Cohere Medicare Advantage Policy - Spinal Cord Stimulators

Clinical Guidelines for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Guideline Information:

Specialty Area: Disorders of the Musculoskeletal System
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Medical Necessity Criteria

Service: Spinal Cord Stimulators

Benefit Category

Prosthetic Devices
Incident to a Physician's Professional Service
Outpatient Hospital Services Incident to a Physician's Service
Outpatient Physical Therapy Services
Physicians' Services

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1-5]

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1-5]

- Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L35136)
- Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L36204)
- Local Coverage Determination (LCD). Spinal cord stimulators for chronic pain (L37632)
- National Coverage Determination (NCD). Electrical nerve stimulators (160.7)
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- Billing and Coding: Spinal cord stimulators for chronic pain (A57792)

Recommended Clinical Approach

A spinal cord stimulator (SCS) is an implantable device that delivers electrical impulses to the spinal cord to alleviate chronic pain. Before the permanent SCS placement, a trial must be conducted to assess if the patient will respond adequately to the SCS. Typically, patients who experience a 50% or greater

improvement in pain are recommended for permanent SCS placement.[6] The device is not appropriate for all patients with chronic pain, and careful patient selection is necessary to achieve optimal outcomes.[1-5] Dorsal root ganglion (DRG) stimulation is done via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable pain of the lower limbs in patients with complex regional pain syndrome (CRPS) types I and II. An SCS is considered a late or last resort after exhausting other treatments for chronic, intractable pain.[7-11]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of spinal cord stimulators. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Surgical complications, including needle puncture leading to nerve injury, lead/sheath trauma, dural puncture/cerebrospinal fluid leak, lead migration, lead fracture, lead retention upon removal/revision, pocket pain, and hematoma. Several of these risks are potentially avoidable with imaging, careful surgical technique, appropriate patient selection, and patient communication.[12,13]
- Postsurgical device-related complications can include lead migration, erosion, lead and sheath fracture or other damage, connection failure, and hardware malfunction.[13,14]
- Other complications can include neurological symptoms such as nerve damage, numbness, paraesthesias, weakness, pain, dural puncture, infection, epidural hematoma, inappropriate stimulation, overstimulation, and headache.[12,14-16]
- Potential delays or denials leading to worsened patient outcomes including increased use of medications, including opioids and others with abuse potential, worsening quality of life, reduced mobility, ongoing and worsening pain, ongoing and worsening muscle atrophy, and delays in physical rehabilitation.[6,16]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved patient outcomes through timely and appropriate access to spinal cord stimulation. SCS has been shown to alleviate chronic intractable pain due to several conditions, e.g., failed back surgery syndrome, complex regional pain syndrome, diabetic peripheral neuropathy.[6,17] A 2007 clinical trial comparing medical management of pain due to failed back surgery syndrome and medical management with SCS (PROCESS trial) reported that while only 7% of the medical management alone patients reported 50% or greater improved pain, 34% of SCS patients reported pain improvement. SCS patients also reported greater quality of life, functional capacity, and treatment satisfaction.[18]
- Reduction or complete elimination of opioid and other potentially dependence-inducing pharmacological treatment use and avoidance of medication-related adverse effects, including disrupted hormonal and immune system functioning, depression, tolerance, and opioid-induced hyperalgesia.[6,18]
- Avoidance of repeated surgeries. In a study comparing outcomes in failed back surgery syndrome patients randomized to either SCS or repeated lumbosacral spine surgery, SCS patients were more satisfied than repeat-surgery patients at three-year followup.[19]
- Improved pain can decrease overall long-term cost of care, improve overall quality of life, and increase the likelihood of returning to work.[6,16]
- Appropriate patient selection and use of SCS trials avoid unnecessary and ineffective invasive surgical procedures.[6,16]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ A **spinal cord stimulator (SCS)** is considered appropriate if **ANY** of the following is **TRUE**:
  - An **SCS trial** is appropriate when **ALL** of the following are **TRUE**[1-5]:
    - Pain has been present for greater than or equal to 6 months; **AND**
    - Documented pain-focused psychological evaluation and clearance within the last 12 months has determined that the patient is a suitable candidate[20]; **AND**
    - The patient has **ANY** of the following conditions:
      - Complex regional pain syndrome (CRPS), also known as reflex sympathetic dystrophy (RSD), as diagnosed by **ALL** of the following, as per Budapest criteria[21-23]:
        - Continued, ongoing pain, disproportionate to any inciting event (e.g., surgery, trauma); **AND**
        - Must report a symptom in **AT LEAST THREE** of the following categories:
          - Sensory: reports of hyperesthesia and/or allodynia; **OR**
          - Vasomotor: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry; **OR**
          - Sudomotor/edema: reports of edema and/or sweating changes and/or sweating asymmetry; **OR**
          - Motor/trophic: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nails, skin); **AND**
        - The patient has signs of **AT LEAST TWO** of the following categories at the time of evaluation:
          - Sensory (e.g., hyperalgesia [to pinprick], allodynia [to light touch]); **OR**
          - Vasomotor (e.g., temperature asymmetry, skin color changes, skin color asymmetry); **OR**
          - Sudomotor or edema (e.g., edema, sweating asymmetry, sweating changes); **OR**

