HE&R NEUROMODULATION

Dorsal Root Ganglion Stimulator (DRG) for lower extremity CRPS I or CRPS II

SAMPLE APPEAL TEMPLATE:

Not Medically Necessary/Investigational/Experimental Template to be considered for appeal purposes by physicians

For independent consideration and review, please make any and all changes that you believe appropriate or disregard these suggestions in their entirety. The physician 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 nor warrant the appropriateness of the use of any particular code. This form letter is intended for prior authorization/appeal purposes, not for promotional purposes. Please see the FDA-approved labeling 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 DRG 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 trial or implant 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.

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, and directions for use. The system is intended to be used with leads and associated extensions that are compatible with the system.

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PLEASE DELETE THIS PAGE BEFORE SUBMISSION

[Physician Letterhead]

Date:

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

Re: Expedited Appeal of Denial for Coverage of the DRG Spinal Column Stimulator for treatment of lower extremity CRPS I & II

Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim # _____

Diagnosis: **[list ICD-10 DX code and diagnosis code descriptor]**

Services:

Code	Description
63650	Percutaneous implantation, neurostimulator electrode array epidural
63650	Percutaneous implantation, neurostimulator electrode array epidural
63685	Implantation or replacement neurostimulator generator

To Whom It May Concern:

I am writing on behalf of my patient, [Add Patient Name Here] to request a reconsideration of the denial for **a dorsal root ganglion (DRG) stimulation [Trial/Implant procedure] to treat complex regional pain syndrome (CRPS) type I or II (also known as causalgia) in the lower extremities.**[1]

I have attached a copy of your denial notice, dated [insert date of denial letter], in which the reason for denial given is "[not medically necessary or experimental/investigational services]. I disagree with this conclusion as my patient meets all of the criteria for dorsal root ganglion stimulation listed below and in my best medical decision making, Dorsal Root Ganglion Stimulation is the only option to offer this patient for relief of chronic pain.

I am requesting an expedited review.
Medical Necessity defined[2]:

At least 6 months of conservative treatment; with no improvement or failure	
Pharmacotherapy	
Physical therapy	
Surgical interventions	
Psychological evaluation performed, confirmed pain is physiological	
No contraindications identified	
Temporary trial performed and indicated greater than 50% pain relief	

Please provide any additional narrative demonstrating patient need and include medical record documentation to support request].

Dorsal Root Ganglion (DRG) Stimulation – Therapy Summary:

Dorsal root ganglion stimulation was approved by the FDA in 2016.[1] Over the past decade, it has been used effectively to treat patients with CRPS I (formerly known as reflex sympathetic dystrophy [RSD]) and CRPS II (also known as causalgia) affecting the lower limbs. The ACCURATE clinical study demonstrated the superior effectiveness of a DRG neurostimulation system compared with traditional tonic stimulation.[3]

The Proclaim™ DRG Neurostimulation System is indicated for spinal column stimulation 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 adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.[1] The effectiveness of DRG neurostimulation for chronic pain management is well documented in a Level I clinical investigation known as the ACCURATE IDE trial.[3] ACCURATE is the largest prospective, randomized comparative-effectiveness trial conducted to date in patients with CRPS types I and II.[3] DRG neurostimulation has been shown to be superior to traditional tonic spinal cord stimulation (SCS) for the indicated CRPS I and II patient population.[3]

Importantly, the evidence supporting DRG therapy extends well beyond the ACCURATE trial. Between 2017 and 2025, 20 U.S. studies involving 780 patients were published that met criteria consistent with the FDA-approved indication. Across these studies, DRG stimulation consistently produced clinically meaningful pain relief.[3-23]

The cumulative body of evidence includes[3-23]:

- Level I evidence from the ACCURATE randomized controlled trial demonstrating superiority over conventional spinal cord stimulation.
- Twenty U.S. clinical studies involving 780 patients consistent with FDA labeling.

Given the substantial body of peer-reviewed clinical evidence, FDA approval, and demonstrated superiority to conventional spinal cord stimulation in appropriately selected patients with CRPS, DRG neurostimulation should be considered medically reasonable and necessary for patients who meet clinical criteria and have failed conservative treatment measures.

ADD WHY YOUR PATIENT SHOULD RECEIVE DRG STIMULATION:
Based on my patient's current clinical condition, the available treatment alternatives considered at this time, and the clinical evidence supporting the use of dorsal root ganglion stimulation, I believe DRG neurostimulation represents the most appropriate treatment option for this patient. Accordingly, this therapy should be considered a covered benefit based on medical necessity.

Given the above information, I request an immediate approval for the DRG stimulation procedure for your beneficiary, Patient Name. I appreciate your reconsideration of this denial. If you have any questions, I can be reached at the contact information listed below.

I have included additional therapy references for your consideration, including medical records, FDA approval letter, and a bibliography of publications in the *References* section demonstrating the safety and efficacy of the Proclaim™ DRG Stimulation System.

Please let me know if I can provide any additional information and thank you for your attention.

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 notes]

References

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