

(70125)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/18	<b>Next Review Date:</b> 01/20
<b>Preauthorization</b>	Yes	<b>Review Dates:</b> 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	

**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: <ul style="list-style-type: none"> <li>• With treatment-refractory chronic pain of the trunk or limbs</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Standard spinal cord stimulation</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Medical therapy</li> <li>• Surgical therapy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Medication use</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With treatment-refractory chronic pain of the trunk or limbs</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• High-frequency spinal cord stimulation</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Standard spinal cord stimulation</li> <li>• Medical therapy</li> <li>• Surgical therapy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Medication use</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With treatment-refractory chronic pain of the trunk or limbs</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Dorsal root ganglion neurostimulation</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Standard spinal cord stimulation</li> <li>• Medical therapy</li> <li>• Surgical therapy</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Medication use</li> <li>• Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>• With critical limb ischemia</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Spinal cord stimulation</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Medical therapy</li> <li>• Revascularization surgery</li> <li>• Amputation</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Overall survival</li> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Morbid events</li> <li>• Hospitalizations</li> <li>• Treatment-related morbidity</li> </ul>

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, medication use, and treatment-related morbidity. Available RCTs are mixed regarding underlying diagnoses in select patient populations. However, those 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, quality of life, 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 case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success at three and 12 months than those receiving standard SCS devices. Both groups experienced paresthesias, but patients in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Patients in the DRG group also reported more reduction in interference with physical functioning and mood states. Rates of serious adverse events were similar. Given that DRG neurostimulation targets a different portion of the sensory pathway and anatomic location than standard SCS, replication is needed in a confirmatory RCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### CRITICAL LIMB ISCHEMIA

For individuals who have critical limb ischemia who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, 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 a systematic review and meta-analysis did report 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, quality of life, 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 more recent RCTs, there was no significant benefit on 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, quality of life, 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 no RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 **investigational** for the treatment of severe and chronic pain of the trunk or limbs.

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

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, 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 one ms.

Other neurostimulators target the dorsal root ganglion. Dorsal root ganglia are located between spinal nerves and the spinal cord on the posterior root and are believed to play an important role in neuropathic pain perception. Two systems have received approval or clearance from FDA.

#### Outcome Measures

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) 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.<sup>1</sup> IMMPACT 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).<sup>2,3</sup>

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

Domain	Outcome Measure	Description	Clinically Meaningful Difference
<b>Pain Intensity</b>			
	<ul style="list-style-type: none"> <li>Numeric rating scale</li> <li>Verbal rating scale</li> <li>Visual analog scale</li> </ul>	Rating of pain intensity on a scale of zero (no pain) to 10 (pain as bad as you can imagine) or from zero to 10 cm	<ul style="list-style-type: none"> <li>Minimally important: 10%-20% decrease</li> <li>Moderately important: 30% or more decrease</li> <li>Substantial: 50% or more decrease</li> </ul>
<b>Physical functioning</b>			
	Disease specific	Measures of the interference of pain with physical functioning	
	<ul style="list-style-type: none"> <li>Multidimensional Pain Inventory<sup>4</sup> Interference Scale</li> </ul>	<ul style="list-style-type: none"> <li>60 items, self-report</li> <li>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</li> <li>Items rated on zero- to six-point scale</li> <li>Interference subscale score calculated by mean of subscale items</li> </ul>	<ul style="list-style-type: none"> <li>0.6-point or more decrease<sup>3</sup></li> </ul>
	<ul style="list-style-type: none"> <li>Brief Pain Inventory<sup>5</sup> Interference Scale</li> </ul>	<ul style="list-style-type: none"> <li>seven items, self-report</li> <li>Measures intensity, quality, relief and interference of pain and patients' ideas of the causes of pain</li> <li>Mean of the seven interference items can be used as a measure of pain interference</li> </ul>	<ul style="list-style-type: none"> <li>one-point decrease<sup>3</sup></li> </ul>
	<ul style="list-style-type: none"> <li>Oswestry Disability Index<sup>6</sup></li> </ul>	Measures functional impairment due to lower back pain: <ul style="list-style-type: none"> <li>10 sections, self-report</li> <li>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</li> <li>Each section is scored on a zero to five scale with five indicating the greatest disability</li> <li>Total score calculated by taking the mean of the section scores and multiplying by 100</li> </ul>	<ul style="list-style-type: none"> <li>10 points<sup>7</sup></li> </ul>
	General	Generic measure of physical functioning	
	<ul style="list-style-type: none"> <li>36-Item Short Form Health Survey</li> </ul>	Measure overall health status: <ul style="list-style-type: none"> <li>36 items, self-report</li> <li>Eight domains: physical function, physical role, general health, bodily pain, mental health, social function, vitality/fatigue, and emotional role</li> <li>Physical Component Summary and Mental Component Summary scores are aggregate scores that can be calculated</li> <li>Higher scores indicate better health status</li> </ul>	<ul style="list-style-type: none"> <li>five-10 points<sup>8-10</sup></li> </ul>

