

Policy:	200602	Initial Effective Date:	10/20/2006
SUBJECT:	Temporary (Trial) Spinal Cord Stimulation for Chronic Pain		
		Annual Review Date:	08/02/2024
		Last Revised Date:	08/02/2024

### Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

**Definition:** Spinal cord stimulation (SCS), also known as dorsal column stimulation, is most used to treat chronic pain. It involves the surgical implantation of an electrode array, sometimes referred to as a lead, in the epidural space of the spinal cord. The electrode array is attached to an extension cable which in turn is attached to a pulse generator, also referred to as a neurostimulator. An electrical impulse generated by the device travels to the lead at the spinal cord and generates a tingling sensation that alters the perception of pain.

Implantation/insertion of a SCS system is performed in two stages. The first stage is a trial stimulation to determine if the patient is a suitable candidate. A successful trial is defined as the patient experiencing and recording  $\geq$ 50% pain relief during the trial. This should occur with stable or reduced pain medications, in particular opioids, and with at least stable or improved levels of daily activity. Only patients who are deemed suitable will go on to permanent implantation/insertion of the SCS system.

#### **Medical Necessity:**

- I. Temporary Trial: The Company considers temporary (trial) spinal cord stimulation medically necessary and eligible for reimbursement providing that *all* of the following medical criteria are met:
  - Chronic neuropathic or ischemic pain, including **1 or more** of the following:
    - 1. Complex regional pain syndrome (previously referred to as reflex sympathetic dystrophy)
    - 2. Failed back surgery syndrome
    - 3. Lower extremity pain at rest due to critical limb ischemia
  - Failed conservative management, including **1 or more** of the following:
    - 1. For limb ischemia, failed surgical or endovascular revascularization, or inoperable vascular disease
    - 2. For neuropathic pain, stellate ganglion or lumbar sympathetic block



- 3. Pharmacotherapy
- 4. Physical therapy
- 5. Psychotherapy or cognitive behavioral therapy
- Favorable psychological evaluation, absence of untreated psychiatric comorbidity, or current treatment in multidisciplinary pain management program; and
- Patient capable of operating stimulating device; and
- No coagulopathy, anticoagulant or antiplatelet therapy or thrombocytopenia (ie, platelet count of less than 75,000/mm<sup>3</sup> (75 x10<sup>9</sup>/L)); and
- No current or chronic infection
- **II. Permanent Implantation:** The Company considers permanent implantation of a spinal cord stimulator **medically necessary** and eligible for reimbursement. Medical Mutual uses MCG Care Guidelines (A-0243) to guide medical necessity determination for implanted electrical stimulation of the spine.

**NOTE:** Spinal cord stimulators using high-frequency spinal cord stimulation (Senza) or burst stimulation (BurstDR) have been determined to be equally effective alternatives to standard stimulators for the medically necessary indications listed above and in MCG Care Guidelines (A-0243).

**NOTE:** Dorsal root ganglion stimulators (e.g. Axium Neurostimulator System) are considered medically necessary to treat complex regional pain syndrome when the other medically necessary indications listed above and in MCG Care Guidelines (A-0243) are met.

**III. Replacement:** The Company considers replacement/upgrade of leads (e.g., lead migration is a frequent complication of spinal cord stimulation and requires revision surgery), implantable pulse generator, external recharger, and patient programmer **medically necessary** and eligible for reimbursement providing medical criteria for permanent implantation of a spinal cord stimulator are met and existing equipment is not under manufacturer warranty.

**NOTE:** Replacement/upgrade of a functioning SCS to a burst or high-frequency spinal cord stimulator is considered not medically necessary.

- **IV. Removal:** The Company considers removal (without revision or replacement) of leads and/or pulse generator **medically necessary** and eligible for reimbursement.
- V. Investigational Procedures or Devices: The Company considers the following spinal cord stimulation procedures or devices investigational and not eligible for reimbursement:
  - Spinal nerve stimulation for *all* other indications (e.g., treatment of cancer related pain, pain secondary to inoperable critical limb ischemia, chronic angina resistant to therapy, pain due to diabetic peripheral neuropathy)



- Spinal cord stimulation using more than 16 electrodes/contacts or more than two percutaneous leads
- Spinal nerve stimulation using the Stimwave Freedom Spinal Cord Stimulation System (Stimwave Technologies Inc.) or a similar system powered by an external radiofrequency transmitter coupled to an implanted receiver

Benefits for investigational services are subject to each specific benefit plan.

