## SAMPLE APPEAL LETTER TEMPLATE FOR

# Spinal Column Stimulation System for Patients with non-surgical back pain

For independent consideration and review, please make any and all changes that you believe appropriate or disregard these suggestions in their entirety. The customer is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. Nothing in this document should be construed as a guarantee by Abbott regarding coverage or payment at any specific level, and Abbott does not advocate or warrant the appropriateness of the use of any particular code. This form letter is intended for prior authorization/appeals purposes, not for promotional purposes. Please see the FDA-approved label for information relevant to any prescribing decisions.

### Instructions for completing the sample appeal letter:

1. Please customize the appeal letter template based on the medical appropriateness of the Spinal Column Stimulator System for your patient. Fields required for customization are **highlighted in yellow**.
2. It is important to provide the most complete information to assist with the appeal of a prior authorization denial.
3. After you have customized the appeal letter, please make sure to delete any specific instructions for completion that are highlighted throughout the letter, so the health plan does not misinterpret the information.

## Do not include this instruction page in your submission.

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**Rx Only**
**Brief Summary:** Prior to using Abbott devices, please review the Clinician's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

**Indications for Use:** Spinal Cord Stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, nonsurgical back pain (without prior surgery and not a candidate for back surgery), and diabetic peripheral neuropathy of the lower extremities.

**Contraindications:** This system is contraindicated for patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

**Warnings/Precautions:** Diathermy therapy, implanted cardiac systems or other active implanted devices, magnetic resonance imaging (MRI), electrosurgery, explosive and flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, pediatric use, pregnancy and nursing, use in patients with diabetes, stimulation modes and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

**Adverse Effects:** Unpleasant sensations, undesirable changes in stimulation, stimulation in unwanted places, lead or implant migration, epidural hemorrhage, hematoma, infection, spinal cord compression, or paralysis from placement of
a lead in the epidural space, cerebrospinal fluid leakage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain at the electrode or IPG site, seroma at IPG site, allergic or rejection response, battery failure, changes in blood glucose levels in response to any adverse effect. Clinician's Manual must be reviewed for
detailed disclosure.

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**Abbott**
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Abbott

[Physician Letterhead]

Date: [_____]

Attention: Appeals Department
Reference number: [_____]
[Payer contact name]
[Payer contact title]
[Street address]
[City, State, zip code]
[Fax]

**Re: Expedited Appeal for Denial of Coverage of Spinal Cord Stimulation Procedure**

Patient Name: [First and Last Name]
Policy Holder Name: [First and Last Name]
Date of Birth: [XX/XX/XXXX]
SS#: [XXX-XX-XXXX]
Insurance Patient ID #: [XXXXXXXXXX]
Group # [XXXXXXXXXX]
Claim #: [XXXXXXXXXX]
Phone #: [XXX-XXX-XXXX]

To Whom It May Concern:

I am writing on behalf of my patient, [Add Patient Name Here] to request a reconsideration of the prior authorization denial for **a spinal column stimulation [Trial/Implant procedure] to treat** [Include Patient's Indication(s) Here.].

Attached is a copy of your denial notice, dated [insert date of denial letter], which states the patient's medical records do not indicate meeting your health plan's designated coverage criteria. I disagree with this conclusion and request a reconsideration as my patient clearly meets the clinical criteria for spinal column stimulation and in my medical judgement this treatment is the best option for my patient.

For reference, spinal column stimulation (SCS) is FDA approved[1] and indicated as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, **non-surgical back pain (without prior surgery and not a candidate for back surgery),** and diabetic peripheral neuropathy of the lower extremities.*[2] Nonsurgical back pain can be caused by a variety of factors; most patients present with more than one pain generator, making a singular unifying diagnosis difficult and uncertain in many cases. Additionally, intervertebral discs, vertebrae and associated joints, soft tissues, and neurogenic vasculature compression can alone or in combination contribute to the painful condition. A subset of these patients show multilevel imaging changes with no definitive causation of symptoms. The result is an underserved population of patients with chronic back pain whose pathology is not correctable with surgery.[3]

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[1] U.S. Food and Drug Administration, P010032 Prodigy, Proclaim XR, Proclaim Plus and Eterna SCS Systems (2023) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010032S191,

* The BurstDR(TM) stimulation mode has not been evaluated for effectiveness in the DPN population.

[2] Abbott. Eterna™ SCS Implantable Pulse Generator Clinician's Manual. 2023.
Abbott. Proclaim™ SCS Implantable Pulse Generator Clinician's Manual 2023.

[3] Deer T, Gilligan C, et. al. Treatment of Refractory Low Back Pain Using Passive Recharge Burst in Patients Without Options for Corrective Surgery: Findings and Results From the DISTINCT Study, a Prospective Randomized Multicenter Controlled Trial. Neuromodulation. 2023 Aug 28:S1094-7159(23)00712-2. doi: 10.1016/j.neurom.2023.07.009. Epub ahead of print. PMID: 37642628.