Emotional functioning

Domain	Outcome Measure	Description	Clinically Meaningful Difference
	<ul style="list-style-type: none"> <li>Beck Depression Inventory<sup>11</sup></li> </ul>	<ul style="list-style-type: none"> <li>21 items, self-report</li> <li>Measures severity of current symptoms of depressive disorders</li> <li>Scores range from zero to 63</li> </ul>	<ul style="list-style-type: none"> <li>five point or more decrease</li> </ul>
	<ul style="list-style-type: none"> <li>Profile of Mood States<sup>12</sup></li> </ul>	<ul style="list-style-type: none"> <li>65 items, self-report</li> <li>Measures total mood disturbance with six subscales: tension, depression, anger, vigor, fatigue, and confusion</li> <li>Scores range from zero to 200</li> </ul>	<ul style="list-style-type: none"> <li>10- to 15-point or greater decrease<sup>3</sup></li> </ul>
Global rating of improvement			
	<ul style="list-style-type: none"> <li>Patient Global Impression of Change</li> </ul>	<ul style="list-style-type: none"> <li>Single-item, self-rating</li> <li>seven-point scale ranging from one (very much worse) to seven (very much improved)</li> </ul>	<ul style="list-style-type: none"> <li>Minimally important: minimally improved</li> <li>Moderately important: much improved</li> <li>Substantial: very much improved<sup>3</sup></li> </ul>

## REGULATORY STATUS

A large number of neurostimulator devices, some used for SCS, have been approved by FDA through the pre-market 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 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.”<sup>13</sup> This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Spinal Modulation) was approved by FDA through the premarket approval process. This implanted device stimulates the dorsal root ganglion. 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 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, FDA approved BurstDR™ stimulation (St. Jude Medical), a clinician programmer application that provides intermittent “burst” stimulation for patients with certain St. Jude SCS devices.

