APPENDIX to Spinal Cord Stimulation Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Spinal cord stimulation (SCS) devices consist of several components:

- A lead that delivers the electrical stimulation to the spinal cord
- An extension wire that conducts the electrical stimulation from the power source to the lead
- A power source that generates the electrical stimulation

The lead may incorporate four to eight electrodes, with eight electrodes more commonly used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk. There are two basic types of power source. In one type, the power source (battery) can be surgically implanted. In 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 what level in the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used. A lead with eight electrodes may be selected for those with complex pain patterns or bilateral pain. 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 is confirmed (defined as at least 50% reduction in pain), the electrodes and radio-receiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels. Computer-controlled programs are often used to assist the physician in studying the millions of programming options when complex systems are used.

Kemler and colleagues (2000) reported on favorable outcomes of SCS among patients with chronic reflex sympathetic dystrophy who were randomized to the SCS arm, as compared to those treated with physical therapy alone. The favorable outcomes were still present at the two-year follow-up (Kemler et al., 2004).

A multicenter randomized trial compared SCS (plus conventional medical management) with conventional medical management (CMM) alone in 100 patients with failed back surgery syndrome (FBSS) (Kumar et al., 2007). Compared with the CMM group, the SCS group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction ($p <$ or $= 0.05$ for all comparisons).

Another study reported five-year outcomes from a randomized trial of 54 patients with complex regional pain syndrome (CRPS) (Kemler et al., 2008). Twenty-four of the 36 patients assigned to SCS and physical therapy were implanted with a permanent stimulator after successful test stimulation, while 18 patients were assigned to physical therapy alone. Five-year follow-up showed a 2.5 centimeter (cm) change in visual analogue scale (VAS) pain score in the SCS group ($n = 20$), and a 1.0 cm change for the control group ($n = 13$). Pain relief at five years was not significantly different between the groups.

An evidence-based review from the American Society of Pain Physicians found the evidence for SCS in FBSS and CRPS strong for short-term relief and moderate for long-term relief (Boswell et al., 2007). Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paraesthesia coverage, paralysis, nerve injury, and death.

Evidence-based guidelines from the European Federation of Neurological Societies found level B (i.e., at least one prospective matched-group cohort study or randomized controlled trial (RCT) in a representative population) evidence for the effectiveness of SCS in FBSS and CRPS type I (Cruccu et al., 2007). The task force indicated implantable stimulators are typically used when all other treatments have failed, and this context should be taken into account when making recommendations.

The National Institute for Health and Clinical Excellence (NICE) stated in NICE Guidance (2008) SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain (measuring at least 50 millimeter (mm) on a zero to 100 mm (VAS) for at least six months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of an assessment by a specialist team.

Simpson and colleagues (2009) performed a systematic review of the literature to obtain clinical and cost-effectiveness data for SCS in adults with chronic neuropathic or ischemic pain with inadequate response to medical or surgical treatment other than SCS. They identified three RCTs

of SCS for neuropathic pain and eight for ischemic pain. Trials for FBSS suggested SCS was more effective than CMM or reoperation in reducing pain. The authors concluded that the evidence suggested SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I.

A systematic review of RCTs and observational studies of SCS in post-lumbar surgery syndrome was undertaken by Frey et al., (2009). Primary outcome measures were short term (< one year) and long-term (> one year) pain relief, and secondary measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake. The authors cautioned that the paucity and heterogeneity of the literature were limitations of the review. Using United States Preventive Services Task Force quality ratings, the authors found Level II-1 evidence (from well-designed controlled trials without randomization) or II-2 evidence (from well-designed cohort or case-control analytic studies, preferably from more than one center or research group) for clinical use of the treatment on a long term-basis.

Limb Ischemia

Critical limb ischemia 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 runoff), it is estimated that amputation will be required in 60% to 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. Klomp and colleagues (1999) conducted a study that randomized 120 patients with critical limb ischemia not suitable for vascular reconstruction to undergo either best medical care or medical care in addition to SCS. The primary endpoint was limb survival at two years. Amputation-free survival was not improved nor was the risk of major amputation significantly reduced. Both groups also reported similar levels of pain reduction. In both groups, the rates of amputation were highest within the first three months of the study, reflecting the limitations with both treatment options.

A systematic review from the Cochrane group on use in peripheral vascular diseases included six European studies of generally good quality with a total of 444 patients (Ubbink & Vermeulen, 2005). None of the studies were blinded due to the nature of the treatment. At 12 months' follow-up, limb salvage improved by 11% compared with any form of conservative treatment with a number needed to treat of 9. The report concluded there was evidence to favor SCS over standard conservative treatment to improve salvage and clinical situation in patients with critical leg ischemia and the benefits of SCS against the possible harm of relatively mild complications and costs must be considered.

Klomp et al., (2009) analyzed the data from five RCTs describing differential treatment effects in subgroups of patients with critical limb ischemia. A total of 332 patients were included. Primary outcomes measures were mortality and limb survival. Using the largest multicenter RCT (n = 120), the authors determined that patients with ischemic skin lesions had a higher risk of amputation compared to patients with other predefined risk factors. They did not find significant interactions between this or any other prognostic factor in the effect of SCS. A subgroup of patients who might be helped by SCS was not identified.

