



Kaiser Permanente Southern California Utilization Management (UM) Criteria for Spinal Cord Stimulators for Management of Chronic Pain-Commercial

Principles

Southern California Permanente Medical Group (SCPMG) provides Spinal Cord Stimulators for the management of chronic pain when medically necessary.

This material reflects the consensus of the SCPMG Regional Pain Management Committee, based on its clinical experience and a review of selected relevant publications. ¹

Brief Description

Spinal cord stimulators (SCS) are self-contained, battery-powered electronic devices that are surgically implanted under the skin. SCS deliver electrical impulses, which decrease the perception of pain. Spinal cord stimulators are intended to treat neuropathic pain. Spinal cord stimulators are not intended to treat nociceptive pain.

SCS systems typically consist of three components: leads, a generator/receiver, and a programmer/transmitter. SCS systems are also referred to as neurostimulators and as implantable pulse generators (IPGs). Different types of SCS systems are available for spinal cord stimulation: low frequency and high frequency, rechargeable and non-rechargeable.

SCS is a specialized device, which stimulates the nervous system by delivering electrical impulses via small electrical leads placed in the epidural space, near the spinal cord. There are two different types of stimulation:

- Spinal Cord Stimulation involves the placement of very small electrodes, called leads, which are placed into the region adjacent to the spinal cord (epidural space) to deliver electrical impulses that decrease the perception of pain.

- Peripheral nerve stimulation works in a similar way. The lead is placed at the site of the peripheral nerve that is causing pain after it exits the spinal cord.

Patients using spinal cord stimulators may eventually require surgery to replace the stimulator's battery. As with all procedures, there is a low risk of infection and post-operative pain. Batteries for most non-rechargeable SCS systems last three to five years, although certain uses of SCS systems shorten the battery life span.

Some uses of SCS systems that place higher demands on the battery are:

- Frequent use
- Programming of more electrodes at a given time, to target pain areas more precisely.
- Increasing the number of pulses per second (frequency), which has been reported to improve stimulation in patients.

1 Summary of Search Strategy

A search of new evidence published between January 1, 2000 and November 31, 2007 was conducted to update evidence previously reviewed by KP CMI for their clinical practice guideline entitled "Chronic Pain Guidelines" last revised 2004. Several Systematic Reviews, Clinical Practice Guidelines and RCTs were found. The references listed below were selected for relevance and usability in summarizing the scientific evidence to date.

Treatment Recommendations:

- The SCS is an option for significant radicular/neuropathic extremity pain, complex regional pain syndrome (CRPS), and peripheral neuropathy (e.g. diabetic neuropathy).
- SCS is an option after more conservative treatments have failed, such as epidural steroid injections.
- A comprehensive multidisciplinary pain team evaluation, including psychological assessment (and patient's or the caregiver's ability to operate the device) is recommended as a prerequisite to determine the appropriate candidates for SCS.
- A trial period (on average around one week) where epidural leads are connected to a temporary external stimulator is recommended prior to permanent implantation of the SCS, in order to determine if the SCS is a treatment option that reduces the patient's pain.
- Encouraging patients to use a variety of pain management strategies following implantation is recommended.

Approving Bodies

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References:

1. Benabid AL, Wallace B, Mitrofanis J, Xia C, Piallat B, Fraix V, Batir A, Krack P, Pollak P, Berger F. Therapeutic electrical stimulation of the central nervous system. *C R Biol.* 2005;328(2):177-86.
2. Bennett DS, Brookoff D. Complex regional pain syndromes (reflex sympathetic dystrophy and causalgia) and spinal cord stimulation. *Pain Med.* 2006;7(Suppl 1):S64-96.
3. Bradley K. The technology: the anatomy of a spinal cord and nerve root stimulator: the lead and the power source. *Pain Med.* 2006;7(Suppl 1):S27-34.
4. Goldenberg PL. History of electrical neuromodulation for chronic pain. *Pain Med.* 2006;7(Suppl 1):S7-S13
5. Harney D, Magner JJ, O'Keeffe D . Complex regional pain syndrome: the case for spinal cord stimulation (a brief review). *Injury.* 2005;36(3):357-62.
6. Hautvast RW, DeJongste MJ, Staal MJ, van Gilst WH, Lie KI. Spinal cord stimulation in chronic intractable angina pectoris: a randomized, controlled efficacy study. *Am Heart J.* 1998 Dec;136(6):1114-20.
7. International Research Foundation for RSD/CRPS. Reflex sympathetic dystrophy/complex regional pain syndrome. 3rd ed. Tampa (FL): International Research Foundation for RSD/CRPS; 2003 Jan 1. 48 p
8. Kaiser Permanente Southern California TAG Unit. Review: Spinal Cord Stimulation for the Treatment of Chronic Pain. May 2006.\
9. Kemler MA, De Vet HC, Barendse GA, Van Den Wildenberg FA, Van Kleef M. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. *Ann Neurol.* 2004 Jan;55(1):13-8.
10. Mailis-Gagnon A, Furlan AD, Sandoval JA, Taylor R. Spinal cord stimulation for chronic pain. *Cochrane Database Syst Rev.* 2004;(3):CD003783.
11. McQuay H J, Moore R A, Eccleston C, Morley S, De C Williams A C. Systematic review of outpatient services for chronic pain control. *Health Technology*

- Assessment. 1997;1(6):1-137. Database of Abstracts of Reviews of Effects 2007 Issue 4
12. Segal R, Stacey BR, Rudy TE, Baser S, Markham J. Spinal cord stimulation revisited. *Neurol Res.* 1998 Jul;20(5):391-6.
 13. Sitzman BT, Gallagher RM. Effectiveness of electrical neuromodulation: an economic paradigm. *Pain Med.* 2006;7(Suppl 1):S185-90.
 14. Taylor RJ, Taylor RS. Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. *Int J Technol Assess Health Care.* 2005;21(3):351-8.
 15. Taylor RS. Spinal cord stimulation in complex regional pain syndrome and refractory neuropathic back and leg pain/failed back surgery syndrome: results of a systematic review and meta-analysis. *J Pain Symptom Manage.* 2006;31(4 Suppl):S13-9.
 16. Turner JA, Loeser JD, Bell KG. Spinal cord stimulation for chronic low back pain: a systematic literature synthesis. *Neurosurgery.* 1995 Dec;37(6):1088-95; discussion 1095-6.
 17. Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischemia. *Cochrane Database Syst Rev.* 2005 Jul 20;(3):CD004001