Medica

# UTILIZATION MANAGEMENT POLICY

TITLE: SPINAL CORD AND DORSAL ROOT GANGLION STIMULATION FOR TREATMENT OF PAIN – MAYO MEDICAL PLAN ONLY

**EFFECTIVE DATE**: May 01, 2024

THIS POLICY APPLIES TO MAYO MEDICAL PLAN (MMP) MEMBERS.

NOTE: Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering medical necessity criteria.

**IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**
*These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.*

*Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.*

PURPOSE
To promote consistency between Utilization Management reviewers by providing the criteria that determine medical necessity.

BACKGROUND
Definitions

I. **Complex regional pain syndrome (CRPS),** (also known as reflex sympathetic dystrophy, algoneurodystrophy/algodystrophy, causalgia syndrome) is a form of chronic pain usually affecting an arm or leg and normally developing after an injury, surgery, infection, stroke, or heart attack. This presentation is known as CRPS Type I. CRPS can also arise from direct injury to a nerve, and is known as CRPS Type 2. In CRPS, the pain intensity is out of proportion to the severity of the initial incident, and its cause is not clearly understood. Symptoms vary, with pain, swelling, redness, and noticeable changes in temperature and hypersensitivity (e.g., to cold and touch) usually occurring first. Over time, the limb may become cold and pale and undergo skin and nail changes, as well as developing muscle spasms and tightening.
II. **Conservative management** should include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy AND at least one complementary conservative treatment strategy.
    1. Physical therapy may be performed by a qualified provide of physical therapy services or constitute a tailored supervised home treatment program.
    2. Complimentary services may include anti-inflammatory medications and analgesics, Adjunctive medications such as nerve membrane stabilizers or muscle relaxants, alternative therapies (e.g., acupuncture, chiropractic manipulation, massage therapy, activity modification, and/or a trial period of rest), or interventional modalities (e.g., epidural injections, facet joint procedures, and sympathetic blocks, as appropriate).
III. A **dorsal root ganglion (DRG)** is a cluster of nerve cell bodies in the posterior roots of spinal nerves that extend outward beyond the vertebrae. Pain signals coming from the lower limbs pass through the DRG to the spinal cord and subsequently to the brain.
IV. **Failed back surgery syndrome (FBSS)**, also known as post laminectomy syndrome, is characterized by nerve root injury causing persistent back and/or leg pain following otherwise successful back surgery,

frequently following a laminectomy. Following spine surgery, major pain relief is expected, but rarely is there total pain relief. A fraction of post-surgical pain is normal. However, the term FBSS is reserved for individuals who continue to suffer from a majority of their pain symptoms following surgery.

V. **Regional sympathetic nerve blocks** include procedures that temporarily obstruct the local function of the sympathetic nervous system. Anesthetic is injected directly over the sympathetic neural structures that serve affected limb(s), such as the stellate ganglion or the lumbar sympathetic chain. Radiologic guidance (fluoroscopy or CT scan) is utilized to ensure accuracy. Regional sympathetic nerve block has been utilized primarily for treatment of complex regional pain syndrome (CRPS). This and other interventional procedures should be considered only when the full spectrum of noninvasive management strategies has not provided sufficient relief of symptoms.

VI. **Significant pain and functional impairment** refer to pain that is at least 3 out of 10 (on a 1-10 pain scale) in intensity and is associated with inability to perform at least two (2) activities of daily living (ADLs) and/or instrumental activities of daily living (IADLs).

VII. **Spinal cord stimulators**, also known as dorsal column stimulators ("stimulators"), are implantable devices used to treat chronic pain. Electrodes are surgically placed within the dura mater via laminectomy, or by percutaneous insertion into the epidural space. Low voltage electrical signals are delivered to the dorsal column of the spinal cord in order to override or mask sensations of pain. Other modalities may include burst stimulation, or high frequency stimulation.

The patient's pain distribution pattern determines the level at which the stimulation lead is placed. The lead may incorporate 4 to 8 electrodes, with 8 electrodes typically used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk.

Implantation is typically a two-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio receiver/transducer are permanently implanted.

Extensive programming of the neurostimulators is often required to achieve optimal pain control.

