



CLINICAL GUIDELINES

CMM-211: Spinal Cord and Dorsal Root Ganglion Stimulation

Version 1.1.2022
Effective September 1, 2022



eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

eviCore's Clinical Review Criteria ("CRC") and related content is made available for the limited uses of: reference; and individual use, only limited to facilitating the determination of medically necessary and appropriate clinical treatment by clinicians for specific delegated patients under their care. The CRC and related content is proprietary information of eviCore, and copyrighted to the full extent of the law. Except as expressly permitted, you may not modify, copy, reproduce, republish, upload, post, transmit, hyperlink to or from, or distribute in any way the CRC, nor may you sell, transfer, distribute, assign, lease, reproduce, or otherwise use the CRC in commerce, in a manner that competes with us or infringes upon our rights, or for any public or commercial endeavor without our prior and express written consent.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2022 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.

Clinical guidelines for medical necessity review of Comprehensive Musculoskeletal Management Services.

Definitions

- **Complex Regional Pain Syndrome (CRPS)** is defined by the International Association for the Study of Pain (IASP) as a variety of painful conditions following injury which appear regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration the expected clinical course of the inciting event and often resulting in significant impairment of motor function, and showing variable progression over time. In addition to injury, CRPS can also occur as a result of various medical disorders or illnesses.
- **Critical limb ischemia (CLI)** describes a condition in which tissue perfusion is reduced such that spinal stimulators may be appropriate for the treatment of intractable rest pain secondary to chronic limb ischemia. Ischemic rest pain is pain that occurs in the toes or in the area of the metatarsal heads. Occasionally, it occurs in the foot proximal to the metatarsal heads. Elevation of the limb above or at the horizontal position aggravates the pain and pendency, to some degree at least, brings relief. The pain is secondary to severe arterial insufficiency resulting in inadequate perfusion to the distal lower extremity.
- **Dorsal root ganglion (DRG) stimulation** is an emerging method of treatment for neuropathic pain. With DRG stimulation leads are placed percutaneously into the epidural space under fluoroscopic guidance directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine. Similar to spinal cord stimulation, a short-term trial (i.e., greater than 48 hours) is recommended using an external pulse generator; upon success of the trial a permanent pulse generator may then be implanted. At this time, the evidence in the peer-reviewed scientific literature is insufficient to support long-term safety and efficacy. The use of this technology for treatment of pain conditions remains under investigation.
- **Failed back surgery syndrome (FBSS)** is lumbar spinal pain of unknown origin despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same spinal region. Procedures/surgery that do not encroach into the spinal canal e.g. interspinous/interlaminar/facet distraction, kyphoplasty/vertebroplasty surgery, etc.
- **High-frequency spinal cord stimulation**, also referred to as kilohertz frequency spinal cord stimulation or HF10, is a type of spinal cord stimulation (SCS) providing a higher frequency than traditional spinal cord stimulator systems. The HF10 SCS uses low-amplitude, high-frequency, and short-duration pulses. HF10 SCS does not generate paresthesia and operates at a frequency of 10,000 Hz to provide pain relief in comparison to traditional spinal cord stimulation systems, which operate at a frequency in the range of 40-60 Hz and do generate paresthesia. As an alternative to traditional dorsal spinal column stimulation, HF10 SCS is proven safe and effective for treatment of chronic, intractable low back and leg pain in patients with failed back surgery syndrome (FBSS).
- **Peripheral nerve stimulation**, in contrast to spinal cord stimulation, involves implantation of electrodes near or on a peripheral nerve to reduce pain. **Peripheral nerve field stimulation** is a technology that involves placement of electrodes subcutaneously within an area of maximal pain, with the objective of stimulating a

region of affected nerves to reduce pain. Depending on the targeted nerve, leads may be placed percutaneously just under the skin or via an open approach for larger deeper peripheral nerves. Similar to spinal cord stimulation, a short term trial is required prior to permanent implantation of a generator. The use of these technologies, used alone or in combination with spinal cord stimulation for treatment of pain conditions is under investigation.

- ◆ **Please note:** this guideline does not apply to simple or complex brain or peripheral (i.e. cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter.
- **Spinal cord stimulation**, also known as dorsal column stimulation or neuromodulation, is a reversible therapy applied for neuropathic pain with techniques that include multi-output implanted pulse generators and a choice of electrodes, some of which can be placed percutaneously. The technical goal of this therapy is to achieve stimulation of paresthesia of the dorsal horn of the spinal cord at a subjectively comfortable level, overlapping an individual's topography of pain. The procedure initially involves a short-term trial (e. g., greater than 48 hours) of percutaneous (temporary) spinal cord stimulation, prior to the subcutaneous (permanent) implantation of the spinal cord stimulation device, to determine whether the spinal cord stimulator device will induce sufficient pain relief to render it medically necessary.