- Motor or trophic (e.g., decreased ROM, motor dysfunction [weakness, tremor, dystonia], trophic changes [hair, nails, skin]); **AND**

- The treatment is a late or last resort as defined by failure of conservative management for greater than 3 months within the last 12 months, including **ALL** of the following, if medically appropriate and not contraindicated[4]:
  - Prescription pain medications(e.g., anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
  - Failed trial of at least 2 neuropathic medications (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, etc.); **AND**
  - Physical therapy, including a home exercise program; **AND**
  - Failure of adequate relief with interventional pain procedure(e.g., sympathetic nerve block); **OR**

- Failed back surgery syndrome (FBSS), post-laminectomy syndrome with **ALL** of the following[4,23-25]:
  - The treatment is a late or last resort as defined by failure of conservative management for greater than 3 months within the last 12 months, including **ALL** of the following, if medically appropriate and not contraindicated[4]:
    - Prescription pain medications(e.g., anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
    - Failed trial of at least 2 neuropathic medications (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, etc.); **AND**
    - Physical therapy, including a home exercise program; **AND**
    - Failure of adequate relief with interventional pain procedure(e.g., epidural steroid injection, facet joint procedures, etc.); **AND**

        - Spine surgeon evaluation within the last 12 months attesting that the patient is not a candidate for further surgical intervention[28]; **OR**
    - Painful diabetic neuropathy (PDN) in a lower extremity as a treatment of late or last resort, defined by **ALL** of the following[4,26-28]:
        - Failure of at least a 3-month trial of at least 2 medications targeting neuropathic pain (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, venlafaxine, desvenlafaxine, etc.); **AND**
        - Documentation (within last 6 months) from primary care physician or endocrinologist that medical management of diabetes and glucose control has been optimized; **AND**
        - Documentation of a hemoglobin A1c (HbA1c) level of 9 or less within the last 3 months; **OR**
    - Chronic intractable back or neck pain with **ALL** of the following[29,30]:
        - The treatment is a late or last resort as defined by failure of conservative management for greater than 3 months within the last 12 months, including **ALL** of the following, if medically appropriate and not contraindicated[4]:
            - Prescription pain medications(e.g., anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
            - Physical therapy, including a home exercise program; **AND**
            - Failure of adequate relief with interventional pain procedure(e.g., epidural steroid injection, facet joint procedures, etc.); **AND**
        - Spine surgeon evaluation within the last 12 months attesting that the patient is not a candidate for surgical intervention due to **ANY** of the following[32]:
            - High surgical risk; **OR**
            - increased risk of perioperative morbidity or mortality due to medical comorbidities; **OR**
    - Inoperable chronic ischemic limb pain secondary to peripheral vascular disease as a treatment of late or

last resort, defined by failure of conservative management for greater than 3 months within the last 12 months including **ALL** of the following if medically appropriate and not contraindicated[4,33,34]:
    - Prescription pain medications(e.g., anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
    - Vascular surgeon evaluation within the last 12 months attesting that the patient is not a candidate for surgical intervention; **AND**
    - Failure of adequate relief with interventional pain procedure(e.g., sympathetic nerve block); **OR**
  - Moderate to severe chronic neuropathic pain as a treatment of late or last resort, defined by failure of conservative management for greater than 3 months within the last 12 months including **ALL** of the following[4,35-38]:
    - Prescription pain medications(e.g., anti-inflammatory medications, non-opioid analgesics, opioid medications, etc.); **AND**
    - Physical therapy, including a home exercise program; **AND**
    - Failed trial of at least 2 neuropathic medications (e.g., gabapentin, pregabalin, duloxetine, amitriptyline, nortriptyline, etc.); **AND**
    - Failure of adequate relief with interventional pain procedure(e.g., nerve blocks , etc.); **OR**
- A **permanent SCS implantation** is appropriate if the patient has had a successful SCS trial, as indicated by **ALL** of the following[1-4,39]:
  - Meets medical necessity criteria for trial; **AND**
  - A temporary SCS trial of at least 3 days; **AND**
  - Demonstrated improved functioning as indicated by **ANY** of the following[20]:
    - At least 50% reduction in target pain during the temporary SCS trial; **OR**
    - At least 50% reduction in the use of analgesic medications during the SCS trial; **AND**
  - Documented improvement in **ANY** of the following during the temporary SCS trial[20]:
    - Ability to perform daily activities; **OR**
    - Quality of life; **OR**
    - Functional disability scale; **OR**
    - Mobility; **OR**

