Protocol

Spinal Cord and Dorsal Root Ganglion Stimulation

(70125)

Medical Benefit		**Effective Date**: 10/01/19	**Next Review Date**: 01/21
Preauthorization	Yes	**Review Dates**: 02/07, 02/08, 03/09, 03/10, 03/11, 03/12, 03/13, 03/14, 03/15, 03/16, 01/17, 07/17, 01/18, 01/19, 07/19, 01/20	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With treatment-refractory chronic pain of the trunk or limbs	Interventions of interest are: • Standard spinal cord stimulation	Comparators of interest are: • Medical therapy • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With treatment-refractory chronic pain of the trunk or limbs	Interventions of interest are: • High-frequency spinal cord stimulation	Comparators of interest are: • Standard spinal cord stimulation • Medical therapy • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With treatment-refractory chronic pain of the trunk or limbs	Interventions of interest are: • Dorsal root ganglion neurostimulation	Comparators of interest are: • Standard spinal cord stimulation • Medical therapy • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With critical limb ischemia	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy • Revascularization surgery • Amputation	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With treatment-refractory angina pectoris	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy • Coronary revascularization	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With heart failure	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy • Coronary revascularization	Relevant outcomes include: • Overall survival • Symptoms • Functional outcomes • Quality of life • Morbid events • Hospitalizations • Treatment-related morbidity
Individuals: • With cancer-related pain	Interventions of interest are: • Spinal cord stimulation	Comparators of interest are: • Medical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

DESCRIPTION

Spinal cord stimulation (SCS) delivers low-voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain; this is achieved through a surgically implanted SCS device, which comes equipped with a radiofrequency receiver. The neurostimulator device is also issued with a standard power source (battery) that can be implanted or worn externally. Other neurostimulators target the dorsal root ganglion.

SUMMARY OF EVIDENCE

TREATMENT-REFRACTORY CHRONIC PAIN

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive standard SCS, the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Available RCTs are heterogeneous regarding underlying diagnoses in select patient populations. However, the trials including patients with underlying neuropathic pain processes have shown a significant benefit with SCS. Systematic reviews have supported the use of SCS to treat refractory trunk or limb pain, and patients who have failed all other treatment modalities have few options. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive high-frequency SCS, the evidence includes three RCTs. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. One RCT comparing high-frequency with standard SCS in patients who had not previously been treated with SCS found a clinically and statistically significant benefit associated with high-frequency SCS. Another RCT in patients who had chronic pain despite previous treatment with standard SCS found no benefit for those receiving high-frequency stimulation compared with sham-control; however, it is difficult to compare these findings with other trials of SCS due to the different patient populations, short treatment

periods, and the crossover period effect. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive dorsal root ganglion (DRG) neurostimulation, the evidence includes an RCT and many case series. Relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success (physical functioning score and QOL measures), at three and 12 months compared with those receiving standard SCS devices. DRG neurostimulation was found to be noninferior to SCS in percentage achieving more than 50% pain reduction, emotional functioning score, and 36-Item Short-Form Health Survey scores. Both groups experienced paresthesias but patients in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Rates of serious adverse events were similar between the two study arms. While most of the case series were small (sample sizes ranged from 10 to 65), all reported results that were consistent with the RCT results. The largest case series had the longest follow-up, reporting continued improvements in pain and psychological scores through three years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Critical Limb Ischemia

For individuals who have critical limb ischemia who receive SCS, the evidence includes several small RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, QOL, morbid events, hospitalizations, and treatment-related morbidity. In some pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation, although one meta-analysis that included a nonrandomized study reported a significant difference. The evidence is insufficient to determine the effects of the technology on health outcomes.