Indications

- The determination of medical necessity for implantation of a dorsal spinal cord stimulator (SCS) is always made on a case-by-case basis.
- A dorsal column stimulator capable of **using either high-frequency or non-high-frequency stimulation** (dual-mode) is considered equally effective alternative for the treatment of any of the medically necessary indications listed below when the device uses non-high-frequency stimulation.
- A dorsal column stimulator **using high frequency** is considered equally effective alternative to non-high-frequency stimulation **only** for the treatment of chronic intractable pain secondary to failed back surgery syndrome (FBSS) as noted below.

Chronic Intractable Pain Secondary to Failed Back Surgery Syndrome (FBSS)

- A short-term trial (e.g., greater than 48 hours) spinal cord stimulation [i.e., non-high-frequency or high-frequency (HF10 SCS)] is considered **medically necessary** for the treatment of chronic, intractable pain secondary to failed back surgery syndrome (FBSS) with intractable neuropathic leg pain (after prior surgery in the same spinal region) when **ALL** of the following criteria are met:
 - ◆ Failure of at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification)
 - ◆ Surgical intervention is not indicated or for patients who do not wish to proceed with spinal surgery

- ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device
- Permanent implantation of a spinal cord stimulator (i.e., non-high-frequency, HF10 SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to failed back surgery syndrome (FBSS) with intractable neuropathic leg pain (after prior surgery in the same spinal region) when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)

- A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) only of the upper and lower extremities when **ALL** of the following criteria are met:
 - ◆ Diagnosis of CRPS/ RSD as evidenced by **ALL** of the following:
 - Continuing pain which is disproportionate to any inciting event
 - Must report at least **ONE** (1) of the symptoms in **THREE of the four** following categories:
 - Sensory: reports of hyperesthesia
 - Vasomotor: reports of temperature asymmetry, skin color changes, and/or skin color asymmetry
 - Sudomotor/edema: reports of edema, sweating changes, and/or sweating asymmetry
 - Motor/trophic: reports of decreased range of motion, motor dysfunction (weakness, tremor, dystonia), and/or trophic changes (hair, nail, skin).
 - Must display at least one (1) sign on physical examination at the time of evaluation in **TWO or MORE** of the following categories:
 - Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch)
 - Vasomotor: evidence of temperature asymmetry, skin color changes, and/or asymmetry
 - Sudomotor/edema: evidence of edema, sweating changes, and/or sweating asymmetry
 - Motor/trophic: evidence of decreased range of motion, motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).
 - There is(are) no other medical or psychological diagnoses that are concordant with the presenting symptoms, signs, and results of relevant studies (e.g. imaging, electrodiagnostic testing, laboratory testing, etc.). Limited to only the extremities and not to the head/face/neck, trunk, perineum/pelvis, or abdominal viscera.

- ◆ Failure of at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification)
 - ◆ Surgical intervention is not indicated
 - ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of SCS or contraindicate placement of the device
- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to CRPS/ RSD when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

Chronic Critical Limb Ischemia (CLI)

- A short-term trial (e.g., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI) when **ALL** of the following criteria are met:
- ◆ Attestation from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction.
 - ◆ Diagnosis of critical limb ischemia when **ALL** of the following criteria are met:
 - Ischemic limb rest pain
 - Rutherford Classification Grade II, Category 4 (see table in **Appendix B**) ischemic rest pain characterized by **BOTH** of the following:
 - Resting ankle pressure <40mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording
 - Toe pressure <30mmHg
 - ◆ Advanced Imaging
 - Angiographic or CT/MR imaging demonstrating multilevel disease with absence of named vessel with flow into the foot
 - ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device
- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to CLI when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

Chronic Stable Angina Pectoris

- A short-term trial (e.g., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris/myocardial ischemia when **ALL** of the following criteria are met:
 - ◆ Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see **Appendix A**)
 - ◆ Attestation that the individual's treating cardiologist confirms coronary artery disease (CAD) and the individual is not a suitable candidate for a revascularization procedure
 - ◆ Optimal medical treatment (OMT) that has failed to adequately improve anginal symptoms including **ALL** of the following:
 - Anti-platelet therapy
 - Statin and/or other lipid-lowering therapy
 - Anti-anginal therapy implemented to pursue a goal heart rate of 60 beats per minute
 - Anti-hypertensive therapy as may be indicated to pursue a goal systolic blood pressure 9 SBP) of less than 140 mmHG and a goal diastolic blood pressure (DBP) of less than 90 mmHG
 - ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental and /or behavioral health conditions/issues (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device
- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris for myocardial ischemia when a beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.