- **A SCS or DRG revision or replacement** is considered appropriate if **ANY** of the following is **TRUE**[1-4,40-43]:
    - SCS/DRG battery malfunction or depletion; **OR**
    - Lead displacement or fracture; **OR**
    - Infection surrounding SCS device; **OR**
    - Hardware-related pain; **OR**
    - An MRI-compatible device is needed due to **ALL** of the following:
        - The patient currently has a non-MRI compatible device; **AND**
        - An MRI is required for concerns of disorders that cannot be properly evaluated by non-MRI imaging modalities; **AND**
        - A physician must attest to the medical necessity of an MRI.

Non-Indications

➔ A **spinal cord stimulator (SCS)** is not considered appropriate if **ANY** of the following is **TRUE**[39]:

- The patient has active substance use disorder[1-3]; **OR**
- More than 2 SCS trials per anatomic spinal region per patient per lifetime is not considered reasonable and necessary[1-3]; **OR**
- A repeat trial after initial trial failure, unless extenuating circumstances were present that contributed to trial failure[1-3]; **OR**
- DRG or SCS trial in a patient with an existing SCS or DRG; **OR**
- Replacement or upgrade when **ANY** of the following is **TRUE**:
    - No documented medical necessity for upgrade of functional, non-MRI compatible SCS device; **OR**
    - The SCS is functioning, and newer technology is requested (including but not limited to BurstDR, high-frequency SCS, closed-loop SCS, etc.); **OR**
    - Lead and electrode replacement as both are not generally required at the time of a generator replacement due to the end of battery life; **OR**
- Trials or implants performed by non-physicians; **OR**
- Dorsal root ganglion (DRG) stimulation for all conditions except complex regional pain syndrome (CRPS) types I and II in the lower extremity[1,44,45].

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of electrode array, plate/paddle, epidural
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, requiring pocket creation and connection between electrode array and pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array
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
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	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
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Petersen et al (2023) conducted a prospective, multicenter, randomized controlled trial (RCT) to assess the effectiveness of spinal cord stimulation (SCS) at a frequency of 10 kHz in managing persistent painful diabetic neuropathy (PDN) that has not responded to conventional treatments. The trial included 216 patients with refractory PDN; researchers compared conventional medical management (CMM) alone with a combination of CMM and 10 kHz SCS. At the 6-month follow-up, patients with inadequate pain relief were given the option to begin the other treatment. The 142 patients treated with the 10 kHz SCS system were followed for 24 months. Results showed that at 24 months, the 10 kHz SCS reduced pain by an average of 79.9% compared to baseline, with 90.1% of patients experiencing at least 50% pain relief. Participants also experienced significant improvements in quality of life and sleep, with 65.7% demonstrating clinically meaningful neurological improvement. The study supports the use of 10 kHz SCS for lasting pain relief and notable improvements in quality of life, sleep, and neurological function over 24 months.[46]

Kapural et al (2023) performed a prospective, multicenter, randomized, single-masked feasibility study to evaluate the safety and efficacy of a novel charge-distributed multiphase stimulation approach throughout an extended trial of SCS. The study included patients with chronic low back or leg pain (or both) who underwent a successful commercial SCS trial. Patients were randomized into 2 groups receiving different multiphase SCS therapies, with varying frequency ranges, over an 11-to-12-day period. Results showed significant reductions in pain intensity for both multiphase therapies compared to baseline. There was no significant difference in pain reduction between the two multiphase therapies. In conclusion, multiphase SCS effectively reduced pain in participants with chronic low back or leg pain, with no unexpected device-related adverse events. Future research should focus on assessing the long-term effectiveness of multiphase stimulation.[47]

