**Clinical Review Criteria**

**Spinal Cord Stimulator for Pain**

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### Criteria

**For Medicare Members**

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<td>CMS Coverage Manuals</td>
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<td>National Coverage Determinations (NCD)</td>
<td>Electrical Nerve Stimulators (160.7) Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1)</td>
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**For Non-Medicare Members**

Dorsal column (spinal cord) neurostimulation is the surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space.

A. Kaiser Permanente covers a **short-term** trial of a dorsal column spinal cord stimulator (SCS) as medically necessary for the treatment of chronic, intractable pain secondary to **ONE of the following** indications:
   1. Failed back syndrome (FBS) with intractable neuropathic leg pain **OR**
   2. Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) when **ALL of the following** criteria are met:
      a. Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification)
      b. Surgical intervention is not indicated
      c. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement

B. Kaiser Permanente covers **permanent** implantation of a dorsal column spinal cord stimulator (SCS) as medically necessary for the treatment of chronic, intractable pain secondary to **ONE of the following** indications:
   1. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation (Member experienced significant pain reduction (50 % or more) with a 3- to 7-day trial)
   2. Covered for the **ONE of the following** indications:
      a. Failed back syndrome (FBS) with intractable neuropathic leg pain **OR**
      b. Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) when **ALL of the following** criteria are met:
         o Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, activity lifestyle modification)
         o Surgical intervention is not indicated
         o An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement
controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement

High Cervical Epidural Neurostimulation (Spinal Cord Stimulator) for Migraine/Cluster Headaches
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Spinal cord stimulation (SCS) involves insertion of a stimulator electrode into the spinal cord that is connected to a power source. Patients are routinely screened for their likelihood of being a good SCS candidate by temporary placement of a percutaneous epidural electrode. Patients who respond well during the trial period (generally defined as 50% pain relief) can undergo permanent electrode placement. Both temporary and permanent devices are manufactured by Medtronics, Inc.

The most common application of SCS in the United States is chronic low back pain; SCS has also been used forplexus lesions, peripheral nerve injury, reflex sympathetic dystrophy, post amputation pain syndromes, spinal cord injury, post cordotomy dysesthesia, peripheral vascular disease and angina pectoris (North, 1995).

MTAC has previously reviewed SCS. The initial review of SCS in April 2000 evaluated the use of SCS to treat intractable pain and was not limited to a particular disease or condition. At that time, the evidence consisted of case series and a small RCT with threats to validity on SCS for failed back pain syndrome (North, 1995). The item failed MTAC evaluation criteria. Conclusions about the North RCT in this review were: “Preliminary results of this RCT show that more patients assigned to reoperation choose to crossover to SCS than patients assigned to SCS opt for re-operation. It is not known from this study whether actual pain relief is greater for SCS than re-operation.”

In October 2000, a second review was conducted due to the publication of a RCT on the effect of SCS on functional status and pain in patients with chronic reflex sympathetic dystrophy (Kemler, 2000). Again, SCS failed MTAC evaluation criteria. Conclusions about the Kemler study in the MTAC report were: “In the intention to treat analysis, this new RCT did not find a difference in functional status improvement between the two groups. There was significantly greater improvement in the SCS group in two outcome measures (pain score as measured by a visual-analogue scale, global perceived effect of intervention), but not in health-related quality of life. A substantial proportion of patients experienced complications. The study had several limitations, which include:

• The choice of physical therapy as the comparison intervention. All patients in the study had already failed 6 months of physical therapy. This may have biased the study towards finding improved outcomes with the SCS intervention, which had not yet been attempted with these patients.
• Potential bias towards more positive responses on self-report measures among patients who received the SCS intervention (a new and more intensive intervention, patients were not blinded).
• The difference in scores between groups on the pain measure, although statistically significant, has unclear clinical significance.
• The analysis that compared patients who actually received SCS to those assigned to physical therapy is subject to selection and observation biases. The analysis is biased towards finding a positive outcome in the SCS group since only patients shown to benefit from SCS during the test period were included and the comparison group included patients previously found to receive no sustained benefit from physical therapy.

Due to the above factors, the new evidence is not sufficient to permit conclusions about the effects of spinal cord stimulation on health outcomes for patients with reflex sympathetic dystrophy.”

The current review attempted to identify any recent literature on the use of SCS for intractable pain; the review was not limited to any specific condition.