Replacement

- Replacement of an existing high-frequency or non-high-frequency dorsal column spinal cord stimulator (SCS) and dorsal root ganglion (DRG) stimulator is considered **medically necessary** when **ANY** of the following criteria are met:
 - ◆ The existing stimulator and/or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty
 - ◆ Revision is required of the electrode percutaneous array(s) or electrode plate/paddle(s)
- Replacement of a malfunctioning dorsal root ganglion (DRG) stimulator with a non-high-frequency or dual-mode dorsal column spinal cord stimulator (SCS) is considered **medically necessary** without a short-term trial (e. g., greater than 48 hours) of the SCS.

Non-Indications

Not medically Necessary- Spinal Cord Stimulator (SCS)

- Replacement of a functioning non-high-frequency dorsal column SCS with a high-frequency SCS is considered **not medically necessary**.

Experimental, Investigational, and/or Unproven (EIU)- Spinal Cord Stimulator (SCS)

- A high-frequency spinal cord stimulator (SCS) is considered **experimental, investigational, and/or unproven (EIU)** for **ANY** other indication, including complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD).
- A high-frequency **or** non-high-frequency dorsal column SCS is considered **EIU** for any other indication, including but not limited to:
 - ◆ Post-amputation pain (phantom limb pain)
 - ◆ Post-herpetic neuralgia
 - ◆ Peripheral neuropathy (e.g. chronic intractable pain from diabetic sensory neuropathy)
 - ◆ Dysesthesias involving the lower extremities secondary to spinal cord injury.
 - ◆ Abdominal/pelvic visceral pain
 - ◆ Chronic cervical or lumbar radiculopathy without prior spinal surgery
 - ◆ Chronic cervical, thoracic, or lumbar axial pain without prior spinal surgery
 - ◆ Failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arm(s) or trunk.
 - ◆ Abdominal pain related to intestinal (mesenteric) ischemic syndrome
 - ◆ Neuropathic pain associated with Multiple Sclerosis
- Generator modes other than tonic-low and high-frequency (e.g., burst-stimulation) are considered **EIU**.

Experimental, Investigational, and/or Unproven (EIU)- Dorsal Root Ganglion (DRG) Stimulator

- Replacement of a dorsal column spinal cord stimulator (SCS) with a dorsal root ganglion (DRG) stimulator is considered **EIU**.
- Dorsal root ganglion stimulation is considered **EIU** for **ALL** indications except as noted above in **CMM-211: Replacement**.

Experimental, Investigational, and/or Unproven (EIU)- Peripheral nerve stimulation

- Peripheral nerve stimulation, including peripheral nerve field stimulation, is considered **EIU** for treatment of acute or chronic pain conditions, including **ANY** of the following:
 - ◆ Failed back surgery syndrome (FBSS) with intractable neuropathic leg pain
 - ◆ Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)
 - ◆ Chronic Critical Limb Ischemia (CLI)
 - ◆ Chronic Stable Angina Pectoris

- ◆ Post-amputation pain (phantom limb pain)
- ◆ Post-herpetic neuralgia
- ◆ Peripheral neuropathy
- ◆ Dysesthesias involving the lower extremities secondary to spinal cord injury

Appendix A

New York Heart Association and Canadian Cardiovascular Society Functional Classifications

Class	New York Heart Association Functional Classification	Canadian Cardiovascular Society Functional Classification
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous or rapid or prolonged exertion at work or recreation.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV	Patient with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

Appendix B

Rutherford Criteria

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic- no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg, but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise and AP after exercise < 50 mmHg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30mmHg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mmHG, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
	6	Major tissue loss- extending above TM level, functional foot no longer salvageable	Same as category 5
AP: ankle pressure; PVR: pulse volume recording; TM: transmetatarsal; TP: toe pressure			

Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definition
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) place via laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurement(s); simple spinal cord, or peripheral (i.e., peripheral nerve, automatic nerve, neuromuscular) neurostimulator pulse generation/transmitter, with intraoperative or subsequent programming
95972	Electrode analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurement(s); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