Zuidema et al (2023) conducted a prospective cohort RCT to assess the enduring impacts of SCS on patients with painful diabetic polyneuropathy (PDPN). The study is an 8-to-10-year follow-up of a previous trial on SCS for PDPN that focused on a subgroup of 19 patients who still used SCS treatment after 8 years. The study notes that pain intensity during the day and night significantly decreased with SCS compared to baseline. More than 50% of patients experienced a pain reduction of more than 30%. However, there were no significant differences in secondary outcomes, such as quality of life, depression, and sleep quality. The conclusion suggests that SCS can remain

an effective long-term treatment for reducing pain intensity in some patients with PDPN who still have the device implanted after 8 years.[48]

In their systematic review and meta-analysis of implanted neuromodulation interventions, which included 908 randomized participants across 35 published or ongoing studies, O'Connell et al (2022) found that patients treated with SCS experienced less pain and a higher quality of life 1-6 months after treatment, compared to patients who received only medical management or physical therapy. However, according to the authors, there is little evidence to suggest that SCS can reduce disability, medication use, or pain in the medium to long-term. Nor is it clear that SCS is cost-effective. The authors also note that possible complications of SCS implantation include lead displacement or fracture, wound infection, and the need for surgical revision or replacement.[49]

In a randomized clinical trial, Hara et al (2022) investigated the efficacy of SCS. The placebo-controlled trial included 50 patients who underwent randomized 3-month periods of spinal cord burst stimulation and placebo stimulation. The study team did not find a significant difference in self-reported disability among trial participants with chronic post-lumbar spine surgery back pain.[50]

Centers for Medicare and Medicaid (CMS) Local and National Coverage determinations state that SCS may be appropriate as a late, if not last, resort treatment for chronic, intractable pain.[1-4] Notably, while neuropathic pain is identified as potentially best-suited for SCS, any severe, nociceptive intractable pain may be relieved by SCS. Regardless of the etiology of the pain, CMS notes the importance of careful patient selection and education prior to SCS implantation, requiring documentation of patient disclosure of all potential risks and benefits as well as psychological clearing.

References

1. Centers for Medicare and Medicaid Services (CMS). Local coverage determination (LCD) - spinal cord stimulators for chronic pain (L35136). Revision Effective Date December 1, 2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35136
2. Centers for Medicare and Medicaid Services (CMS). Local coverage determination (LCD) - spinal cord stimulators for chronic pain (L36204). Revision Effective Date December 1, 2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36204&ver=22
3. Centers for Medicare and Medicaid Services (CMS). Local coverage determination (LCD) - spinal cord stimulators for chronic pain (L37632). Revision Effective Date May 13, 2021. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37632&ver=26
4. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD) - electrical nerve stimulators (160.7). Effective Date August 8, 1995. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=240&NCDver=1
5. Centers for Medicare and Medicaid Services (CMS). National coverage determination (NCD) - Assessing patient's suitability for electrical nerve stimulation therapy (160.7.1). Revision Effective Date June 19, 2006. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=63
6. Deer TR, Mekhail N, Provenzano D, et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*. 2014;17(6):515-550. doi:10.1111/NER.12208
7. Kapural L, Peterson E, Provenzano DA, et al. Clinical evidence for spinal cord stimulation for failed back surgery syndrome (FBSS): Systematic review. *Spine*. 2017;42(Suppl 14):S61-S66. doi:10.1097/BRS.0000000000002213. PMID: 28441313
8. Sdrulla AD, Guan Y, Raja SN. Spinal cord stimulation: Clinical efficacy and potential mechanisms. *Pain Practice*. 2018;18(8):1048-1067. doi:10.1111/papr.12692
9. Hagedorn JM, Romero J, Ha CT, D'Souza RS. Patient satisfaction with spinal cord stimulation and dorsal root ganglion stimulation for chronic intractable pain: A systematic review and meta-analysis. *Neuromodulation*. 2022;25(7):947-955. doi:10.1016/j.neurom.2022.04.043

