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Medical Policy Manual

Topic: Spinal Cord Stimulation for Treatment of Pain

Date of Origin: January 1996

Section: Surgery

Last Reviewed Date: January 2014

Policy No: 45

Effective Date: April 1, 2014

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

Spinal cord stimulation delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. The neurophysiology of pain relief after spinal cord stimulation is uncertain, but may be related to either activation of an inhibitory system or blockage of facilitatory circuits. Spinal cord stimulation devices consist of several components:

1. The lead which delivers the electrical stimulation to the spinal cord

2. An extension wire which conducts the electrical stimulation from the power source to the lead

3. A power source which generates the electrical stimulation

The lead may incorporate from four to eight electrodes. There are two basic types of power source. In one type the power source (battery) can be surgically implanted. In another 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 eight

electrodes may be more commonly selected for those with complex pain patterns, bilateral pain, or pain extending from the limbs to the trunk. Implantation of the spinal cord stimulator is typically a two-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness, defined as at least 50% reduction in pain, is confirmed, the electrodes and radio-receiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming of the neurostimulators in order to identify the optimal electrode combinations and stimulation channels. Computer controlled programs are often used to assist the physician in studying the numerous programming options when complex systems are used.

Spinal cord stimulation has been used in a variety of chronic refractory pain conditions, including pain associated with cancer, failed back syndromes, arachnoiditis, visceral pain, and chronic reflex sympathetic dystrophy. There has also been interest in spinal cord stimulation as a treatment of chronic refractory angina pectoris and treatment of chronic limb ischemia, primarily in patients who are poor candidates for revascularization. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from stroke or spinal cord injury).

Note: Deep brain stimulation as a treatment of movement disorders (e.g., Parkinson's Disease) is addressed in a separate medical policy (see Cross References below).

MEDICAL POLICY CRITERIA

I. An *initial trial period* of spinal cord stimulation with *temporarily implanted* electrodes may be considered **medically necessary** when all of the following criteria (I. A – E) are met:

A. Presence of severe and chronic refractory pain of the trunk or limbs, *other than* critical limb ischemia

B. The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated.

C. Trunk and limb pain is neuropathic in nature; i.e. resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to the following:

1. Failed back surgery syndrome
2. Complex regional pain syndrome (i.e., reflex sympathetic dystrophy)
3. Arachnoiditis
4. Radiculopathies
5. Phantom limb/stump pain
6. Peripheral neuropathy

D. No serious untreated drug habituation exists.

E. Patient has been carefully screened, evaluated and diagnosed by appropriate consultants

of different specialties, who document agreement with application of these therapies or, at a minimum, do not object to application of these therapies.

II. Following an initial trial period of spinal cord stimulation in patients meeting criteria I. A.-E. above, *permanent implantation* of electrodes for ongoing spinal cord stimulation may be considered **medically necessary** when at least 50% pain relief has been demonstrated during the trial therapy.

III. Spinal cord stimulation is considered **investigational** for all other indications, including but not limited to treatment of the following:

A. Cancer-related pain

B. Central deafferentation pain (related to CNS damage from a stroke or spinal cord injury)

C. Chronic pelvic pain

D. Chronic refractory angina pectoris

E. Critical limb ischemia as a technique to forestall amputation

F. Headache, including but not limited to chronic cluster headaches

G. Nociceptive pain (resulting from irritation, not damage to the nerves)

H. Postherpetic neuralgia

I. Visceral pain

J. Vulvodynia; vulvar vestibulitis

SCIENTIFIC EVIDENCE

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 discussion focuses on the investigational indications noted in III. above.

Cancer-related Pain

In 2013, a Cochrane review by Lihua and colleagues did not identify any RCTs evaluating the efficacy of SCS in adult patients with cancer-related pain.[2] Four case series[3-6] using a before-after design with a total of 92 patients were identified. 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.[7-12]

Spinal Cord Stimulation as an Alternative to Medical Management

Systematic Reviews

- Taylor and colleagues conducted a systematic review of 5 randomized controlled trials comparing active SCS with placebo (4 studies) or no treatment (1 study).[13] 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 2 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.

Randomized Controlled Trials

Two RCTs have been published since the above systematic review:

- Lanza and colleagues reported on a small RCT from Italy where 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).[14] 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 5 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.

- Zipes and colleagues published the results from a multi-center RCT (n=68) which compared high SCS (2 hours of stimulation 4 times per day) versus sham SCS (1 minute of stimulation once per day) among patients with angina who were not candidates for revascularization.[15] The study was terminated (at 6 months) due to slow enrollment. Rate of angina attacks was the primary outcome of interest, along with total exercise time and exercise time to onset of angina. No differences were found between groups in any of these outcomes at 6 months, 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.

