POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, permanent implantation of a spinal cord stimulator has been medically proven to be effective and therefore, medically appropriate for treatment of patients with failed back syndrome (FBS) with intractable neuropathic leg pain or for Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) when all the following criteria have been met:
   A. Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);
   B. Surgical intervention is not indicated;
   C. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement; and
   D. At least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

II. Based upon our criteria and assessment of peer-reviewed literature, permanent implantation of a spinal cord stimulator has been medically proven to be effective and therefore, medically appropriate for treatment of patients with chronic critical limb ischemia (CLI) when all of the following criteria are met:
   A. Failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management (e.g., revascularization); and
   B. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement; and
   C. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.

III. Based upon our criteria and assessment of peer-reviewed literature, permanent implantation of a spinal cord stimulator has been medically proven to be effective and therefore, medically appropriate for treatment of patients with chronic, intractable pain secondary to chronic stable angina pectoris for myocardial ischemia when all of the following criteria are met:
   A. Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV; and
   B. Individual has documented significant coronary artery disease (CAD) and is not a suitable candidate for a revascularization procedure; and
   C. Optimal pharmacological treatment using anti-anginal medications (e.g., long-acting nitrates, beta-adrenergic blockers, or calcium-channel antagonists) has failed to adequately improve anginal symptoms; and
   D. An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement; and
E. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.

IV. Based upon our criteria and assessment of peer-reviewed literature, the replacement of a malfunctioning dorsal column spinal cord stimulator (SCS) and/or battery/generator is considered medically necessary for an individual who meets ALL of the above criteria and the existing stimulator and/or battery/generator replacement are/is no longer under warranty.

V. Based upon our criteria and assessment of peer-reviewed literature, implantation of a spinal cord stimulator has not been medically proven to be effective and is considered investigational for all other indications, including but not limited to:
   A. Post-amputation pain (phantom limb pain)
   B. Post-herpetic neuralgia
   C. Peripheral neuropathy
   D. Dysesthesias involving the lower extremities secondary to spinal cord injury.

VI. Based upon our criteria and assessment of peer-reviewed literature, implantation of a high frequency spinal cord stimulator has not been medically proven to be effective and is considered investigational.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia. In occipital nerve stimulation the neurostimulator delivers electrical impulses via insulated lead wires tunneled under the skin near the occipital nerves at the base of the head. Currently, there is no FDA approved device for this indication.

POLICY GUIDELINES:

I. The implantation of a spinal cord stimulator is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) need to have been tried and failed or have been judged unsuitable or contraindicated. Duration of refractory pain is six months or greater.

II. Documentation must reflect an objective measure of a 50% reduction in pain scores with a temporarily implanted electrode in order to precede permanent implantation.

III. Patients are to be carefully screened, evaluated, and diagnosed by a multidisciplinary team prior to application of these therapies. This evaluation may include a psychological evaluation to exclude any major mental disability or drug habituation that would negatively influence the outcome of the treatment. Please to Refer to Corporate Medical Policy #3.01.02 regarding Psychological Testing.

IV. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Spinal cord stimulation (SCS) is used to treat chronic back and extremity pain and consists of electrical stimulation of the dorsal columns by electrodes implanted in the epidural space. 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 facilitatory circuits. Spinal cord stimulation devices consist of implantable electrodes, a receiver/transducer and a programmable transmitter that may be worn externally or implanted. Implantation of the spinal cord stimulator is typically a two-step process. Initially the electrode(s) is temporarily implanted in the epidural space, allowing a trial period of stimulation. This trial period will typically last for a period of 3 to 7 days. Once treatment effectiveness has been established, the electrode(s) and receiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming to determine the optimum levels of stimulation to provide pain relief. There are two basic types of power source. In 1 type, the power source (battery) can be surgically implanted. In another, a radio-frequency 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 utilized in a variety of refractory neuropathic pain conditions, including pain associated with failed back syndrome, arachnoiditis, peripheral neuropathy and complex regional pain syndrome. Complex regional pain syndrome (CRPS) is a chronic pain condition most often affecting one of the limbs (arms, legs, hands, or feet), usually after an injury or trauma to that limb. CRPS is believed to be caused by damage to, or malfunction of, the peripheral and central nervous systems. The central nervous system is composed of the brain and spinal cord, and the peripheral nervous system involves nerve signaling from the brain and spinal cord to the rest of the body. CRPS is characterized by prolonged or excessive pain and mild or dramatic changes in skin color, temperature, and/or swelling in the affected area. There are two similar forms, called CRPS-I and CRPS-II, with the same symptoms and treatments. CRPS-II (previously called causalgia) is the term used for patients with confirmed nerve injuries. Individuals without confirmed nerve injury are classified as having CRPS-I (previously called reflex sympathetic dystrophy syndrome). People with CRPS also experience constant or intermittent changes in temperature, skin color, and swelling of the affected limb. This is due to abnormal microcirculation caused by damage to the nerves controlling blood flow and temperature. An affected arm or leg may feel warmer or cooler compared to the opposite limb. The skin on the affected limb may change color, becoming blotchy, blue, purple, pale, or red.