10. Duarte RV, 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
11. 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. doi:10.1097/ALN.0000000000000774. PMID: 26218762
12. Horan M, Jacobsen AH, 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*. 2021;24(4):729-737. doi:10.1111/NER.13171
13. Sivanesan E, Bicket MC, Cohen SP. Retrospective analysis of complications associated with dorsal root ganglion stimulation for pain relief in the FDA MAUDE database. *Reg Anesth Pain Med*. 2019;44(1):100-106. doi:10.1136/RAPM-2018-000007
14. Eldabe S, Buchser E, Duarte RV. Complications of spinal cord stimulation and peripheral nerve stimulation techniques: A review of the literature. *Pain Med*. 2016;17(2):325-336. doi:10.1093/PM/PNV025
15. Hanna J, Saad R, Sibai N. Dorsal root ganglion stimulation—implant. In: Neuromodulation Techniques for the Spine. 13th ed. Chapter 13. 109-119. Elsevier LTD; 2024.
16. Candan B, Gungor S. Current and evolving concepts in the management of complex regional pain syndrome: A narrative review. *Diagnostics*. 2025;15(3):353. doi:10.3390/DIAGNOSTICS15030353
17. Hong A, Varshney V, Hare GMT, Mazer CD. Spinal cord stimulation: A nonopioid alternative for chronic pain management. CMAJ. 2020;192(42):E1264-E1267. doi:10.1503/CMAJ.200229
18. 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*. 2007;132:179-188. doi:10.1016/j.pain.2007.07.028
19. North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: A randomized, controlled trial. *Neurosurgery*. 2005;56(1):98-106. doi:10.1227/01.NEU.0000144839.65524.E0
20. Shanthanna H, Eldabe S, Provenzano DA, et al. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. *Reg Anesth Pain Med*. 2023;48(6):273. doi:10.1136/RAPM-2022-104097
21. Harden RN, Bruehl S, Perez RS, Birklein F, Marinus J, Maihofner C, Lubenow T, Buvanendran A, Mackey S, Graciosa J, Mogilevski M. 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
22. Geurts JW, Smits H, Kemler MA, Brunner F, Kessels AGH, van Kleef M. Spinal cord stimulation for complex regional pain syndrome type I: A prospective cohort study with long-term follow-up. *Neuromodulation*. 2013;16(6):523-529. doi:10.1111/NER.12024
23. Cruccu G, Garcia-Larrea L, Hansson P, et al. EAN guidelines on central neurostimulation therapy in chronic pain conditions. *Eur J Neurol*. 2016;23(10):1489-1499. doi:10.1111/ENE.13103
24. US Food & Drug Administration (FDA). Summary of safety and effectiveness data (SSED). U.S. Food and Drug Administration. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022B.pdf.
25. Ganty P, Sharma M. Failed back surgery syndrome: A suggested algorithm of care. *Br J Pain*. 2012;6(4):153. doi:10.1177/2049463712470222
26. US Food & Drug Administration (FDA). Summary of safety and effectiveness data (SSED). U.S. Food and Drug Administration. Published July 16, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130022S039B.pdf
27. Henson NC, Varhabhatla Z, Bebic A, Kaye RD, Yong J, Urman JS, Merkow J. Spinal cord stimulation for painful diabetic peripheral neuropathy: a systematic review. *J Pain Res*. doi:10.1007/s40122-021-00282-9
28. Yeung AM, Huang J, Nguyen KT, et al. Spinal cord stimulation for painful diabetic neuropathy. *J Diabetes Sci Technol*. 2022;18(1):168. doi:10.1177/19322968221133795
29. Amirdelfan K, Vallejo R, Benyamin R, et al. High-frequency spinal cord stimulation at 10 kHz for the treatment of combined neck and arm pain: Results from a prospective multicenter study. *Neurosurgery*. 2020;87(2):176-185. doi:10.1093/NEUROS/NYZ495
30. 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):59-66. doi:10.1111/NER.12006
31. North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care. Published online 2020. Accessed April 3, 2025. www.spine.org
32. 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;58:481-496. doi:10.1227/01.NEU.0000192162.99567.96
33. Ubbink DT, Vermeulen H. Spinal cord stimulation for critical leg ischemia: A review of effectiveness and optimal patient selection. *J Pain Symptom Manage*. 2006;31(4 Suppl). doi:10.1016/J.JPAINSYMMAN.2005.12.013

34. Gazzeri R, Castrucci T, Luigi M, Leoni G, Mercieri M, Occhigrossi F. Spinal cord stimulation for intractable chronic limb ischemia: A narrative review. *J Cardiovas Dev Dis*. 2024;11(9):260. doi:10.3390/JCDD11090260
35. Bates D, Schultheis BC, Hanes MC, et al. A comprehensive algorithm for management of neuropathic pain. *Pain Medicine*. 2019;20:S2–S12. doi:10.1093/pm/pnz075
36. National Institute for Health and Care Excellence (NICE). Neuropathic pain in adults: pharmacological management in non-specialist settings. Clinical guideline (CG173). National Institute for Health and Care Excellence. Published November 20, 2013. Last updated September 22, 2020. Available at: https://www.nice.org.uk/guidance/cg173
37. Moisset X. Neuropathic pain: Evidence-based recommendations. *Presse Méd.* 2024;53(2):104232. doi:10.1016/J.LPM.2024.104232
38. Cruccu G, Aziz TZ, Garcia-Larrea L, et al. EFNS guidelines on neurostimulation therapy for neuropathic pain. *Eur J Neurol*. 2007;14(9):952-970. doi:10.1111/J.1468-1331.2007.01916.X
39. Boswell MV, Trescot AM, Datta S, et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician*. 2007 Jan;10(1):7-111. PMID: 17256025.
40. Deer TR, Pope JE, Falowski SM, Pilitsis JG, Hunter CW, Burton AW, Connolly AT, Verrills P. Clinical longevity of 106,462 rechargeable and primary cell spinal cord stimulators: Real world study in the Medicare population. *Neuromodulation*. 2023 Jan 1;26(1):131-8. doi.org/10.1016/j.neurom.2022.04.046.
41. Goudman L, Moens M, Kelly S, Young C, Pilitsis JG. Incidence of infections, explanations, and displacements/mechanical complications of spinal cord stimulation during the past eight years. *Neuromodulation*. 2024 Aug 1;27(6):1082-9. doi.org/10.1016/j.neurom.2023.09.001.
42. Esquer Garrigos Z, Farid S, Bendel MA, Sohail MR. Spinal cord stimulator infection: Approach to diagnosis, management, and prevention. *Clin Infect Dis*. 2020 Jun 10;70(12):2727-35. doi.org/10.1093/cid/ciz994.
43. Hasoon J, Vu PD, Mousa B, Markaryan AR, Sarwary ZB, Pinkhasova D, Chen GH, Gul F, Robinson CL, Simopoulos TT, Gill J. Device-related complications associated with cylindrical lead spinal cord stimulator implants: A comprehensive review. *Curr Pain Headache Rep*. 2024 Jun 8:1-7. doi.org/10.1007/s11916-024-01280-0.
44. United States Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED): Dorsal root ganglion stimulator for pain relief (P150004). Published February 11, 2016. Accessed November 12, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150004b.pdf
45. 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*. 2017; 158(4): 669-681. http://dx.doi.org/10.1097/j.pain.0000000000000814
46. Petersen EA, Stauss TG, Scowcroft JA, et al. Long-term efficacy of high-frequency (10 kHz) spinal cord stimulation for the treatment of painful diabetic neuropathy: 24-month results of a randomized controlled trial. *Diabetes Res Clin Pract*. 2023 Sep:203:110865. doi: 10.1016/j.diabres.2023.110865. PMID: 37536514; PMCID: PMC10801706.
47. Kapural L, Patterson DG, Li S, et al. Multiphase spinal cord stimulation in participants with chronic back or leg pain: Results of the BENEFIT-02 randomized clinical trial. *Neuromodulation*. 2023 Oct;26(7):1400-1411. doi: 10.1016/j.neurom.2023.05.006. PMID: 37589641.
48. Zuidema X, van Daal E, van Geel I, et al. Long-term evaluation of spinal cord stimulation in patients with painful diabetic polyneuropathy: An eight-to-ten-year prospective cohort study. *Neuromodulation*. 2023 Jul;26(5):1074-1080. doi: 10.1016/j.neurom.2022.12.003. PMID: 36587999.
49. O'Connell NE, Ferraro MC, Gibson W, Rice ASC, Vase L, Coyle D, Eccleston C. Implanted spinal neuromodulation interventions for chronic pain in adults. *Cochrane Database Syst Rev*. 2021, Issue 12. Art. No.: CD013756. DOI: 10.1002/14651858.CD013756.pub2. Accessed 13 November 2024.
50. Hara S, Andresen H, Solheim O, et al. Effect of spinal cord burst stimulation vs placebo stimulation on disability in patients with chronic radicular pain after lumbar spine surgery: A randomized clinical trial. *JAMA*. 2022;328(15):1506–1514. doi:10.1001/jama.2022.18231

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