Spinal Cord Stimulation as an Alternative to Coronary Artery Bypass Surgery

Systematic Reviews

- Taylor and colleagues also reviewed the use of SCS compared with coronary artery bypass grafting (CABG) in the review detailed above, although only a single study (the ESBY study, detailed below) was identified.[13]

Randomized Controlled Trials

The Electrical Stimulation versus Coronary Bypass (ESBY) study randomized 104 patients with chronic refractory angina to SCS or CABG.[10-12] Patients were included in the study only if the CABG was considered solely as a technique for reducing angina pain. The primary outcomes, measured after six months, were symptom relief and myocardial ischemia (as measured by exercise tests). At six months, both treatments were associated with similar improvement in symptom relief. Among those undergoing CABG, there was greater improvement in various cardiac function measures, such as exercise capacity and less ST segment depression.

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 and Meta-Analyses

- 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 6 studies with a total of 444 patients.[16] 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:[17]

> The same meta-analysis, performed with the, in our view proper amputation data input of 5 randomised studies [instead of 4 RCTs and a non-randomized study], generates 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 5 RCTs identified in the 2013 Cochrane review. .[18] 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.

- Simpson et al. systematic review described above also reviewed studies on SCS for treatment of inoperable critical limb ischemia.[19] Four RCTs met inclusion criteria; comparators were conventional medical management (CMM)[20-23], oral analgesics[24], or prostaglandin E1 injection[25]. The authors concluded that evidence for a treatment difference was found in reduction of analgesics up to 6 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.

Nonrandomized Trials

The remaining evidence is limited to a small number of studies that are difficult to compare due to heterogeneity of participants and outcomes measured, and inconsistent findings. Evidence from case series, observational studies, and retrospective reviews are considered unreliable due to the following:

- Non-random allocation of treatment which may introduce selection or response bias.
- Lack of appropriate comparison groups, which does not permit conclusions on the efficacy of SCS compared to other treatment options.
- Small study populations which limit the ability to rule out the role of chance as an explanation of findings.
- Variable patient baseline characteristics such as severity of conditions and co-morbidities which may bias treatment effect estimates.

Other Conditions

Although the use of SCS for other conditions such as visceral pain has been reported, no randomized controlled trials investigating these indications have been published.

Clinical Practice Guidelines

American Society of Interventional Pain Physicians (ASIPP)[26]

- 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[27] and 2012[28]) 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)."[29] 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).[30] The guidelines conclude that "studies of spinal cord stimulation suggest that this technique might have some use as a method to relieve angina n 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."

Summary

Chronic Neuropathic Trunk and Limb

The available evidence from systematic reviews, randomized controlled trials, numerous nonrandomized studies, and most clinical practice guidelines have found support for the use of spinal cord stimulation (SCS) when all other treatment modalities have failed to adequately reduce symptoms in this patient population for whom there are limited options. Therefore, spinal cord stimulation may be considered medically necessary in specific groups of patients for treatment of chronic refractory pain of the trunk or limbs.

Chronic Refractory Angina

Current evidence on the use of spinal cord stimulation (SCS) in chronic refractory angina consists of discrepant results from small randomized controlled trials; while some studies have reported benefit, the majority have not. Such evidence does not permit conclusions about the safety and effectiveness of SCS on pain related to angina; therefore use of SCS for this indication is considered investigational. Larger randomized comparative trials are needed to establish the relative treatment benefit of SCS over both placebo and standard medical care.

Critical Limb Ischemia

The available evidence on spinal cord stimulation (SCS) for the management of critical limb ischemia is inconsistent. Current systematic reviews of published clinical trial data do not consistently report finding evidence for treatment benefit related to limb survival, pain relief, health-related quality of life, or any other outcomes associated with treatment of critical limb ischemia. Therefore, SCS for the treatment of critical limb ischemia is considered investigational.

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CROSS REFERENCES

Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83

Interferential Current Stimulation, Durable Medical Equipment, Policy No. 83.07

Sympathetic Therapy for the Treatment of Pain, Durable Medical Equipment, Policy No. 83.08

Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. 44

Deep Brain Stimulation, Surgery, Policy No. 84

Occipital Nerve Stimulation, Surgery, Policy No. 174

Peripheral Subcutaneous Field Stimulation, Surgery, Policy No. 188

CODES	NUMBER	DESCRIPTION
CPT	63650	Percutaneous implantation of neurostimulator electrode array; epidural
	63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
	63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
	63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
	63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
	63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
	63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
	63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95971	simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

CODES	NUMBER	DESCRIPTION
	95973	complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
HCPCS	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