Regence

NOTE: This policy is not effective until July 1, 2026.

Medical Policy Manual Surgery, Policy No. 45

Spinal Cord and Dorsal Root Ganglion Stimulation

Effective: July 1, 2026

Next Review: April 2027
Last Review: March 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Standard and high-frequency spinal cord stimulation, as well as dorsal root ganglion stimulation, delivers electrical stimulation to the spinal cord using implanted electrodes to block pain sensation. Dorsal root ganglion stimulation is different from spinal cord stimulation in terms of the placement of the electrodes.

MEDICAL POLICY CRITERIA

Notes:

- Please see the Regulatory Status section for a list of standard (non-high frequency), high-frequency, and dorsal root ganglion devices.
- Clinical documentation to support criteria is required (See Required Documentation)

Medically Necessary

I. Short-term trial of spinal cord stimulation (standard or high frequency) may be considered **medically necessary** when <u>one or more</u> of the following Criteria is met:

A. Treatment of chronic intractable pain secondary to failed back surgery syndrome when all of the following are met:

1. There is clinical documentation that a minimum of six months of conservative nonoperative therapy failed to adequately treat the patient's current symptoms (e.g., physical therapy, pharmacotherapy, cognitive behavioral therapy, activity lifestyle modification); and
2. Surgical intervention is contraindicated or the individual does not wish to proceed with spinal surgery; and
3. Attestation from a licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters level counselor, or Psychiatric-Mental Health Nurse Practitioner (PMHNP) demonstrating there are no inadequately controlled mental and/or behavioral health conditions that would impact the perception of pain or negatively impact or contraindicate placement of the device; or

B. Treatment of complex regional pain syndrome or reflex sympathetic dystrophy when all of the following are met:

1. Symptoms are limited to only the upper and lower extremities; and
2. Confirmed diagnosis of complex regional pain syndrome or reflex sympathetic dystrophy including all of the following:
    a. Continuing pain that is disproportionate to any inciting event; and
    b. One or more symptoms in three or more of the following categories:
        i. Sensory (reports of hyperesthesia); or
        ii. Vasomotor (temperature asymmetry, skin color changes, or skin color asymmetry); or
        iii. Sudomotor (edema, sweating changes, or sweating asymmetry); or
        iv. Motor (decreased range of motion, weakness, tremor, dystonia, or trophic changes; and
    c. Physical exam findings demonstrating two or more of the following:
        i. Sensory (evidence of hyperalgesia or allodynia); or
        ii. Vasomotor (evidence of temperature asymmetry, skin color changes, or asymmetry); or
        iii. Sudomotor (evidence of edema, sweating changes, or sweating asymmetry); or
        iv. Motor (evidence of decreased range of motion, weakness, tremor, dystonia, or trophic changes; and
3. No other medical or psychological diagnosis that are concordant with the presenting symptoms are documented; and
4. There is clinical documentation that a minimum of six months of conservative nonoperative therapy failed to adequately treat the patient's current symptoms (e.g., physical therapy, pharmacotherapy, cognitive behavioral therapy, activity lifestyle modification); and

5. Surgical intervention is not indicated; and
6. Attestation from a licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters level counselor, or Psychiatric-Mental Health Nurse Practitioner (PMHNP) demonstrating there are no inadequately controlled mental and/or behavioral health conditions that would impact the perception of pain or negatively impact or contraindicate placement of the device; or

C. Treatment of chronic critical limb ischemia when all of the following are met:
1. Attestation from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction; and
2. Confirmed diagnosis of chronic critical limb ischemia including all of the following:
   a. Ischemic limb rest pain; and
   b. Rutherford Classification Grade II, Category 4 ischemic rest pain characterized by both of the following:
      i. Resting ankle pressure of less than 40mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording; and
      ii. Toe pressure less than 30mmHg; and
3. Advanced imaging (angiographic, CT, or MRI) demonstrating multilevel disease with absence of named vessel flowing into the foot; and
4. Attestation from a licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters level counselor, or Psychiatric-Mental Health Nurse Practitioner (PMHNP) demonstrating there are no inadequately controlled mental and/or behavioral health conditions that would impact the perception of pain or negatively impact or contraindicate placement of the device; or

D. Treatment of chronic stable angina pectoris when all of the following are met:
1. Attestation by treating cardiologist confirms coronary artery disease and the individual is not suitable for a revascularization procedure; and
2. Canadian Cardiovascular Society functional class III or IV angina pectoris; and
3. Optimal medical management has failed to adequately improve anginal symptoms including all of the following:
   a. Anti-platelet therapy; and
   b. Statin or other lipid lowering therapy; and
   c. Anti-anginal therapy implemented to pursue a goal heart rate of 60 beats per minute; and
   d. Anti-hypertensive therapy as may be indicated to pursue a goal systolic blood pressure of less than 140mmHg and a goal diastolic blood pressure of less than 90mmHg; and
4. Attestation from a licensed psychologist, psychiatrist, LCSW/LICSW, licensed masters level counselor, or Psychiatric-Mental Health Nurse Practitioner (PMHNP) demonstrating there are no inadequately controlled mental and/or

behavioral health conditions that would impact the perception of pain or negatively impact or contraindicate placement of the device

II. Permanent implantation of a spinal cord stimulator may be considered **medically necessary** when Criterion I is met and there has been at least a 50% reduction in pain during the short-term trial.

III. Revision(s) to an existing spinal cord stimulator may be considered **medically necessary** after the device has been placed.

IV. The replacement of all or part of an existing spinal cord stimulator and/or generator is considered **medically necessary** when the existing spinal cord stimulator and/or generator is malfunctioning, cannot be repaired, and is no longer under warranty.

V. Short-term trial of dorsal root ganglion stimulation may be considered **medically necessary** for severe and chronic refractory pain of the trunk or limbs due to type I or type II complex regional pain syndrome, including reflex sympathetic dystrophy or causalgia, when all of the following Criteria are met:

   A. There is clinical documentation that a minimum of six months of conservative nonoperative therapy failed to adequately treat the patient's current symptoms (e.g., physical therapy, pharmacotherapy, cognitive behavioral therapy, activity lifestyle modification); and

   B. Surgical intervention is contraindicated or the individual does not wish to proceed with surgery; and

   C. Attestation from a behavioral health provider demonstrating there are no inadequately controlled mental and/or behavioral health conditions that would impact the perception of pain or negatively impact or contraindicate placement of the device

VI. Permanent implantation of a dorsal root ganglion stimulator may be considered **medically necessary** when Criterion V. is met and there has been at least a 50% reduction in pain during the short-term trial.

