

SCS sample letter of appeal: Patient with no prior back surgery

Place this letter on your organization's letterhead and provide the following information in the header:

Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID #, Group #, and Date of Birth

Dear _____,

I am writing to request a reconsideration for the denial of coverage for my patient **[insert patient name]**, for the trial stage for spinal cord stimulation (SCS) for the treatment of **[insert primary diagnosis chronic radicular pain, herniated disc, or degenerative disc disease]**.

The reason given for coverage denial is **[insert denial reason]**.

[insert patient name] has chronic **[insert diagnosis]** and has tried and failed the following more conservative treatment options: **[list other treatments tried, length of time and outcome of each]**

[insert patient name] is currently not a candidate for back surgery as determined by **[insert physician name, reason why is not a candidate for surgery, including any imaging findings confirming there is no clear surgical target]**. Since my patient has tried and failed

conservative treatment options for **[insert length of treatment in months/years]**, and since back surgery is not indicated, SCS is the next appropriate treatment option for this patient.

This is supported by the North American Spine Society (NASS) in their evidence based SCS coverage recommendations, where they recommend that SCS be utilized when "there is no identifiable cause for the patient's pain that can be reasonably addressed with surgery or the risks of surgical treatment are too high."¹ If coverage of a SCS trial is not granted, my patient will have to continue with conventional medical management (CMM), which includes oral opioids, which have not provided adequate pain relief.

There are currently five randomized controlled trials at various stages of completion evaluating the use of SCS in patients with chronic, refractory pain who have not undergone prior back surgery and either were not a candidate for spine surgery or who declined surgery.

A brief overview of these RCTs is provided here, and I point you to the more detailed attached bibliography for a full review of the clinical evidence:

1. Primary endpoint: All trials defined the primary endpoint as a $\geq 50\%$ reduction in pain relief relative to baseline, as measured by VAS scores.²⁻⁶
 - At three-month follow-up, all trials achieved their primary endpoint of statistically significant improvement in pain control for the intervention arm (SCS) relative to CMM (or in one trial traditional tonic stimulation).
 - At 12-month follow-up responder rates in the SCS arms ranged from 76.8% - 84.0%
 - Two studies have completed 24-month follow-up, with responder rates in the SCS arms of 81.6% and 88.4%, confirming durability of efficacy.^{3,4}
2. Profound responder rate: One trial has reported a “profound responder” rate, defined as a $\geq 80\%$ reduction in pain relief relative to baseline, as measured by VAS scores.³
 - At 24-months follow-up the profound responder rate in the SCS arm was 58.5%
3. Additional secondary outcomes collected and reported in the trials include: Oswestry Disability Index (ODI), quality of life as measured by the EQ-5D, functional outcomes via the PROMIS-29, the patient global impression of change (PGIC), and opioid use.

Prior studies have shown selected patients treated with SCS are able to reduce oral opioid consumption.⁷⁻⁹ Earlier consideration of SCS before escalated dosage or chronic use of opioids has the potential to improve patient outcomes when other treatment options have not provided adequate pain relief.⁷⁻⁹

Based on the medical necessity of this therapy for my patient and the published clinical evidence that demonstrates the effectiveness of SCS for this patient population, I request that you reconsider your non-coverage decision.

I thank you for your expeditious review of this information. If you have any questions, please contact me at **[insert contact info]**.

Sincerely,

_____, MD

References

1. (NASS) NASS. Spinal Cord Stimulation: Defining Appropriate Coverage Positions. <https://www.spine.org/Product-Details?productid=%7B4FB04810-7AB3-E711-8113-0050569159BF%7D>. Published 2017. Accessed 04-15-2024.
2. Deer T, Gilligan C, Falowski S, 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;26(7):1387-1399.
3. Patel NP, Jameson J, Johnson C, et al. Durable responses at 24 months with high-frequency spinal cord stimulation for nonsurgical refractory back pain. *J Neurosurg Spine*. 2024;40(2):229-239.
4. Kallewaard JW BB, Van Paesschen R, et al. DTM SCS for Indicated Chronic Back Pain Patients Ineligible for Spine Surgery: EU RCT Outcomes. *North American Neuromodulation Society (NANS) Annual Meeting*. 2024.
5. North J PJ, Calodney A, et al. Comparing SCS and conventional medical management in patients with no prior back surgery (SOLIS RCT). *American Society of Regional Anesthesia and Pain Medicine Annual Meeting*. 2023.
6. White T JR, Almonte W, et al. DTM SCS for Indicated Chronic Back Pain Patients Refractory to Spine Surgery: US RCT Outcomes. *North American Neuromodulation Society (NANS) Annual Meeting*. 2024.
7. Fraifeld EM, Hatheway JA, Ricker CN. Systemic Opioid Prescribing Patterns and Total Cost of Care in Patients Initiating Spinal Cord Stimulation Therapy: A Retrospective Analysis. *Pain Med*. 2021;22(4):784-799.
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.
9. Sharan AD, Riley J, Falowski S, et al. Association of Opioid Usage with Spinal Cord Stimulation Outcomes. *Pain Med*. 2018;19(4):699-707.