Medtronic
Engineering the extraordinary

Spinal cord stimulation Patient access resource

January 2026

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Document overview

Overview

This document outlines resources available to support patient access to Spinal Cord Stimulation procedures.

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Medicare

Coverage landscape and medical necessity

Jurisdiction & States Covered	MAC	NCD	LCD	LCA
J15: KY, OH	CGS (A Celerian Group Company)	Link	N/A	N/A
JN: FL; PR, US Virgin Island	FCSO (First Coast Service Options Inc.)	Link	N/A	N/A
J6: IL, MN, WI JK: CT, ME, MA, NH, NY, RI, VT	NGS (National Government Services)	Link	N/A	N/A
JE: CA, HI, NV JF: AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	Noridian	Link	Link	Link
JH: AR, CO, LA, MS, NM, OK, TX JL: DE, DC, MD, NJ, PA	Notivas	Link	N/A	N/A
JM: NC, SC, VA, WV JJ: AL, GA, TN	Palmetto	Link	Link	Link
J5: IA, KS, MO, NE J8: IN, MI	WPS (Wisconsin Physician Services)	Link	N/A	N/A

Medicare SCS conditions for coverage (National Coverage Determination (NCD) 160.7: Electrical nerve stimulators)

1. The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
2. With respect to item #1, 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;
3. 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);
4. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item #3) must be available;
5. Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Medicare prior authorization

Prior Authorization: Sometimes required

Medicare prior authorization (PA) for Spinal Cord Stimulation (SCS) may be required under two distinct pathways, depending on the procedure type, the site of service, and sometimes the state in which the service is performed:

1. **Medicare Hospital Outpatient Department (OPD) Prior Authorization Model**
   Effective in 2021, this national, mandatory, model applies to select procedures furnished in the Hospital Outpatient Department (HOPD) setting.

2. **WISeR (Wasteful and Inappropriate Service Reduction) Prior Authorization Model**
   Effective in 2026, this model applies to select procedures and is limited to services performed in six pilot states: Arizona, New Jersey, Ohio, Oklahoma, Texas, and Washington. While not required, if providers do not submit a prior authorization, the claim is subject to automatic post-procedure and prepayment review.

To determine whether prior authorization is required, healthcare providers (HCPs) must first identify which Medicare pathway applies to the service. The sections below outline each pathway and describe when prior authorization is required.

1 Hospital OPD PA Model

Nationwide
Site of Service: Outpatient Hospital

Prior Authorization Code Trigger
CPT **63650**

Prior Authorization Not Required
CPT **63655**
CPT **63685**

Exclusion: Prior authorization is not required in the Inpatient Hospital setting.

2 WISeR PA Model

Applies only in AZ, NJ, OH, OK, TX, and WA
Site of Service: Office, Outpatient Hospital, ASC

Prior Authorization Code Trigger
CPT **63655**

Associated Codes*
CPT **63685** (Included in the prior authorization request when billed in association with CPT 63655)

Prior Authorization Not Required
CPT **63650**

Exclusion: Prior authorization is not required in the Inpatient Hospital setting.

CPT code definitions
63650 Percutaneous implantation of neurostimulator electrode array, epidural
63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685 Insertion or replacement of spinal neurostimulator pulse generator/receiver

*Associated codes, also referred to as associated items or services, are procedures, supplies, or services that are furnished in connection with, or as part of, a primary procedure subject to the WISeR Prior Authorization Model. These items or services are integral, ancillary, or otherwise related to the provision of the primary service and may be billed separately using distinct CPT®, HCPCS, or revenue codes. When required under WISeR, associated codes must be included in the prior authorization request to allow CMS to assess medical necessity for the applicable items and services furnished during the episode of care.[1]

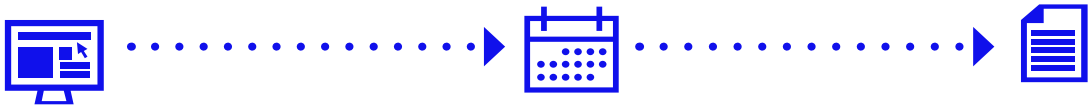
[1] Centers for Medicare & Medicaid Services (CMS). WISeR (Wasteful and Inappropriate Service Reduction) Prior Authorization Model – Operational Guide. References to "associated items or services" and submission requirements for prior authorization requests.

Medicare prior authorization

1 Hospital OPD Services Model Details

Medicare requires prior authorization for SCS when CPT 63650 is billed in an outpatient hospital department. Critical Access Hospitals (CAHs) and Indian Health Services are exempt from this requirement. Prior authorization is required if seeking payment with Medicare as secondary.

Prior authorization request process



Submit to MAC using MAC portal, electronic submission of medical documentation (esMD), mail or fax

Up to 7 calendar days for a decision

Provisional affirmation valid 120 days from date decision was made

Many MACs have a cover sheet or other templates available when creating a PA request.