VII. Revision(s) to an existing dorsal root ganglion stimulator may be considered **medically necessary** after the device has been placed.

VIII. The replacement of all or part of an existing dorsal root ganglion stimulator and/or generator is considered **medically necessary** when the existing dorsal root ganglion stimulator and/or generator is malfunctioning, cannot be repaired, and is no longer under warranty.

Not Medically Necessary

IX. Short-term trial of spinal cord stimulation for chronic intractable pain secondary to failed back surgery syndrome, complex regional pain syndrome, reflex sympathetic dystrophy, chronic critical limb ischemia, or chronic stable angina pectoris is considered **not medically necessary** when Criterion I. is not met.

X. Permanent implantation of a spinal cord stimulator for chronic intractable pain secondary to failed back surgery syndrome, complex regional pain syndrome, reflex sympathetic dystrophy, chronic critical limb ischemia, or chronic stable angina pectoris is considered **not medically necessary** when Criterion II. is not met.

XI. Replacement of all or part of an existing spinal cord stimulator and/or generator is considered **not medically necessary** when Criterion IV. is not met.

XII. Short-term trial of dorsal root ganglion stimulation for severe and chronic refractory pain of the trunk or limbs due to type I or type II complex regional pain syndrome, including reflex sympathetic dystrophy or causalgia, is considered **not medically necessary** when Criterion V. is not met.

XIII. Permanent implantation of a dorsal root ganglion stimulator for severe and chronic refractory pain of the trunk or limbs due to type I or type II complex regional pain syndrome, including reflex sympathetic dystrophy or causalgia is considered **not medically necessary** when Criterion VI. is not met.

XIV. Replacement of all or part of an existing dorsal root ganglion stimulator and/or generator is considered **not medically necessary** when Criterion VIII. is not met.

Investigational

XV. Spinal cord stimulation is considered **investigational** for all other indications.

XVI. Dorsal root ganglion stimulation is considered **investigational** for all other indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

REQUIRED DOCUMENTATION

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Current Symptomology
- Documentation of other treatment modalities (pharmacological, psychological, surgical, or physical if applicable) tried and failed or judged to be unsuitable or contraindicated

CROSS REFERENCES

1. Deep Brain Stimulation, Surgery, Policy No. 84
2. Occipital Nerve Stimulation, Surgery, Policy No. 174
3. Implantable Peripheral Nerve Stimulation and Peripheral Subcutaneous Field Stimulation, Surgery, Policy No. 205

BACKGROUND

Spinal cord stimulation (SCS; also called dorsal column stimulation) involves the use of low-level epidural electrical stimulation of the spinal cord dorsal columns. The neurophysiology of pain relief after SCS is uncertain but may be related to either activation of an inhibitory system or to blockage of facilitative circuits. SCS has been used in a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and complex regional pain syndrome (i.e., chronic reflex sympathetic dystrophy). There has also been interest in SCS as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients with refractory chest pain.

SCS devices consist of several components: (1) the lead that delivers the electrical stimulation to the spinal cord; (2) an extension wire that conducts the electrical stimulation from the power source to the lead; and (3) a power source that generates the electrical stimulation. The lead may incorporate from 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns. There are two basic types of power source. One type, the power source (battery), can be surgically implanted. The other, a radiofrequency receiver, is implanted, and the power source is worn externally with an antenna over the receiver. Totally implantable systems are most commonly used.

The patient's pain distribution pattern dictates at what level in the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used; for example, a lead with 8 electrodes may be selected for those with complex pain patterns or bilateral pain. Implantation of the spinal cord stimulator is typically a 2-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio-receiver/transducer are permanently implanted. Successful SCS may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Traditional SCS devices use electrical stimulation with a frequency on the order of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency of electrical stimulation (10,000 Hz) than predicate devices was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The high-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS. In addition, in 2016, FDA approved a clinician programmer "app" that allows an SCS device to provide stimulation in "bursts" rather than at a constant rate. Burst stimulation is proposed to provide pain relief with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of 1 ms.

Another variation on SCS stimulation is the wireless injectable stimulator. These miniaturized neurostimulators are transforaminally placed at the dorsal root ganglion (DRG) and are used to treat pain. DRG are located between spinal nerves and the spinal cord on the posterior root and are believed to play an important role in neuropathic pain perception. Two systems have received approval or clearance from FDA.

REGULATORY STATUS

A large number of neurostimulator devices, some used for spinal cord stimulation (SCS), have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process. Examples of fully implantable SCS devices approved through the PMA process include the Cordis programmable neurostimulator (Cordis Corp., Downers Grove, IL), approved in 1981, the Itrel□ (Medtronic, Minneapolis, MN), approved in 1984, the Genesis and Eon devices (St Jude Medical) in 2001 and the Precision Spinal Cord Stimulator (Advanced Bionics, Switzerland), approved in 2004. FDA product code: LGW.

In May 2015, the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp., Menlo Park, CA), a totally implantable neurostimulator device, was approved by FDA for the following indications: chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome (FBSS), intractable low back pain, and leg pain. This device uses a higher frequency of electrical stimulation (10 kHz) than

standard devices.

Two wireless injectable neurostimulators have been approved or cleared by FDA. In February 2016, FDA approved the Axium Neurostimulator System (Spinal Modulation, Menlo Park, CA) through the PMA process. The device is indicated as an aid the management of moderate-to-severe intractable pain of the lower limbs in adults with complex regional pain syndrome types 1 and II. In August 2016, the Freedom Spinal Cord Stimulator (Stimwave Technologies, Fort Lauderdale, FL) was cleared by FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs.

In October 2016, FDA approved BurstDR stimulation (St Jude Medical, Plano, TX), a clinician programmer application that provides intermittent “burst” stimulation for patients with certain St Jude SCS devices.

EVIDENCE SUMMARY

The principal outcomes for treatment of pain are symptom relief and improved functional level. Relief of pain is a subjective outcome and can be influenced by nonspecific effects, placebo response, the natural history of the disease, and regression to the mean. Therefore, randomized controlled trials (RCTs) are important to control for nonspecific effects and to determine whether any treatment effect provides a significant advantage over the placebo/sham treatment or other treatments. Appropriate comparison groups depend on the condition being treated and may include placebo/sham stimulation, or medical or surgical management.