Medical Technology Assessment Committee (MTAC)
High Cervical Epidural Neurostimulation (Spinal Cord Stimulator) for Migraine/Cluster Headaches
BACKGROUND
Implanted electrical stimulation devices have been used for the management of chronic intractable pain since the late 1960s. One of the most commonly used devices is the spinal cord stimulation (SCS) system. This consists of a lead tipped with 4-16 electrodes and a small implantable device. The latter may be battery operated, or powered by an externally worn power source. Electrical current from the lead generates paraesthesia that can be adjusted in intensity and location to achieve the optimum pain relief (North 2003, 2005, Buchser 2006). Candidates for this therapy include patients with intractable chronic pain of the body and limbs, continued pain after back surgery, reflex sympathetic dystrophy, and complex regional pain syndrome. SCS has been used for decades to treat neurogenic pain. It is now being evaluated for the use in patients with migraines and cluster headaches. Patients with pacemakers, implantable cardioverter defibrillators, untreated drug addicts, and pregnant women are not candidates for the therapy (Arcidicono 2006). It is also contraindicated for patients with chronic anticoagulation, severe distortion or disease of the spinal column, or infection at the insertion site. Patient cooperation is essential for the successful use of SCS therapy. It should not be used by patients who cannot operate the device e.g. those with cognitive, psychiatric, or psychomotor disorders (North 2003, North 2005, and Arcidicono 2006). Spinal cord stimulation was approved by the FDA for the treatment of chronic intractable pain in the trunk and limbs, but it has not been approved for the use in migraines and cluster headaches. This technology has been reviewed previously for the use in back pain, leg pain, refractory angina, and critical leg ischemia.

04/19/2010: MTAC REVIEW
High Cervical Epidural Neurostimulation (Spinal Cord Stimulator) for Migraine/Cluster Headaches

Evidence Conclusion: Currently, there is insufficient evidence to evaluate this technology as the literature only consists of case reports and case series with less than twenty-five participants. Two randomized controlled trials, the Precision Implantable Stimulator for Migraine (PRISM) and the Occipital Nerve Stimulator for the Treatment of Intractable chronic Migraine (ONSTIM), have recently been completed and results are pending.

Articles: Currently, there is insufficient evidence to evaluate this technology as the literature only consists of case reports and case series with less than twenty-five participants. Two randomized controlled trials, the Precision Implantable Stimulator for Migraine (PRISM) and the Occipital Nerve Stimulator for the Treatment of Intractable chronic Migraine (ONSTIM), have recently been completed and results are pending.

The use of High cervical epidural neurostimulation (Spinal Cord Stimulator) for the treatment of migraine/cluster headaches does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Spinal Cord Stimulators in the Treatment of Intractable Pain
04/12/2000: MTAC REVIEW

Evidence Conclusion: There is weak evidence from the case series studies that about half of patients with back or extremity pain who tolerate SCS for a year have a successful outcome one year post-implantation. The Broggi et al. study provides weak evidence that long term success rates (i.e. 5 years) are low. Conclusions about efficacy cannot be drawn from the RCT because of the small sample size, high refusal rate and poor outcome measurement. Complications from SCS are mainly minor, but these often require reoperation. There is insufficient evidence to draw conclusions about the efficacy of SCS for peripheral vascular diseases, peripheral neuropathy, multiple sclerosis and reflex sympathetic dystrophy.

Articles: Articles were selected based on study type; there was one randomized controlled trial (RCT), there were no cohort studies or meta-analyses. The remaining empirical studies were case series. Most addressed one clinical area (predominantly failed back surgery syndrome) and several addressed intractable pain in multiple clinical areas. There was one small case series each on peripheral vascular disease (n=10), reflex sympathetic dystrophy (n=12) and peripheral neuropathy (n=10). Articles on critical limb ischemia, angina pectoris and spinal cord injury were not considered for this review (these conditions were not specified in the MTAC request).

The use of Spinal Cord Stimulators in the treatment of intractable pain does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

10/11/2000: MTAC REVIEW
Spinal Cord Stimulators in the Treatment of Intractable Pain

Evidence Conclusion: In the intention to treat analysis, this new RCT did not find a difference in functional status improvement between the two groups. There was significantly greater improvement in the SCS group in two outcome measures (pain score as measured by a visual-analogue scale, global perceived effect of intervention), but not in health-related quality of life. A substantial proportion of patients experienced complications.