Prior authorization: Links

Jurisdiction & States Covered	MAC	Hospital OPD PA Site
J15: KY, OH	CGS (A Celerian Group Company)	Link
JN: FL; PR, US Virgin Island	FCSO (First Coast Service Options Inc.)	Link
J6: IL, MN, WI JK: CT, ME, MA, NH, NY, RI, VT	NGS (National Government Services)	Link
JE: CA, HI, NV JF: AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	Noridian	Link
JH: AR, CO, LA, MS, NM, OK, TX JL: DE, DC, MD, NJ, PA	Notivas	Link (JH) Link (JL)
JM: NC, SC, VA, WV JJ: AL, GA, TN	Palmetto	Link
J5: IA, KS, MO, NE J8: IN, MI	WPS (Wisconsin Physician Services)	Link

Possible outcomes

Provisional affirmation decision: Procedure is approved. Medicare will list a PA unique tracking number (UTN) on the decision notice. Hospital must include the UTN on the claim to receive payment.

Non-affirmation decision: Procedure is **not** approved. Medicare will provide a reason for the decision. Re-submit a PA if additional documentation can address the decision (include initial documentation and original UTN).

Medicare prior authorization

1 Hospital OPD Services Model Details

Medicare prior authorization: Important information

- A Provider Transaction Access Number (PTAN) is a unique ID for Medicare-enrolled providers, groups, and facilities. It verifies provider status and tracks requests. Medicare Part A processes prior authorizations, so requests with Part B PTANs are rejected. Learn more in the PTAN Department of Health and Human Services document.

- The following facilities are classified as Outpatient Hospital Departments (OPDs)
  - Use the 13x claims form.
  - Bill with site of service codes 19 or 22.
  - Include certain Ambulatory Surgery Centers (ASCs).

- CMS may exempt a hospital from the prior authorization process for SCS if the provider demonstrates compliance by achieving a provisional affirmation rate of at least 90% during a semi-annual assessment.

- MACs include the PA unique tracking number (UTN) on the decision notice, which must be submitted with the claim for payment.

- If the trial and implant are both performed at the same outpatient hospital, PA is only required for the trial and the UTN received for the trial must be placed on both the trial and implant claims.

- For electronic claims, enter the 14-byte UTN in positions 1–18; FISS shifts it to positions 19–32, auto filling zeros in the first field. The Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.

- For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN.

Medicare prior authorization

2 WISeR Model Details

Medicare requires prior authorization when CPT 63655 is billed for permanent implantation with a surgical paddle lead. This requirement applies across all sites of service except Inpatient Hospital and is limited to services furnished in the following WISeR pilot states: Arizona, New Jersey, Ohio, Oklahoma, Texas, and Washington.

Prior authorization request process

Submit to WISeR 3rd Party Participant or MAC using fax, mail, electronic portal or electronic submission of medical documentation (esMD)

Standard: 3 business days for a decision
Expedited: 2 business days for a decision
Pre-payment review: Provider has 45 days to submit documentation; determination within 3 days of receipt

Provisional affirmation for standard and expedited valid 120 days from date decision was made.
No validity period for pre-payment review because this is at the claim level.

Prior authorization: Links

Jurisdiction	State	MAC	WISeR 3rd Party Participant
J15	OH	CGS	Innovaccer Inc.
JF	AZ	Noridian	Zyter Inc.
JF	WA	Noridian	Virtix Health LLC
JH	OK	Novitas	Humata Health, Inc.
JH	TX	Novitas	Cohere Health, Inc.
JL	NJ	Novitas	Genzeon Corporation

Possible outcomes

Provisional affirmation decision: The procedure is approved, and Medicare will issue a Prior Authorization Unique Tracking Number (UTN) on the decision notice. The UTN must be included on the claim to receive payment; if it is not reported, the claim will be routed to pre-payment review.

Non-affirmation decision: The procedure is not approved, and Medicare will provide the reason. Providers may resubmit with corrected or additional documentation—there is no limit to the number of resubmissions—and may also request a peer-to-peer review with a clinician of relevant specialty. For any resubmission, the beneficiary's first and last name, date of birth, and the original UTN must be included exactly as listed on the initial decision notice.

Pre-payment review: If prior authorization is not obtained in advance or the UTN is not reported on the claim, the claim will be routed to pre-payment medical review. Additional documentation may be required before payment is released, and if the claim is denied, the provider and beneficiary retain full Medicare appeal rights.

Medicare prior authorization

2 WISeR Model Details

Medicare prior authorization: Important information

- A Provider Transaction Access Number (PTAN) is a unique ID for Medicare-enrolled providers, groups, and facilities. It verifies provider status and tracks requests. Medicare Part A processes prior authorizations, so requests with Part B PTANs are rejected. Learn more in the PTAN Department of Health and Human Services document.