In the evaluation of the risks for implantable devices, observational studies can provide data on the likelihood of potential complications. The following complications for spinal cord stimulation (SCS) have been reported:[1]

- Lead migration, connection failure, generator failure, and/or lead breakage
- Superficial and deep infection with or without abscess
- Hematoma
- Nerve injury

The following evidence summary focuses on the investigational indications noted in the policy criteria.

CANCER-RELATED PAIN

In 2015, Peng published an update to their 2013 systematic review, to evaluate the effectiveness of SCS for cancer-related pain compared with standard care using conventional analgesic medication.[2, 3] The literature search yielded 430 initial articles; however, just 18 were deemed relevant to include in the review. No RCTs were identified that evaluated the efficacy of SCS in adult patients with cancer-related pain. No new publications were identified, since the four case series[4-7] using a before-after design, with a total of 92 patients, included in the original review. In the absence of randomized controlled studies, the efficacy of SCS for treating cancer-related pain cannot be determined.

CHRONIC REFRACTORY ANGINA

Two populations of patients have been studied: 1) patients who were not considered candidates for a revascularization procedure due to comorbidities or other factors, where SCS

was compared to continued medical management; or 2) patients who would be considered candidates for a revascularization procedure for the purpose of symptom relief only, where SCS was compared to coronary artery bypass grafting. Aggregating results across these different patient populations may yield misleading conclusions about treatment effect or patient selection criteria as these patient populations may not be interchangeable (both sets of patients may not be eligible for both procedures). Therefore, the trials included in this review for each of these distinct patient populations are discussed separately below.[8-13]

Systematic Reviews

In 2016, Pan identified 12 RCTs that evaluated SCS in patients with refractory angina pectoris.[14] Most studies had small sample sizes (ie <50 patients) and together there were a total of 476 patients. Reviewers did not report the control interventions reported in the RCTs. Pooled analyses favored the SCS group in most cases for exercise time after intervention, pain level (VAS score) and angina frequency, but there was not a significant difference between intervention and control groups on physical limitation and angina stability.

A 2015 systematic review by Tsigaridas included nine RCTs evaluating SCS for refractory angina, seven of which compared SCS to low or no stimulation and two of which compared SCS to alternative medical or surgical therapy for angina.[15] Similar to the Taylor et al. review described below, the authors found that most RCTs were small and variable in quality based on assessment with the modified Jadad score. The authors reported: “two of the RCTs were of high quality; two were of low quality and the remaining ones were of intermediate quality.” Most trials which compared SCS to low or no stimulation, found improvements in outcomes with SCS; however, given limitations in the evidence base, the authors concluded that larger multicenter RCTs are needed to assess the efficacy of SCS for angina.

In 2009 Taylor published a systematic review of five randomized controlled trials comparing active SCS with placebo (four studies) or no treatment (one study).[16] The studies included for analysis were judged to be of moderate or poor quality (based on a lack of reported treatment randomization and/or treatment blinding among cited limitations). Follow-up ranged from 48 hours to two-months and study size ranged from 22 to 30 patients. Primary outcomes identified by the review included impact on health-related quality of life, functional class and exercise capacity. Of these outcomes, active treatment was significantly associated with improvement in exercise capacity and health-related quality of life. No other differences between groups were identified. However, these results are limited by the moderate to poor quality of the reviewed studies which, because of their small sample sizes and limited follow-up duration, do not answer questions about the long-term durability of this type of treatment. In addition, the lack of distinction between placebo- and natural history- controlled groups does not allow for isolation of any treatment benefit of SCS over and beyond that conferred by placebo alone.

In 2008, a systematic review of the literature based on the Swedish Council on Technology Assessment in Health Care report on SCS in severe angina pectoris was published.[17] Seven controlled studies (five randomized), two follow-up reports, and a preliminary report, as well as two nonrandomized studies determined to be of medium-to-high quality were included in the review.

- The largest RCT[11-13] included 104 subjects and compared SCS and coronary artery bypass graft (CABG) in patients accepted for CABG and who were considered to have only symptomatic indication (i.e., no prognostic benefit) for CABG, according to the American College of Cardiology/American Heart Association guidelines, to run an

increased risk of surgical complications, and to be unsuitable for percutaneous transluminal coronary angioplasty. Between-group differences on nitrate consumption, anginal attack frequency, and self-estimated treatment effect were not statistically significant at the 6-month follow-up. At the 5-year follow-up, significantly fewer patients in the CABG group were taking long-acting nitrates, and between-group differences on quality of life and mortality were not significant.

- A 2006 report by McNab compared SCS and percutaneous myocardial laser revascularization (PMR) in a study with 68 subjects.[10] Thirty subjects in each group completed a 12-month follow-up, and differences on mean total exercise time and mean time to angina were not significant. Eleven participants in the SCS group and 10 in the PMR group had no angina during exercise.
- The remaining RCTs included in the systematic review included 25 or fewer subjects.

Randomized Controlled Trials

Patient populations had failed back surgery syndrome, diabetic neuropathy, and complex regional pain syndrome. The comparators were primarily conventional medical management, although one RCT compared spinal cord stimulation with reoperation for failed back surgery syndrome, and another compared spinal cord stimulation with physical therapy. All RCTs reported results at 6 months. The most common primary outcome reported was a responder outcome of 50% reduction in pain; Kemler (2000) reported absolute change in visual analog scale pain score.[18] Consistent with clinical practice, RCTs included a trial period of spinal cord stimulation, usually a few days to a week. Patients not reporting improvement in pain during the trial period did not continue receiving spinal cord stimulation during the remainder of follow-up. In most RCTs, these patients were included in the intention-to-treat analyses either as failures to respond or using imputation techniques. All RCTs with the responder primary outcomes reported clinically and statistically significant differences in the primary outcomes at 6 months, favoring spinal cord stimulation (spinal cord stimulation range, 39%-63% vs. comparator range, 5%-12%). Outcomes measuring the reduction in analgesic use were consistently numerically larger for spinal cord stimulation but not statistically significant in all studies. Four of the 5 studies did not report differences in functional, quality of life, or utility outcomes. Device-related complications ranged from 17% to 32%, with the most common being infection and discomfort or pain due to positioning or migration of electrodes or leads. However, two studies reported dural puncture headaches and Slangen (2014) reported a dural puncture headache ending in death.[19] Two studies reported longer-term results for both treatment groups. In each, results continued to favor spinal cord stimulation at 2 years, but for 1 with 5 years of follow-up, results were not statistically significant at 5 years.