The study had several limitations, which include: The choice of physical therapy as the comparison intervention. All patients in the study had already failed 6 months of physical therapy. This may have biased the study towards finding improved outcomes with the SCS intervention, which had not yet been attempted with these patients. Potential bias towards more positive responses on self-report measures among patients who received the SCS intervention (a new and more intensive intervention, patients were not blinded). The difference in scores between groups on the pain measure, although statistically significant, has unclear clinical significance. The analysis that compared patients who actually received SCS to those assigned to physical therapy is subject to selection and observation biases. The analysis is biased towards finding a positive outcome in the SCS group since only patients shown to benefit from SCS during the test period were included and the comparison group included patients previously found to receive no sustained benefit from physical therapy. Due to the above factors the new evidence is not sufficient to permit conclusions about the effects of spinal cord stimulation on health outcomes for patients with reflex sympathetic dystrophy.

Articles: The search yielded 184 articles. Many of these were reviews or opinion pieces, were on related procedures or evaluated SCS for indications other than pain relief. There were 4 new RCT publications, but none of these was a new study comparing SCS to an alternative intervention. The new articles consisted of an additional publication on the Kemler 2000 data previously reviewed by MTAC, two studies that compared different SCS techniques (two types of electrodes in North, 2002 and two ways to adjust stimulation in North, 2003), and one study that compared two types of drugs given to patients who had SCS implanted (Harke, 2001). No new large case series or cohort studies were identified. There was no new evidence to critically appraise.

The use of Spinal Cord Stimulators in the treatment of intractable pain does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

12/04/2006: MTAC REVIEW
Spinal Cord Stimulators in the Treatment of Intractable Pain

Evidence Conclusion: Spinal cords stimulation (SCS) in complex regional pain syndrome (CRPS) and refractory neuropathic back and leg pain/failed back surgery syndrome (FBSS) Kemler et al, studied the effect of SCS plus physical therapy versus physical therapy alone, in the treatment of 54 patients with resistant chronic reflex sympathetic dystrophy. The trial was randomized and controlled, and the patients were followed up for 24 months. However, the patients and providers were not blinded, and the primary outcomes were mainly self-reported and subject to bias. There was no comparison arm with a sham treatment to exclude the placebo effect and reduce bias. The SCS therapy was compared to physical therapy, which is not the ideal control as the study participants were those who did not have a sustained response to standard treatment including physical therapy. The results of the trial show that patients randomized to receive SCS plus PT (ITT analysis) or those who actually received a permanent SCS implant plus PT had statistically greater improvement in the two self-reported outcome measures (pain score as measured by a visual-analogue scale, global perceived effect of intervention). No statistical difference between two groups in the functional status was observed. There was significant improvement in the QoL among patients who actually received the SCS implant plus PT vs. PT alone. The SCS therapy was associated with side effects among all patients who received it, and 38% needed a reoperation related to the implant. North and colleagues’ (2005) RCT evaluated the use of spinal cord stimulation versus reoperation for the treatment of patients with failed back surgery syndrome (FBSS). The investigators included 50 patients with pain refractory to conservative treatment, with concordant neurological, tension, and/or mechanical signs and imaging findings of neural compression. The follow-up duration was 2 years, and the study outcomes were the frequency of crossover to alternative procedure, pain control and patient satisfaction. The results show that significantly more patients in the SCS group achieved >50% pain relief compared with those who underwent reoperation (37.5% vs. 12%, p< 0.02). They also required significantly less opioid analgesics. The rate of cross over to the other treatment was significantly less among those randomized to spinal cord stimulation. The trial had several exclusion criteria, which may limit generalization of the results. Spinal cord stimulation for the management of refractory angina pectoris: The published studies on the use of SCS for the treatment of refractory angina were all conducted in Europe. In the ESBY trial, 104 patients at high risk for coronary artery bypass surgery were randomized to SCS or CABG. The follow-up duration was 4.8 years, and the primary outcome was the effect of

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treatment on angina. The trial was randomized, controlled, and had clinically important outcomes. However, due to the nature of the intervention it was unblinded, it was relatively small, and may have had insufficient power to detect statistically significant differences between the two intervention groups. No comparison was made to a sham treatment, thus the placebo effect of the SCS cannot be ruled out. The results of the study show that there was a significant improvement in the quality of life in the two treatment groups when compared to baseline. The differences in the observed improvement in quality of life and survival were not significant between the two interventions. The study was not designed as equivalence study, and the absence of significant difference does not necessarily indicate that the two treatments were comparable or equivalent. The SPIRIT trial compared the effects of SCS versus percutaneous myocardial laser revascularization, on treadmill exercise time, among patients with refractory angina pectoris. The trial was randomized and controlled. However, it was unblinded, with an intermediate primary outcome, and short follow-up duration. Its results show that there were no significant differences between the two treatment groups in the exercise tolerance at 3 and 12 months (primary outcome). Also, no significant differences were observed in the 2 or more points improvement on the Canadian Cardiovascular Society angina class, or quality of life. Patients in the SCS group had a significantly higher event rate mainly angina or system related. A placebo effect may contribute to the improvement in anginal symptoms after SCS. The only sham controlled RCT conducted was a very small trial (n=25) that implanted the SCS in all patients but was left it inactivated for 6 weeks in the control group. The study was too small, had only 6 weeks of follow-up, and other limitations. Spinal cord stimulation for the management of critical leg ischemia (CLI)