- MACs include the PA unique tracking number (UTN) on the decision notice, which must be submitted with the claim for payment.

- For electronic claims, enter the 14-byte UTN in positions 1–18; FISS shifts it to positions 19–32, auto filling zeros in the first field. The Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.

- For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN.

To support medical necessity, documentation must include:

- Condition requiring procedure and relevant physical exam
- Evidence that SCS is a late or last resort for patients with chronic intractable pain, after failure or contraindication of at least one conservative treatment tried and failed:
    - Medications, PT, injections, surgery, or cognitive behavioral therapy
- Multidisciplinary team evaluation (psychological, surgical, and medical)
- Successful trial stimulation showing ≥ 50% pain reduction and improvement in function.

    Note: *The NCD does not require documentation of functional improvement after a trial; however, the WISeR Operational Guide includes this element. It is recommended to incorporate both pain and functional outcomes in your PA request.*

- Documentation confirming the patient is not a candidate for percutaneously placed leads.

    Note: *The NCD does not specify this requirement; however, the WISeR Operational Guide does. Include documentation supporting the clinical rationale for using a surgical (laminectomy) approach instead of a percutaneous lead.*

Commercial payer

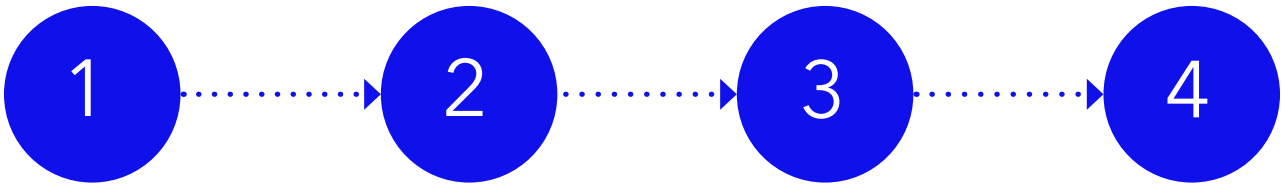
Prior Authorization: Usually required

Most commerciall payers require prior authorization (PA) for SCS trial and implant procedures. Revisions and removals can vary by payer, CPT code and procedure. Many payers utilize a 3rd party to complete the prior authorization review on their behalf.

Pre-Determination: Not required, but possible option

If a prior authorization is not required, a pre-determination (PD) may be available. A pre-determination, often referred to as a courtesy review, is a review of the patient's medical history to determine if they meet the payer's medical policy criteria for the procedure.

Prior authorization request process



1. Confirm PA requirement with payer. If PA is not required, is PD available?
2. Review medical policy against patient history to ensure all criteria has been met.
3. Submit PA to payer or 3rd party reviewer.
4. PA: Up to 10-14 business days for decision.
   PD: Up to 30 business days for decision.

Possible Outcomes

Approval: Patient meets the medical policy criteria for the procedure requested. Most approvals for PA/PD will have a reference number. Valid dates can vary from one specific date to a date range up to 6 months or longer. A hard copy letter is often mailed to the HCP and the patient.

Denial: Patient **does not** meet the medical policy criteria for the procedure requested. A hard copy letter is often mailed to the HCP and the patient. The letter will list the denial reasons and any options to appeal the decision.

Split Decision: If mulitple CPT codes are requested, the reviewer could approve one or more codes and deny other code(s) on the request. Some codes do not require authorization and if requested, they can be denied.

Commerical payer best practices

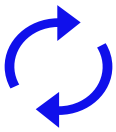
Identify a staff member to coordinate all prior authorizations.

Leverage payer websites/portals to ensure following latest coverage and submission requirements (Electronic submission typically expedites response).

Ensure the patient clinical information submitted reflects the payer's coverage criteria being met (less is more - submitting the patient's entire chart is typically ineffective).

Consider including a clear and concise letter of medical necessity to summarize how the patient has met the payer's coverage criteria.

Submit information and track with payer until a coverage decision is made (always request documentation and share with facility, as appropriate).



Closely monitor 3rd party vendor (e.g., eviCore) authorizations and engage both vendor/payer if denials occur due to inconsistencies between the vendor and payer's policy.

Commerical prior authorization checklists

These checklists summarize general medical necessity criteria common across payers, followed by more specific criteria unique to large national payers. Given requirements can change at any time, it is best practice to check the payer website to confirm the most current criteria.

General Documentation Requirements for SCS Trial

- ☐ Indicate if request is for trial or permanent implantation
- ☐ Details on all prior conservative treatments tried and failed for ≥ 6 months or documentation supports have been judged to be unsuitable or contraindicated:
  - Pharmacological
  - Surgical
  - Physical Therapy
  - Psychological Therapy
- ☐ Screening, evaluation, and diagnosis by multidisciplinary team (including psychological and physical evaluation)
- ☐ Surgical intervention not indicated
- ☐ No untreated substance use disorder(s)
- ☐ Psychological evaluation completed

General Documentation Requirements for SCS Implant

- ☐ Evidence of successful trial (≥50% pain reduction)
- ☐ Some payers require documentation of improved functioning, check the specific payer policy if required
- ☐ Trial duration ≥ 3 days

Additional Payer-Specific Requirements

The notes below are requirements unique to each payer in addition to general documentation. Please refer to the full policy for additional information.