In another small pilot RCT, conducted by Eldabe in 2016 to address uncertainties related to recruitment, outcome measures, and care standardization for a larger trial comparing SCS to usual care for refractory angina, enrollment was planned for 45 patients, but the trial failed to meet its enrollment target.[20] Among the 29 patients randomized to SCS (n=15) or usual care (n=14), there were no significant differences in primary or secondary outcomes between groups, but the trial was underpowered.

In 2012 Zipes published the results from a multi-center, single-blind RCT (n=68) which compared high SCS (two-hours of stimulation four times per day) versus sham SCS (one-minute of stimulation once per day) among patients with angina who were not candidates for

revascularization.[21] The study was terminated (at 6 months) due to slow enrollment and per the Data Safety Monitoring Board recommendation that the study be terminated for futility based on an interim data analysis. The 68 subjects who underwent SCS implantation were randomized to either high stimulation (n=32) or low stimulation (control group; n=36). The low-stimulation control was designed so that patients would feel paresthesia, but the effect of stimulation would be subtherapeutic. Major adverse cardiac events (MACE) and rate of angina attacks were the primary outcomes of interest, along with total exercise time and exercise time to onset of angina. At 6 months an intention-to-treat analysis was conducted; data was available only for 58 of the 68 subjects (85%) No differences were found between groups in any of the outcomes, prompting the researchers to conclude the SCS was not more effective than placebo. However, long-term differences between groups are still not known as the study was terminated early. In addition, the small sample size may have been underpowered for assessing clinically meaningful differences.

In 2011 Lanza reported on a small RCT in which 25 patients were randomly assigned to 1 of 3 treatment groups: SCS with standard levels of stimulation (n=10), SCS with low-level stimulation (75% to 80% of the sensory threshold) (n=7), or SCS with very low intensity stimulation (n=8).[22] Thus, patients in groups 2 and 3 were unable to feel sensation during stimulation. After a protocol adjustment at 1 month, patients in the very low intensity group were re-randomized to one of the other groups after which there were 13 patients in the standard stimulation group and 12 patients in the low-level stimulation group. At the 3-month follow-up (2 months after re-randomization), there were statistically significant between-group differences in 1 of 12 outcome variables. There were a median of 22 angina episodes in the standard stimulation group and 10 in the low-level stimulation group (p=0.002), indicating evidence for a significantly higher rate of angina episodes with standard SCS treatment. Non-significant variables included use of nitroglycerin, quality of life (VAS), Canadian Cardiovascular Society angina class, exercise-induced angina, and five sub-scales of the Seattle angina questionnaire. The small sample size and short-term follow-up does not permit conclusions about the long-term safety and effectiveness of SCS in these patients.

Section Summary

Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some studies have reported benefit, most have not. In two of the larger, more recent RCTs that enrolled more than 100 patients reported no benefit on the primary outcomes. Overall, this evidence is mixed and is not sufficient to allow conclusions on whether health outcomes are improved.

CRITICAL LIMB ISCHEMIA

Critical limb ischemia (CLI) is described as pain at rest or the presence of ischemic limb lesions. If the patient is not a suitable candidate for limb revascularization (typically due to insufficient distal run-off), it is estimated that amputation will be required in 60-80% of these patients within a year. Spinal cord stimulation has been investigated in this small subset of patients as a technique to relieve pain and decrease the incidence of amputation.

Systematic Reviews

In 2015, Aub Dabrh conducted a systematic review of non-revascularization-based treatments, including SCS, for patients with critical limb ischemia also included five RCTs.[23] In pooled analysis, the authors found that SCS was associated with reduced risk of amputation (odds

ratio [OR], 0.53; 95% CI, 0.36 to 0.79). However, the reviewers concluded that there was "relatively low quality of the evidence mainly due to imprecision (ie, small sample size and wide CIs) and the risk of bias."

A 2013 update of a systematic review from the Cochrane group on use of SCS in non-reconstructible chronic critical leg ischemia (NR-CCLI) included 10 articles of six studies with a total of 444 patients.[24] None of the studies were blinded due to the nature of the treatment. One of the studies was non-randomized and one included only patients with ischemic ulcers. Treatment groups received SCS along with the same standard nonsurgical treatment as the control groups. At 12, 18 and 24 months follow-up individual studies showed a trend toward a better limb salvage that did not reach statistical significance. However, when results were pooled, a small but significant decrease in amputations was found for the SCS group at 12 months follow-up (pooled risk difference (RD): -0.11, 95% confidence interval: -0.20 to -0.02). The 11% difference in the rate of limb salvage means that 9 patients would need to be treated to prevent one additional amputation (number needed to treat [NNT]: 9, 95% CI: 5 to 50). Upon excluding results from the non-randomized trial from the analysis, the treatment difference for the group treated with SCS was no longer significant (pooled RD: -0.09, 95% confidence interval: -0.19 to 0.01). When results from the study with patients in Fontaine stage IV (the most severe stage of critical limb ischemia) were excluded, the direction of treatment benefit switched (from negative to positive, RD: 0.13, 95% CI 0.02 to 0.23), indicating evidence for increased risk of amputation following treatment with SCS.

Outcomes for pain relief and ulcer healing could not be pooled and the researchers reported mixed findings. Quality of life was unchanged in both control and treatment groups. The overall risk of complications or additional SCS treatment was 17%. Nevertheless, the report concluded that "There is evidence that SCS is better than conservative treatment alone to achieve amputation risk reduction, pain relief and improvement of the clinical situation" in patients with chronic critical leg ischemia. This seemingly incongruous conclusion may be explained by the authors' conclusion that, "The benefits of SCS against the possible harm of relatively mild complications and costs must be considered." A potential conflict of interest was noted for the principal investigator, who was part of the non-randomized study included in the analysis. Published comments by Klomp and Steyerberg strongly criticized the inclusion of this non-randomized trial, along the exclusion of data from a randomized study from the pooled analysis, stating:[25]

The same meta-analysis, performed with a different amputation data input of five randomized studies [instead of 4 RCTs and a non-randomized study], generated a risk difference of -0.07 (95% CI: -0.17 to +0.03) instead of -0.13 (95% CI: -0.22 to -0.04). The main conclusion, that spinal cord stimulation is better than conservative treatment alone in achieving a reduction in amputation risk, is not justified. If SCS is beneficial, the magnitude of the effect is very small.