References

1. Abraham M, Potdar A, Ward M, Herschman Y, Mammis A. Risk Factors Associated with Lead Migration Requiring Revision in Dorsal Root Ganglion Stimulation. *World Neurosurg.* 2019;128:e649-e652. doi:10.1016/j.wneu.2019.04.225.
2. Al-Kaisy A, Van Buyten JP, Smet I, et al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med.* 2014;15(3):347-354.
3. Amann W, Berg P, Gersbach P, et al; European Peripheral Vascular Disease Outcome Study SCS- EPOS. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). *Eur J Vasc Endovasc Surg.* 2003;26(3):280-286.
4. American College of Occupational and Environmental Medicine. *Occupational Medicine Practice Guideline, 2nd Ed.* 2008.
5. American Medical Association. *Current Procedural Terminology–2014 Professional Edition.*
6. Baber, Z and Erdeck. Failed back surgery syndrome: current perspectives. *J Pain Res.* 2016;9: 979–987.
7. Barolat G, Knobler RL, Lublin FD. Trigeminal neuralgia in a patient with multiple sclerosis treated with high cervical spinal cord stimulation. Case report. *Appl Neurophysiol.* 1988;51(6):333-337.
8. 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.* 2016;17(12): 2326-36.
9. Boden WE, O'Rourke RA, Teo KK, et al. Impact of Optimal Medical Therapy With or Without Percutaneous Coronary Intervention on Long-Term Cardiovascular End Points in Patients With Stable Coronary Artery Disease (from the COURAGE Trial). *Am J Cardiol.* 2009;104(1):1-4. doi:10.1016/j.amjcard.2009.02.059.
10. Burns B, Watkins L, Goadsby PJ. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. *Neurology.* 2009; 72: 341–345.
11. Burns B, Watkins L, Goadsby PJ. Treatment of hemicrania continua by occipital nerve stimulation with a bion device: long-term follow-up of a crossover study. *Lancet Neurol.* 2008;7:1001–12.
12. Carter SA. The definition of critical limb ischemia of the lower limb and distal systolic pressures. *Br J Surg.* 1983 Mar;70(3):188-9.
13. Caylor J, Reddy R, Yin S et al. Spinal cord stimulation in chronic pain: evidence and theory for mechanisms of action. *Bioelectron Med.* 2019;5(1). doi:10.1186/s42234-019-0023-1.
14. Chen J, Hesseltine A, Nashi S et al. A Real-World Analysis of High-Frequency 10 kHz Spinal Cord Stimulation for the Treatment of Painful Diabetic Peripheral Neuropathy. *J Diabetes Sci Technol.* 2021;193229682110603. doi:10.1177/19322968211060316.
15. Claeys L, Berg W, Jonas S. Spinal cord stimulation in the treatment of chronic critical limb ischemia. *Acta Neurochir Suppl.* 2007;97(Pt 1):259-265.
16. Conte M, Bradbury A, Kolh P et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. *J Vasc Surg.* 2019;69(6):3S-12S.e40. doi:10.1016/j.jvs.2019.02.016.
17. Cranley J. Ischemic Rest Pain. *Arch Surg.* 1969;98(2):187. doi:10.1001/archsurg.1969.01340080079015.
18. Cruccu G, Aziz T, Garcia-Larrea L, et al. EFNS guidelines on neurostimulation therapy for neuropathic pain. *Eur J Neurol.* 2007;14(9):952-970.
19. Daoussi C, Benbow SJ, MacFarlane IA. Electrical spinal cord stimulation in the long-term treatment of chronic painful diabetic neuropathy. *Diabet Med.* 2005;22:393–398.
20. De Andres J, Monsalve-Dolz V, Fabregat-Cid G et al. 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 Medicine.* 2017;18: 2401-2421.
21. Deer T, Pope J, Hayek S, et al. Neurostimulation for the treatment of axial back pain: A review of mechanisms, techniques, outcomes, and future advances. *Neuromodulation.* 2014; 17(suppl 2): 52-68.
22. Deer T, Pope J, Hunter C et al. Safety Analysis of Dorsal Root Ganglion Stimulation in the Treatment of Chronic Pain. *Neuromodulation.* 2019;23(2):239-244. doi:10.1111/ner.12941. Epub 2019 Mar 12.
23. 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. *Pain.* 2017;158(4):669-681. doi:10.1097/j.pain.0000000000000814.
24. Deer TR, Pope JE, Lamer TJ, et al. The Neuromodulation Appropriateness Consensus Committee on Best Practices for Dorsal Root Ganglion Stimulation. *Neuromodulation.* 2018;22(1):1-35. doi:10.1111/ner.12845.
25. de Vos CC, Meier K, Zaalberg PB, et al. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicenter randomized clinical trial. *Pain.* 2014;155:2426–2431. 10.1016/j.pain.2014.08.031.
26. Duarte R, Nevitt S, Maden M et al. Spinal cord stimulation for the management of painful diabetic neuropathy: a systematic review and meta-analysis of individual patient and aggregate data. *Pain.* 2021;162(11):2635-2643. doi:10.1097/j.pain.0000000000002262.
27. Esposito M, Malayil R, Hanes M, Deer T. Unique Characteristics of the Dorsal Root Ganglion as a Target for