Aetna: Policy 0194, Effective 7/29/2025

- ☐ For indications other than FBSS/CRPS: pain intensity VAS ≥ 5 present for ≥ 12 months
- ☐ Physical Therapy in-person (not virtual) by a licensed physical therapist for ≥ 6 weeks within the past year
- ☐ If a patient has history of spine surgery they must be ≥ 6 months post-operative
- ☐ Functional disability with Oswestry Disability Index (ODI) score ≥ 21

Commerical prior authorization checklists

Anthem: Policy MSK01-0725.1v2, Effective 7/26/2025
Note: For most plans, Anthem follows Carelon criteria, a 3rd party company

All indications except CRPS and DPN:

☐ At least 1 surgical opinion has been obtained to ensure no surgically correctable lesion

☐ Evidence of functional improvement after trial (Note: policy does not specify what level of functional improvement with what scale)

CRPS:

☐ Failed trial of regional sympathetic blocks

DPN:

☐ Painful DPN ≥ 12 months

☐ Pain intensity VAS ≥ 5

☐ Moderate-severe neuropathy on electromyography / nerve conduction studies

☐ Confirmation of DPN diagnosis by at least 1 other specialist

☐ BMI ≤ 35

☐ HbA1c ≤ 10%

☐ Average daily opioid morphine milligram equivalent (MME) ≤ 120 mg

☐ Failure or intolerance to multiple pharmacologic agents in at least 2 categories:

- Antidepressants
- Anticonvulsants
- Topicals (eg capsaicin)

Commerical prior authorization checklists

Cigna: Policy CMM-211, Effective 05/01/2024
Note: For most plans, Cigna follows EviCore criteria, a 3rd party company.

All indications:

☐ Surgical intervention is not indicated or the individual does not wish to proceed with spinal surgery

CRPS:

☐ At least 1 symptom in 3 of 4 following categories:

- Sensory: hyperesthesia
- Vasomotor: temperature asymmetry, skin color changes, skin color asymmetry
- Sudomotor/edema: edema, sweating changes, sweating asymmetry
- Motor/trophic: decreased range of motion, motor dysfunction (weakness, tremor, dystonia), trophic changes (hair, nail, skin)

☐ At least 1 sign at time of physical evaluation in ≥ 2 of the following categories:

- Sensory: hyperalgesia (to pinprick), allodynia (to light touch)
- Vasomotor: temperature asymmetry, skin color changes, skin color asymmetry
- Sudomotor/edema: edema, sweating changes, sweating asymmetry
- Motor/trophic: decreased range of motion, motor dysfunction (weakness, tremor, dystonia), trophic changes (hair, nail, skin)

Commerical prior authorization checklists

Humana: Policy HUM-1215-006, Effective 9/2/2025
Note: Humana should follow Medicare NCD coverage requirements as they only cover Medicare Advantage patients. In practice, below are common requirements they are applying for PAs.

CRPS:

☐ Physical therapy (PT) - no specification on number of visits

☐ Treated with and failed aggressive PT with desensitization - no definition of what "aggressive" entails

DPN:

☐ Glycemic control prior to SCS Trial - no specific HbA1c level is stated

FBSS:

☐ Physical therapy - no specification on number of visits

Low back pain, in the absence of FBSS:

☐ When accompanied by predominantly radicular pain

☐ Individual is not a surgical candidate or does not wish to have the surgical procedure

☐ Physical therapy - no specification on number of visits

Commerical prior authorization checklists

United Healthcare

Note: United follows InterQual® criteria, a 3rd party company. While United maintains their own policy, some additional requirements applied to PAs are only published in the InterQual policy.

All Indications:

☐ Platelet level > 50,000/μL or close co-management by a hematologist

FBSS:

☐ Minimum trial length ≥ 5 days

CRPS:

☐ Symptom of burning pain

☐ At least two of the following symptoms:

- Allodynia or hyperalgesia
- Edema
- Skin color asymmetry
- Sweating asymmetry
- Skin temperature asymmetry
- Trophic changes
- Decreased ROM or motor dysfunction

☐ Home exercise of PT/OT for ≥ 6 weeks

☐ Antidepressant or antiepileptic drugs for ≥ 4 weeks

☐ Sympathetic block

☐ Minimum trial length ≥ 5 days

DPN:

☐ Symptom of burning pain

☐ At least two of the following symptoms:

- Numbness
- Sensory loss
- Parasthesia

☐ Home exercise of PT/OT for ≥ 8 weeks

☐ Antidepressant or antiepileptic drugs for ≥ 12 weeks or not tolerated due to side effects

☐ Minimum trial length ≥ 7 days

Sample letter instructions

These documents are sample letter templates that providers can use as a guide to create a patient- specific letter for prior authorization or appeal. To be effective, the letter **must be customized to the specific circumstances of each patient and their payer.** The requesting provider is responsible for ensuring accuracy and adequacy of all information provided. Use of these templates does not guarantee authorization or payment.