In 2009, Klomp and colleagues published a meta-analysis of the same five RCTs identified in the 2013 Cochrane review.[26] The authors did not find a statistically significant difference in the rate of amputation in the treatment and control groups. There was a relative risk of amputation of 0.79 and a risk difference of -0.07 (p=0.15). They found insufficient evidence that SCS is more efficacious than best medical treatment alone. They also conducted additional analyses of data from their 1999 RCT to identify factors associated with a better or worse prognosis. They found that patients with ischemic skin lesions had a higher risk of amputation compared to patients with other risk factors. There were no significant interactions between this or any other prognostic factor. The analyses did not identify any subgroup of patients who might

benefit from SCS.

In 2009, Simpson systematic review described above also reviewed studies on SCS for treatment of inoperable critical limb ischemia.[27] Four RCTs met inclusion criteria; comparators were conventional medical management (CMM)[28-31], oral analgesics[32], or prostaglandin E1 injection[33]. The authors concluded that evidence for a treatment difference was found in reduction of analgesics up to six months, but not at 18 months. However, no between-group differences were found in pain relief, limb survival, health-related quality of life, or any other outcomes.

Randomized Controlled Trials

There have been no new randomized trials published since those included in the systematic reviews summarized above.

Conclusion

A number of small RCTs of SCS versus usual care have been completed on patients with critical limb ischemia. In pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation, although one systematic review and meta-analysis did report a significant difference. This evidence is not sufficient to conclude that SCS improves outcomes for patients with critical limb ischemia.

HEART FAILURE

Systematic Reviews

Ashrafpour (2024) conducted a systematic review of four studies with 125 participants with HF who received SCS therapy.[34] Individuals had HF classified within the New York Heart Association (NYHA) range of 2.2 ± 0.4 to 3. The primary endpoints assessed included changes in HF-related symptoms, left ventricular function, VO_2 max, and NT-proBNP levels. All studies confirmed the safety and feasibility of SCS, though clinical outcomes varied. Two studies reported improvements in NYHA classification, Minnesota Living with Heart Failure Questionnaire (MLHFQ) scores, and quality of life (QoL) metrics. However, only one study demonstrated positive effects on left ventricular ejection fraction (LVEF) and VO_2 max. None of the studies observed significant changes in NT-proBNP levels following SCS therapy.

Variability in outcomes may be attributed to methodological differences, particularly in the techniques used to induce stimulation. Further research is necessary to establish a standardized approach for implementing SCS in patients with HF.

Randomized Controlled Trials

In 2016, Zipes reported the results of the DEFEAT-HF trial, a prospective, multicenter, single-blind RCT trial comparing SCS with active stimulation to sham control in patients with New York Heart Association functional class III heart failure with a left ventricular ejection fraction of 35% or less.[35] Sixty-six patients were implanted with an SCS and randomized in a 3:2 manner to SCS ON (n=42) or SCS OFF (sham; n=24). For the study’s primary end point (change in left ventricular end systolic volume index from baseline to six months), there was no significant difference between groups (p=0.30). Other end points related to heart failure hospitalization and heart failure-related QOL scores and symptoms did not differ significantly between groups. After completion of the six month randomization period, all subjects received active SCS

stimulation. From baseline to 12 months of follow-up, there were no significant echocardiographic treatment effects in the overall patient population in echocardiographic parameters (p=0.36). The study was originally powered based on a planned enrollment of 195 implanted patients, but enrollment was stopped early due to enrollment futility. The nonsignificant difference between groups may have been the result of underpowering. However, the absence of any treatment effects or between-group differences are further suggestive of a lack of efficacy of SCS for heart failure.

Findings of a small pilot crossover RCT evaluating SCS for heart failure were published in 2014 by Torre-Amione.[36] Eligibility included symptomatic heart failure despite optimal medical therapy, left ventricular ejection fraction less than 30%, hospitalization or need for intravenous inotropic support in the past year, and inability to walk more than 450 meters on a six-minute walk test. All patients had an implanted heart device. Nine patients underwent SCS implantation. The efficacy of SCS therapy was assessed by changes in patient symptoms, LV function, and BNP level. In all cases, ICD sensing, detection, and therapy delivery were unaffected by SCS. Symptoms were improved in the majority of patients with SCS, while markers of cardiac structure and function were, in aggregate, unchanged. Two patients had minor implant-related events and no reported implant-related HF exacerbations or hospitalizations. These small, preliminary pilot studies were intended to report first-in-human feasibility and safety to support further study. RCTs with large sample sizes and long-term follow-up are needed to draw conclusions on the safety and effectiveness of the therapy for this indication.

Nonrandomized Studies

In 2015 Tse performed a small, nonrandomized, prospective, multicenter pilot trial in male patients with New York Heart Association (NYHA) class III HF, left ventricular ejection fraction (LVEF) 20%-35%, and implanted defibrillator device who were prescribed stable optimal medical therapy.[37] Seventeen patients underwent implantation of a SCS device (cases) and four patients who did not fulfill the study criteria served as nontreated controls. At six-month follow up, no deaths or device-device interactions were reported. Composite score improved by 4.2 ± 1.3 in all cases, and 11 cases (73%) showed improvement in ≥4 of 6 efficacy parameters, including NYHA class ($p = 0.002$); peak maximum oxygen consumption ($p = 0.013$); LVEF ($p<0.001$); and LV end-systolic volume ($p = 0.002$). No improvements were observed in the four controls.

DORSAL ROOT GANGLION STIMULATION

Systematic Review

Campos-Fajardo (2024) published a systematic review of 29 studies which included patients with a range of diagnoses for which DRGS beyond its traditional use in complex regional pain syndrome.[38] Outcomes included improvements in pain control, functional capacity, and quality of life. The authors reported statistically significant reductions in pain at short, middle, and long-term patient visits. Among the 29 articles reviewed, 20 employed the visual analog scale (VAS) to evaluate average baseline pain levels, as well as pain intensity at short-term intervals (1–6 months post-implant) and over longer durations of 12 to 24 months. The average initial pain score was 7.8 out of 10, which decreased to 3.6 out of 10 after one to two years of treatment. This reflects an average pain reduction of 55.6% across the studies.