The published studies on the use of SCS for the treatment of critical leg ischemia were also conducted in European countries. The three meta-analyses published by Ubbink and colleagues (2004, 2005, and 2006) pooled data from 5 RCTs and one non-randomized controlled trial. The sample sizes in these trials varied from 37 to 120 with a total of 444 participants. All suffered from inoperable CLI with ischemic rest pain or ulcers < 3cm in diameter. In these trials, the patients received standard control treatment with or without SCS, and the primary outcome was limb salvage (no amputation of foot or higher within 12 months). The meta-analysis had valid methodology. The trials included were small, but were judged by the authors to have good quality. The results of the analysis indicate that highly selected patients with inoperable critical limb ischemia had better outcomes with the SCS therapy compared to those who were treated conservatively. They experienced significantly less amputation rates in 12 months (NNT to salvage a limb was 9), and showed significant clinical improvement (NNT to improve the condition from critical leg ischemia to claudications =3). The procedure was not associated with a difference in mortality or QoL vs. conservative treatment. Conclusion: There is insufficient evidence to determine the long-term benefits and safety of SCS therapy among patients with refractory neuropathic back and leg pain, failed back surgery, and chronic reflex sympathetic dystrophy. There is insufficient published evidence to determine the long-term efficacy and safety of SCS in treating patients with chronic refractory angina. There is fair evidence from a meta-analysis of small trials that the addition of SCS to the standard conservative therapy for patients with chronic critical leg ischemia may improve the clinical condition of the leg and lead to less amputation rates.

Articles: The search yielded 199 articles. Many were reviews or opinion pieces, or small case series with no control or comparison groups. Spinal cords stimulation (SCS) in complex regional pain syndrome (CRPS) and refractory neuropathic back and leg pain/failed back surgery syndrome (FBSS) The search revealed 2 systematic reviews (Taylor 2004, and Taylor 2006) of studies that used spinal cords stimulation in complex regional pain syndrome (CRPS) and refractory neuropathic back, and leg pain/failed back surgery syndrome (FBSS). It also revealed a RCT on SCS for chronic pain (North 2005), and a more recent publication with a longer-term follow-up for a RCT (Kemler 2000) that was previously reviewed for MTAC in 2000. Several small case series with no comparison or control groups were also identified. The 2 systematic reviews were conducted by the same principal author, and had several limitations. The results of the included RCTs were presented individually without pooling of data, and the results of case series were pooled. The quality of the included case series was poor as judged by the authors; they were heterogeneous, and subject to bias. Due to these as well as other limitations, the meta-analyses were not presented in evidence tables. Evidence tables were constructed for the North et al RCT, and the more recent publication of Kemler and colleagues’ RCT with the 2-year follow-up data. Spinal cord stimulation for the management of refractory angina pectoris: The literature search revealed three RCTs and several case series. One RCT compared SCS with coronary artery bypass grafting (ESBY trial), another compared it with percutaneous myocardial laser revascularization (SPIRIT), and in the third trial (Hautvast 1998) all patients received the SCS implant but the stimulator was inactivated in the control group for the 6 weeks of study. This last trial was not critically appraised due to its small sample size (n=25), short follow-up duration as well as other limitations in the trial. The ESBY and SPIRIT trials were critically appraised. Spinal cord stimulation for the management of critical leg ischemia: The literature search revealed 5 randomized controlled trials, and one non-randomized comparative study on the use of SCS for the treatment of critical leg ischemia. It also revealed three systematic reviews; all conducted by the same principal authors. These analyses pooled the results of the published RCTs. All three were critically appraised and presented in one evidence table. The following articles were critically appraised: Kemler MA, deVet HCW, Barendse GAM, et al. the effect of spinal cord stimulation in...

The use of Spinal Cord Stimulators in the treatment of intractable pain, angina or leg ischemia does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

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**Codes**
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