- Neuromodulation. *Pain Med.* 2019;20(Supplement_1):S23-S30. doi:10.1093/pm/pnz012.
28. Fontaine D, Christophe Sol J, Raoul S, Fabre N, Geraud G, Magne C et al. Treatment of refractory chronic cluster headache by chronic occipital nerve stimulation. *Cephalalgia.* 2011;31:1101–5.
 29. Forouzanfar T, Kemler M, Weber W, et al. Spinal cord stimulation in complex regional pain syndrome: cervical and lumbar devices are comparably effective. *Br J Anaesth.* 2004;92(3):348-53.
 30. Gersbach P, Argitis V, Gardaz JP et al. Late outcome of spinal cord stimulation for unreconstructable and limb-threatening lower limb ischemia. *Eur J Vasc Endovasc Surg.* 2007;33(6):717-724.
 31. Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: A systemic review. *Pain Physician* 2016; 19(1):E33-54.
 32. Harden R, Bruehl S, Perez R, et al. Validation of proposed diagnostic criteria (the “Budapest criteria”) for complex regional pain syndrome. *Pain.* 2010;150:268–74.
 33. Harden RN, Bruehl S, Perez R et al. Validation of proposed diagnostic criteria (the “Budapest Criteria”) for Complex Regional Pain Syndrome. *Pain.* 2010;150(2):268-274. doi:10.1016/j.pain.2010.04.030.
 34. Harden RN, Bruehl S, Stanton-Hicks M, Wilson PR. Proposed new diagnostic criteria for complex regional pain syndrome. *Pain Med.* 2007;8:326–31.
 35. Harke H, Gretenkort P, Ladleif H, Rahman S. Spinal cord stimulation in sympathetically maintained complex regional pain syndrome type I with severe disability. A prospective clinical study. *Eur J Pain.* 2005;9(4):363-373.
 36. Harvey AM. Classification of chronic pain—descriptions of chronic pain syndromes and definitions of pain terms. *Clin J Pain.* 1995;11(2); 179.
 37. Henson J, Varhabhatla N, Bebic Z et al. Spinal Cord Stimulation for Painful Diabetic Peripheral Neuropathy: A Systematic Review. *Pain Ther.* 2021;10(2):895-908. doi:10.1007/s40122-021-00282-9.
 38. Horan M, Jacobsen A, Scherer C et al. Complications and Effects of Dorsal Root Ganglion Stimulation in the Treatment of Chronic Neuropathic Pain: A Nationwide Cohort Study in Denmark. *Neuromodulation.* 2020. doi:10.1111/ner.13171.
 39. Huang KT, Martin J, Marky A, et al. A national survey of spinal cord stimulation trial-to-permanent conversion rates. *Neuromodulation.* 2015; 18:133-9.
 40. Huygen F, Kallewaard J, Nijhuis H et al. Effectiveness and Safety of Dorsal Root Ganglion Stimulation for the Treatment of Chronic Pain: A Pooled Analysis. *Neuromodulation.* 2020 Feb;23(2):213-221. doi:10.1111/ner.13074.Epub 2019 Nov 15.
 41. Jivegård L, Augustinsson L, Holm J, et al. Effects of spinal cord stimulation (SCS) in patients with inoperable severe lower limb ischaemia: a prospective randomised controlled study. *Eur J Vasc Endovasc Surg.* 1995;9(4):421-425.
 42. Kapural L, Narouze S, Janicki TI, Mekhail N. Spinal cord stimulation is an effective treatment for the chronic intractable visceral pelvic pain. *Pain Med.* 2006;7(5):440-443.
 43. Kapural L, Peterson E, Provenzano D, Staats P. Clinical Evidence for Spinal Cord Stimulation for Failed Back Surgery Syndrome (FBSS). *Spine.* 2017;42;14S, S61–S66.
 44. 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.* 2015;123(4):851-860.
 45. 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.* 2016 Sep 6.
 46. Kemler M, Barendse GA van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med.* 2000;343(9):618-624.
 47. Kemler M, de Vet H, Barendse G, 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.* 2008;108(2):292-298.
 48. Kemler M, de Vet H, Barendse G, et al. Spinal cord stimulation for chronic reflex sympathetic dystrophy – five year follow-up. *N Engl J Med.* 2006;354(22):2394-2396.
 49. Kemler M, de Vet H, Barendse G, 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.* 2004;55:13-18.
 50. Kemler M, Furnee C. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. *Neurology.* 2002;59(8):1203-1209.
 51. Klomp H, Spincemaille G, Steyerberg E, et al. Spinal-cord stimulation in critical limb ischaemia: a randomised trial. ESES Study Group. *Lancet.* 1999;353(9158):1040-1044.
 52. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery.* 2006;58(3):481-496; discussion 481-96.
 53. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicenter randomized controlled trial in patients with failed back surgery syndrome. *Pain.* 2007;132(1-2): 179-88.

