic pain of other etiologies.

**Medical Necessity of Leads and Electrodes/Contacts:**

For spinal cord stimulation lead placement procedures, Medicare has established medically unlikely edits for both the physician and facility services. Medicare has established a MUE of 2 for "percutaneous implantation of neurostimulator electrode array, epidural" (CPT code 63650), an MUE of 1 for laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural" (CPT code 63655) and an MUE of 1 for "insertion and replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling" (CPT code 63685).

**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-10 Codes
Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural [not covered for dorsal root ganglion stimulation]</td>
</tr>
<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
</tr>
<tr>
<td>63661</td>
<td>Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63662</td>
<td>Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63664</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>63688</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
</tr>
</tbody>
</table>

CPT codes not covered for indications listed in the CPB:

3D neural targeting spinal cord stimulation - no specific code:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95925</td>
<td>Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs [intraoperative]</td>
</tr>
<tr>
<td>95926</td>
<td>in lower limbs [intraoperative]</td>
</tr>
<tr>
<td>95927</td>
<td>in the trunk or head [intraoperative]</td>
</tr>
<tr>
<td>95928</td>
<td>Central motor evoked potential study (transcranial motor stimulation); upper limbs [intraoperative]</td>
</tr>
<tr>
<td>95929</td>
<td>lower limbs [intraoperative]</td>
</tr>
<tr>
<td>95938</td>
<td>Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs [intraoperative]</td>
</tr>
<tr>
<td>95939</td>
<td>Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs [intraoperative]</td>
</tr>
<tr>
<td>+95940</td>
<td>Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure) [MEP and SSEP]</td>
</tr>
<tr>
<td>+95941</td>
<td>Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure) [MEP and SSEP]</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95970</td>
<td>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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
</tr>
<tr>
<td>95971</td>
<td>simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
</tr>
<tr>
<td>95972</td>
<td>complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
</tr>
</tbody>
</table>

HCPCS codes covered if selection criteria are met:

- **A4290** Sacral nerve stimulation test lead, each
- **C1767** Generator, neurostimulator (implantable), nonrechargeable
- **C1778** Lead, neurostimulator (implantable)
- **C1787** Patient programmer, neurostimulator
- **C1816** Receiver and/or transmitter, neurostimulator (implantable)
- **C1820** Generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
- **C1822** Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system


<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>C1883</td>
<td>Adaptor/extension, pacinglead or neurostimulator lead (implantable)</td>
</tr>
<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8684</td>
<td>Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
<tr>
<td>L8695</td>
<td>External recharging system for battery (external) for use with implantable neurostimulator, replacement only</td>
</tr>
</tbody>
</table>

HCPCS codes not covered for indications listed in the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0453</td>
<td>Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure) [MEP and SSEP]</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B02.21 - B02.29</td>
<td>Zoster [herpes zoster] with other nervous system involvement</td>
</tr>
<tr>
<td>G03.9</td>
<td>Meningitis, unspecified [lumbar arachnoiditis]</td>
</tr>
<tr>
<td>G54.6 - G54.7</td>
<td>Phantom limb syndrome</td>
</tr>
<tr>
<td>G90.50 - G90.59</td>
<td>Complex regional pain syndrome I</td>
</tr>
<tr>
<td>I20.0 - I20.9</td>
<td>Angina pectoris [intractable angina in members who are not surgical candidates and whose pain is unresponsive to all standard therapies]</td>
</tr>
<tr>
<td>I73.00 - I73.9</td>
<td>Other peripheral vascular diseases [with chronic ischemic limb pain]</td>
</tr>
<tr>
<td>M96.1</td>
<td>Postlaminectomy syndrome, not elsewhere classified [failed back surgery syndrome]</td>
</tr>
<tr>
<td>S22.000+ - S22.089+</td>
<td>Fracture of thoracic and lumbar vertebra, sacrum and coccyx [must be billed an incomplete spinal cord injury code]</td>
</tr>
<tr>
<td>S23.100+ - S23.171+</td>
<td>Subluxation and dislocation of thoracic and lumbar vertebra, sacrum and coccyx</td>
</tr>
<tr>
<td>S33.100+ - S33.39x+</td>
<td>Incomplete spinal cord lesion</td>
</tr>
<tr>
<td>S34.3xx+</td>
<td>Injury of caudaequina</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:

[http://qawww.aetna.com/cpb/medical/data/100_199/0194_draft.html](http://qawww.aetna.com/cpb/medical/data/100_199/0194_draft.html)
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A52.11</td>
<td>Tabes dorsalis</td>
</tr>
<tr>
<td>C00.0 - C96.9</td>
<td>Malignant neoplasms</td>
</tr>
<tr>
<td>D00.0 - D09.9</td>
<td>Carcinoma in situ</td>
</tr>
<tr>
<td>D43.0 - D43.2</td>
<td>Neoplasm of uncertain behavior of brain</td>
</tr>
<tr>
<td>F10.182, F10.282, F10.982</td>
<td>Alcohol abuse/dependence/use with alcohol-induced sleep disorder</td>
</tr>
<tr>
<td>F51.01 - F51.9</td>
<td>Sleep disorders not due to a substance or known physiological condition</td>
</tr>
<tr>
<td>G11.0 - G11.9</td>
<td>Hereditary ataxia</td>
</tr>
<tr>
<td>G20</td>
<td>Parkinson's disease</td>
</tr>
<tr>
<td>G43.001 - G43.919</td>
<td>Migraine</td>
</tr>
<tr>
<td>G44.1</td>
<td>Vascular headache, not elsewhere classified</td>
</tr>
<tr>
<td>G47.00 - G47.9</td>
<td>Sleep disorders</td>
</tr>
<tr>
<td>G50.0</td>
<td>Trigeminal neuralgia</td>
</tr>
<tr>
<td>G54.8</td>
<td>Other nerve root and plexus disorders</td>
</tr>
<tr>
<td>G56.00 - G58.9</td>
<td>Mononeuropathies of upper and lower limbs</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>G89.21 - G89.4</td>
<td>Chronic pain, not elsewhere classified</td>
</tr>
<tr>
<td>I47.0 - I47.9</td>
<td>Paroxysmal tachycardia</td>
</tr>
<tr>
<td>I49.01</td>
<td>Ventricular fibrillation</td>
</tr>
<tr>
<td>I69.093, I69.193, I69.293, I69.393, I69.893, I69.993</td>
<td>Ataxia following cerebrovascular disease</td>
</tr>
<tr>
<td>K31.84</td>
<td>Gastroparesis</td>
</tr>
<tr>
<td>K58.0 - K58.9</td>
<td>Irritable bowel syndrome</td>
</tr>
<tr>
<td>K62.89</td>
<td>Other specified diseases of anus and rectum [perirectal pain]</td>
</tr>
<tr>
<td>K83.8</td>
<td>Other specified diseases of biliary tract [Sphincter of Oddi dysfunction]</td>
</tr>
<tr>
<td>L59.9</td>
<td>Other disorders of skin and subcutaneous tissue related to radiation [radiation-induced brain injury or stroke]</td>
</tr>
<tr>
<td>M50.00 - M50.93</td>
<td>Cervical disc disorders</td>
</tr>
<tr>
<td>M51.04 - M51.07</td>
<td>Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders with myelopathy</td>
</tr>
<tr>
<td>M51.24 - M51.27, M51.9</td>
<td>Other and unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc displacement</td>
</tr>
<tr>
<td>M53.3</td>
<td>Sacrococcygeal disorders, not elsewhere classified</td>
</tr>
<tr>
<td>M53.82</td>
<td>Other specified dorsopathies, cervical region</td>
</tr>
<tr>
<td>M54.2</td>
<td>Cervicalgia</td>
</tr>
<tr>
<td>M54.11 - M54.13</td>
<td>Radiculopathy [cervical region]</td>
</tr>
<tr>
<td>M62.40 - M62.49</td>
<td>Contracture of muscle [spasticity of muscle]</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>M62.830</td>
<td>Muscle spasm of back</td>
</tr>
<tr>
<td>M96.1</td>
<td>Postlaminectomy syndrome, not elsewhere classified [failed cervical spine surgery syndrome]</td>
</tr>
<tr>
<td>N94.0 - N94.9</td>
<td>Pain and other conditions associated with female genital organs and menstrual cycle [inguinal pain - female] [chronic pelvic pain]</td>
</tr>
<tr>
<td>R10.0 - R10.9</td>
<td>Abdominal and pelvic pain [inguinal pain - male] [chronic visceral] [chronic pelvic pain]</td>
</tr>
<tr>
<td>R25.0 - R25.9</td>
<td>Abnormal involuntary movements [spasticity]</td>
</tr>
<tr>
<td>R26.0 - R27.9</td>
<td>Abnormalities of gait and mobility and other lack of coordination</td>
</tr>
<tr>
<td>R40.0 - R40.4</td>
<td>Somnolence, stupor and coma</td>
</tr>
<tr>
<td>R51</td>
<td>Headache</td>
</tr>
<tr>
<td>S06.0x0+ - S06.9x9+</td>
<td>Intracranial injury [radiation-induced brain injury]</td>
</tr>
<tr>
<td>S10.0xx+ - S10.97x+</td>
<td>Superficial injury of neck</td>
</tr>
<tr>
<td>S12.000+ - S12.691+</td>
<td>Fracture of cervical vertebra and other parts of neck</td>
</tr>
<tr>
<td>S13.100+ - S13.29x+</td>
<td>Subluxation and dislocation of cervical vertebra</td>
</tr>
<tr>
<td>S14.0xx+ - S14.9xx+</td>
<td>Injury of nerves and spinal cord at neck level</td>
</tr>
<tr>
<td>S22.000+ - S22.089+ - S32.000+ - S32.2xx+</td>
<td>Fracture of thoracic and lumbar, sacrum and coccyx</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>S24.101+</td>
<td>Spinal cord injury, incomplete [thoracic, lumbar, sacrum, coccyx and cauda equine]</td>
</tr>
<tr>
<td>S24.109+</td>
<td>[can be billed with/without ICD-10 code for fracture]</td>
</tr>
<tr>
<td>S24.151+</td>
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<tr>
<td>S24.159+</td>
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<tr>
<td>S34.101+</td>
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<td>S34.109+</td>
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<td>S34.121+</td>
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<td>S34.129+</td>
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<td>S34.132+</td>
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<td>S34.139+</td>
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<tr>
<td>T66.xxx+</td>
<td>Radiation sickness, unspecified [radiation-induced brain injury or stroke]</td>
</tr>
</tbody>
</table>