- Please do not include this instruction page to avoid misinterpretation of your request as a form letter.
- It is recommended that providers use their business letterhead as appropriate.
- Please customize the letter using information pertinent to yourself, your patient, and their condition/procedure. All letter content can be edited.
- This letter is not intended to replace any professional judgement; it is merely to assist with the prior authorization or appeal request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to contact the patient's insurance for prior authorization or appeal timelines, submission processes, and requirements.

Sample letter of general medical necessity

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

This letter is to request a prior authorization for a spinal cord stimulation (SCS) trial in my patient, _____, for the control of chronic, intractable pain of the trunk and/or limbs who is suffering from **[Report patient conditions/diagnosis code(s) here.]**. This patient has chronic, intractable pain that is refractory to more conservative treatments.

As an intervention for chronic, intractable pain of the trunk and/or limbs, spinal cord stimulation can be an effective alternative or adjunct treatment to other therapies that have failed to manage pain on their own.

Spinal Cord Stimulation (SCS) is a therapy that interrupts pain messages before they reach the brain and has proven to provide long-term effective pain relief and improve quality of life.[1-3] In addition to pain relief, spinal cord stimulation is more cost-effective than conventional medical management and reoperation.[4,5] Multiple studies have provided clinical evidence to suggest some patients treated with Spinal Cord Stimulation (SCS) may be able to reduce oral opioid consumption.[6-8] Furthermore, spinal cord stimulation is also more effective than repeat surgery for persistent radicular pain after lumbosacral spine surgery.[9]

With this therapy, trial stimulation is done to determine whether the patient is likely to benefit from SCS therapy. Trial stimulation involves the placement of one or more leads connected to an external power source for several days. This allows patients to temporarily experience stimulation and the effect it has on controlling pain symptoms and make an informed choice about the risks and benefits of pursuing the therapy. If the patient has a successful trial, implant of the neurostimulation system may proceed.

Based upon my review, I believe that this patient is an excellent candidate for this therapy.

[Explain the clinical rationale leading to the decision to recommend SCS.].

- Describe the patient's current status, including diagnosis, complaints, and level of impairment.
- Characterize the patient's symptoms. Detail functional impairments and state how quality of life, activities of daily living, caregiver (if applicable), employment, etc., are affected.
- Document chronological history
- Describe whether this is a late or last resort treatment for this patient and mention other treatments (pharmacological, surgical or psychological therapies) that have been tried and the results of those treatments. (Some payers require six months of conservative treatment modalities for non-malignant pain.)
- If the patient has not had prior back surgery, discuss their underlying condition of degenerative disc disease (DDD), herniated disc (HD), and radicular pain syndrome and why they are not a surgical candidate.
- Describe whether the patient has been evaluated by a multidisciplinary team and the results of psychological testing that has been done.

Since this patient fits the selection criteria and has not responded to other treatments, I recommend a trial stimulation. The decision to implant the system will be based on the patient's response to the trial stimulation. Based on the above information demonstrating medical necessity for this patient, I request

Sample letter of general medical necessity

authorization for the trial.

Thank you for your review of this information and for your coverage consideration. If you have any questions, please contact me at **[phone or e-mail address]**.

Sincerely,
_____, MD

References

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2. Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. 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.
3. 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. 2008;63(4):762-770.
4. North RB, Kidd D, Shipley J, Taylor RS. 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):361-369.
5. Taylor RJ, Taylor RS. 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.
6. Sharan AD, Riley J, Falowski S, et al. Association of opioid usage with spinal cord stimulation outcomes. Pain Med. 2018;19(4):699-707. A non-randomized analysis of Truven Health Marketscan databases from January 2010 to December 2014 based on the fi rst occurrence of an SCS implant (N= 5,476).
7. Gee L, Smith HC, Ghulam-Jelani Z, et al. Spinal Cord Stimulation for the Treatment of Chronic Pain Reduces Opioid Use and Results in Superior Clinical Outcomes When Used Without Opioids. Neurosurgery. 2019;84(1):217-226. A non-randomized prospective cohort study of SCS patients between September 2012 and August 2015 (N=86 [n=53 on opioids]).
8. Pollard EM, Lamer TJ, Moeschler SM, et al. The effect of spinal cord stimulation on pain medication reduction in intractable spine and limb pain: a systematic review of randomized controlled trials and meta-analysis. J Pain Res. 2019;12:1311-1324. A research review summarising SCS studies with respect to opioid use and a further meta-analysis of comparative SCS RCTs of 1 year or greater duration (N=489).
9. 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):98-107.

