

LETTER OF MEDICAL NECESSITY TEMPLATE

Template to be considered for prior authorization by physicians

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

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Instructions for completing the sample prior authorization letter:

1. Please customize the letter of medical necessity 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 a prior authorization request.
3. After you have customized the letter of medical necessity, **please make sure to delete** any specific instructions for completion that are highlighted throughout the letter, so the healthplan does not misinterpret the information.

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Rx Only

Brief Summary: Prior to using these devices, please review the User's Guide 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.

Indications for Use: 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.**

*Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study.

**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. 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).

Contraindications: Patients who are unable to operate the system, who are poor surgical risks. Patients who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems or other active implantable devices, magnetic resonance imaging (MRI), computed tomography (CT), electrosurgery devices, ultrasonic scanning equipment, therapeutic radiation, explosive and flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery, equipment and vehicles, pediatric use, pregnancy, and case damage.

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, tissue damage or nerve damage, paralysis, weakness, clumsiness, numbness, sensory loss, or pain below the level of the implant, pain where needle was inserted or at the electrode site or at IPG site, seroma at implant site, headache, allergic or rejection response, battery failure and/or leakage. User's Guide must be reviewed for detailed disclosure.

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PLEASE DELETE THIS PAGE BEFORE SUBMISSION

[Physician Letterhead]

[Date:]

Attention: Pre-Determination Department

[Payer Name]

[Patient's ID#]

[Street address]

[City, State, zip code]

To Whom It May Concern:

Please consider this prior authorization request for the above patient to have 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 limbs.^{1,2}

Unlike other pain management procedures, the benefit of DRG therapy to the patient can be assessed from the trial procedure, which is prior to the system implant. During the trial procedure, temporary leads are placed in the epidural space adjacent to the DRG and are attached to an external power source to provide therapy. The trial procedure allows patients to temporarily experience neurostimulation and the effect it has on controlling their pain, in order to make an informed choice about pursuing the therapy.

DRG Stimulation – Therapy:

Proclaim Dorsal Root Ganglion neurostimulation system was FDA-approved on November 28, 2016. The therapy has been used to effectively treat patients with CRPS I (formerly known as regional sympathetic dystrophy) and CRPS II (also known as causalgia) in the lower limbs.³ The effectiveness of dorsal root ganglion (DRG) neurostimulation for the management of chronic pain is well-documented in the ACCURATE trial; a prospective, multicenter, randomized controlled study (N=152) comparing DRG stimulation to traditional spinal cord stimulation (SCS) in patients with chronic neuropathic pain of the lower limbs due to CRPS or causalgia, with a 12-month follow-up.³ The ACCURATE randomized controlled trial demonstrated that DRG stimulation provided superior outcomes compared to traditional SCS for patients with CRPS and causalgia.³ DRG therapy achieved significantly greater pain relief, with an 84.1% reduction in VAS scores at 3 months versus 70.9% for SCS ($P < 0.0004$) and 81.4% at 12 months ($P < 0.0004$) versus 70.9% and 66.5% for SCS.³ In addition to greater pain relief, DRG therapy resulted in statistically significant improvements in physical function (SF-36 Physical Component Summary, $P = 0.04$), mood (Profile of Mood States, $P \leq 0.021$), and health-related quality of life (SF-36 general health and social functioning, $P = 0.03$) at 12 months³.

Furthermore, as referenced in policy 7.01.25, the Blue Cross Blue Shield Association has determined that the clinical evidence for DRG stimulation is sufficient to determine that the technology results in a meaningful improvement in the net health outcome for individuals with treatment-refractory chronic pain of the lower limbs in adult patients with complex regional pain syndrome (CRPS) types I and II.⁴

¹ Proclaim DRG FDA Approval letter (on file at Abbott)

² Dorsal Root Ganglion (DRG) Instructions for Use (IFU) (on file at Abbott)

³ Deer, T., Levy, R. (2017). ACCURATE study: 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. *Pain*, 158(4), 669-681.

⁴ Evidence Street[†] ID 7.01.25, Spinal Cord and Dorsal Root Ganglion Stimulation, published May 06, 2019

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 DRG stimulation, I believe this is the best treatment for [insert Patient's name] at this time and therefore should be a covered benefit based upon medical necessity. My patient has tried and failed other treatment options that are listed below:

History

DESCRIPTION	LIST HERE
ICD-10 Diagnosis code (specify region of impact):	
Medications:	
Conservative Therapies: Example - physical therapy, etc.	
Psychological evaluation:	<input type="checkbox"/> YES <input type="checkbox"/> NO
Injections:	
Surgeries	
Candidate for further surgery?	

[Add additional information as needed. If the patient has already had a DRG stimulation trial and this is a pre-authorization letter for a permanent DRG stimulation implant, indicate whether the trial resulted in > 50% in pain reduction and degree in improvement.]

My patient has undergone a careful screening evaluation and diagnosis by multiple prior physicians. The DRG neurostimulation therapy I recommend has several distinct advantages for [insert patient's name]. DRG therapy has been proven clinically effective as seen in the ACCURATE study and offers the prospect of improving patient's pain (pain reduction in VAS), physical function (SF-36 Physical Component), mood (Profile of Mood States), and quality of life (SF-36 general health and social functioning).³

Given the above information, I request a pre-authorization for a DRG stimulation [trial/implant] procedure for your beneficiary, [Patient Name]. If you have any questions or would like additional therapy references for your consideration, including medical records, FDA-approval letter, and/or a bibliography of publications demonstrating the safety and efficacy of the Proclaim DRG Stimulation System, I can be reached at the contact information listed below. Thank you for your attention to this request.

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]