Treatment-Refractory Angina Pectoris

For individuals who have treatment-refractory angina pectoris who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, QOL, morbid events, hospitalizations, and treatment-related morbidity. Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some have reported benefit, most have not. In two recent RCTs, there was no significant benefit in the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Heart Failure

For individuals who have heart failure who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, QOL, morbid events, hospitalizations, and treatment-related morbidity. One small pilot crossover study (n=9) reported at least one adverse event in two patients with the device turned on and in two patients with the device turned off. A sham-controlled randomized trial (n=66) did not find significant differences between groups but might have been underpowered to do so. The evidence is insufficient to determine the effects of the technology on health outcomes.

Cancer-Related Pain

For individuals who have cancer-related pain who receive SCS, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, medication use, and treatment-related morbidity. No RCTs evaluating SCS in this population were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Spinal cord stimulation with standard or high-frequency stimulation may be considered **medically necessary** for

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.

Dorsal root ganglion neurostimulation is 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 to forestall amputation and treatment of refractory angina pectoris, heart failure and cancer-related pain.

POLICY GUIDELINES

Patient selection focuses on determining whether 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 (pharmacologic, surgical, psychological, or physical, if applicable) have 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 surgery syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, and 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 central nervous system 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.

“Burst” neurostimulation is an alternate programming of a standard SCS device. A clinician programmer application is used to configure a standard SCS device to provide stimulation in “bursts” rather than at a constant (“tonic”) rate.

MEDICARE ADVANTAGE

The implantation of dorsal column or depth brain stimulators may be considered **medically necessary** as therapy for the relief of chronic intractable pain, if all of the conditions listed below have been met:

- 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.

BACKGROUND

CHRONIC PAIN

Spinal cord stimulation (SCS) 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 (i.e., chronic reflex sympathetic dystrophy). There has also been interest in SCS as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients with refractory chest pain.

Spinal Cord Stimulation

SCS-also called dorsal column stimulation-involves the use of low-level epidural electrical stimulation of the spinal cord dorsal columns. The neurophysiology of pain relief after SCS is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits.

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 electricity. The lead may incorporate from four to eight electrodes, with eight electrodes more commonly used for complex pain patterns. There are two basic types of power source: one type, the power source (battery), can be surgically implanted or worn externally with an antenna over the receiver; the other, a radiofrequency receiver, is implanted. Totally implantable systems are most commonly used.

The patient's pain distribution pattern dictates at what level of 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 SCS may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency (10,000 Hz) than predicate devices, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS. In 2016, the FDA approved a clinician programmer application that allows an SCS device to provide stimulation in bursts rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five, 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of 1 ms.

The incidence of adverse events related to spinal cord stimulation have been reported to occur in 30% to 40% of cases.[1] Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration or lead failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache (estimated incidence, up to 0.3%) and neurological damage (estimated incidence, 0.25%).

Other neurostimulators target the dorsal root ganglion (DRG). Dorsal root ganglia consists of sensory cell bodies that transmit input from the peripheral nervous system to the central nervous system, and play a role in neuropathic pain perception. Dorsal root ganglia are located in the epidural space between spinal nerves and the spinal cord on the posterior root in a minimal amount of cerebrospinal fluid, amenable to epidural access. Two systems targeting the DRG have received approval or clearance from the FDA.

A retrospective analysis of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database provided information on complications related to the use of DRGstimulation.[2] The MAUDE database was queried for DRG stimulation reports through 2017, identifying 979 episodes. Complications were predominantly device-related (47%; lead migration and lead damage), with the remaining comprised of procedural complications (28%; infection, new neurologic symptoms, and dural puncture), patient complaints (12%; site pain and unwanted stimulation), serious adverse events (2.4%), and "other" complications (4.6%). The prevalence of complications cannot be estimated using the MAUDE database; while facilities are mandated to report events, patients and health care providers may report events but are not mandated to do so.

Outcome Measures

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials group has provided recommendations for four core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[3] The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (see Table 1).[4,5]

Table 1. Health Outcome Measures Relevant to Trials of Chronic Pain

Domain	Outcome Measure	Description	Clinically Meaningful Difference
Pain intensity			
	• Numeric rating scale • Verbal rating scale • Visual analog scale	Rating of pain intensity on a scale of 0 (no pain) to 10 (pain as bad as you can imagine) or from 0 to 10 cm	• Minimally important: 10%-20% decrease • Moderately important: ≥30% decrease • Substantial: ≥50% decrease[5]
Physical functioning			
	Disease specific	Measures of the interference of pain with physical functioning	
	• Multidimensional Pain Inventory[6] Interference Scale	• 60 items, self-report • 12 subscales: interference, support, pain severity, self-control, negative mood, punishing responses, solicitous responses, distracting responses, household chores, outdoor work, activities away from home, and social activities • Items rated on 0- to 6-point scale • Interference subscale score calculated by mean of subscale items	• ≥0.6-point decrease[5]
	• Brief Pain Inventory[7] Interference Scale	• 7 items, self-report • Measures intensity, quality, relief and interference of pain and patients' ideas of the causes of pain • Mean of the 7 interference items can be used as a measure of pain interference	• 1-point decrease[5]
	• Oswestry Disability Index[8]	Measures functional impairment due to lower back pain: • 10 sections, self-report	• 10 points[9]

Domain	Outcome Measure	Description	Clinically Meaningful Difference
		• Sections: intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel • Each section is scored on a 0 to 5 scale with 5 indicating the greatest disability • Total score calculated by taking the mean of the section scores and multiplying by 100	
	General	Generic measure of physical functioning	
	• 36-Item Short Form Health Survey	Measure overall health status: • 36 items, self-report • 8 domains: physical function, physical role, general health, bodily pain, mental health, social function, vitality/fatigue, and emotional role • Physical Component Summary and Mental Component Summary scores are aggregate scores that can be calculated • Higher scores indicate better health status	• 5-10 points[10-12]
Emotional functioning			
	• Beck Depression Inventory[13]	• 21 items, self-report • Measures severity of current symptoms of depressive disorders • Scores range from 0 to 63	• ≥5-point decrease[5]
	• Profile of Mood States[14]	• 65 items, self-report • Measures total mood disturbance with 6 subscales: tension, depression, anger, vigor, fatigue, and confusion • Scores range from 0 to 200	• ≥10- to 15-point decrease[5]
Global rating of improvement			
	• Patient Global Impression of Change	• Single-item, self-rating • 7-point scale ranging from 1 (very much worse) to 7 (very much improved)	• Minimally important: minimally improved • Moderately important: much improved • Substantial: very much improved5

REGULATORY STATUS

A large number of neurostimulator devices, some used for SCS, have been approved by the FDA through the premarket approval process. Examples of fully implantable SCS devices approved through the premarket approval process include the Cordis programmable neurostimulator (Cordis Corp.), approved in 1981; the Itrel® (Medtronic), approved in 1984; the Genesis and Eon devices (St. Jude Medical), approved in 2001; and the Precision Spinal Cord Stimulator (Advanced Bionics), approved in 2004. FDA product code: LGW.

In 2015, the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp.), a totally implantable neurostimulator device, was approved by the FDA for the following indications: "chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome (FBSS), intractable low back pain, and leg pain."[15] This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Abbott) was approved by the FDA through the premarket approval process. This implanted device stimulates the DRG. Further, it is indicated as an aid in the management of moderate-to-severe intractable pain of the lower limbs in adults with complex regional pain syndrome types I and II.

In August 2016, the Freedom Spinal Cord Stimulator (Stimwave Technologies), a wireless injectable stimulator, was cleared for marketing by the FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs. The Freedom device has implantable or injectable microstimulators that contain electrode(s). The microstimulators with electrodes are powered by a wireless battery pack worn externally. The device can be placed to target the spinal cord (i.e., levels T7 to L5) or to target the dorsal root ganglion.

In October 2016, the FDA approved BurstDR™ stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for patients with certain St. Jude SCS devices.

In August 2017, the Precision™ Spinal Cord Stimulator (Boston Scientific) was approved by the FDA through the premarket approval process.

RELATED PROTOCOL

Deep Brain Stimulation

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

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

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