



NEUROMODULATION THERAPY ACCESS COALITION

POSITION STATEMENT ON SPINAL CORD NEUROSTIMULATION

Introduction:

Spinal cord stimulation (SCS) is an established treatment for chronic neuropathic pain, which can arise after nerve or nervous system injury. SCS is minimally invasive, non-destructive, and reversible; thus, pain specialists can conduct a temporary screening trial with an external pulse generator to assess whether a patient should proceed to implantation of the entire system.

The U.S. Food and Drug Administration (FDA) recognizes SCS as an aid in the management of chronic intractable pain of the trunk or limbs, including unilateral or bilateral pain associated with so-called “failed back surgery syndrome,” which is generally defined as pain continuing or resuming despite an operative procedure undertaken to correct the cause of the pain.

The reversibility of SCS is one of its most important features; unlike other surgical procedures that are commonly performed to relieve pain, SCS does not ablate pain pathways or change a patient’s spinal anatomy.

Based on peer-reviewed evidence demonstrating the cost-effectiveness of SCS in relieving chronic pain while improving quality of life and functional outcomes, SCS is covered by virtually all governmental and private payers in the U.S.

SCS Effectively Reduces Chronic Neuropathic Pain:

While often considered a symptom, chronic pain is itself a disease that imposes severe emotional, physical, economic, and social stress on patients and their families. North reports, “Because unrelieved pain and suffering are too costly for society and for patients and their families, and because the implantable technologies are known to be efficacious when used appropriately in the context of the pain treatment continuum, not using these technologies because they are deemed too costly by some makes no sense ... and ultimately increases patients’ and society’s costs.”

SCS has been in use for more than 40 years and has helped more than 100,000 patients worldwide who experienced intractable severe pain despite exhausting all other methods of pain treatment, including surgical procedures and the use of powerful analgesics. During this time, the application of SCS has continually evolved and improved, with the result that indications are more clearly defined and technology and procedures have improved. Peer-reviewed scientific journals have published a large body of clinical

evidence demonstrating the positive benefits of SCS through randomized controlled trials, long-term case series of clinical outcomes, and cost-effectiveness studies. This evidence led to widespread acceptance of SCS.

SCS is Broadly Recommended as a Medically Necessary Treatment by Payers:

SCS is a covered benefit under Medicare and other governmental health care programs, all major commercial health plans, and most Workers' Compensation programs in the U.S. The Centers for Medicare and Medicaid Services (CMS) provided national coverage for SCS after determining that the therapy met the agency's stringent requirements for medical necessity. Most major private payers including Aetna, Cigna, United Healthcare, Blue Cross/Blue Shield, and Health Net, have formal coverage policies for SCS. The US Military Health System also covers SCS for active and retired military personnel and their families.

Pain management physicians and relevant national medical societies agree that SCS is an appropriate treatment for chronic neuropathic pain patients meeting the following criteria:

- Other treatment modalities have failed or are unsuitable or contraindicated;
- The patient has undergone careful screening, evaluation, and diagnosis by a multidisciplinary team; and
- The patient demonstrates adequate pain relief in a clinically appropriate screening trial.

Position Statement:

SCS is a safe, effective, and widely accepted therapy covered by a wide range of public and private payers. It is critical that patients with chronic, intractable pain have access to SCS because, for appropriate candidates, no other treatment options exist, and their condition is often partially or completely disabling. SCS provides a means to relieve pain, restore function, and improve the quality of life for these patients.

Despite its widespread acceptance and appropriate coverage, some payers and stakeholders discourage or unduly limit access to SCS. Therefore, the following organizations strongly support appropriate access to SCS as a therapy option for properly selected patients with chronic neuropathic pain, encourage payers to ensure such access through their coverage and reimbursement policies, and stand ready as advocates for policies that preserve patient access to this important therapy.

Approved by:

American Academy of Pain Medicine (www.painmed.org)
American Society of Interventional Pain Physicians (www.asipp.org)
International Spine Intervention Society (www.spinalinjection.org)
Neuromodulation Therapy Access Coalition (www.neuromodulationaccess.org)
North American Neuromodulation Society (www.neuromodulation.com/chapter/northamerica)

Approved: June 5, 2008

Appendix – Supporting Literature

Randomized Controlled Trials

Kemler MA, de Vet HC, Barendse GA, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg.* 2008 Feb;108(2):292-8.