Spinal cord stimulation is generally not effective in treating nociceptive pain (pain resulting from irritation, as opposed to damage to the nerves) and central deafferentation pain (pain related to central nervous system damage from a stroke or spinal cord injury).

It is recommended that candidates for SCS undergo a psychological evaluation prior to surgery. The purpose of the evaluation is to assess the potential role that psychological factors (e.g., anxiety, depression, underlying mental illness) may have in influencing the success of surgery and to offer appropriate recommendations with regard to psychological management.

Spinal cord stimulation has also been investigated as a treatment for pain associated with cervical trauma or disc herniation, chronic refractory angina pectoris and critical limb ischemia in patients who are not candidates for revascularization procedures.

A spinal cord stimulation system capable of delivering stimulation frequencies up to 10 kHz has been developed. It delivers HF10™ SCS therapy, a therapy that uses proprietary waveform with stimulation frequencies up to 10 kHz. In contrast to other currently available systems that use frequencies in the range of 50 Hz (referred to as tonic spinal cord stimulation), this innovation does not require or produce paresthesia to achieve clinical efficacy. Potential proposed benefits of higher frequency stimulation include a lower incidence of paresthesias, which are a recognized side effect of SCS.

Burst stimulation is proposed to relieve pain with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices.

**RATIONALE:**

**Traditional stimulation**

Totally implantable spinal cord (dorsal column) stimulator systems are regulated by the FDA as class III pre-market-approval (PMA) devices. Several devices have received FDA PMA approval. Examples of these devices include, but are not limited to, the Precision™ Spinal Cord Stimulator System, and the Genesis™ IPG System. Systems with external transmitters are regulated by the FDA as Class II 510(K) devices. The FDA gave 510 K approval for Advanced Neuromodulation systems to market their Renew spinal cord stimulator, to Medtronic for its Spinal Cord and Peripheral Nerve Stimulation Systems, X-trel®3 and Synergy®; Spinal Cord Stimulation Systems, and to Micronet Medical, Inc for its Axcess Spinal Cord Stimulation Lead. St. Jude Medical has also received FDA approval for its Protege MRI™ spinal cord stimulation system.
There is sufficient evidence in the peer-reviewed literature to permit conclusions that the technology provides significant and sustained relief of pain with minimal side effects in appropriately selected patients with chronic nonmalignant pain. Studies investigating the effectiveness of SCS as a treatment for patients with chronic back/extremity pain report successful management of pain, a substantial decrease in narcotic use and an improvement in the quality of life. Studies support the use of spinal cord stimulation for patients with CRPS in the upper extremities through outcomes that demonstrate reduction in pain intensity and increased quality of life (e.g., Harke, et al. 2005; Kemler, et al. 2006; Kumar, et al. 2011; Geurts, et al. 2013).

One essential step toward the effective use of SCS in potential patients is a trial of the system through percutaneous lead placement. This trial will determine the effectiveness in relieving pain (greater than 50% pain relief) and improving the quality of life in patients with refractory neuropathic pain.


There is evidence to favor spinal cord stimulation over standard conservative treatment to improve limb salvage and clinical situation in patients with inoperable chronic critical leg ischemia.

Studies found that spinal cord stimulation improved both the quality of life and cardiac parameters of patients with refractory angina pectoris.

High-frequency stimulation

Nevro (Menlo Park, Calif) has gained FDA 510(k) clearance for its Senza spinal cord stimulation system intended for chronic pain treatment in May 2015. The device administers the company’s HF10 therapy in the trunk and/or limbs, which treats unilateral or bilateral pain related to failed back surgery, intractable low back pain and leg pain. The therapy is the only SCS therapy FDA-indicated to alleviate pain without paresthesia (a constant tingling sensation associated with traditional SCS techniques). The evidence for high-frequency SCS in individuals who have treatment-refractory chronic pain of the trunk or limbs includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency to standard stimulation found a large and statistically significant benefit associated with high-frequency SCS. In contrast, a smaller study found no benefit for those receiving high-frequency stimulation compared with sham control. Given the uncertainty in these findings, additional trials are needed to corroborate the benefit of high-frequency stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODES: Number Description
Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 63650 Percutaneous implantation of neurostimulator electrode array; epidural
63655 Laminectomy for implantation neurostimulator electrode plate/paddle; epidural
63661 Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662 Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy when performed

Proprietary Information of Excellus Health Plan, Inc.
HCPCS:

63663 Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s) including fluoroscopy, when performed

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

95970-95973 Neurostimulator programming and analysis (code range)

REFERENCES:


Proprietary Information of Excellus Health Plan, Inc.


* Key article

KEY WORDS:
Burst stimulation, Dorsal column, Dorsal root ganglion, High-frequency neurostimulation, Neuromodulation, Neurostimulation, Wireless neurostimulation.
There is currently a National Coverage Determination (NCD) for electrical nerve stimulators that includes dorsal column stimulators. Please refer to the following NCD website for Medicare Members: