

MEDICAL POLICY	Back: Implantable Spinal Cord and Dorsal Root Ganglion Stimulation (All Lines of Business Except Medicare)
Effective Date: 3/1/2021	Medical Policy Number: 28
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Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- Indication for the requested device
- For Failed Back Surgery Syndrome and Complex Regional Pain Syndrome, documentation of a spinal surgeon consult with the opinion that the patient is not a surgical candidate
- Medical records must document that a detailed neurological examination has been performed by, or reviewed by the operating physician, within 3 months prior to implantation.
- Clinical documentation of extent and response to conservative care (see [Policy Guidelines](#) for all requirements and exceptions), as applicable to the policy criteria, including outcomes of any procedural interventions, medication use and physical therapy notes

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- Evaluation and documentation of the extent and specifics of one or more of the functional impairments or disabilities
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues if and when present
- For cases of Complex Regional Pain Syndrome, documentation of condition using the Budapest criteria (see [Policy Guidelines](#) for outlined criteria)
- All other medical records and chart notes pertinent to the request, such as:
 - History
 - Physical examination
 - Treatment plan

POLICY CRITERIA

Spinal Cord Stimulation

- I. The **initial trial period** (3-7 days) of an implantable spinal cord stimulator (low-frequency or high-frequency) may be considered **medically necessary and covered** when **all** of the following (A.-F.) criteria are met:
 - A. The patient has been experiencing persistent debilitating neuropathic pain (see [Policy Guidelines](#)) **and**
 - B. Documentation that age-appropriate activities of daily living are moderately or severely impacted (see [Policy Guidelines](#)) **and**
 - C. Member's neuropathic pain is due to one of the following:
 1. Failed Back Surgery Syndrome (FBSS) (excluding failed neck surgery syndrome) with radicular pain (see [Policy Guidelines](#) for indications of radicular pain); **or**
 2. Complex Regional Pain Syndrome (CRPS) Type 1 (see [Policy Guidelines](#) for Budapest Criteria); **or**
 3. Diabetic Peripheral Neuropathy; **and**
 - D. For Failed Back Surgery Syndrome and Complex Regional Pain Syndrome, there is documentation that surgical intervention is not indicated and spinal cord stimulation treatment is used only as last resort;* **and**
 - E. There is clinical documentation of compliance with a minimum of 6 months of conservative treatment immediately prior to stimulator trial that failed to adequately treat the patient's symptoms, including **both** of the following (1. and 2.):
 1. Active participation in a physical therapy program for the duration of conservative management; **and**
 2. Standard therapy with NSAIDs, tricyclic antidepressants, and anticonvulsants (unless contraindicated or unable to tolerate); **and**
 - F. A psychological evaluation identifies no problematic emotional reactions, maladaptive thinking and behavior, and/or social problems that may contribute to pain and disability.* The psychological evaluation should include documentation of valid and reliable

assessments (see [Policy Guidelines](#) for examples of validated evaluations) of **all** of the following (1.-5.):

1. subjective pain intensity; **and**
2. mood and personality; **and**
3. activity interference; **and**
4. pain beliefs; **and**
5. coping

*Note: A second opinion by a plan-designated provider may be required at the discretion of the Medical Director.

- II. **Permanent implantation** of an implantable spinal cord stimulator (low-frequency or high-frequency) may be considered **medically necessary and covered** following the initial trial period (3-7 days) in patients meeting criteria I. A.-E. above, when there is clinical documentation of at least a 50% reduction in pain during the trial period as measured by a standardized rating scale (see [Policy Guidelines](#)).
- III. An implantable spinal cord stimulator (initial trial period or permanent implantation of a low-frequency or high-frequency device) is considered **investigational and is not covered** when criteria I. or II. above is not met, including, but not limited to, the following conditions:
 - Intractable Angina Pectoris
 - Non-Specific Chronic Back and/or Leg Pain
 - Critical Limb Ischemia
 - Failed Neck Surgery Syndrome
 - Chemotherapy-induced peripheral neuropathy and/or pain
- IV. The use of a clinician programmer application (e.g., St. Jude Medical™ Clinician Programmer app) to provide burst spinal cord stimulation is considered **investigational and is not covered**.

Replacement of Spinal Cord Stimulator Devices

- V. Replacement of an existing low-frequency or high-frequency spinal cord stimulator and/or battery/generator may be considered **medically necessary and covered** when **all** of the following (A.-C.) criteria are met:
 - A. The existing stimulator and/or battery/generator is malfunctioning; **and**
 - B. The existing stimulator and/or battery/generator cannot be repaired; **and**
 - C. The existing stimulator and/or battery/generator is no longer under warranty
- VI. Replacement of an existing, mechanically functioning, low-frequency or high-frequency spinal cord stimulator and/or battery/generator is considered **not medically necessary and is not**

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covered when criterion V. above is not met. Replacement is not covered for inadequate pain relief.

VII. Replacement of a mechanically functioning low-frequency spinal cord stimulator with a high-frequency spinal cord stimulator is considered **not medically necessary and is not covered**. Replacement is not covered for inadequate pain relief.

Dorsal Root Ganglion Stimulation

VIII. Dorsal root ganglion stimulation (e.g., Axium™ Neurostimulator System by St. Jude Medical™) is considered **investigational and is not covered**.

POLICY GUIDELINE

Definitions

Activities of daily living: The activities of daily living (ADLs) is a term used to describe essential skills that are required to independently care for oneself.¹ Examples may include, but are not limited to, the following:

- Ambulating
- Feeding
- Dressing
- Personal hygiene
- Transportation and shopping
- Meal preparation
- Housecleaning and home maintenance

Budapest Criteria for Complex Regional Pain Syndrome: To make a clinical diagnosis, the following must be met:

- Continuing pain, which is disproportionate to any inciting event.
- Must report at least one symptom in all four of the following categories:
 - Sensory – reports of hyperaesthesia and/or allodynia
 - Vasomotor – reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry
 - Sudomotor/edema – reports of edema and/or sweating changes and/or sweating asymmetry
 - Motor/trophic – reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).

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- Must display at least one sign at time of evaluation in two or more of the following categories:
 - Sensory – evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or temperature sensation and/or deep somatic pressure and/or joint movement)
 - Vasomotor – evidence of temperature asymmetry (>1 °C) and/or skin color changes and/or asymmetry
 - Sudomotor/edema – evidence of edema and/or sweating changes and/or sweating asymmetry
 - Motor/trophic – evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)
- There is no other diagnosis that better explains the signs and symptoms²

Validated Psychological Evaluations Examples

- Subjective pain intensity: Visual analogue scales, electronic pain ratings to obtain time-stamped multiple assessments of pain in the patient’s natural environment, and verbal scales used to describe the quality of pain
- Mood and personality: Minnesota Multiphasic Personality Inventory, Minnesota Multiphasic Personality Inventory—2, Symptom Checklist—90—Revised, the Beck Depression Inventory, and the Hospital Anxiety and Depression Scale
- Activity Interference: Short-Form Health Survey, West Haven-Yale Multidimensional Pain Inventory, and the Pain Disability Index
- Pain Beliefs and Coping: Coping Strategies Questionnaire, Pain Management Inventory, Pain Self-Efficacy Questionnaire, Survey of Pain Attitudes, Inventory of Negative Thoughts in Response to Pain, Pain Catastrophizing Scale

Persistent, debilitating pain: Persistent, debilitating (or disabling) pain is defined as significant level of pain on a daily basis defined on a Visual Analog Scale as greater than “5” (moderate). The scale ranges from “0” (no pain) to “10” (as bad as it could be).

Radicular pain: Dysfunction of a nerve root associated with pain, sensory impairment, weakness, or diminished deep tendon reflexes in a nerve root distribution.³ Signs and symptoms of radiculopathy must be confirmed by imaging studies and may include any of the following:

- Pain that radiates into the distal portion of the extremities following the nerve root distribution for the proposed intervention
- Numbness and tingling in a dermatomal distribution
- Muscular weakness in a pattern associated with spinal nerve root compression
- Increased or abnormal reflexes corresponding to affected nerve root level
- Loss of sensation in a dermatomal pattern.

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CPT/HCPCS CODES

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Prior Authorization Required	
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, 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
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
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

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L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

No Prior Authorization Required

95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

Unlisted Codes
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**

64999	Unlisted procedure, nervous system
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DESCRIPTION

Neuropathic Pain

Neuropathic pain is defined as, “pain generated and perpetuated by the nervous system itself, without any ongoing stimuli from injury.”⁴ Commonly, neuropathic pain is refractory to standard pain therapies, can increase in severity over time, and can significantly impact quality of life. Neuropathic pain treatment typically includes pharmacological therapy in conjunction with psychosocial support and physical therapy. Examples of neuropathic pain include, but are not limited to, failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) type 1, and diabetic peripheral neuropathy (DPN).

Failed Back Surgery Syndrome (FBSS)

FBSS is a, “generalized term used to describe the condition of patients who have not had a successful result with back surgery or spine surgery and have experienced continued pain after surgery.”⁵ The most common causes of continuous pain after back surgery are improper preoperative patient selection, recurring disc herniation, technical error during surgery, and post-operative scar tissue. Preventative measures can be taken to help eliminate or reduce FBSS, such as special techniques used during back surgery along with stretching and physical therapy after surgery.

Complex Regional Pain Syndrome (CRPS) Type 1

CRPS is a, “chronic pain condition that most often affects one limb (arm, hand, leg, or foot) usually after an injury.”⁶ CRPS is believed to be due to damage or malfunction of the peripheral and central nervous systems. Indications of CRPS commonly include prolonged and excessive pain, changes in skin color, changes in skin temperature, and/or swelling in the affected area. CRPS is divided into two types: CRPS type 1 and CRPS type 2. Individuals classified as CRPS type 1 do not have a confirmed nerve injury (this type was previously known as reflex sympathetic dystrophy syndrome). Individuals classified as CRPS type 2 have an associated, confirmed nerve injury (this type was previously known as causalgia).

Diabetic Peripheral Neuropathy (DPN)

“Diabetic neuropathies are a family of nerve disorders caused by diabetes.”⁷ Diabetic neuropathy may be classified as peripheral, autonomic, proximal, or focal. Diabetic peripheral neuropathy causes pain and numbness in the toes, feet, legs, hands, and/or arms. Symptoms may also include extreme sensitivity to touch and loss of balance and/or coordination; most often exacerbated at night. Due to the numbness caused by diabetic peripheral neuropathy, blisters and sores may appear on the numb areas of the feet and go unnoticed. If untreated, this can cause severe infections and subsequent amputation.

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Implantable Spinal Cord Stimulation (SCS)

SCS is a treatment designed to help suppress pain in specific areas for individuals suffering from chronic, refractory, neuropathic pain; most commonly, failed back surgery syndrome, complex regional pain syndrome type 1, and diabetic peripheral neuropathy. The SCS device works by delivering electrical currents through the spinal column in order to disrupt the transmission of pain signals.⁸ SCS consists of a generator that is implanted subcutaneously and directly connects to electrodes implanted in the epidural space. SCS implantation is conducted in two phases: the trial phase and the permanent implantation phase. During the trial phase, electrodes are implanted temporarily and connected to the generator. The generator is then programmed with stimulation parameters customized to the specific areas of pain. This trial phase determines if the SCS device adequately relieves pain (defined as ≥50% pain relief) before proceeding to permanent implantation. If the trial phase provides adequate pain relief, the SCS device (electrodes and generator) will be permanently implanted. Conventional SCS systems require little maintenance by the patient, but a surgical procedure is required to replace the power source when it runs out. More recently, rechargeable SCS systems have become available where the patient is responsible for recharging the power source. These typically last longer than conventional systems but will eventually require a surgical procedure to replace the power source.⁹

High-Frequency Spinal Cord Stimulation (SCS)

The design of high-Frequency SCS is the same as conventional SCS; however, this newer technology uses high frequency (10,000 Hz) electrical pulses instead of the low frequency traditionally used.¹⁰ While both high- and low-frequency systems effectively relieve radicular pain in the legs and feet, low-frequency therapy has generally not worked as well for back pain.¹¹

Spinal Cord Stimulation with the Burst Clinician Programmer Application

Another expansion in the technology of SCS is a clinician programmer application that allows a standard SCS device to deliver stimulation in bursts. Standard SCS devices produce, “tonic waveforms in which pulses are delivered at a consistent frequency, pulse width, and amplitude.”¹² Burst stimulation is a, “waveform that delivers groups of pulses at high frequency and at amplitudes much lower than tonic stimulation.”¹² The burst stimulation therapy is purported to mimic the natural rhythm of neurons firing and help reduce paresthesia (burning or tingling sensations) often produced by SCS therapy. The technology works by having the clinician download a computer application which is paired with the SCS generator. The clinician is then able to use the app to change from tonic to burst stimulation, or vice versa.

Dorsal Root Ganglion (DRG) Stimulation

Dorsal root ganglion stimulation is a pain therapy indicated for individuals with complex regional pain syndrome types 1 or 2. “Rather than working through the spinal cord, this therapy is applied to the dorsal root ganglion, a group of specialized nerves near the spinal cord at the base of each branching spinal nerve.”¹⁰ The DRG stimulator consists of electrical leads and an implanted pulse generator. The

electrical leads are threaded through the epidural space and attached over the DRG. The pulse generator is also implanted subcutaneously. Patients can switch between stimulation settings using an external hand-held controller.¹³

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of spinal cord stimulation as a treatment for chronic intractable neuropathic pain. Below is a summary of the available evidence identified through August 2020.

Low-Frequency Spinal Cord Stimulation (SCS)

- In 2020, Duarte and colleagues published a systematic review and meta-analysis of placebo/sham controlled randomized trials of SCS for neuropathic pain.¹⁴ Two reviewers independently screened all publications and found 8 randomized trials that met the inclusion criteria. All trials had a crossover design, 3 trials were specifically for failed back surgery syndrome, one trial was specifically for complex regional pain syndrome, and 4 trials included participants with a range of conditions. Types of stimulations investigated in the studies included paraesthesia inducing (low-frequency), subthreshold, burst, and high-frequency SCS. Risk of bias ranged from some concern to high risk of bias, with no studies considered to have low risk of bias. Meta-analysis of data from 155 participants found that there was a significant reduction in pain intensity during active stimulation treatment periods compared to control treatment periods, with a pooled mean difference of -1.15 (95% CI, -1.75 to -0.55; P= 0.001). Larger treatment effects were seen in trials using placebo control compared to sham control, implying there was risk of poor blinding and placebo effect in the results. There was high heterogeneity between the comparisons, a wide range of spinal stimulation treatments, and high risk of bias, therefore it is difficult to determine efficacy based on this review.
- In 2018 (reviewed in 2020), Hayes conducted an evidence review to evaluate spinal cord stimulation (SCS) for the treatment of neuropathic pain.⁸ This review searched the literature through November 2018 and evaluated a total of 24 publications. These studies included 13 randomized controlled trials or crossover trials comparing SCS with standard treatments for neuropathic pain, and 10 nonrandomized cohort or observational studies. Sample sizes ranged from 27 to 198 patients and follow-up times varied from 2 months to 5 years. The patient populations included those with a confirmed diagnosis of failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) type 1, or diabetic peripheral neuropathy (DPN). Several studies also excluded patients with uncontrolled psychological comorbidities and/or required psychological rehabilitation during the study period. Outcomes of interest included pain, need for further surgery to resolve pain, health-related quality of life, global perceived improvement, functional status, use of pain medications, and complications and/or side effects of SCS.

A total of 3 RCTs evaluated SCS for FBSS. Two of these studies compared SCS with reoperation and reported significantly more patients in the reoperation group crossed over to SCS treatment (54%

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and 67%) compared to the SCS patients choosing to change over to reoperation (17% and 21%). Also, more patients in the SCS group achieved $\geq 50\%$ pain relief than the reoperation group at the long-term follow-up (47% vs 12%). The third RCT compared SCS with conventional medical management (CMM) and reported that a greater proportion of SCS patients achieved $\geq 50\%$ pain relief compared to the CMM patients (48% vs 9%).

One RCT evaluating SCS for CRPS Type 1 was included in the evidence review. SCS patients experienced significantly more improvement in pain on the visual analog scale (VAS) compared with the physical therapy (PT) control group at 6-months follow-up (-2.4 vs 0.2 cm where a negative value reflects less pain) and 24 months follow-up (-2.1 vs 0 cm). There were no significant group differences at 3, 4, and 5-year follow-up.

A total of 2 RCTs evaluated SCS for DPN. One RCT compared SCS with best medical therapy (BMT) and patients in the SCS group achieved an average of 60% pain relief at one month follow-up. This pain relief was maintained through 6-months follow-up. The SCS group also showed significant reductions in VAS scores and improved quality of life over the 6-month time period. A second RCT reported that SCS was associated with $\geq 50\%$ pain relief during the day and at night. Also, the overall rate of treatment success was significantly higher in the SCS group compared to the BMT control group (59% vs 7%). This RCT also found the pain severity index and the pain inference index to be significantly lower in SCS patients compared to the BMT patients (4.0 vs 6.5 and 3.5 vs 5.5, respectively).

In regards to safety, the most common complications reported in these studies included lead migration (1.7%-10% of patients), loss of therapeutic effect (7%-12%), incision site pain (6%-12%), and infection (1.3%-10%).: Reoperation due to infection, defective wiring, lead migration, unsatisfactory electrode placement, pain at the surgical site, or removal/preimplantation of the device was required in 3% to 42% of patients. The incidence of reoperation also increased over time.

The level of evidence was determined to be "low" for SCS for treatment of neuropathic pain. Hayes concluded that consistent evidence demonstrated that SCS can reduce the severity of neuropathic pain for patients with FBSS. Mixed evidence supported the efficacy of SCS for the treatment of CRPS and DPN. Hayes ultimately assigned a C rating (potential but unproven benefit), for spinal cord stimulation (SCS) for the treatment of chronic neuropathic pain associated with failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), or diabetic peripheral neuropathy (DPN) that has not adequately responded to standard nonsurgical therapies.⁸

- In 2018, the Washington State Health Care Authority conducted a systematic review evaluating the efficacy of spinal cord stimulation.¹⁵ Independent investigators searched the literature through June 2018, identified eligible studies, assessed study quality and extracted data. In total, 5 studies (n=375) were included for review (3 RCTs, 1 case series evaluating safety and 1 cost-utility analysis).

Three of the 5 studies evaluated efficacy. One small RCT compared SCS to conventional medical care in patients with diabetic neuropathy, and reported improvements in pain and quality of life at 6-

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month follow-up. Two small crossover trials with very short follow-up (2 or 3 weeks) reported inconsistent results among patients receiving either SCS or sham stimulation. Although each of these 3 studies reported significant improvements in pain at short-term follow-up, the clinical relevance of these findings was unclear. Investigators also judged SCS to be less safe than alternative treatments proposed for patients with chronic neuropathic pain, with the number of trial-reported complications ranged from 8% to 100%. The device-related complication rate requiring revision ranged from 25% to 38% of patients at short term follow up, and 42% to 60% at up to 5 year follow-up.

Study limitations include small total patient sample sizes, weak or inappropriate comparators, subjective and/or inconsistently supported outcomes, industry funding, a lack of patient-selection criteria and a lack of trials with a sham stimulation arm. Investigators concluded that, at best, weak evidence demonstrated short-term improvements among SCS patients, but that no medium- or long-term evidence demonstrated the efficacy or safety of SCS.

- In 2018, Mekhail and colleagues conducted a systematic review and meta-analysis of RCTs to evaluate the efficacy of SCS across a range of outcomes.¹⁶ Independent investigators searched the literature through September 2016, identified eligible studies, assessed study quality and extracted data. Outcomes of interest included: perceived pain relief or change in pain score; functional status; quality of life; psychological impact; analgesic medication utilization; patient satisfaction with SCS therapy; and health care cost and utilization. In total, 21 studies were included for qualitative and quantitative analysis. Studies assessed SCS efficacy on trunk and limb pain (TLP), inclusive of failed back surgery syndrome (FBSS); ischemic pain, inclusive of refractory angina pectoris (RAP), critical limb ischemia (CLI) and cardiac X syndrome (CXS); and neuropathic pain, composed of complex regional pain syndrome (CRPS) and painful diabetic neuropathy (PDN).

Seven RCTs with significant heterogeneity evaluated SCS for the treatment of TLP found SCS to provide superior analgesia when compared to conventional medical management and repeat lumbosacral surgery. Six of the 7 RCTs for TLP reported a significant improvement in patient satisfaction with active SCS therapy. Eight RCTs reported data for RAP patients, indicating pain relief as either a function of the number of weekly episodes of angina attacks or the change in usage of rescue nitrates per week. Compared to patients receiving medical management or sham stimulation, SCS provided superior analgesia and improved functional outcomes. Compared to patients receiving active controls, however, SCS patients' analgesia and functional outcomes were not significantly improved. Three RCTs reported outcomes for CLI, with mixed results. Outcomes regarding analgesia were inconsistently superior to conventional medical management. One study reported significantly improved wound healing, resulting in inconclusive findings among SCS patients, whereas quality-of-life measures between SCS and controls were comparable. The generalizability of results is limited, however, as all data derive from only 1 RCT. Two RCTs have evaluated SCS outcomes for CRPS to date, both of which reported significant improvements in pain relief, with improvement in quality of life in one study and improvements in patient satisfaction and psychological impact in another. Two high-quality RCTs reported data for PDN, indicating that SCS provides reliable analgesia and improvements in quality of life, with some evidence of an analgesic-

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sparing effect and improved patient satisfaction at 2-year follow-up. Only 1 RCT evaluated SCS for CXS patients, reporting improvements in perceived pain relief, functional status, quality-of-life, and analgesic requirements.

One strength of this study is its comprehensive summation of SCS efficacy on relevant clinical outcomes to date. Study limitations across reviewed studies included heterogeneity in study design, outcome measures and patient populations; as well as the exclusion of non-RCT studies which may have contained clinically relevant data. Only 2 of the 21 RCTs included for review were determined to be of “high quality.” Scaled data from each individual were not merged into a unified numerical result, and so no meta-analysis was conducted.

- In 2018, Moens and colleagues conducted a systematic review and meta-analysis evaluating return-to-work rates among patients with chronic pain treated with SCS.¹⁷ Investigators systematically searched the literature through October 2017, identified eligible studies, assessed study quality and pooled data using random effects meta-analysis. In total, 15 articles were included for review of which 7 provided sufficient data for meta-analysis (n=824). Investigators found that SCS intervention resulted in a higher prevalence of patients at work compared with baseline (OR 2.15; 95% CI, 1.44-3.21; I2 = 42%; p<0.001). SCS treatment also resulted in higher odds of returning to work compared to patients who did not receive SCS (OR 29.06; 95% CI, 9.73-86.75; I2 = 0%; p <0.001). Limitations in reviewed studies included small sample sizes, inadequate follow-up, a lack of comparator groups. Limitations in the systematic review itself included moderate heterogeneity across study designs, and the evaluation of a surrogate outcome measure (i.e. return to work), which may not indicate long-term pain relief. The work status of included patients (e.g. type of job, full-time, part-time) was also not included. Additionally, the study’s lead investigator has financial conflicts of interests with two SCS device manufacturers. Investigators concluded that additional, larger studies were needed to better establish validity.
- Hayes and ECRI conducted 8 evidence reviews evaluating 9 different SCS devices.¹⁸⁻²⁶ Each report concluded that evidence evaluating the safety and efficacy of individual SCS devices was inconclusive due to the low quantity and quality of studies conducted to date.

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A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of high-frequency spinal cord stimulation as a treatment for chronic intractable neuropathic pain. Below is a summary of the available evidence identified through August 2020.

Systematic reviews

- In 2014 (updated 2019), ECRI conducted a systematic review evaluating the safety and efficacy of the Senza II SCS system for the treatment of chronic pain.²⁷ Having systematically searched the literature through April 2019, ECRI included four studies for review (1 RCT and 3 case series). The RCT (n=198) reported greater rates of >50% pain reduction on the visual analog scale (VAS) score in

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patients with chronic back or leg pain at 2-year follow-up among Senza patients compared to patients receiving standard SCS (84.5% versus 43.8% for back pain and 83.1% versus 55.5% for leg pain, $p < 0.001$). Patients also experienced greater physical function (ODI score normalization in 24% versus 9%) and satisfaction with Senza than with conventional SCS (60% versus 40%). Adverse events were comparable in both groups. The three case series ($n = 359$) reported 60% to 73% pain score reduction, in addition to improvements in disability and pain-related quality of life (QOL) at 2-year follow-up. ECRI concluded that limited evidence indicated that Senza reduced pain by more than 50%, and more effectively than standard SCS. Nonetheless, ECRI assessed the evidence base as being at risk of bias due to the lack of blinding in the RCT, the lack of control groups in the case series and the lack of long-term data. Investigators called for double-blind, sham-controlled RCTs with long-term follow-up. Long-term efficacy data are especially important as Senza is intended to be used as a long-term or lifelong therapy. Two ongoing RCTs ($n = 456$) evaluating the efficacy of medical therapy with and without Senza may partially address evidence gaps; however, these studies are not expected to report outcomes beyond 6-months.

- In 2018, Hayes conducted a “search & summary” of studies evaluating the efficacy of Senza for the treatment of chronic pain. Having reviewed 8 abstracts, Hayes concluded that evidence published to date was insufficient to assess the safety and efficacy of Senza.²⁸
- A 2019 systematic review by Pollard and colleagues investigated the effect of SCS on pain medication reduction in intractable spine and limb pain.²⁹ Five randomized controlled trials ($n = 489$) were analyzed. Overall, the odds of reducing opioid consumption were significantly increased in the SCS group compared to medical therapy (OR: 8.60; 95% CI, 1.93–38.30). One trial compared high-frequency to conventional SCS and found that 34% versus 26% of patients were able to reduce opioid use, but this was not significant. While there was an overall reduction in pain drug use, the authors found that there was a moderate risk of bias among trials and that data is limited. Pollard et al concluded that results should be treated with caution and clinical significance of these findings require further trials.

Randomized Controlled Trials (RCTs)

- The 2015 Hayes evidence review (updated 2020) on spinal cord stimulation for relief of neuropathic pain also evaluated a randomized controlled trial (RCT) examining high-frequency (HF-10) spinal cord stimulation (SCS) for the treatment of chronic intractable back and/or leg pain.^{8,30} Participants were eligible for inclusion if they met the following criteria:
 - Chronic, intractable pain of the trunk and/or limbs, refractory to conservative therapy for a minimum of 3 months (previous conservative treatments included pain medications, physical therapy, spinal injections, pharmacological, and behavioral treatment)
 - Average back pain intensity score of 5 or greater out of 10 cm on the visual analog scale (VAS)
 - Average leg pain intensity score of 5 or greater out of 10 cm on the VAS
 - An Oswestry Disability Index (ODI) version 2.1a score of 41 to 80 out of 100
 - An appropriate candidate for the surgical procedure

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Participants were excluded based on the following criteria:

- Active disruptive psychological or psychiatric disorder or other known condition significant enough to impact perception of pain
- Inability to comply with the intervention or evaluate treatment outcomes
- Mechanical spine instability based on flexion/extension films of the lumbar spine
- Prior experience with SCS

A total of 171 patients were randomized 1:1 to either HF-10 SCS or standard SCS and followed for 12 months. The primary outcome of interest was responder rate (defined as $\geq 50\%$ back pain reduction from baseline) at 3 months, with secondary outcomes of interest being responder rates at 6 months and 12 months follow-up. A significantly greater percentage of the HF-10 patients experienced $\geq 50\%$ back pain relief compared with the conventional SCS patients at 3 months (84.3% vs. 43.8%, $P < 0.001$), 6 months (76.4% vs. 51.9%, $P < 0.001$), and 12 months (78.7% vs. 51.3%, $P < 0.001$). Similarly, a significantly greater percentage of HF10 patients experienced $\geq 50\%$ leg pain relief at 3 months (83.1% versus 55.0%, $P < 0.001$), 6 months (80.9% versus 54.4%, $P < 0.001$), and 12 months (78.7% versus 51.3%, $P < 0.001$). At 12 months, 68.5% of HF10 patients versus 36.3% of SCS patients reported a back pain score ≤ 2.5 ($P < 0.001$); for leg pain, 67.4% (HF10) versus 42.5% (SCS) reported a leg pain score ≤ 2.5 ($P < 0.001$). At 12 months, 62.9% of HF10 patients had minimal or moderate disability compared with 45.7% of SCS patients (as measured by the Oswestry Disability Index; $P = 0.03$)

Hayes determined this RCT to be of good quality. The evidence review concluded a C rating for, "high-frequency SCS for the treatment of chronic, intractable back and leg pain that has not responded adequately to standard nonsurgical therapies."⁴

- In 2016, Kapural et al. reported the 2 year results of the RCT described above for high-frequency (HF-10) spinal cord stimulation (SCS) compared to standard SCS for the treatment of chronic back and leg pain (the Hayes evidence review only evaluated results through 12 months).³¹ At 24 months, a significantly greater percentage of the HF-10 patients experienced $\geq 50\%$ back pain and leg pain relief compared with the standard SCS patients (back pain: 76.5% vs 49.3%, $P < .001$ for non-inferiority and superiority; leg pain: 72.9% vs 49.3%, $P < .001$ for non-inferiority and $P = .003$ for superiority). Also at 24 months, back pain and leg pain decreased to a greater degree with HF-10 compared to standard SCS (back: 66.9% vs. 41.1%, $P < .001$ for non-inferiority and superiority; leg: 65.1% vs. 46.0%, $P < .001$ for non-inferiority and $P = .002$ for superiority).

This study was determined to be of good methodological quality with several strengths, including:

- Randomized, controlled design comparing two different treatments
- The recruitment of participants from 11 different comprehensive pain centers
- Large sample size
- Extended follow-up period
- High subject retention (94.4% of HF10 patients and 87.7% of standard SCS patients at 2-year follow-up)

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- The use of standardized outcome measures (e.g., VAS and ODI)
- The use of intention to treat analysis
- Sufficiently powered to detect statistically significant differences between groups
- Analysis of non-inferiority as well as superiority

Limitations were identified in the lack of blinding of participants (this was noted by the authors to be impractical because standard SCS produces paresthesia) and investigators (this was also noted by the authors to be impractical due to differences in stimulator lead placement and device programming). Another limitation was the heterogeneity at baseline between patient groups for specific pain diagnoses. The authors stated, “this etiological heterogeneity reflects the diversity of patients seen when managing chronic back and leg pain, and is therefore a clinically relevant population to evaluate, especially given the pragmatic nature of this study.”³¹ The authors concluded “the study demonstrates long-term superiority of HF10 therapy compared with traditional SCS in treating both back and leg pain.”³¹

- In 2019, Bolash and colleagues published the preliminary results of a multicenter, randomized controlled trial comparing wireless high-frequency (HF) SCS (10 kHz) with multi-waveform low-frequency (LF) SCS to manage chronic pain in subjects with failed back surgery syndrome.³² The primary endpoint was the percentage of subjects who responded to wireless SCS therapy for back pain, defined as a $\geq 50\%$ reduction in VAS score. Ninety-nine subjects were randomized in a 1:1 ratio between the two groups. At the time of this publication, 83 subjects reached the 3-month endpoint, and 72 had reached the 6-month endpoint. In the HF group, 92% of subjects had a response ($\geq 50\%$ reduction in VAS score), and 84% had a response in the LF group. HF was found to be noninferior to LF ($p=0.00008$), but not superior ($P=0.2$). Mean VAS scores for back and leg pain decreased significantly for the HF group, 77% and 76%, respectively, and for the LF group, 64% and 64%, respectively, for the LF arm. In addition, most subjects experienced significant improvements in VAS, Oswestry Disability Index, European Quality of Life 5 Dimension questionnaire, Patient Global Impression of Change, and sleep duration. There was only one treatment-related serious adverse event among the subjects. Twenty-six subjects experienced 37 adverse events. Limitations of the study included small sample size, lack of blinding for both subjects and investigators, and no control group. The authors conclude that both HF and LF SCS are effective treatments for patients with chronic pain from failed back surgery syndrome.

Psychological assessment pre-spinal cord stimulator trial

Psychological assessment is designed to identify problematic emotional reactions, maladaptive thinking and behavior, and social problems that contribute to pain and disability. Psychological evaluations should include the assessment of sensory, affective, cognitive, and behavioral components of the pain experience, expectations of the benefit of an implanted device, and identification of personality and psychosocial factors that can influence treatment outcome. A psychological evaluation is necessary to identify the right patient to achieve maximum benefit from an implanted device. Psychological evaluations should include valid and reliable assessments of all of the following: subjective pain intensity, mood and personality, activity interference, pain beliefs, and coping.³³

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Investigational Conditions for Spinal Cord Stimulation

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of spinal cord stimulation as a treatment for intractable angina pectoris (IAP), non-specific back and/or leg pain, critical limb ischemia (CLI), and failed neck surgery syndrome (FNSS). Below is a summary of the available evidence identified through August 2020.

Intractable Angina Pectoris

- In 2014 (archived in 2019), Hayes conducted an evidence review to evaluate electrical spinal cord stimulation for the treatment of intractable angina pectoris (IAP).³⁴ The review included a total of 10 studies, of which 9 were randomized controlled trials (RCTs) and one was a cohort study. The sample sizes ranged from 15 to 153 patients and follow-up times varied from 48 hours to 5 years. Primary outcomes of interest included angina symptom frequency, angina pain severity relief, and quality of life. Secondary outcomes of interest were exercise capacity, anti-ischemic effect, nitrate intake, heart rate variability, and complications.

Overall, the evidence for SCS to treat intractable angina pectoris was mixed. In regards to angina symptom frequency, SCS showed improvement in 2 out of 7 studies; however, in 4 studies SCS was no more effective than placebo and one study did not report statistical analyses. The Hayes review also stated, “the sample sizes of these studies may have been too small to detect moderate to small treatment effects.”³⁴ For the outcome of angina pain severity, the results of 2 RCTs were mixed. One study reported significantly reduced angina pain in SCS patients while the other study reported no significant improvement in angina pain in SCS patients. Out of 5 studies evaluating quality of life, 4 reported improvements in the SCS group compared to the control group.

A total of 5 studies evaluated exercise capacity. SCS was shown to improve exercise duration compared to the control in 2 studies; however, in 2 studies no significant improvements were seen in the SCS groups and 1 study did not report statistical analyses. A total of 5 studies evaluated anti-ischemic effect, and 2 found a significant difference between the SCS group and control group. In regards to nitrate consumption, 7 studies evaluated this outcome and 3 studies found no significant difference between groups. In 3 other studies, SCS reduced nitrate intake in the SCS group while it remained stable in the control group. The last study did not report statistical analyses. SCS and heart rate variability was evaluated in 2 studies and was found to have no effect. In regards to complications, the commonly reported event was infection (0%-2%) and lead dislocation (1%-6%).

Hayes rated the quality of evidence evaluating SCS for IAP to be low. Study limitations included, but were not limited to, small sample sizes, lack of blinding, short follow-up (only 2 publications reported follow-up >1 year), and subjective outcome measures (e.g., having groups keep a patient diary to report pain symptoms). Ultimately, the Hayes review concluded, “the current evidence is insufficient to draw conclusions regarding the efficacy and safety of spinal cord stimulation (SCS) for intractable angina pectoris (IAP).”³⁴

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- In a systematic review discussed above,¹⁶ 8 RCTs reported outcomes for IAP, which collectively concluded pain relief to be a function of either the number of weekly episodes of angina attacks, or of the change in usage of rescue nitrates per week. Compared to patients receiving medical management or sham stimulation, SCS provided superior analgesia and improved functional outcomes. Compared to patients receiving active controls, however, IAP patients’ analgesia and functional outcomes were not significantly improved by SCS.

Non-Specific Back and/or Leg Pain

Systematic Reviews

- In 2005, Taylor and colleagues conducted a systematic review (reported in two publications) to evaluate spinal cord stimulation (SCS) for chronic back and leg pain (CBLP) and failed back surgery syndrome (FBSS).^{35,36} Independent authors systematically identified evidence, evaluated quality, and assessed heterogeneity. The authors found no randomized controlled trials of SCS for CBLP without failed back surgery. A total of 27 case series were identified that evaluated SCS for CBLP without failed back surgery. The authors stated the case series had, “inadequate reporting which prevented an appropriate assessment of methodologic quality; however when the relevant information was reported, the quality of these case series was in general relatively poor.” Also, no case series prospectively studied patients with CLBP.

Based on the pooled outcomes of the case series, 62% of patients had greater than 50% of pain relief shortly following SCS implantation. However, pooling of data was inappropriate due to significant heterogeneity between studies (P<0.001). Also, the authors pooled the case series for both CBLP and FBSS; therefore, this proportion does not represent only patients with CBLP. The proportion of patients with greater than 50% pain relief decreased by 5% for every 10 months of follow-up. Pain relief was also 15-20% lower in studies rated to be of higher quality. Overall, 43% of patients experienced an adverse event related to SCS. Common complications included electrode or lead problems (27%), infection (6%), generator problems (6%), extension cable problems (10%), and other (e.g., cerebrospinal fluid leak in 7% of patients).

Strengths of this systematic review include the systematic review of literature by independent authors following a pre-defined protocol. However, significant limitations severely impact the validity of this study. Firstly, meta-analysis was inappropriate due to significant heterogeneity reported between studies; therefore, the pooled data results are inaccurate. Also, the authors combined both patient populations, CBLP and FBSS, which does not permit conclusions regarding SCS for a specific patient population. Lastly, the poor-quality of included studies (small case series) in this review of evidence invalidates the reliability of the results.

- A 2019 systematic review by Odonkor and colleagues compared SCS and conventional therapies (CT) for the treatment of chronic low back and leg pain.³⁷ The review found 11 studies that met their inclusion criteria (n=31,439 SCS patients and 299,182 CT patients). In six studies evaluating cost-effectiveness, SCS was associated with favorable outcomes and found to be more cost-effective

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than conventional treatment approaches for LBP. Three studies including pain relief outcomes and results were inconclusive due to large discrepancies between trials, patient types, and time. The systematic review found that 4 of 11 studies have moderate quality of evidence while the other 6 had low quality and high risk of bias. The review had a number of limitations:

- High variability in study design and outcome measures
- High variability in patient population and causes of pain
- Poor quality of trials analyzed
- Potential unmeasured confounders

Authors concluded that there is weak to moderate evidence to support the use of SCS as a cost-effective treatment for low back and leg pain.

Randomized Controlled Trials (RCTs)

No RCTs were identified evaluating spinal cord stimulation for non-specific back pain conditions and pain conditions not related to failed back surgery syndrome, complex regional pain syndrome, or diabetic peripheral neuropathy.

Nonrandomized Studies

Nonrandomized studies of spinal cord stimulation for chronic back pain are all small, retrospective case series of very poor quality. These studies were included in the systematic review described above by Taylor and colleagues.

Critical Limb Ischemia

Systematic Reviews

- In a systematic review discussed above,¹⁶ 3 RCTs reported outcomes for critical limb ischemia, with mixed results. Outcomes regarding analgesia were inconsistently superior to conventional medical management. One study reported significantly improved wound healing, resulting in inconclusive findings among SCS patients, whereas quality-of-life measures between SCS and controls were comparable. The generalizability of results is limited, however, as these data derive from only 1 RCT.
- In 2013, Ubbink and colleagues conducted a systematic review and meta-analysis to evaluate spinal cord stimulation for non-reconstructable chronic critical limb ischemia.³⁸ Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The authors aimed to find evidence for an improvement on limb salvage, pain relief, and the clinical situation using SCS compared to conservative treatment along. A total of 6 studies (reported in 10 publications) were identified as eligible for inclusion; thus producing a sample size of n=444 patients. The selected studies were determined to be of good quality (all but one were randomized); however, blinding was not done in any study due to the nature of SCS.

The results indicated a trend toward better limb salvage at 12 months, 18 months, and 24 months

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follow-up; however, there were not statistically significant differences between groups. When the results were pooled, a small significant decrease in amputations was found in the SCS group at 12 months follow-up. Of note, when the authors excluded the nonrandomized study results from pooled analysis, the treatment difference between groups for amputations was no longer significant. Although more prominent in the SCS group, significant pain relief was seen in both groups. No significant differences were seen between groups for ulcer healing. Common complications in the SCS group included implantation problems (9%) and changes in stimulation requiring re-intervention (15%). Infection at the site of the leads or pulse generator occurred in 3% of patients. The overall risk of complications or additional SCS treatment was 17%.

Strengths of this study include the systematic review of evidence by independent authors following a predefined protocol, assessment of quality, and inclusion of mostly randomized controlled trials. However, the results of the systematic review varied. Due to the limited number of studies included in the review, publication bias is also probable. Also of note, a conflict of interest was noted for the lead author who contributed to studies included in the analysis. The authors conclude the evidence is promising for SCS to improve limb salvage in patients with CLI but stated, “the benefits must be considered against the possible harm of relatively mild complications and the costs.”³⁸

- In 2009, Klomp et al. conducted a systematic review and meta-analysis to evaluate the evidence on efficacy of spinal cord stimulation in patients with critical limb ischemia.³⁹ Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The authors identified 5 randomized controlled trials eligible for inclusion, all of which were included in the Ubink et al. study described above, resulting in a sample size of n=332 patients. The outcomes of interest were mortality and limb survival.

Meta-analysis including all randomized data showed insufficient evidence to conclude SCS is more effective than best medical treatment for chronic limb ischemia. The results also indicated patients with ischemic skin lesions had a higher risk of amputation compared to patients with other risk factors. The authors identified no significant interactions between any prognostic factor and the efficacy of SCS. Strengths of this study include the systematic review of evidence by independent authors following a predefined protocol, assessment of quality, and inclusion of mostly randomized controlled trials. Due to the limited number of studies included in the review, publication bias is also probable. The authors concluded the meta-analysis revealed, “no data to support a more favorable treatment effect in any group with chronic limb ischemia.”³⁹

Randomized Controlled Trials (RCTs)

A total of five RCTs were identified for the evaluation of SCS for critical limb ischemia⁴⁰⁻⁴⁴; however, all RCTs were included in the systematic reviews described above. A search of clinicaltrials.gov identified no new or upcoming RCTs since those included in the systematic reviews.

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Failed Neck Surgery Syndrome

In 2017 (archived 2018), Hayes conducted a review of abstracts published through June 2017, evaluating spinal cord stimulation for the treatment of failed neck surgery syndrome.⁴⁵ In total, 7 abstracts were retrieved (n=448), each comprising mixed patient cohorts, including patients presenting with failed neck surgery syndrome (1 prospective uncontrolled study, 5 retrospective uncontrolled studies, and 1 review article. Hayes concluded that this body of evidence was insufficient to assess the safety and/or impact of SCS on the relief of pain in the management of patients with failed neck surgery syndrome.

Nonrandomized Studies

A total of 6 nonrandomized studies were identified that evaluated spinal cord stimulation in the cervical region to treat failed neck surgery syndrome.⁴⁶⁻⁵⁰ All studies were determined to be of poor methodological quality due to their nonrandomized retrospective observational or case series design and small sample sizes. The results of these studies suggest spinal cord stimulation of the cervical spine may improve symptoms of failed neck surgery syndrome; however, due to the poor methodological quality of these studies this evidence does not support medical necessity. Additional studies of good methodological quality (e.g., randomized controlled trials) are needed in order to confirm the long-term safety and efficacy of spinal cord stimulation for failed neck surgery syndrome.

In 2017, Hayes conducted a “search & summary” evaluating spinal cord stimulation for relief of pain secondary to failed neck surgery syndrome.⁴⁵ The search and summary identified the same publications cited above and concluded, “there is insufficient published evidence to assess the safety and/or impact of SCS on the relief of pain in the management of patients with failed neck surgery syndrome.”

Chemotherapy-induced peripheral neuropathy

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of spinal cord stimulator therapy to treat chemotherapy-induced peripheral neuropathy through December 10, 2020.

In 2015, Peng and colleagues published a Cochrane systematic review on spinal cord stimulation for cancer-related pain in adults, updating a previous review published in 2013.⁵¹ No randomized trials were found, but 4 before-and-after case series studies were included in the review, totalling 92 participants. There was high heterogeneity in patient population, treatment, and data reporting. Pain, measured through VAS score, was improved in all studies. All trials were small and non-randomized, carrying a high risk of all types of bias. The authors concluded “current evidence is insufficient to establish the role of SCS in treating refractory cancer-related pain.”⁵¹

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Spinal Cord Stimulation with Burst Stimulation Technology

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of spinal cord stimulation with burst stimulation technology as a treatment for chronic intractable neuropathic pain. Below is a summary of the available evidence identified through August 2020.

Systematic Reviews

- In the 2018 update (reviewed in 2020) to its 2015 report,⁸ discussed above, Hayes assessed 2 studies evaluating the efficacy of burst stimulation. Both studies reported improved pain relief compared to patients receiving SCS, but no differences in quality of life or functionality. Despite these findings, Hayes assessed the overall quality of evidence as “very low” and ultimately assigned a D2 rating (insufficient evidence) for burst-frequency SCS for the treatment of chronic neuropathic pain that has not responded adequately to standard nonsurgical therapies.
- In 2018 systematic review conducted by the Washington State Health Care Authority,¹⁵ discussed above, investigators assessed three studies evaluating the efficacy of burst stimulation. Each of the three studies were short-term crossover studies (follow-up: 2 to 3 weeks) in patients already receiving traditional SCS. Systematic review investigators concluded that larger studies with longer follow-up, comparing burst stimulation to non-stimulation therapy and placebo groups are needed in patients naïve to stimulation.
- In 2016, Hou and colleagues conducted a systematic review to evaluate burst spinal cord stimulation for chronic back and limb pain.⁵² The objective of this study was to determine the effects of burst SCS on pain relief for various conditions, including failed back surgery syndrome and peripheral diabetic neuropathy. Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The American Academy of Neurology (AAN) Classification of Evidence Guidelines Process Manual was used to grade the evidence and the risk of bias. A total of five studies were identified as eligible for inclusion; thus producing a sample size of n=117 patients. All studies were rated a class IV study, defined by AAN as studies that did not include patients with the disease, did not include patients receiving different interventions, undefined or unaccepted interventions or outcome measures, and/or no measures of effectiveness or statistical precision presented or calculated.

The results of the studies selected for review indicated burst SCS may cause more pain reduction for short-term duration compared to tonic SCS. The burst SCS devices were also shown to reduce paresthesia (tingly or burning sensation) commonly seen in patients with SCS. However, the authors stated the evidence for burst SCS in treating chronic intractable pain is “fair and limited.” The level of evidence was rated to be a U, defined by AAN as the available evidence is insufficient to support or refute the efficacy of an intervention. Strengths of this study include the systematic review of evidence by independent authors following a predefined protocol and the assessment of quality and level of evidence following the AAN Classification of Evidence Guidelines Process Manual. Limitations were identified in poor quality of included studies and the paucity of available literature.

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Ultimately, the authors concluded, “further research is needed with larger sample sizes and standardized study designs.”⁵²

- A 2019 systematic review by Chakaravarthy and colleagues analyzed the effectiveness of burst SCS on pain intensity and patient-reported outcomes.⁵³ Fifteen articles, totalling 427 subjects, were included. One randomized trial was found (reviewed below), 11 studies were prospective, and 3 were retrospective case reports. Burst SCS pain scores were compared to tonic SCS and baseline scores. The weighted pooled mean pain score was 76.7 (± 27.4) at baseline, and was reduced to 49.2 (±12.9) with tonic SCS, and 36.7 (± 11.6) with burst SCS. Among studies that reported patient preference, 65% of subjects stated that they preferred burst SCS, 20% preferred tonic SCS, and 16% had no preference or preferred some other SCS waveform. Limitations of the study reduce the generalizability of the results. More long-term randomized trials are needed to determine superiority of burst SCS. Limitations of the review include:
 - Nonrandomized trials design for all but one study included.
 - Short term follow up
 - High heterogeneity among participants, interventions, trial design, and statistical analyses
 - High risk of bias among trials

Randomized Controlled Trials (RCTs)

- In 2018, Deer and colleagues conducted an RCT evaluating the safety and efficacy of SCS with burst stimulation for the treatment of chronic pain of the trunk and/or limbs. Having successfully completed a tonic SCS trial, 100 subjects were randomized to receive either tonic or burst stimulation for 3 months. After 3 months, patients used their stimulation mode of choice for one year. The primary outcome of interest was within-subject difference between tonic and burst SCS for mean daily overall visual analogue pain score. Investigators conducted an intention-to-treat analysis, reporting that burst stimulation was superior to tonic stimulation for improving pain (p <0.017). Additionally, more subjects (70.8%) preferred burst stimulation through one year than tonic stimulation, although a substantial minority preferred the latter. No unanticipated adverse events were reported. Limitations include the study’s small sample size, inadequate follow-up, potential for carry-over effects between treatments due to the lack of a washout period, lack of non-SCS controls and investigators’ conflicts of interest with the device manufacturer. Investigators called for additional studies that compare tonic and burst stimulation, and employ both stimulation modes during the evaluation period.

A search of clinicaltrials.gov identified three RCTs currently in progress evaluating burst SCS for the treatment of chronic intractable pain (NCT03595241, NCT03546738, and NCT03419312).

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Dorsal Root Ganglion Stimulation

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of dorsal root ganglion stimulation as a treatment for complex regional pain syndrome. Below is a summary of the available evidence identified through August 2020.

Systematic Reviews

- In 2017 (updated 2018), Hayes conducted a systematic review evaluating the efficacy of dorsal root ganglion (DRG) stimulation for the treatment of complex regional pain syndrome (CRPS).⁵⁴ Hayes identified 3 studies that met inclusion criteria (1 fair-quality RCT; 1 very-poor quality pretest-posttest study; and 1 crossover study). All studies reported improvements in patients’ pain, quality of life and mood at 12 months follow-up. Study limitations included the limited body of evidence, the lack of studies comparing patient groups receiving either DRG stimulation or SCS, and the lack of standardized treatment parameters. Hayes concluded that “very low” quality evidence suggested that DRG stimulation may result in treatment success, reductions in pain and improvements in QOL compared to both baseline assessments and SCS treatment. Hayes ultimately assigned a D2 rating (insufficient evidence) for DRG stimulation for the treatment of CRPS.
- Three systematic reviews were published on the efficacy of dorsal root ganglion for various pain syndromes that hold similar results to the Hayes review above.⁵⁵⁻⁵⁷ All reviews only included one RCT, reviewed by Hayes and summarized below (Deer et al).⁵⁸ Most studies were industry funded were limited by small sample size, short-term follow up, no blinding or randomization, and high risk of bias.
 - Vuka and colleagues included 29 studies, 1 RCT, 8 retrospective cohort studies, 2 case series, and 18 case reports.⁵⁵ Sample sizes ranged from 1-66 patients, excluding the RCT, which included 152 participants. Most studies reported positive but inconclusive results on DRS effect on pain. The authors concluded that only the RCT provided evidence to support use of DRS for pain, and more high-quality RCTs with sufficient number of participants are needed.
 - Deer and colleagues included 6 studies, one RCT and 5 prospective studies with sample sizes ranging from 10-62 participants.⁵⁶ The authors concluded that efficacy can only be determined from the RCT included.
 - Huygen and colleagues conducted a pooled analysis of 1 RCT and 6 observational studies, many of which were addressed in the reviews by Deer et al and Vuka et al.⁵⁷ Pooled results from sample sizes ranging from 9-55 participants showed decrease in pain scores by 58% in 12 months.
- In a systematic review discussed above,¹⁶ investigators summarized the finding for the Deer et al. study discussed below,⁵⁸ which found DRGS to provide effective analgesia for CRPS. Systematic review investigators nonetheless concluded that “additional RCTs are required to attain higher levels of evidence for a multitude of outcomes.”¹⁶

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- In 2017, ECRI conducted an evidence review evaluating the efficacy of DRG stimulation for the treatment of CRPS.⁵⁹ ECRI systematically searched the literature through October 2017, ultimately including 9 studies for review. Investigators found low quality evidence indicating that patients treated with DRG stimulation experienced >50% pain relief compared to patients treated with SCS at 3 month follow-up. Low quality evidence suggested that adverse events were also higher in patients treated with DRG stimulation compared to those treated with SCS at 12 month follow-up. “Very low” quality evidence reported improvements in quality of life (brief pain inventory, profile of mood states) and physical function among patients receiving DRG stimulation. Investigators found no data addressing the comparable efficacy of DRG stimulation compared to pharmacotherapy, sympathetic blocks and anesthesia. ECRI called for additional, controlled trials to evaluate treatment efficacy, concluding that studies to date failed to establish the safety, efficacy, or superiority of DRG stimulation compared to SCS.
- In 2017, Duong and colleagues conducted a systematic review of RCTs to evaluate the efficacy of various treatments for Complex regional pain syndrome (CRPS), including SCS and dorsal root ganglion stimulation (DRG stimulation).⁶⁰ Investigators systematically searched the literature through August 2017, identified eligible studies, assessed study quality and extracted data. In total, 3 studies investigating either SCS or DRGS were included for review. Investigators concluded that, compared to SCS, DRGS significantly improved analgesia, function and mood at 1-year follow-up among CRPS patients. Nonetheless, investigators called additional studies with long-term follow-up were required to validate the safety and efficacy of DRGS for CRPS.
- In 2013, Pope et al. conducted a systematic review to evaluate dorsal root ganglion therapeutics to treat chronic pain.⁶¹ The objective of this study was to review historical and current therapeutics for treating chronic pain directed at the dorsal root ganglion (DRG) and identify future trends in this treatment modality. Independent reviewers systematically searched research databases, identified relevant studies, assessed quality, and extracted data. The authors identified 3 studies eligible for inclusion, of which 2 were case reports and one was a nonrandomized feasibility trial.

The nonrandomized feasibility trial prospectively followed patients (n=10) over a 4 week time period that had been diagnosed with chronic intractable neuropathic pain. A total of 9 patients completed the trial, and 8 patients experienced a, “clinically meaningful (>30%) reduction in pain, as measured using a visual analog scale, with an average pain reduction of 70%.”⁶¹ A majority (7/9) of these patients also reduced their utilization of pain medication. The two case studies included in the systematic review described successful treatment of discogenic pain and cervicogenic headache.

Although strengths were identified in the systematic review of evidence by independent authors following a predefined protocol, the reliability of this study is severely limited due to the paucity of available high-quality literature on DRG. The authors concluded “despite a robust understanding of the DRG and its importance in acute nociception, as well as the development and maintenance of chronic pain, relatively poor evidence exists regarding current therapeutic strategies.”⁶¹

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Randomized Controlled Trials (RCTs)

- In 2017, Deer and colleagues conducted a randomized comparative trial to evaluate dorsal root ganglion stimulation (DRG) for the treatment of complex regional pain syndrome (CRPS) or causalgia in the lower extremities.⁵⁸ Patients were eligible for inclusion if they experienced chronic (≥ 6 months) intractable (failed ≥ 2 drugs from different classes) neuropathic pain of the lower limbs associated with CRPS or causalgia. A total of 152 patients were randomized to DRG or SCS, and 115 had a successful temporary trial to move on to permanent implantation (n=61 DRG, n=54 SCS). Patient follow-up occurred at 3, 6, and 12 months. The primary outcome of interest was treatment success (defined as $\geq 50\%$ reduction in VAS score and no stimulation-related neurological defects). Long-term outcomes and adverse events were also assessed through 12 months. The trial was also designed to evaluate noninferiority and superiority, if noninferiority was met.

A total of 10 patients were lost to follow-up; thus 105 patients had data available at 12 months (n=55 DRG, n=50 SCS). At 3-month follow-up, treatment success was achieved by 81.2% of patients in the DRG group and 55.7% in the SCS group. The noninferiority margin was also met and DRG was found to be statistically superior to SCS ($p < 0.001$). At 12-month follow-up, treatment success was achieved by 74.2% of patients in the DRG group and 53% of patients in the SCS group. Noninferiority was also met, and DRG was found to be statistically superior to SCS ($P < 0.001$) at 12-months follow-up. In regards to safety, 21 serious adverse events were reported in 19 patients (n=8 DRG, n=11 SCS; not statistically significant).

Strengths of this study include the randomized controlled design, large sample size, use of a comparator group, and evaluation of both noninferiority and superiority. Limitations were identified in the lack of blinding, short follow-up period, and losses to follow-up. Also, funding bias is possible due to the study being sponsored by St. Jude Medical (the manufacturer of DRG stimulators). This RCT shows promising results for DRG stimulation and the treatment of CRPS; however, additional studies with longer follow-up are required in order to confirm the long-term durability and safety of DRG stimulation.

Nonrandomized Studies

Seven additional nonrandomized studies were identified that evaluated dorsal root ganglion stimulation for the treatment of chronic intractable pain.⁶²⁻⁶⁸ All studies were determined to be of poor methodological quality due to their nonrandomized retrospective observational or case series design, small sample sizes, short follow-up periods, and authors' financial conflicts of interest. The results of these studies suggest dorsal root ganglion stimulation may improve symptoms of complex regional pain syndrome; however, due to the poor methodological quality of these studies this evidence does not support medical necessity.

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EVIDENCE SUMMARY

The evidence confirms the efficacy and safety of low-frequency spinal cord stimulation (SCS) for the treatment of chronic intractable neuropathic pain secondary to failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS) type 1, and diabetic peripheral neuropathy (DPN). The evidence from one randomized controlled trial confirms the efficacy and safety of high-frequency SCS through two years; however, this study did not define the patient population that would benefit the most from high-frequency stimulation. Therefore, the evidence remains inefficient regarding the patient populations outside of FBSS, CRPS type 1, and DPN.

There is insufficient evidence to conclude SCS is efficacious for the treatment of chronic back pain of no specific cause. The majority of high-quality evidence for SCS is specific to patients with definitive causes of pain (e.g., failed back surgery syndrome and complex regional pain syndrome); therefore, it is difficult to make conclusions regarding this treatment for non-specific pain. Additional, high-quality studies are needed to confirm the clinical utility and safety of SCS for non-specific chronic back pain.

There is not enough evidence to conclude SCS is efficacious for the treatment of intractable angina pectoris. While available evidence is promising, substantial uncertainty remains regarding the effectiveness and safety of SCS for treatment of angina.

There is insufficient evidence to conclude SCS is safe and effective for the treatment of chronic intractable pain secondary to failed neck surgery syndrome or chronic limb ischemia. Additional studies of good methodological quality (e.g., randomized controlled trials) are needed in order to confirm the long-term safety and efficacy of spinal cord stimulation for these indications.

There is not enough evidence to conclude burst stimulation provided through a clinician programmer application significantly improves treatment outcomes compared to conventional or high-frequency SCS. Further randomized controlled trials are needed to confirm the efficacy, clinical significance, and safety of this new SCS technology.