Abbott's DISTINCT study, evaluates the effectiveness of BurstDR™ SCS Therapy (n=162) compared to conventional medical management (CMM) (n=107), enrolling a total of 270 participants[4] with an average pain duration of 12 years. It is the largest randomized controlled trial for SCS in people who suffer from chronic refractory back pain when surgery is not an option.[3,5] In addition, the effectiveness of the BurstDR™ SCS Therapy has been previously demonstrated in the SUNBURST Clinical study.[6] The DISTINCT multidisciplinary study, which included orthopedic and neurosurgical spine surgeons and interventional pain physicians, is a prospective, multicenter, randomized, controlled clinical study with an optional crossover component and with follow-up at 1, 3, 6, 9, 12, 18 and 24 months. Results at 6-months demonstrated 85.2% of patients implanted with BurstDR™ SCS therapy achieved significant back pain reduction, with average overall pain reduced by 69.7%.[3] In addition, the 12-month results from the DISTINCT study demonstrated long term, sustained improvements in chronic back pain patients for whom surgery is not an option. [7,8]

Randomized controlled trials also have shown that some patients with SCS have less pain and better health-related quality of life and functional capacity than those receiving just medical management or reoperation.*[6,3] Lastly, the NICE guideline for SCS recommends it is used as a treatment option for adults with chronic pain of the neuropathic origin.[9]

**[Explain why SCS should be approved for the condition you are seeking. Include details to support your diagnosis including length of condition, other management options tried, mental health evaluation, confirmation from other specialties that surgery is not an option, and any other mitigating factors. Also consider requesting a peer-to-peer call to discuss further.]**

SCS is appropriate for my patient because it is a FDA approved therapy that has been proven to yield positive results for patients with chronic, intractable pain as explained above.[6,3] Based upon my patient's current clinical situation, the other potential options for treatment which were considered at this time, and the clinical evidence which supports the use of spinal cord stimulation, I believe this is the best treatment for [insert patient name] at this time and therefore should be a covered benefit based upon medical necessity.

Given the above information, I request an immediate approval for the spinal cord stimulation procedure for your beneficiary, [Patient Name]. I appreciate your reconsideration of this denial. I have included additional information for your consideration including the patient's medical records and can provide a bibliography of relevant publications demonstrating the safety and efficacy of spinal cord stimulation if you would like. Please let me know if I can provide any additional information and I appreciate your attention to this important matter.

Sincerely,

[Physician's name and credentials]
[Title]
[Name of practice]
[Street address]
[City, State, zip code]
[Email address]
[Phone number]

Enclosures:
[Patient medical records/chart note]

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[4] Abbott Medical Devices. Spinal cord stimulation vs. medical management for low back pain (DISTINCT). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 May 8]. Available from: http://clinicaltrials.gov/ct2/show/NCT04479787 NLM Identifier: NCT04479787.

[5] *Abbott. Data on File. DISTINCT Clinical Study Memo. (MAT-2305432). 2023.*

[6] Deer T, Slavin KV, Amirdelfan K, et al. Success using neuromodulation with BURST (SUNBURST) study: results from a prospective, randomized controlled trial using a novel burst waveform. Neuromodulation. 2018;21(1):56-66. doi:10.1111/ner.12698
**These are descriptive endpoints observed from the SUNBURST and DISTINCT studies*

[7] Yue JJ, Gilligan CJ, Falowski S, et al. Surgical treatment of refractory low back pain using implanted BurstDR spinal cord stimulation (SCS) in a cohort of patients without options for corrective surgery: findings and results from the DISTINCT study, a prospective randomized multi-center-controlled trial. North American Spine Society Journal. 2024;100508. doi:10.1016/j.xnsj.2024.100508.
*Patients may report more than 1 treatment condition.

[8] These results are from Phase II of the DISTINCT study. Abbott's labeling includes results from Phase I of the study.

[9] National Institute for Health and Care Excellence (NICE). Spinal Cord Stimulation for Chronic Pain of Neuropathic or Ischemic Origin. 2008 https://www.nice.org.uk/Guidance/TA159

## References


1. U.S. Food and Drug Administration , P010032/S191 Prodigy, Proclaim XR, Proclaim Plus and Eterna SCS Systems (2023) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P010032S191

2. Abbott. Eterna™ SCS Implantable Pulse Generator Clinician's Manual. 2025,
Abbott. Proclaim™ SCS Implantable Pulse Generator Clinician's Manual 2025

3. Deer T, Gilligan C, Falowski S, Desai M, Pilitsis J, Jameson J, Moeschler S, Heros R, Tavel E, Christopher A, Patterson D, Wahezi S, Weisbein J, Antony A, Funk R, Ibrahim M, Lim C, Wilson D, Fishell M, Scarfo K, Dickerson D, Braun E, Buchanan P, Levy RM, Miller N, Duncan J, Xu J, Candido K, Kreiner S, Fahey ME, Yue J. Treatment of Refractory Low Back Pain Using Passive Recharge Burst in Patients Without Options for Corrective Surgery: Findings and Results From the DISTINCT Study, a Prospective Randomized Multicenter Controlled Trial. Neuromodulation. 2023 Oct;26(7):1387-1399. doi: 10.1016/j.neurom.2023.07.009. Epub 2023 Aug 28. PMID: 37642628

4. Abbott Medical Devices. Spinal cord stimulation vs. medical management for low back pain (DISTINCT). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 May 8]. Available from: http://clinicaltrials.gov/ct2/show/NCT04479787 NLM Identifier: NCT04479787.

5. Abbott. Data on File. DISTINCT Clinical Study Memo. (MAT-2305432). 2023.

6. Deer T, Slavin KV, Amirdelfan K, et al. Success using neuromodulation with BURST (SUNBURST) study: results from a prospective, randomized controlled trial using a novel burst waveform. Neuromodulation. 2018;21(1):56-66. doi:10.1111/ner.12698

7. Yue JJ, Gilligan CJ, Falowski S, et al. Surgical treatment of refractory low back pain using implanted BurstDR spinal cord stimulation (SCS) in a cohort of patients without options for corrective surgery: findings and results from the DISTINCT study, a prospective randomized multi-center-controlled trial. North American Spine Society Journal. 2024;100508. doi:10.1016/j.xnsj.2024.100508.

8. National Institute for Health and Care Excellence (NICE). Spinal Cord Stimulation for Chronic Pain of Neuropathic or Ischemic Origin. 2008. https://www.nice.org.uk/guidance/ta159/chapter/1-Guidance.