Device-related infections were the most frequently reported complication, affecting 5.2% of patients. Electrode migration followed closely at 5.0% and was the leading reason for reintervention. Postsurgical pain was noted in 4.8% of cases. Additionally, 3.96% of patients experienced either a lack of effectiveness or worsening of their baseline pain. Equipment damage and electrode fractures were also observed, occurring in 3.75% and 3.33% of patients, respectively.

This systematic review has several limitations. A primary limitation is the variability among the included studies in terms of design, patient populations, and outcome measures. This inconsistency made it unsuitable to conduct a meta-analysis, requiring instead a narrative approach to synthesizing the findings. Additionally, some studies had relatively short follow-up periods, which may not adequately reflect the long-term effectiveness and potential complications of DRGS. To address this gap, future research should incorporate extended follow-up durations.

Stelter (2021) published a systematic review of 28 reports consisting of 354 patients evaluating the evaluating the efficacy of dorsal root ganglion stimulation for non-complex regional pain syndromes.[39] The authors reported that the majority of patients demonstrated at least a 50% mean pain reduction at their last follow-up time following treatment. Additional outcomes assessed including physical function, quality of life, and pain medication use also showed significant improvements.

Deer (2020) published a systematic literature review of three studies of dorsal root ganglion neurostimulation for the treatment of pain.[40] This review concluded that dorsal root ganglion neurostimulation has level II evidence (moderate) for treating chronic focal neuropathic pain and complex regional pain syndrome based on 1 high-quality pivotal RCT (ACCURATE) and 2 lower quality studies.

Huygen (2020) reported a pooled analysis of prospective studies of dorsal root ganglion stimulation for the treatment of chronic pain.[41] One RCT was included (ACCURATE) which is described in the following section and 6 prospective, single-arm, observational studies were included. The analysis included 217 patients with a permanent implant at 12-month follow-up. Analysis of pooled data showed an overall weighted mean pain score of 3.4, with 63% of patients reporting ≥50% pain relief. Effectiveness sub-analyses in CRPS-I, causalgia, and back pain resulted in a mean reduction in pain intensity of 4.9, 4.6, and 3.9 points, respectively. The pooled analysis showed a pain score for primary affected region ranging from 1.7 (groin) to 3.0 (buttocks) and responder rates of 80% for foot and groin, 75% for leg, and 70% for back. A substantial improvement in all PROs was observed at 12 months.

Vuka (2019) conducted a systematic review of the use of dorsal root ganglion stimulation for various pain syndromes (for example, complex regional pain syndrome, diabetic and non-diabetic peripheral neuropathy).[42] The literature search, conducted through September 2018, identified 29 studies for inclusion, 1 RCT, (ACCURATE trial; discussed below) and the remaining were case series or case reports. The median sample size was 6 (range 1 to 152). Most of the studies reported positive results with dorsal root ganglion stimulation. No meta-analyses could be conducted.

A systematic review, published in 2013 by Pope, evaluated therapeutics for chronic pain that target the dorsal root ganglion.[43] This review focused on ganglionectomy, and radiofrequency

treatment of the dorsal root ganglion, with discussion of electrical stimulation of the DRG as an emerging therapy. Three studies of electrical DRG stimulation were included in the review, two case reports and one nonrandomized feasibility trial. The Deer feasibility trial (described below) prospectively followed 10 patients with chronic, intractable neuropathic pain, over four weeks.[44] Eight of the nine patients who completed the trial experienced a clinically meaningful (>30%) reduction in pain, as measured using a visual analog scale, with an average pain reduction of 70%. Seven of the nine reduced their utilization of pain medication. There were no adverse events reported. The two case studies included in the review described successful treatment of cervicogenic headache, post-herpetic neuralgia, and discogenic pain.

Randomized Controlled Trials

One RCT, the ACCURATE study, compared wireless injectable neurostimulators and standard SCS.[45] The trial, published by Deer in 2016, was a multicenter unblinded noninferiority trial. Eligibility criteria included chronic (≥6 months) intractable (failed ≥2 drugs from different classes) neuropathic pain of the lower limbs associated with a diagnosis of CRPS or causalgia and no previous neurostimulation. Patients were randomized to receive DRG stimulation with the Axium device or standard SCS. They first underwent a temporary trial of stimulation lasting 3 to 30 days, depending on the protocol at each site. Patients who had 50% or greater reduction in lower limb pain after the temporary trial were eligible for permanent stimulation. Those who failed temporary stimulation exited the trial but were included in the analysis as treatment failures. Implanted patients were followed for 12 months, with assessments at 3, 6, 9, and 12 months postimplant.

A total of 152 patients were randomized and 115 (n=61 DRG, n=54 SCS) had a successful temporary trial and continued to permanent implantation. Twelve-month data were available for 105 patients (55 patients in the DRG group, 50 in the SCS group). The primary outcome was a composite measure of treatment success. Success was defined as: (1) 50% or greater reduction in VAS score from baseline to the end of the trial phase; (2) VAS at 3 months that was 50% or greater lower than baseline; and (3) no stimulation-related neurologic deficits experienced during the study. The noninferiority margin was set at 10%; the trial was designed such that, if the noninferiority end point was met, a superiority analysis was also performed. Treatment success at 3 month was achieved by 55 (81.2%) of 69 patients in the DRG arm and 39 (55.7%) of 70 in the SCS arm. The noninferiority margin was met, and DRG was found to be statistically superior to SCS ($p<0.001$). At the 12-month follow-up, the primary end point was achieved by 49 (74.2%) of 66 in the DRG group and 35 (53%) of 66 in the SCS group and, again, DRG was considered noninferior to SCS and also superior ($p<0.001$). In terms of paresthesias, at 3 months and 12, SCS patients were significantly more likely to report paresthesias in nonpainful areas than DRG patients. At 3 months, 84.7% of DRG patients and 65% of SCS patients reported paresthesias only in their painful areas; at 12 months, these percentages were 94.5% and 61.2%, respectively. Twenty-one serious adverse events occurred in 19 patients (8 in the DRG group, 11 in the SCS group; difference between groups, p=NS). A limitation of the study was that it was unblinded and industry-sponsored, which could potentially bias outcome assessment and reporting.