### **Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for CPT Codes L8678, 63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688



### **Sources of Information:**

- Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med.* 2014;15(3): 347-354.
- American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. 2010;112(4):810-833.
- Berger AA, Liu Y, Possoit H, Rogers AC, Moore W, Gress K, Cornett EM, Kaye AD, Imani F, Sadegi K, Varrassi G, Viswanath O, Urits I. Dorsal Root Ganglion (DRG) and Chronic Pain. Anesth Pain Med. 2021. 11(2):e113020.
- Centers for Medicare & Medicaid Services: national coverage determination for electrical nerve stimulators (160.7) Effective date August 07, 1995.
- Deer TR, Mekhail N, Provenzano D, et al.; Neuromodulation Appropriateness Consensus Committee. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*. 2014;17(6):515-550.
- Deer TR, Skaribas IM, Haider N, et al. Effectiveness of cervical spinal cord stimulation for the management of chronic pain. *Neuromodulation*. 2014. 17(3):265-271.
- Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017 Apr;158(4):669-681.
- Hayes, Inc. (2021, December 28). Health Technology Assessment. *Dorsal Root Ganglion Stimulation for the Treatment of Complex Regional Pain Syndrome*. Annual Review (2023, March 27). Lansdale, PA.
- Hayes, Inc. (2018, December 21). Health Technology Assessment. *Spinal Cord Stimulation For Relief Of Neuropathic Pain.* Annual Review (2023, March 27). Lansdale, PA.
- Kapural, L., Yu, C., Doust, M. et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg PainThe SENZA-RCT Randomized Controlled Trial. Anesthesiology: The Journal of the American Society of Anesthesiologists. 2015. 123(4), 851-860.
- Kinfe TM, Pintea B, Vatter H. Is spinal cord stimulation useful and safe for the treatment of chronic pain of ischemic origin? A review. *Clin J Pain*. 2016. 31(1):7-13.
- Kumar K, North R, Taylor R, et al. Spinal Cord Stimulation vs. Conventional Medical Management: A Prospective, Randomized, Controlled, Multicenter Study of Patients with Failed Back Surgery Syndrome (PROCESS Study). Neuromodulation. 2005 Oct;8(4):213-8.
- Levy RM, Mekhail N, Kramer J, et al. Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II. J Pain. 2020. Mar-Apr;21(3-4):399-408.
- Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. 2013;16(2 Suppl):S49-S283.



- Mekhail N, Deer TR, Kramer J, et al. Paresthesia-Free Dorsal Root Ganglion Stimulation: An ACCURATE Study Sub-Analysis. Neuromodulation. 2020 Feb;23(2):185-195.
- Mekhail N, Deer TR, Poree L, Staats PS, Burton AW, Connolly AT, Karst E, Mehanny DS, Saweris Y, Levy RM. Cost-Effectiveness of Dorsal Root Ganglion Stimulation or Spinal Cord Stimulation for Complex Regional Pain Syndrome. Neuromodulation. 2021. 24(4):708-718
- Naoum JJ, Arbid EJ. Spinal cord stimulation for chronic limb ischemia. *Methodist Debakey Cardiovasc J*. 2013;9(2):99-102.
- National Institute for Health and Care Excellence (NICE). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE Technology Appraisal Guidance. TA159. October 2008. Retrieved from https://www.nice.org.uk/guidance/ta159
- Peng L, Min S, Zejun Z, Wei K, Bennett MI. Spinal cord stimulation for cancer-related pain in adults. *Cochrane Database Syst Rev.* 2015;6:CD009389.
- Taylor RS, Desai MJ, Rigoard P, Taylor RJ. Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis. *Pain Pract.* 2014. 14(6):489-505.

Applicable Code(s):	
CPT:	63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688
HCPCS:	C1767, C1778, C1820, C1897, L8678, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, L8695
ICD10 Procedure:	00HU0MZ, 00HU3MZ, 00HU4MZ, 00HV0MZ, 00HV3MZ and 00HV4MZ

This document is subject to the disclaimer found at <u>http://www.medmutual.com/provider/MedPolicies/Disclaimer.aspx</u>. If printed, this document is subject to change. Always verify with the most current version of the official document at <u>http://www.medmutual.com/provider/MedPolicies/Disclaimer.aspx</u>.