Sample letter of medical necessity painful diabetic peripheral neuropathy

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

This letter is to request a prior authorization of spinal cord stimulation (SCS) therapy for my patient _____, for the control of painful diabetic peripheral neuropathy (DPN).

SCS therapy is used for the control of chronic, intractable pain of the trunk and/or limbs and is indicated for the treatment of diabetic peripheral neuropathy (DPN) of the lower extremities (see below for details). With this therapy, trial stimulation is done to determine whether the patient is likely to benefit from SCS therapy. Trial stimulation involves the placement of one or more leads connected to an external power source for several days. This allows patients to temporarily experience stimulation and the effect it has on controlling pain symptoms and make an informed choice about the risks and benefits of pursuing the therapy. If the patient has a successful trial (as measured by the patient's improvement in pain relief and function), implant of the neurostimulation system may proceed.

DPN is a chronic debilitating condition that can develop among patients with diabetes that is characterized by burning, tingling "pins and needles", numbness, weakness, and pain.[1] Diabetes can damage blood vessels supplying nerves causing a peripheral neuropathy, typically of the feet and legs.[1] This is typically a distal symmetrical sensorimotor type of neuropathy involving both small and large (mixed sensorimotor) fibres.[2] Over time as the neuropathies progress, patients experience disturbance of light touch sensation, sensitivity to pressure and vibration, and joint position sense.[2]

DPN adversely affects the individual's quality of life including physical and emotional functioning, sleep, and global quality-of-life.[3] Patients also have significant risk of adverse clinical outcomes, including an amputation risk 16 times higher than diabetic patients without neuropathy.[4]

As an intervention for chronic back and/or leg pain, spinal cord stimulation can be an effective alternative or adjunct treatment to other therapies that have failed to manage pain on their own. An implantable spinal cord stimulator delivers small electrical signals through a lead implanted in the epidural space. Pain signals are inhibited before they reach the brain. Instead of pain, patients may feel pain relief. The FDA approved spinal cord stimulation therapy in 1989 and Medicare published a National Coverage Decision (160.7) for spinal cord stimulation in 1995. The Medtronic Spinal Cord Stimulator System received FDA approval for painful diabetic peripheral neuropathy of the lower extremities on January 21, 2022.

Based on my review detailed below, I believe _____, is an excellent candidate for this therapy. This patient has lived with diabetes for **XX** years and with severe DPN for **YY** years, according to referring physician _____.

Document Current Findings/Status

- Describe the patient's current status, including diagnosis, complaints, and level of impairment.
- Characterize the patient's symptoms. Detail functional impairments and state how quality of life, activities of daily living, caregiver (if applicable), employment, etc., are affected.

Sample letter of medical necessity painful diabetic peripheral neuropathy

Document Chronological History

- Describe whether this is a late or last resort treatment for this patient and mention other treatments (pharmacological, surgical or psychological therapies) that have been tried and the results of those treatments. (Some payers have unique coverage criteria for DPN. Refer to the applicable payer SCS medical policy to determine if the patient has met the required criteria and document accordingly.)

Thank you for your review of this information and for your coverage consideration. If you have any questions, please contact me at **[phone or e-mail address]**.

Sincerely,
_____, MD

References

1. NIH. What Is Diabetic Neuropathy? https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/nerve-damage-diabetic-neuropathies/what-is-diabetic-neuropathy. Published 2018. Accessed January 12, 2022.
2. Galer BS, Gianas A, Jensen MP. Painful diabetic polyneuropathy: epidemiology, pain description, and quality of life. Diabetes Res Clin Pract. 2000;47(2):123-128.
3. O'Connor AB. Neuropathic pain: quality-of-life impact, costs and cost effectiveness of therapy. Pharmacoeconomics. 2009;27(2):95-112.
4. Kiyani M, Yang Z, Charalambous LT, et al. Painful diabetic peripheral neuropathy: Health care costs and complications from 2010 to 2015. Neurol Clin Pract. 2020;10(1):47-57.

Sample letter of general appeal

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

I am writing to appeal the denial of coverage for my patient, _____, for **[Pick One: Trial or Implantation]** of a system for spinal cord stimulation (SCS) for the treatment of chronic pain. The reason given for coverage denial is _____.