ICD-10 codes contraindicated for this CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F45.0-</td>
<td>Somatoform disorders</td>
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<tr>
<td>F45.9</td>
<td></td>
</tr>
<tr>
<td>I01.0</td>
<td>Diseases of the circulatory system</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

**Dorsal Column Stimulator for Chronic Pain**


13. Midha M, Schmitt JK. Epidural spinal cord stimulation for the control of spasticity in spinal cord injury patients lacks long-term efficacy and


31. Taylor RS, Van Buyten JP, Buchser E. Spinal cord stimulation for complex regional pain syndrome: A systematic review of the clinical and cost-


60. Foye PM. Coccydynia (coccygodynia). UpToDate Inc., Waltham, MA. Last reviewed October 2016.


Dorsal Column Stimulator for Angina Pectoris


3. de Jongste MJL, Staal MJ. Preliminary results of a randomized study on the clinical efficacy of spinal cord stimulation for refractory severe


**Cervical Spinal Cord Stimulation**


Dorsal Column Stimulator for Conditions Other Than Pain

2. Clavo B, Robaina F, Jorge IJ, et al. Spinal cord stimulation as adjuvant during chemotherapy and reirradiation treatment of recurrent high-


High-Frequency Spinal Cord Stimulation


Spinal Cord Stimulators Using More Than 16 Contacts or More Than 2 Percutaneous Leads


Dorsal Root Ganglion Stimulation


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number:
0194 Spinal Cord Stimulation

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania  revised 08/01/2018