## RELATED PROTOCOL

Deep Brain Stimulation

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

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

## REFERENCES

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

1. Turk DC, Dworkin RH, Allen RR, et al. Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. *Pain*. Dec 2003;106(3):337-345. PMID 14659516
2. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. Jan 2005;113(1-2):9-19. PMID 15621359
3. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain*. Feb 2008;9(2):105-121. PMID 18055266
4. Kerns RD, Turk DC, Rudy TE. The West Haven-Yale Multidimensional Pain Inventory (WHYMPI). *Pain*. Dec 1985;23(4):345-356. PMID 4088697
5. Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. *Ann Acad Med Singapore*. Mar 1994;23(2):129-138. PMID 8080219
6. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine (Phila Pa 1976)*. Nov 15 2000;25(22):2940-2952; discussion 2952. PMID 11074683
7. Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine (Phila Pa 1976)*. Jan 1 2008;33(1):90-94. PMID 18165753
8. Wells GA, Tugwell P, Kraag GR, et al. Minimum important difference between patients with rheumatoid arthritis: the patient's perspective. *J Rheumatol*. Mar 1993;20(3):557-560. PMID 8478873
9. Kosinski M, Zhao SZ, Dedhiya S, et al. Determining minimally important changes in generic and disease-specific health-related quality of life questionnaires in clinical trials of rheumatoid arthritis. *Arthritis Rheum*. Jul 2000;43(7):1478-1487. PMID 10902749
10. Angst F, Aeschlimann A, Stucki G. Smallest detectable and minimal clinically important differences of rehabilitation intervention with their implications for required sample sizes using WOMAC and SF-36 quality of life measurement instruments in patients with osteoarthritis of the lower extremities. *Arthritis Rheum*. Aug 2001;45(4):384-391. PMID 11501727
11. Beck ATS, R.A. Beck Depression Inventory. San Antonio, TX: Psychological Corporation; 1993.
12. Curran SL, Andrykowski MA, Studts JL. Short Form of the Profile of Mood States (POMS-SF): Psychometric information. *Psychol Assess* 1995;7:80-83. PMID
13. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Senza Spinal Cord Stimulation (SCS) System 2015; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf13/P130022b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022b.pdf). Accessed March 23, 2018.



14. North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery*. Dec 2005;56(1):98-106; discussion 106-107. PMID 15617591
15. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain*. Nov 2007;132(1-2):179-188. PMID 17845835
16. Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med*. Aug 31 2000;343(9):618-624. PMID 10965008
17. Kapural L, Yu C, Doust MW, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT randomized controlled trial. *Anesthesiology*. Oct 2015;123(4):851-860. PMID 26218762
18. Visnjevac O, Costandi S, Patel BA, et al. A comprehensive outcome-specific review of the use of spinal cord stimulation for complex regional pain syndrome. *Pain Pract*. Apr 2017;17(4):533-545. PMID 27739179
19. O'Connell NE, Wand BM, McAuley J, et al. Interventions for treating pain and disability in adults with complex regional pain syndrome. *Cochrane Database Syst Rev*. Apr 30 2013(4):Cd009416. PMID 23633371
20. Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: a systematic review. *Pain Physician*. Jan 2016;19(1):E33-54. PMID 26752493
21. Kapural L, Peterson E, Provenzano DA, et al. Clinical evidence for spinal cord stimulation for failed back surgery syndrome (FBSS): systematic review. *Spine (Phila Pa 1976)*. Jul 15 2017;42 Suppl 14:S61-S66. PMID 28441313
22. Frey ME, Manchikanti L, Benyamin RM, et al. Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review. *Pain Physician*. Mar-Apr 2009;12(2):379-397. PMID 19305486
23. Simpson EL, Duenas A, Holmes MW, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess*. Mar 2009;13(17):iii, ix-x, 1-154. PMID 19331797
24. National Institute for Health and Care Excellence (NICE). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin [TA159]. 2008; <https://www.nice.org.uk/guidance/TA159>. Accessed March 23, 2018.
25. Kemler MA, De Vet HC, Barendse GA, et al. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. *Ann Neurol*. Jan 2004;55(1):13-18. PMID 14705107
26. Slangen R, Schaper NC, Faber CG, et al. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. *Diabetes Care*. Nov 2014;37(11):3016-3024. PMID 25216508
27. Bicket MC, Dunn RY, Ahmed SU. High-frequency spinal cord stimulation for chronic pain: pre-clinical overview and systematic review of controlled trials. *Pain Med*. Dec 2016;17(12):2326-2336. PMID 28025366
28. Perruchoud C, Eldabe S, Batterham AM, et al. Analgesic efficacy of high-frequency spinal cord stimulation: a randomized double-blind placebo-controlled study. *Neuromodulation*. Jul-Aug 2013;16(4):363-369; discussion 369. PMID 23425338
29. Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery*. Oct 2008;63(4):762-770; discussion 770. PMID 18981888
30. Kemler MA, de Vet HC, Barendse GA, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg*. Feb 2008;108(2):292-298. PMID 18240925
31. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicentre randomized clinical trial. *Pain*. Nov 2014;155(11):2426-2431. PMID 25180016