Medical Necessity of the Therapy:

- Review the payer prior authorization denial letter and address the reasons for denial.
- For trial prior authorization denial
  - Describe the patient's current status, including diagnosis, complaints, and level of impairment.
  - Characterize the patient's symptoms. Detail functional impairments and state how quality of life, activities of daily living, caregiver (if applicable), employment, etc., are affected.
  - Document chronological history
  - Describe whether this is a late or last resort treatment for this patient and mention other treatments (pharmacological, surgical or psychological therapies) that have been tried and the results of those treatments. (Some payers require six months of conservative treatment modalities for non-malignant pain.)
  - If the patient has not had prior back surgery, discuss their underlying condition of degenerative disc disease (DDD), herniated disc (HD), and radicular pain syndrome and why they are not a surgical candidate.
- For implant prior authorization denial
  - Provide documentation of percent of pain relief and increased function from the trial. (Most payers require greater than 50% pain relief)

Spinal Cord Stimulation (SCS) is a therapy that modifies pain messages before they reach the brain and has proven to provide long-term effective pain relief and improve quality of life.[1-3] In addition to pain relief, spinal cord stimulation is more cost-effective than conventional medical management and reoperation.[4,5] Multiple studies have provided clinical evidence to suggest some patients treated with Spinal Cord Stimulation (SCS) may be able to reduce oral opioid consumption.[6-8] Furthermore, spinal cord stimulation is also more effective than repeat surgery for persistent radicular pain after lumbosacral spine surgery.[9]

Based on the medical necessity of this therapy for my patient, I request that you reconsider your non-coverage decision so that my patient who suffers from chronic pain can receive this potentially life-changing therapy.

I thank you for your expeditious review of this information and for reconsidering your coverage decision. If you have any questions before that time, please contact me at **[phone or e-mail address]**.

Sincerely,
_____, MD

Sample letter of general appeal

References

1. Harke H, Gretenkort P, Ladleif HU, 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.
2. Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. 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.
3. 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. 2008;63(4):762-770.
4. North RB, Kidd D, Shipley J, Taylor RS. 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):361-369.
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8. Pollard EM, Lamer TJ, Moeschler SM, et al. The effect of spinal cord stimulation on pain medication reduction in intractable spine and limb pain: a systematic review of randomized controlled trials and meta-analysis. J Pain Res. 2019;12:1311-1324. A research review summarising SCS studies with respect to opioid use and a further meta-analysis of comparative SCS RCTs of 1 year or greater duration (N=489).
9. 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):98-107.

Sample letter of appeal painful diabetic peripheral neuropathy

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

I am writing to appeal the denial of coverage for my patient, _____, for **[Pick One: Trial or Implantation]** of a system for spinal cord stimulation (SCS) for the treatment of chronic pain due to painful diabetic peripheral neuropathy (DPN). The reason given for coverage denial is _____.

Medical Necessity of the Therapy:

- Review the payer prior authorization denial letter and address the reasons for denial
- For trial prior authorization denial
  - Describe the patient's current status, including diagnosis, complaints, and level of impairment.
  - Characterize the patient's symptoms. Detail functional impairments and state how quality of life, activities of daily living, caregiver (if applicable), employment, etc., are affected.
  - Describe whether this is a late or last resort treatment for this patient and mention other treatments (pharmacological, surgical or psychological therapies) that have been tried and the results of those treatments. (Some payers have unique coverage criteria for painful DPN. Refer to the applicable payer SCS medical policy to determine if the patient has met the required criteria and document accordingly.)
- For implant prior authorization denial
  - Provide documentation of percent of pain relief and increased function from the trial. (Most payers require greater than 50% pain relief)

SCS therapy is used for the control of chronic, intractable pain of the trunk and/or limbs and is indicated for the treatment of painful diabetic peripheral neuropathy (DPN) of the lower extremities (see below for details). With this therapy, trial stimulation is done to determine whether the patient is likely to benefit from SCS therapy. Trial stimulation involves the placement of one or more leads connected to an external power source for several days. This allows patients to temporarily experience stimulation and the effect it has on controlling pain symptoms and make an informed choice about the risks and benefits of pursuing the therapy. If the patient has a successful trial (as measured by the patient's improvement in pain relief and function), implant of the neurostimulation system may proceed.

DPN is a chronic debilitating condition that can develop among patients with diabetes that is characterized by burning, tingling "pins and needles", numbness, weakness, and pain.[1] Peripheral neuropathy develops over time due to uncontrolled blood glucose levels and high levels of triglycerides which can damage the blood vessels supplying nerves, typically of the feet and legs.[1] This is typically a distal symmetrical sensorimotor type of neuropathy involving both small and large (mixed sensorimotor) fibres.[2] Over time as the neuropathies progress, patients experience disturbance of light touch sensation, sensitivity to pressure and vibration, and joint position sense.[2] Painful DPN adversely affects the individual's quality of life including physical and emotional functioning, sleep, and global quality-of-life.[3] Patients also have significant risk of adverse clinical outcomes, including an amputation risk 16 times higher than diabetic patients without neuropathy.[4]

As an intervention for chronic back and/or leg pain, spinal cord stimulation can be an effective alternative

Sample letter of appeal diabetic peripheral neuropathy

or adjunct treatment to other therapies that have failed to manage pain on their own. An implantable spinal cord stimulator delivers small electrical signals through a lead implanted in the epidural space. Pain signals are inhibited before they reach the brain. Instead of pain, patients may feel pain relief. The FDA approved spinal cord stimulation therapy in 1989 and Medicare published a National Coverage Decision (160.7) for spinal cord stimulation in 1995. The Medtronic Spinal Cord Stimulator System received FDA approval for painful diabetic peripheral neuropathy of the lower extremities on January 21, 2022.

