Protocol

Spinal Cord Stimulation

(70125)

Medical Benefit		**Effective Date**: 07/01/14	**Next Review Date**: 03/15
Preauthorization	Yes	**Review Dates**: 02/07, 02/08, 03/09, 03/10, 03/11, 03/12, 03/13, 03/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Spinal cord stimulation (SCS) delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. Spinal cord stimulation devices have a radiofrequency receiver that is surgically implanted and a power source (battery) that is either implanted or worn externally.

Background

Spinal cord stimulation (SCS) devices consist of several components: 1) the lead that delivers the electrical stimulation to the spinal cord; 2) an extension wire that conducts the electrical stimulation from the power source to the lead; and 3) a power source that generates the electrical stimulation. The lead may incorporate from 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.

Spinal cord stimulation has been used in a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and complex regional pain syndrome (CRPS) (i.e., chronic reflex sympathetic dystrophy). There has also been interest in spinal cord stimulation as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients with refractory chest 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 facilitative circuits.

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 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.

Regulatory Status

A number of total implanted spinal cord stimulators have received U.S. Food and Drug Administration (FDA)

premarket approval (PMA). The Cordis programmable neurostimulator from Cordis, Corp. was approved in 1981, and the Itrel(R) manufactured by Medtronic was approved in 1984. In April 2004, Advanced Bionics received PMA for its Precision Spinal Cord Stimulator as an aid in management of chronic, intractable trunk and limb pain. All are fully implanted devices.

Related Protocol

Deep Brain Stimulation

Policy (Formerly Corporate Medical Guideline)

Spinal cord stimulation may be considered **medically necessary** for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies, when performed according to Policy Guidelines.

Spinal cord stimulation is considered **investigational** in all other situations including but not limited to treatment of critical limb ischemia as a technique to forestall amputation, treatment for refractory angina pectoris and treatment of cancer-related pain.

Policy Guideline

Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations may apply.

- 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;
- Pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy. 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 CNS damage from a stroke or spinal cord injury);
- No serious untreated drug habituation exists;
- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Medicare Advantage

The implantation of a spinal cord stimulator may be considered **medically necessary** as therapy for the relief of chronic intractable pain, subject to the following conditions:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
- Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
- Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation (such screening must include psychological, as well as physical evaluation);

- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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