32. Duarte RV, Andronis L, Lenders MW, et al. Quality of life increases in patients with painful diabetic neuropathy following treatment with spinal cord stimulation. *Qual Life Res.* Jul 2016;25(7):1771-1777. PMID 26694963
33. De Andres J, Monsalve-Dolz V, Fabregat-Cid G, et al. Prospective, randomized blind effect-on-outcome study of conventional vs. high-frequency spinal cord stimulation in patients with pain and disability due to failed back surgery syndrome. *Pain Med.* Dec 1 2017;18(12):2401-2421. PMID 29126228
34. Kapural L, Yu C, Doust MW, et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results from a multicenter, randomized, controlled pivotal trial. *Neurosurgery.* Nov 2016;79(5):667-677. PMID 27584814
35. Al-Kaisy A, Palmisani S, Smith TE, et al. Long-term improvements in chronic axial low back pain patients without previous spinal surgery: a cohort analysis of 10-kHz high-frequency spinal cord stimulation over 36 months. *Pain Med.* Oct 24 2017. PMID 29077889
36. Hou S, Kemp K, Grabois M. A systematic evaluation of burst spinal cord stimulation for chronic back and limb pain. *Neuromodulation.* Jun 2016;19(4):398-405. PMID 27139915
37. De Ridder D, Vanneste S, Plazier M, et al. Burst spinal cord stimulation: toward paresthesia-free pain suppression. *Neurosurgery.* May 2010;66(5):986-990. PMID 20404705
38. De Ridder D, Plazier M, Kamerling N, et al. Burst spinal cord stimulation for limb and back pain. *World Neurosurg.* Nov 2013;80(5):642-649.e641. PMID 23321375
39. Schu S, Slotty PJ, Bara G, et al. A prospective, randomised, double-blind, placebo-controlled study to examine the effectiveness of burst spinal cord stimulation patterns for the treatment of failed back surgery syndrome. *Neuromodulation.* Jul 2014;17(5):443-450. PMID 24945621
40. Kriek N, Groeneweg JG, Stronks DL, et al. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. *Eur J Pain.* Mar 2017;21(3):507-519. PMID 27714945
41. Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation With BURST (SUNBURST) Study: results from a prospective, randomized controlled trial using a novel burst waveform. *Neuromodulation.* Jan 2018;21(1):56-66. PMID 28961366
42. Chang Chien GC, Mekhail N. Alternate intraspinal targets for spinal cord stimulation: a systematic review. *Neuromodulation.* Oct 2017;20(7):629-641. PMID 28160397
43. Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain.* Apr 2017;158(4):669-681. PMID 28030470
44. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Axiom Neurostimulator System. 2016; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/P150004b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150004b.pdf). Accessed February 2, 2018.
45. Liem L, Russo M, Huygen FJ, et al. One-year outcomes of spinal cord stimulation of the dorsal root ganglion in the treatment of chronic neuropathic pain. *Neuromodulation.* Jan 2015;18(1):41-48; discussion 48-49. PMID 25145467
46. Schu S, Gulve A, Eldabe S, et al. Spinal cord stimulation of the dorsal root ganglion for groin pain-a retrospective review. *Pain Pract.* Apr 2015;15(4):293-299. PMID 24690212
47. Weiner RL, Yeung A, Montes Garcia C, et al. Treatment of FBSS low back pain with a novel percutaneous DRG wireless stimulator: pilot and feasibility study. *Pain Med.* Oct 2016;17(10):1911-1916. PMID 27125284
48. Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia. *Cochrane Database Syst Rev.* Feb 28 2013;2(2):CD004001. PMID 23450547
49. Klomp HM, Steyerberg EW, Habbema JD, et al. What is the evidence on efficacy of spinal cord stimulation in (subgroups of) patients with critical limb ischemia? *Ann Vasc Surg.* May-Jun 2009;23(3):355-363. PMID 19128928
50. Klomp HM, Spincemaille GH, Steyerberg EW, et al. Spinal-cord stimulation in critical limb ischaemia: a randomised trial. ESES Study Group. *Lancet.* Mar 27 1999;353(9158):1040-1044. PMID 10199350