I thank you for your expeditious review of this information and for reconsidering your coverage decision. If you have any questions before that time, please contact me at **[phone or e-mail address]**.

Sincerely,
_____, MD

References

1. NIH. What Is Diabetic Neuropathy? https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/nerve-damage-diabetic-neuropathies/what-is-diabetic-neuropathy. Published 2018. Accessed January 12, 2022.
2. Galer BS, Gianas A, Jensen MP. Painful diabetic polyneuropathy: epidemiology, pain description, and quality of life. Diabetes Res Clin Pract. 2000;47(2):123-128.
3. O'Connor AB. Neuropathic pain: quality-of-life impact, costs and cost effectiveness of therapy. Pharmacoeconomics. 2009;27(2):95-112.
4. Kiyani M, Yang Z, Charalambous LT, et al. Painful diabetic peripheral neuropathy: Health care costs and complications from 2010 to 2015. Neurol Clin Pract. 2020;10(1):47-57.

Sample letter of appeal non-surgical refractory back pain

If you have a prior authorization denial for a patient with any of the following conditions and is not eligible for spine surgery, contact Medtronic Reimbursement at neuro.us.reimbursement@medtronic.com for an appeal letter template and bibliography.

- Non-surgical back with degenerative disc disease
- Herniated disc
- Radicular pain syndrome/Radiculopathy

Additional resources

Patient Access Support (PAS)

Patient Access Support (PAS) is available to facilitate patient access to Medtronic Pain Interventions products and therapies by providing HCPs who request PAS on behalf of their patients with assistance in obtaining patient coverage decisions from payers.

Patient Access Connect (PAC)

The Medtronic Patient Access Connect (PAC) is a digital solution for streamlining the prior authorization process so patients can access pain intervention therapies more efficiently.

- Simple submissions: Leverage an intuitive, user-friendly interface.
- Real-time case tracking: Monitor progress of submissions in real time.
- Automated notifications: Receive instant updates and notifications for case statuses.
- Centralized case access: Access prior authorization records from one convenient location.
- Data insights: Gain insights into submission trends and approval rates.

Additional resources

Coding and payment guide

Click here to access the current coding and payment guide.

Psychological evaluation provider-care guide

For comprehensive resources on psychological evaluations, including online telehealth options, payer requirements, and coding and payment guidance, please contact Medtronic Reimbursement at neuro.us.reimbursement@medtronic.com

Bibliographies

For additional literature on any of the conditions listed below, please contact Medtronic Reimbursement at neuro.us.reimbursement@medtronic.com, and a bibliography will be provided.

- Closed-loop SCS
- Diabetic peripheral neuropathy
- Non-surgical refractory back pain

Warranty information

For warranty information, contact the Medtronic Warranty team:

Email: rs.rtgwarranty@medtronic.com

Phone: 877-359-6407

Visit our warranty website

Contact us

For additional information, contact the Medtronic Reimbursement Support team:

Email: neuro.us.reimbursement@medtronic.com

Visit our reimbursement website

Patient Access Connect (PAC) Portal

SPINAL CORD STIMULATION BRIEF SUMMARY

INDICATIONS Spinal cord stimulation (SCS) is indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain. **CONTRAINDICATIONS** Diathermy - Energy from diathermy can be transferred through the implanted system and cause tissue damage resulting in severe injury or death. **WARNINGS** Sources of electromagnetic interference (e.g., defibrillation, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device. Patients with diabetes may have more frequent and severe complications with surgery. A preoperative assessment is advised for some patients with diabetes to confirm they are appropriate candidates for surgery. **PRECAUTIONS** Safety and effectiveness has not been established for pediatric use, pregnancy, unborn fetus, or delivery. Avoid activities that put stress on the implanted neurostimulation system components. Recharging a rechargeable neurostimulator may result in skin irritation or redness near the implant site. **ADVERSE EVENTS** May include: undesirable change in stimulation (uncomfortable, jolting or shocking); hematoma, epidural hemorrhage, paralysis, seroma, infection, erosion, device malfunction or migration, pain at implant site, loss of pain relief, and other surgical risks. Adverse events may result in fluctuations in blood glucose in patients with diabetes. Refer to www.medtronic.com for product manuals for complete indications, contraindications, warnings, precautions and potential adverse events. Rx only. Rev 0422