There is insufficient evidence to conclude dorsal root ganglion (DRG) stimulation is safe and effective for the treatment of chronic intractable pain secondary to complex regional pain syndrome. Additional good quality studies with longer follow-up are needed to confirm the long-term safety and efficacy of DRG stimulation.

CLINICAL PRACTICE GUIDELINES

Spinal Cord Stimulation

Colorado Division of Worker’s Compensation

The 2014 Colorado Division of Worker’s Compensation evidence-based clinical practice guidelines on low back pain medical treatment stated implantable spinal cord stimulators are, “reserved for those low

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back pain patients with pain, radiculopathy, and failed surgery of greater than six months duration who have not responded to the standard non-operative or operative intervention.”⁶⁹

American Pain Society (APS)

The 2009 APS evidence-based clinical practice guideline for interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain stated, “in patients with persistent and disabling radicular pain following surgery for herniated disc and no evidence of a persistently compressed nerve root, it is recommended that clinicians discuss risks and benefits of spinal cord stimulation as an option (weak recommendation, moderate-quality evidence).”⁷⁰ The guideline recommended clinicians discuss with patients the high rate of complications associated with spinal cord stimulator placement. The APS guideline stated, “there is insufficient evidence (no randomized trials) to guide recommendations on spinal cord stimulation for nonspecific low back pain (insufficient level of evidence).”⁷⁰ The guideline also stated that “published case series of spinal cord stimulation for low back pain not related to previous back surgery provide very weak evidence because they used an uncontrolled study design and were of very low methodologic quality.”⁷⁰

National Institute for Health and Care Excellence (NICE)

- In 2019, NICE concluded that Senza SCS was “at least as effective as low-frequency SCS in reducing pain and functional disability.” Investigators recommended the device for patients with residual chronic neuropathic back or leg pain at least 6 months after back surgery despite conventional medical management.⁷¹
- The 2008 NICE evidence-based clinical practice guideline (reviewed 2014) evaluating spinal cord stimulation (SCS) for chronic pain of neuropathic or ischemic origin evaluated 11 randomized controlled trials (RCTs): two studies evaluated SCS for treatment of failed back surgery syndrome, one RCT evaluated SCS for complex regional pain syndrome (CRPS) Type I, and eight RCTs evaluated SCS in patients with ischemic pain. The guideline stated:

“Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who:

- continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and
- who have had a successful trial of stimulation

Spinal cord stimulation is not recommended as a treatment option for adults with chronic pain of ischemic origin except in the context of research as part of a clinical trial. Such research should be designed to generate robust evidence about the benefits of spinal cord stimulation (including pain relief, functional outcomes and quality of life) compared with standard care.”⁷²

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American Society of Interventional Pain Physicians (ASIPP)

The 2003 (updated 2013) ASIPP evidence-based clinical practice guideline for interventional techniques in chronic spinal pain stated, “the evidence for SCS is fair in managing patients with failed back surgery syndrome (FBBS).” The guideline also stated “SCS is indicated in chronic low back pain with lower extremity pain secondary to FBBS, after exhausting multiple conservative and interventional modalities.”⁷³

Spinal Cord Stimulation for Chronic Refractory Angina Pectoris

American Association of Thoracic Surgery/American College of Cardiology Foundation/American College of Physicians/American Heart Association/Preventive Cardiovascular Nurses Association/Society for Cardiovascular Angiography and Interventions/Society of Thoracic Surgeons

The 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS evidence-based clinical practice guideline for the diagnosis and management of patients with stable ischemic heart disease stated, “spinal cord stimulation may be considered for relief of refractory angina in patients with stable ischemic heart disease (Level of evidence: C, defined as very limited populations evaluated and/or only consensus opinion of experts, case studies, or standard of care).” The guideline concluded, “studies of spinal cord stimulations suggest that this technique might have some use as a method to relieve angina in patients with symptoms that are refractory to standard medical therapy and revascularization. There is a paucity of data on the mechanisms and long-term risks and benefits of this therapeutic approach, however.”⁷⁴

Dorsal Root Ganglion Stimulation

Consensus Statements

In 2018, an industry-funded consensus committee endorsed DRG stimulation for the treatment of CRPS.⁷⁵ This endorsement was made on the basis of a non-systematic review of the literature and committee member experience.

REGULATORY STATUS

FDA-Approved Low-Frequency Spinal Cord Stimulation Devices

There are several FDA-approved low-frequency spinal cord stimulation devices. Devices approved under the premarket approval (PMA) process can be found in the FDA’s PMA database under the product code LGW.⁷⁶ Devices approved under the 510(k) approval process can be found in the FDA’s 510(k) database under the product codes GZB or GZF.⁷⁷

Note: This list is not all inclusive. Please refer to the FDA databases cited above for more information.

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DEVICE NAME, MANUFACTURER, PRODUCT CODE	INDICATIONS FOR USE	CONTRAINDICATIONS FOR USE
SPRINT PNS System by SPR Therapeutics ⁷⁸ 510K Product code: NHI	The SPRINT Peripheral Nerve Stimulation (PNS) System is indicated for up to 60 days in the back and/or extremities for: <ul style="list-style-type: none"> • Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain; • Symptomatic relief of post-traumatic pain; • Symptomatic relief of post-operative pain. 	<ul style="list-style-type: none"> • The SPRINT PNS System is not intended to treat pain in the craniofacial region.
StimRouter Neuromodulation System by Bioness, Inc. ⁷⁹ 510k Product Code: GZF	The StimRouter Neuromodulation System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medications).	<ul style="list-style-type: none"> • The StimRouter is not intended to treat pain in the craniofacial region.
Genesis™ and Eon™ Family Neurostimulation (IPG) Systems by St. Jude Medical™ ⁸⁰ PMA Product Code: LGW	Genesis Neurostimulation (IPG) System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: <ul style="list-style-type: none"> • Failed back surgery syndrome • Intractable low back and leg pain 	<ul style="list-style-type: none"> • Patients with demand type cardiac pacemakers • Patients that are unable to operate the system or fail to receive effective pain relief during trial stimulation should not be implanted with a SCS
Precision™ Spinal Cord Stimulation (SCS) System by Advanced Bionics Corp. ⁸¹ PMA Product Code: LGW	The Advanced Bionics PRECISION™ Spinal Cord Stimulator System (PRECISION™ System) is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: <ul style="list-style-type: none"> • Failed back surgery syndrome 	<ul style="list-style-type: none"> • Have failed trial stimulation by failing to receive effective pain relief • Are poor surgical risks • Are pregnant • Are unable to operate the SCS system

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	<ul style="list-style-type: none"> Intractable low back pain and leg pain. 	
<p>Algovita™ Spinal Cord Stimulation (SCS) System by Nuvecetra Corp.⁸²</p> <p>PMA Product Code: LGW</p>	<p>The Algovita™ Spinal Cord Stimulation (SCS) system is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain and leg pain.</p>	<ul style="list-style-type: none"> Shortwave, microwave and/or therapeutic ultrasound diathermy must not be used on SCS patients. The energy generated by diathermy can be transferred through the SCS system, causing tissue damage at the lead site which may result in severe injury or death. Subjects who fail to receive effective pain relief during a stimulation trial.
<p>Freedom Spinal Cord Stimulator (SCS) System™ by Stimwave Technologies Inc.⁸³</p> <p>510k Product Code: GZB</p>	<p>The Stimwave Technologies Incorporated Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.</p>	<ul style="list-style-type: none"> Poor surgical risks Pregnancy Inability to operate system Exposure to shortwave, microwave, or ultrasound diathermy Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy Implanted cardiac systems

FDA-Approved High-Frequency Spinal Cord Stimulation Devices

Currently, there is one FDA-approved high-frequency spinal cord stimulation device. The Senza High Frequency Spinal Cord Stimulation System received FDA-approval on May 8, 2015, under the premarket approval process (PMA): PMA# P130022.

DEVICE NAME, MANUFACTUER, & PRODUCT CODE	INDICATIONS FOR USE	CONTRAINDICATIONS FOR USE
<p>Senza® High Frequency Spinal Cord Stimulation System by Nevro™ Corp.⁸⁴</p>	<p>The Senza neuromodulation system is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following:</p> <ul style="list-style-type: none"> Failed back surgery syndrome Intractable low back pain and/or leg pain. 	<ul style="list-style-type: none"> Not being able to operate the Senza system Not being able to have the SCS surgery Failing to receive effective pain relief during trial stimulation.

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The FDA has published a letter of recommendations to Health Care Providers on the trial stimulation period before implanting a spinal cord stimulator, alerting providers of reports of serious side effects associated with the device. The FDA requests that providers report problems with devices through their website.⁸⁵

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

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