51. Abu Dabrh AM, Steffen MW, Asi N, et al. Nonrevascularization-based treatments in patients with severe or critical limb ischemia. *J Vasc Surg*. Nov 2015;62(5):1330-1339 e1313. PMID 26409842
52. Pan X, Bao H, Si Y, et al. Spinal cord stimulation for refractory angina pectoris: a systematic review and meta-analysis. *Clin J Pain*. Jun 2017;33(6):543-551. PMID 27875377
53. Tsigaridas N, Naka K, Tsapogas P, et al. Spinal cord stimulation in refractory angina. A systematic review of randomized controlled trials. *Acta Cardiol*. Apr 2015;70(2):233-243. PMID 26148385
54. Zipes DP, Svorkdal N, Berman D, et al. Spinal cord stimulation therapy for patients with refractory angina who are not candidates for revascularization. *Neuromodulation*. Nov-Dec 2012;15(6):550-558; discussion 558-559. PMID 22494013
55. Lanza GA, Grimaldi R, Greco S, et al. Spinal cord stimulation for the treatment of refractory angina pectoris: a multicenter randomized single-blind study (the SCS-ITA trial). *Pain*. Jan 2011;152(1):45-52. PMID 21084162
56. Torre-Amione G, Alo K, Estep JD, et al. Spinal cord stimulation is safe and feasible in patients with advanced heart failure: early clinical experience. *Eur J Heart Fail*. Jul 2014;16(7):788-795. PMID 24961194
57. Zipes DP, Neuzil P, Theres H, et al. Determining the feasibility of spinal cord neuromodulation for the treatment of chronic systolic heart failure: The DEFEAT-HF Study. *JACC Heart Fail*. Feb 2016;4(2):129-136. PMID 26682789
58. Lihua P, Su M, Zejun Z, et al. Spinal cord stimulation for cancer-related pain in adults. *Cochrane Database Syst Rev*. Feb 28 2013;2(2):CD009389. PMID 23450600
59. Peng L, Min S, Zejun Z, et al. Spinal cord stimulation for cancer-related pain in adults. *Cochrane Database Syst Rev*. Jun 29 2015;6(6):CD009389. PMID 26121600
60. Mekhail NA, Mathews M, Nageeb F, et al. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract*. Mar-Apr 2011;11(2):148-153. PMID 21371254
61. Lanza GA, Barone L, Di Monaco A. Effect of spinal cord stimulation in patients with refractory angina: evidence from observational studies. *Neuromodulation*. Nov-Dec 2012;15(6):542-549; discussion 549. PMID 22364309
62. Dworkin RH, O'Connor AB, Kent J, et al. Interventional management of neuropathic pain: NeuPSIG recommendations. *Pain*. Nov 2013;154(11):2249-2261. PMID 23748119
63. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*. Apr 2013;16(2 Suppl):S49-283. PMID 23615883
64. Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician*. Jan 2007;10(1):7-111. PMID 17256025
65. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7). 1995; <https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=240&ncdver=1&DocID=160.7&bc=gAAAABAAAA&>. Accessed March 23, 2018.
66. MedtronicNeuro (sponsor). Prospective, Randomized Study of Multicolumn Implantable Lead Stimulation for Predominant Low Back Pain (PROMISE) (NCT01697358). 2017; <https://clinicaltrials.gov/ct2/show/NCT01697358?term=NCT01697358&rank=1>. Accessed March 23, 2018.
67. National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7), Effective Date of this Version 8/7/1995.