Kemler MA, DeVet HC, Barendse GA, et al. 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;55:13-8.

Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med* 2000;343:618–24.

Kumar K, Taylor RS, Jacques L, Eldabe S, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007;132:179-188.

North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery* 2005;56:98-106; discussion 106-7.

North RB, Kidd DH, Lee MS. Spinal cord stimulation versus operation for failed back surgery syndrome: a prospective, randomized controlled trial. *Acta Neurochir Suppl* 1995;64:106-8.

North RB, Kidd DH, Lee MS. A prospective randomized study of spinal cord stimulation versus reoperation for failed back surgery syndrome: initial results. *Stereotact Funct Neurosurg* 1994;62:267-72.

Tesfaye S, Watt J, et al., Electrical spinal-cord stimulation for painful peripheral neuropathy. *Lancet.* 1996;348:1698-701.

Long-Term Outcomes Studies

Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurg.* 2006;58:481-496.

Kumar K, Nath R, Wyant GM. Treatment of chronic pain by epidural spinal cord stimulation: a 10-year experience. *J Neurosurgery* 1991;75(3):402-7.

North RB, Kidd DH, Zahurak M, et al. Spinal cord stimulation for chronic, intractable pain: experience over two decades. *Neurosurgery* 1993;32(3):384-94; discussion 394-95.

North RB, Ewend MG, Lawton MT, et al. Failed back surgery syndrome: 5-year follow-up after spinal cord stimulator implantation. *Neurosurgery* 1991;28(5):692-99.

Practice Guidelines and Position Statements

American Society of Anesthesiologists Task Force on Pain management. Practice guidelines for chronic pain management. A report from the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section. *Anesthesiology*. 1997 Apr;86(4):995-1004.

Boswell MV, Shah RV, Everett CR, et al. (American Society of Interventional Pain Physicians). Interventional techniques in the management of chronic spinal pain: evidence-based practice guidelines. *Pain Physician*. 2005;8:1-47.

Boswell MV, et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007;10:7-111.

Cruccu G, Aziz TZ, Garcia-Larrea L, et al. EFNS guidelines on neurostimulation therapy for neuropathic pain. *Eur J Neurol*. 2007 Sep;14(9):952-70.

North R, Shipley J, Prager J, et al. Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. *Pain Med*. 2007 Dec;8 Suppl 4:S200-75.

Stanton-Hicks M, Burton AW, Bruehl SP, et al. An updated interdisciplinary clinical pathway for CRPS: report of an expert panel. *Pain Practice* 2002;2:1-16.

Stojanovic MP, Abdi A. Spinal cord stimulation, a focused review. *Pain Physician* 2002 5(2):156-166.

Cost Effectiveness

Bell GK, Kidd D, North RB. Cost effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. *J Pain Symptom Manage* 1997;13:286-295.

Hornberger J, Kumar K, Verhulst E, et al. Rechargeable spinal cord stimulation versus nonrechargeable system for patients with failed back surgery syndrome: a cost-consequences analysis. *Clin J Pain*. 2008;24:244-252.

Kemler MA, Furnee CA. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology* 2002;59:1203-09.

Manca A, Kumar K, Taylor RS, et al. A multicentre randomised controlled trial comparing spinal cord stimulation with conventional medical management for neuropathic pain in patients with failed back surgery syndrome (PROCESS trial): quality of life, resource consumption and costs. *Eur J Pain*, in press, 2008.

North RB, Kidd D, Shipley J, Taylor R. Spinal cord stimulation versus reoperation for failed back surgery syndrome: A cost effectiveness and cost utility analysis based on a randomized, controlled trial. *Neurosurgery* 61(2):361-369, 2007.

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* 21:351-355, 2005.

Taylor RS, Taylor RJ, Van Buyten J-P, et al. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. *J Pain Sympt Manage* 27(4):370-378, 2004.