Mekhail (2019) conducted a sub-analysis on the patients receiving DRG neurostimulation in the ACCURATE study, to evaluate the occurrence and risk factors for paresthesia.[46] Among the 61 patients with DRG implants, the rates of paresthesia at 1 month, 3 months, 6 months, 9 months, and 12 months were 84%, 84%, 66%, 62%, and 62%, respectively. The patients who were parasthesia-free reported similar or better outcomes for pain and quality of life. Risk

factors for parasthesia occurrence included higher stimulation amplitudes and frequencies, number of implanted leads, and younger age.

Nonrandomized Studies

Several case series have been published.[47-49] The largest of them are summarized below. Liem (2015) reported on the outcomes of an industry-sponsored multicenter, prospective trial of DRG stimulation at six months[50] and one year.[47] The trial consisted of a run-in period in which 51 participants received DRG stimulation via leads connected to an external stimulator, followed by surgical placement of a fully-implanted neurostimulator in 32 of the 39 patients that achieved 50% or greater pain relief during the run-in period. More than half of the patients with fully implanted DNG stimulators reported at least 50% relief in pain, as measured by visual analog scale. Average pain ratings were 58% lower than baseline at six months and 56% lower at 12 months post-implantation. Patients also reported improved quality of life and mood by questionnaire (EQ-5D-3L and POMS). Over 12 months, there were 86 adverse events reported in 29 patients, including temporary motor stimulation (12 events), CSF leak (seven events) and infection (seven events). Approximately half of these events were judged by the investigators to be related to the device. Seven subjects had their devices removed and were withdrawn from the study.

A subgroup analysis of the Liem study examined positional effects on paresthesia during DRG stimulation in the 32 patients with implanted neurostimulators.[51] Paresthesia and pain relief achieved with spinal cord stimulation can change as patients change position from upright to prone or supine, causing uncomfortable sensations. This study found no statistically significant difference in paresthesia intensity by body position. In order to truly determine the efficacy and safety of DRG stimulation well designed comparative studies with long-term follow-up must be performed to compare it to standard spinal cord stimulation.

Schu reported on an industry-sponsored multicenter European case series of 29 patients treated with DRG stimulation for chronic neuropathic groin pain.[48] Of the 29 patients who underwent a 30-day trial period, 25 (86.2%) underwent implantation with the Axium DRG device. Final lead placement between T12 and L4 was determined based on patient feedback during paraesthesia mapping. Data analysis was based on the results of 23 patients with a mean follow-up of 27.8 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. Adverse events were not reported. The authors stated that paraesthesia was largely unaffected by positional changes. Limitations of this study include small sample size, lack of comparative data, and potential bias inherent in pain as a subjective outcome measure.

In 2013 Deer conducted an industry-sponsored case series to evaluate the efficacy and safety of the Axium DRG system in ten patients with chronic intractable pain of the trunk and/ or limbs.[44] The study was conducted across four centers for a period of four weeks. The study protocol and lead implantation procedures were similar to those reported by Liem above; however, only results of trial DRGS over a period of three to seven days were reported. On average, there was a 70% reduction in pain following stimulation ($p = 0.0007$). Eight of the nine patients experienced a clinically meaningful (>30%) reduction in pain, and seven of the nine reduced their pain medication utilization. The study did not consider longer term effects with a permanently implanted device. Seventeen adverse events occurred of which 14 were considered to be device-related; none were thought to be serious.

PRACTICE GUIDELINE SUMMARY

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS (ASIPP)[52]

In 2013, the ASIPP updated their evidence-based guidelines for interventional techniques in the management of chronic spinal pain. The guidelines included the statement that there is fair evidence in support of SCS in managing patient with failed back surgery syndrome.

AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION AND THE AMERICAN HEART ASSOCIATION (ACCF/AHA)

Guidelines from the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) published in 2007 with focused updates in 2011[53] and 2012[54]) for the management of patients with unstable angina/non ST-Elevation myocardial infarction state:

> "Transcutaneous electrical nerve stimulation and spinal cord stimulation for continued pain despite the implementation of Class I measures may be considered for patients with syndrome X. (Level of Evidence: B)."[55] However, the level of evidence indicates that the "treatment usefulness/ efficacy [is] less well established" and that this recommendation may be based on a single randomized controlled trial or one or more non-randomized studies.

The 2012 updated joint ACCF/AHA guidelines recommend that SCS may be considered for relief of refractory angina in patients with stable ischemia heart disease (Level of evidence: C, defined as very limited populations evaluated and/or only consensus opinion of experts, cases studies, or standard of care).[56] The guidelines conclude:

> "Studies of spinal cord stimulation suggest that this technique might have some use as a method to relieve angina in patients with symptoms that are refractory to standard medical therapy and revascularization. There is a paucity of data on the mechanisms and long-term risks and benefits of this therapeutic approach, however."

NEUROPATHIC PAIN SPECIAL INTEREST GROUP OF THE INTERNATIONAL ASSOCIATION FOR THE STUDY OF PAIN[57]

In 2013, the Neuropathic Pain Special Interest Group of the International Association for the Study of Pain (NeuPSIG) published consensus recommendations on management of neuropathic pain. The recommendations supporting the use of SCS for failed back surgery syndrome and for complex regional pain syndrome we rated as weak (quality of evidence moderate to low; strength of recommendation weak to inconclusive). The recommendation for SCS for postherpetic neuralgia was also rated as weak (quality of evidence low; strength of recommendation inconclusive).

INTERNATIONAL NEUROMODULATION SOCIETY[58]

The International Neuromodulation Society convened a Neuromodulation Appropriateness Consensus Committee (NACC) to develop best practices for the use of DRG stimulation for the treatment of chronic pain syndromes. The NACC was comprised of experts in anesthesiology, neurosurgery, and pain medicine. The NACC performed a systematic literature search through June 2017 and identified 29 publications providing evidence for the consensus recommendations. The evidence was graded using the modified Pain Physician criteria and the USPSTF criteria. The NACC report gave a strong recommendation that DRG stimulation is recommended for CRPS type I or type II.