54. Lam CM, Monroe BR. Successful treatment of central pain and spasticity in patient with multiple sclerosis with dorsal column, paresthesia-free spinal cord stimulator: A case report. *A A Pract.* 2019;12(9):308-312.
55. Lambrou G, Matharu M. Occipital nerve stimulation in primary headache syndromes. *Ther Adv Neurol Disord* 2012;5(1):57-67.
56. Latif O, Nedeljkovic S, Stevenson L. Spinal cord stimulation for chronic intractable angina pectoris: a unified theory on its mechanism. *Clin Cardiol.* 2001;24:533-541.
57. Levy R, Mekhail N, Kramer J et al. Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II. *J Pain.* 2020;21(3-4):399-408. doi:10.1016/j.jpain.2019.08.005.
58. Lipton R, Goadsby P, Cady R, Aurora SK, Grosberg B, Freitag F et al. PRISM study: occipital nerve stimulation for treatment-refractory migraine. *Cephalalgia.* 2009;29:30.
59. Magis D, Allena M, Bolla M, De Pasqua V, Remacle JM, Schoenen J. Occipital nerve stimulation for drug-resistant chronic cluster headache: a prospective pilot study. *Lancet Neurol.* 2007;6: 314–321.
60. Magis D, Gerardy PY, Remacle JM, Schoenen J. Sustained effectiveness of occipital nerve stimulation in drug-resistant chronic cluster headache. *Headache.* 2011;51:1191–201.
61. Magis D, Schoenen J. Advances and challenges in neurostimulation for headaches. *Lancet Neurol.* 2012;11:708–19.
62. Mailis-Gagnon A, Furlan A, Sandoval J, Taylor R. Spinal cord stimulation for chronic pain, *Cochrane Database Syst Rev.* 2004;3:CD003783.
63. Mannheimer C, Eliasson T, Augustinsson LE, et al. Electrical stimulation versus coronary artery bypass surgery in severe angina pectoris: the ESBY study. *Circulation.* 1998;97:1157-1163.
64. Marin JC, Goadsby P. Response of SUNCT (short-lasting unilateral neuralgiform headaches with conjunctival injection and tearing), SUNA (short-lasting unilateral neuralgiform headaches with autonomic symptoms) and primary stabbing headaches to occipital nerve stimulation (ONS). *Neurology.* 2010;74:P04.006, abstract.
65. McGreevy K, Williams K. Contemporary insights into painful diabetic neuropathy and treatment with spinal cord stimulation. *Curr Pain Headache Rep.* 2012;16:43-49.
66. Mekhail NA, Mathews M, Nageeb F, et al. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract.* 2011;11:148-53.
67. Mekhail N, Visnjevac O, Azer G, Mehanny D, Agrawal P, Foorsov V. Spinal Cord Stimulation 50 Years Later. *Reg Anesth Pain Med.* 2018;43(4):391-406. doi:10.1097/aap.0000000000000744.
68. Mesaroli G, Hundert A, Birnie K, Campbell F, Stinson J. Screening and diagnostic tools for complex regional pain syndrome: a systematic review. *Pain.* 2020;162(5):1295-1304. doi:10.1097/j.pain.0000000000002146.
69. Misra S, Shishehbor M, Takahashi E et al. Perfusion Assessment in Critical Limb Ischemia: Principles for Understanding and the Development of Evidence and Evaluation of Devices: A Scientific Statement from the American Heart Association. *Circulation.* 2019;140(12). doi:10.1161/cir.0000000000000708.
70. National Institute for Health and Care Excellence (NICE). *Pain (chronic neuropathic or ischaemic)-spinal cord stimulation: final appraisal determination.* September 2008.
71. North R, Calkins S, Campbell D, et al. Automated, patient-interactive, spinal cord stimulator adjustment: a randomized controlled trial. *Neurosurgery.* 2003;52(3):572-580.
72. North RB, Campbell JN, James CS, et al. Failed back surgery syndrome: Five year followup in 102 patients undergoing repeated operation. *Neurosurgery.* 1991; 28; 28: 685-91.
73. North R, Kidd D, Farrokhi F, Piantadosi S. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery.* 2005;56(1):98-106.
74. North R, Kidd D, Lee M, et al. A prospective, randomized study of spinal cord stimulation versus reoperation for failed back surgery syndrome: initial results. *Stereotact Funct Neurosurg.* 1994;62:267-272.
75. North R, Kidd H, Piantadosi S. Spinal cord stimulation versus reoperation for failed back surgery syndrome: a prospective, randomized study design. *Acta Neurochir.* 1995;64(Suppl):106-8.
76. North R, Kidd D, Shipley J, Taylor R. Spinal cord stimulation versus reoperation for failed back surgery syndrome: a cost effectiveness and cost utility analysis based on a randomized, controlled trial. *Neurosurgery.* 2007;61(2):361-368.
77. Novo S, Coppola G, Milio G. Critical Limb Ischemia: Definition and Natural History. *Curr Drug Targets Cardiovasc Haematol Disord.* 2004;4(3):219-225. doi:10.2174/1568006043335989.
78. Olek MJ, Narayan RN, Frohman EM, Frohman TC. Symptom management of multiple sclerosis in adults. *UpToDate Inc.*, Waltham, MA. <https://www.uptodate.com/contents/symptom-management-of-multiple-sclerosis-in-adults>.
79. Pedrini L, Magnoni F. Spinal cord stimulation for lower limb ischemic pain treatment. *Interact Cardiovasc Thorac Surg.* 2007;6(4):495-500.
80. Perruchoud C, Eldabe S, Batterham AM, et al. Analgesic efficacy of high-frequency spinal cord stimulation: A randomized double-blind placebo controlled study. *Neuromodulation.* 2013; 16(4): 363-9.
81. Petersen E, Stauss T, Scowcroft J et al. Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients

- With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. *Diabetes Care*. 2021;45(1):e3-e6. doi:10.2337/dc21-1813.
82. Rapcan R, Mlaka J, Venglarcik M, et al. High-frequency - spinal cord stimulation. *Bratisl Lek Listy*. 2015;116(6):354-356.
 83. Reed K. Peripheral neuromodulation and headaches: history, clinical approach, and considerations on underlying mechanisms. *Curr pain Headache Rep*. 2013;17:305.
 84. Reed KL, Black SB, Banta CJ 2nd, Will KR. Combined occipital and supraorbital neurostimulation for the treatment of chronic migraine headaches: initial experience. *Cephalalgia*. 2010;30:260–71.
 85. Russo M, Van Buyten JP. 10-kHz high-frequency SCS therapy: A clinical summary. *Pain Med*. 2015;16(5):934-942.
 86. Saper JR, Dodick DW, Silberstein SD, McCarville S, Sun M, Goadsby PJ. Occipital nerve stimulation for the treatment of intractable chronic migraine headache: ONSTIM feasibility study. *Cephalalgia*. 2011;31:271–85.
 87. Schwedt TJ, Dodick DW, Trentman TL, Zimmerman RS. Response to occipital nerve block is not useful in predicting efficacy of occipital nerve stimulation. *Cephalalgia*. 2007;27: 271–274.
 88. Scovell S, Hamdan A. Celiac artery compression syndrome. *UpToDate Inc.*, Waltham, MA. <https://www.uptodate.com/contents/celiac-artery-compression-syndrome>. Last reviewed December 2020.
 89. Shanahan P, Watkins L, Matharu M. Treatment of medically intractable short- lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT) and short-lasting unilateral neuralgiform headache attacks with autonomic symptoms (SUNA) with occipital nerve stimulation (ONS) in 6 patients. *Cephalalgia*. 2009;29:150.
 90. Silberstein S, Dodick D, Saper J, Huh B, Slavin KV, Sharan A et al. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: Results from a randomized, multicenter, double-blinded, controlled study. *Cephalalgia*. 2012;32(16):1165–79.
 91. Sitzman B, Provenzano D. Best Practices in Spinal Cord Stimulation. *Spine*. 2017: 42; 14S, S67–S71.
 92. Sivanesan E, Bicket M, Cohen S. Retrospective analysis of complications associated with dorsal root ganglion stimulation for pain relief in the FDA MAUDE database. *Regional Anesthesia & Pain Medicine*. 2019;44(1):100-106. doi:10.1136/rapm-2018-000007.
 93. Sivanesan E, Cohen S. Response to “Safety Analysis of Dorsal Root Ganglion Stimulation in the Treatment of Chronic Pain”. *Neuromodulation: Technology at the Neural Interface*. 2019;22(4):503-504. doi:10.1111/ner.12971.
 94. Skaribas I, Calvillo O, Delikanaki-Skaribas E. Occipital peripheral nerve stimulation in the management of chronic intractable occipital neuralgia in a patient with neurofibromatosis type 1: a case report. *J Med Case Rep*. 2011;5:174.
 95. Slangen R, Pluijms WA, Faber CG, Dirksen CD, Kessels AG, van Kleef M. Sustained effect of spinal cord stimulation on pain and quality of life in painful diabetic peripheral neuropathy. *Br J Anaesth* 2013;111:1030–1031.
 96. 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*. 2014;37:3016–3024.
 97. Slangen R, Schaper N, Faber C et al. Spinal Cord Stimulation and Pain Relief in Painful Diabetic Peripheral Neuropathy: A Prospective Two-Center Randomized Controlled Trial. *Diabetes Care*. 2014;37(11):3016-3024. doi:10.2337/dc14-0684.
 98. Stancák A, Kozák J, Vrba I, et al. Functional magnetic resonance imaging of cerebral activation during spinal cord stimulation in failed back surgery syndrome patients. *Eur J Pain*. 2008;12(2):137-48.
 99. Stanton-Hicks M, Burton A, Bruehl S, et al. An updated interdisciplinary clinical pathway for CRPS: report of an expert panel. *Pain Pract*. 2005; 84(3):S4-S16.
 100. Sundaraj S, Johnstone C, Noore F, et al. Spinal cord stimulation: a seven-year audit. *J Clin Neurosci*. 2005 Apr;12(3):264-270.
 101. Taylor R, Buyten J, Buchser E. Spinal cord stimulation for complex regional pain syndrome: A systematic review of the clinical and cost-effectiveness literature and assessment of prognostic factors. *Eur J Pain*. 2006;10(2):91-101.
 102. Taylor RS, Desai MJ, Rigoard P, Taylor RJ. Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: A systemic review and meta-regression analysis. *Pain Pract*. 2014; 14(6): 489-505.
 103. Taylor R, Taylor R. Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. *Int J Technol Assess Health Care*. 2005;21(3):351-358.
 104. TenVaarwerk I, Jessurun G, DeJongste M, et al. Clinical outcome of patients treated with spinal cord stimulation for therapeutically refractory angina pectoris. The Working Group on Neurocardiology. *Heart*. 1999;82(1):82-88.
 105. Tesfaye S, Watt J, Benbow S, et al. Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy. *Lancet*. 1996;348:1698-1701.
 106. Tiede J, Brown L, Gekht G, et al. Novel spinal cord stimulation parameters in patients with predominant back pain. *Neuromodulation*. 2013;16(4):370-375.
 107. Ubbink D, Vermeulen H. Spinal cord stimulation for critical leg ischemia: a review of effectiveness and optimal patient selection. *J Pain Symptom Manage*. 2006;31:S30-S35.
 108. Ubbink D, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg

- ischaemia. *Cochrane Database Syst Rev.* 2005;CD004001.
109. van Beek M, Geurts J, Slangen R et al. Severity of Neuropathy Is Associated With Long-term Spinal Cord Stimulation Outcome in Painful Diabetic Peripheral Neuropathy: Five-Year Follow-up of a Prospective Two-Center Clinical Trial. *Diabetes Care.* 2017;41(1):32-38. doi:10.2337/dc17-0983.
110. van Beek M, Slangen R, Schaper N, Faber C, Joosten E, Dirksen C, van Dongen R, Kessels A, van Kleef M. Sustained treatment effect of spinal cord stimulation in painful diabetic peripheral neuropathy: 24-month follow-up of a prospective two-center randomized controlled trial. *Diabetes Care.* 2015;38:e132-e134.
111. van Buyten JP, Al-Kaisy A, Smet I, Palmisani S, Smith T. High-frequency spinal cord stimulation for the treatment of chronic back pain patients: Results of a prospective multicenter European clinical study. *Neuromodulation.* 2013; 16(1): 59-65.
112. Weiner RL, Reed KL. Peripheral neurostimulation for control of intractable occipital neuralgia. *Neuromodulation.* 1999;2:217–22.
113. Whelton PK, Carey RM, Aronow WS, et.al. 2017 ACC/ AHA/ AAPA/ ABC/ ACPM/ AGS/ APhA/ ASH/ ASPC/ NMA/ PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2018;71:e127–248. doi:10.1016/j.jacc.2017.11.00.
114. Workloss Data Institute. *Official Disability Guidelines* 2008.