Refractory Angina

Spinal cord stimulation has been used for treatment of refractory angina in Europe for 20 years and much of the literature on SCS comes from European centers. A systematic review of the literature based on the Swedish Council on Technology Assessment in Health Care report on long-standing pain was revised with an updated literature review and conclusions (Bet al., 2008). Seven controlled studies (five of them randomized), two follow-up reports, and a preliminary report as well as two non-randomized studies determined to be of medium-to-high quality were included in the review. The authors concluded there is strong evidence that SCS gives rise to symptomatic benefits (decrease in anginal attacks) and improved quality of life in patients with severe angina pectoris. They added SCS does not seem to have any negative effects on mortality in these patients (limited scientific evidence).

The British Pain Society 2005 recommendations for clinical practice stated that there is good quality evidence that SCS can be effective for patients with refractory angina pectoris.

The European Society of Cardiology guidelines on management of stable angina pectoris did not include SCS in its list of conclusions and recommendations but stated SCS is a well established method used for the management of refractory angina (Fox et al., 2006). Patients experienced a favorable analgesic effect and positive effects on symptoms when treated with SCS. A significant increase in the average exercise time was demonstrated on treadmill testing. They also pointed out that the available clinical trials were small and long-term effects were unknown.

McNab et al., (2006) compared SCS and percutaneous myocardial revascularization (PMR) in a study with 68 subjects. 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 in the SCS group and ten in the PMR group had no angina during exercise.

A pilot RCT by Eddicks et al., (2007) examined the therapeutic effects of subthreshold SCS in patients with refractory angina in a placebo-controlled study. Twelve patients already receiving SCS were selected. They were then randomized to receive SCS at three different stimulation timing and output parameters or to placebo (low output) for four-week intervals. They concluded that there is strong evidence SCS provides symptomatic benefits and improved quality of life for refractory angina.

Taylor et al., (2009) included seven RCTs in a systematic review of SCS in the treatment of refractory angina. The authors noted trials were small and varied considerably in quality. They concluded that compared to a "no stimulation" control, there was some evidence of improvement in all outcomes following SCS implantation with significant gains observed in pooled exercise capacity and health related quality of life. However, further high quality RCT and cost effectiveness evidence is needed before SCS can be accepted as a routine treatment for refractory angina.

Klomp et al., (2009) (in a systematic review noted previously) also examined the evidence for SCS for the treatment of refractory angina. They concluded the evidence from angina trials suggested SCS was more effective than "no SCS" or an "inactive SCS" for nitrate consumption, frequency of angina attacks, exercise duration and time to angina at short term (six to eight weeks). Spinal cord stimulation was less effective than CABG in reducing consumption of long-

acting nitrates and SCS was less effective than CABG in increasing maximum workload capacity. The authors suggested there may be a need for development of selection criteria for critical limb ischemia and there may be short-term clinical benefits of SCS for refractory angina.

In summary, the available evidence for the use of SCS in the treatment of refractory angina and critical limb ischemia consists of case series and small controlled trials with limited methodology and follow-up. It is not sufficient to conclude SCS improves health outcomes for patients with these conditions. Therefore SCS as a treatment of critical limb ischemia to forestall amputation and as a treatment for refractory angina pectoris is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	63185	Laminectomy with rhizotomy; 1 or 2 segments
	63190	Laminectomy with rhizotomy; more than 2 segments
	63650	Percutaneous implantation of neurostimulator electrode array, epidural
	63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
	63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed

Type	Number	Description
	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
	64555	Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
	64565	Percutaneous implantation of neurostimulator electrodes; neuromuscular
	64573	Incision for implantation of neurostimulator electrodes; cranial nerve
	64575	Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
	64577	Incision for implantation of neurostimulator electrodes; autonomic nerve
	64580	Incision for implantation of neurostimulator electrodes; neuromuscular
	64585	Revision or removal of peripheral neurostimulator electrodes
	64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
	95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

Type	Number	Description
	95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
	95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (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)
HCPC	C1767	Generator, neurostimulator (implantable), nonrechargeable
	C1778	Lead, neurostimulator (implantable)
	C1787	Patient programmer, neurostimulator
	C1816	Receiver and/or transmitter, neurostimulator (implantable)
	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1897	Lead, neurostimulator test kit (implantable)
	L8680	Implantable neurostimulator electrode (with any number of contact points), each

Type	Number	Description
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	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
	L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only
ICD9 Procedure	03.93	Implantation or replacement of spinal neurostimulator lead(s)
	04.92	Implantation or replacement of peripheral neurostimulator lead(s)
	86.94	Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable
	86.95	Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable
	86.96	Insertion or replacement of other neurostimulator pulse generator
	86.97	Insertion or replacement of single array rechargeable neurostimulator pulse generator
	86.98	Insertion or replacement of dual array rechargeable neurostimulator pulse generator
ICD9 Diagnosis	All Diagnoses	

Type	Number	Description
Place of Service	All Places of Service	

Tables

N/A

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Neuromuscular and Functional Electrical Stimulation
- Electrical Stimulation for Pain
- Deep Brain Stimulation
- Sacral Nerve Neuromodulation/Stimulation
- Gastric Electrical Stimulation
- Urinary Incontinence Outpatient Treatment

Key / Related Searchable Words

N/A

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
10/1/2010	BCBSA Medical Policy adoption	Medical Policy Committee
10/29/2010	Coding Update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the policy statement for this policy

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