AMERICAN SOCIETY OF PAIN AND NEUROSCIENCE

The American Society of Pain and Neuroscience issued a comprehensive guideline in 2021 on the management of cancer-related pain.[59] The guideline found that spinal cord stimulation may be considered for 1) treatment of refractory cancer pain (Level II-3-C evidence: multiple series compared over time, with or without intervention, and surprising results in noncontrolled experience; treatment is neither recommendable nor inadvisable), and 2) on a case-by-case basis for "pain that is related to cancer treatment such as chemotherapy-induced peripheral neuropathy" (level III-C evidence: clinical experiences-based opinions, descriptive studies, clinical observations, or reports of expert committee; treatment is neither recommendable nor inadvisable).

ASPN also published consensus guidelines on interventional therapies for knee pain in 2022.[60] The guidelines state that "Chronic pain that is refractory to acute treatment is managed by progressing to spinal cord stimulator, dorsal root ganglion stimulator, or botulinum toxin (Botox) injection." They also include the statement that "DRG [Dorsal Root Ganglion Stimulation] is a safe and effective treatment option for chronic post-surgical and focal neuropathic pain of the knee (ie, complex regional pain syndrome [CRPS]); Level I, Grade A, Consensus Strong."

Consensus guidelines on interventional therapies for back pain were also published in 2022 and made the following recommendations for SCS: following lumbar surgery (Level I-A, Grade A), treatment of non-surgical low back pain (Level I-C, Grade B), and treatment of lumbar spinal stenosis (Level I-C, Grade C).[61]

SUMMARY

SPINAL CORD STIMULATORS

Medically Necessary

There is enough research to show that spinal cord stimulation (SCS) including high frequency SCS for the treatment of chronic intractable pain secondary to failed back surgery syndrome, complex regional pain syndrome, reflex sympathetic dystrophy, chronic critical limb ischemia, or chronic stable angina pectoris when all other treatment modalities have failed to adequately reduce symptoms may improve health outcomes. In addition, practice guidelines recommend SCS for select patients. Therefore, SCS including temporary and the potential permanent implantation may be considered medically necessary for treatment of chronic refractory pain of the trunk or limbs when policy criteria are met.

In certain situations, a spinal cord stimulator may require revision after it has been placed. In these cases, revision may be medically appropriate to allow for the proper functioning of the device. Therefore, revision(s) to an existing spinal cord stimulator may be considered medically necessary after the device has been placed.

In certain situations, a spinal cord stimulator may no longer be able to perform its basic function due to damage or wear. When a stimulator is out of its warranty period and cannot be repaired adequately to meet the patient’s medical needs, replacement of the device may be medically appropriate. Therefore, replacement of all or part of a spinal cord stimulator may be considered medically necessary when device replacement Criteria are met.

Not Medically Necessary

When a stimulator is in its warranty period or can be repaired or adapted adequately to meet the patient's medical needs, replacement of the device is not medically appropriate. Therefore, replacement of all or part of a spinal cord stimulator is considered not medically necessary when device replacement Criteria are not met.

When criteria are not met, spinal cord stimulation for chronic intractable pain secondary to failed back surgery syndrome, complex regional pain syndrome, reflex sympathetic dystrophy, chronic critical limb ischemia, or chronic stable angina pectoris is not clinically appropriate and is therefore considered not medically necessary.

Investigational

There is not enough research to show that spinal cord stimulation (SCS), including standard or high frequency, in the treatment of conditions other than chronic intractable pain secondary to failed back surgery syndrome, complex regional pain syndrome, reflex sympathetic dystrophy, chronic critical limb ischemia, or chronic stable angina pectoris can improve health outcomes or is more effective than standard of care. Therefore, the use of SCS, including standard or high frequency, is considered investigational for the treatment of all other conditions.

DORSAL ROOT GANGLION STIMULATORS

Medically Necessary

There is enough research to show that dorsal root ganglion (DRG) stimulation for the treatment of severe and chronic refractory pain of the trunk or limbs due to type I or type II complex regional pain syndrome, including reflex sympathetic dystrophy or causalgia, when all other treatment modalities have failed to adequately reduce symptoms may improve health outcomes. In addition, practice guidelines recommend DRG stimulation for select patients. Therefore, DRG stimulation may be considered medically necessary for treatment of severe and chronic refractory pain of the trunk or limbs due to type I or type II complex regional pain syndrome, including reflex sympathetic dystrophy or causalgia when policy criteria are met.

In certain situations, a dorsal root ganglion stimulator may require revision after it has been placed. In these cases, revision may be medically appropriate to allow for the proper functioning of the device. Therefore, revision(s) to an existing spinal cord stimulator may be considered medically necessary after the device has been placed.

In certain situations, a dorsal root ganglion stimulator may no longer be able to perform its basic function due to damage or wear. When a stimulator is out of its warranty period and cannot be repaired adequately to meet the patient's medical needs, replacement of the device may be medically appropriate. Therefore, replacement of all or part of a spinal cord stimulator may be considered medically necessary when device replacement Criteria are met.

Not Medically Necessary

When a stimulator is in its warranty period or can be repaired or adapted adequately to meet the patient's medical needs, replacement of the device is not medically appropriate.

Therefore, replacement of all or part of a dorsal root ganglion stimulator is considered not medically necessary when device replacement Criteria are not met.

When criteria are not met, dorsal root ganglion stimulation for severe and chronic refractory pain of the trunk or limbs due to type I or type II complex regional pain syndrome, including reflex sympathetic dystrophy or causalgia, is not clinically appropriate and is therefore considered not medically necessary.

Investigational

For all other indications, there is not enough research to show that dorsal root ganglion (DRG) stimulation is safer and/or more effective than standard of care when policy criteria are not met. Therefore, the use of dorsal root ganglion stimulation is considered investigational when policy criteria are not met.

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CODES

NOTE: HCPCS code C1823 is NOT the correct code to use for reporting these services. Please refer to the codes listed below for guidance.

Codes	Number	Description
CPT	0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed
	0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator
	0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
	0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection

Codes	Number	Description
		algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters
	63650	Percutaneous implantation of neurostimulator electrode array; epidural
	63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
	63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
	63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
	63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	;with simple spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter, programming by physician or other qualified health care professional
	95972	;with complex spinal cord, or peripheral (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
HCPCS	C1767	Generator, neurostimulator (implantable), nonrechargeable
	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
	C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Date of Origin: *January 1996*