HE&R NEUROMODULATION

Dorsal Root Ganglion Stimulator (DRG) for lower extremity CRPS I or CRPS II[1]

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 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 nor 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 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.

Disclaimer:
This material and the information contained herein is for general information purposes only and is not intended, and does not constitute, legal, reimbursement, business, clinical, or other advice. Furthermore, it is not intended to and does not constitute a representation or guarantee of reimbursement, payment, or charge, or that reimbursement or other payment will be received. It is not intended to increase or maximize payment by any payer. Similarly, nothing in this document should be viewed as instructions for selecting any particular code, and Abbott does not advocate or warrant the appropriateness of the use of any particular code. The ultimate responsibility for coding and obtaining payment/reimbursement remains with the customer. This includes the responsibility for accuracy and veracity of all coding and claims submitted to third-party payers. In addition, the customer should note that laws, regulations, and coverage policies are complex and are updated frequently, and, therefore, the customer should check with its local carriers or intermediaries often and should consult with legal counsel or a financial, coding, or reimbursement specialist for any questions related to coding, billing, reimbursement or any related issues. This material reproduces information for reference purposes only. It is not provided or authorized for marketing use.

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Information contained herein for DISTRIBUTION in the U.S. only.

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117, USA, Tel: 1 651 756 2000
™ Indicates a trademark of the Abbott group of companies.
‡ Indicates a third-party trademark, which is property of its respective owner.
www.neuromodulation.abbott
©2023 Abbott. All rights reserved. MAT-2304406 v1.0

[1] Proclaim DRG Clinician's Manual; Instructions for Use Website (sjm.com)

[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 ICD10 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 spinal column stimulation [Trial/Implant procedure] of the dorsal root ganglion (DRG) 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 spinal column stimulation in the epidural space 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	

[2] Palmetto GBS Spinal Cord Stimulator Checklist

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

DRG Stimulation (Dorsal Root Ganglion) – Therapy Summary:

Spinal column stimulation has been an FDA approved therapy for the treatment of chronic pain since 1989. Over the past few decades, it has been used to effectively treat patients with CRPS I (formally known as regional sympathetic dystrophy or RSD) and CRPS II (also known as causalgia) in the lower limbs. The ACCURATE clinical study demonstrates the superior effectiveness over tonic stimulation with a DRG neurostimulation in reducing pain and allowing patients in this population to be active once again.[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[4] pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II.[3],[5] The effectiveness of DRG neurostimulation for the management of chronic pain is well-documented in a Level-1 clinical investigation, known as the ACCURATE IDE trial.[1] ACCURATE is the largest prospective, randomized comparative effectiveness trial to date for the CRPS I and II patient population.[1] DRG neurostimulation has been proven superior as compared to traditional tonic SCS for the indicated patient population of CRPS I and II.[1]

Please note, in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed the diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively. CRPS II (causalgia) is defined as a painful condition arising from damage to a nerve. Nerve damage may result from traumatic or surgical nerve injury. Changes secondary to neuropathic pain seen in CRPS I (RSD) may be present but are not a diagnostic requirement for CRPS II (causalgia) i.e., Budapest criteria is not a diagnostic requirement for CRPS II.[6] DRG stimulation also demonstrated improvements over baseline in quality-of-life measures based on SF-36 scores at 12 months.[1]

ADD WHY YOUR PATIENT SHOULD RECEIVE DRG Stimulation:
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 dorsal root ganglion stimulation, I believe this is the best treatment for this patient 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 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 Literature 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]

3 Deer, T., Levy, R. (2017). 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 (ACCURATE). *Pain*, 158(4), 669-681. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5359787/
4 Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least two prior pharmacologic treatments from at least two different drug classes and continued their pharmacologic therapy during the clinical study
5 Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia as complex regional pain syndrome (CRPS) types I and II, respectively.
6 Abbott Proclaim™ DRG Neurostimulation System Clinician's Manual. Plano, TX 2018. Instructions for Use Website (sjm.com)

Enclosures:
[Patient medical records/chart notes]