BENEFIT CONSIDERATIONS

1. Prior authorization **is required** for both spinal cord stimulation trial and permanent implantation, including reoperation. Please see the prior authorization list for product specific prior authorization requirements.
2. Prior authorization **is not required** for removal without intended reoperation/implantation.
3. Coverage may vary according to the terms of the member's plan document.
4. Spinal cord stimulation of the dorsal column for treatment of intractable pain *is investigative and therefore not covered* for all other indications not addressed in the Medical Necessity Criteria, including but not limited to:
   a. Use of spinal cord stimulation for the treatment of critical limb ischemia to forestall amputation, refractory angina pectoris, heart failure, and cancer-related pain
   b. Repeat trial of spinal cord stimulation if the initial trial failed
   c. Replacement of a conventional spinal cord stimulator with a burst, high frequency, or dorsal root ganglion stimulator in the absence of an indication for stimulator removal
   d. Dorsal root ganglion neurostimulation for any non-CRPS lower extremity indication
   e. Dorsal root ganglion neurostimulation in patients with CRPS lower extremity who currently have a spinal cord stimulator or who have previously failed spinal cord stimulation therapy
   f. Simultaneous placement of a dorsal column and dorsal root ganglion stimulator.
5. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
6. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

**SPINAL CORD STIMULATION**

NOTE: Prior authorization **is required** for spinal cord stimulation trial and permanent implantation, including reoperation.

I. Indications for **trial** spinal cord stimulation:
Documentation in the medical records indicates that **all of the following** criteria have been met:
A. The patient has chronic intractable neuropathic pain of the trunk and/or limbs associated with at least **one of the following** conditions:
1. ***Lumbrosacral arachnoiditis*** as documented by high levels of protein in the cerebrospinal fluid and/or imaging (MRI or myelograhy)
2. ***Nerve root injuries*** that are post-surgical after a spine surgery (e.g., failed back syndrome)
3. ***Complex regional pain syndrome (CRPS)***, type I or type II (formerly known as reflex sympathetic dystrophy or causalgia) when **all of the following** criteria are met:
a. Continuing pain that is disproportionate to any inciting event
b. **At least one symptom** demonstrated in **at least three of the following** categories:
1) Sensory: hyperesthesia or allodynia
2) Vasomotor: temperature asymmetry, skin color changes, skin color asymmetry
3) Sudomotor/Edema: edema, sweating changes, or sweating asymmetry
4) Motor/Trophic: decreased range of motion, motor dysfunction (e.g., weakness, tremor, dystonia), or trophic changes (e.g., hair, nail, skin).
c. **At least one sign** at time of evaluation in **at least two** of the following categories:
1) Sensory: evidence of hyperalgesia (to pinprick), allodynia (to light touch, temperature sensation, deep somatic pressure, or joint movement)
2) Vasomotor: evidence of temperature asymmetry (>1°C), skin color changes or asymmetry
3) Sudomotor/Edema: Evidence of edema, sweating changes, or sweating asymmetry
4) Motor/Trophic: evidence of decreased range of motion, motor dysfunction (e.g., weakness, tremor, dystonia), or trophic changes (e.g., hair, nail, skin)
5) No other diagnosis better explaining the signs and symptoms.
d. Documentation of **all of the following**:
1) Level of pain and disability in the moderate-to-severe range
2) Failure of at least two weeks of conservative management
3) Documentation of ongoing participation in a comprehensive pain management program
4) Procedure being performed unilaterally.
B. Severe pain and disability with documented pathology or an objective basis for the pain documented in the medical record.
C. Dorsal column stimulation is being used as a late or last resort after documentation of **one of the following**:
1. Failure of at least six consecutive months of physician-supervised multimodal conservative management (e.g., activity modification, supervised physical therapy or home treatment program, anti-inflammatory medications/analgesics, nerve membrane stabilizers/muscle relaxants, minimally invasive injections/nerve blocks).
2. Inability to perform or continue conservative management (e.g., intractable pain so severe that physical therapy is not possible).
D. Failed trial of regional sympathetic blocks in the case of CRPS.
E. The individual has been evaluated by a pain management specialist prior to implantation.
F. At least one surgical opinion has been obtained to ensure that the patient does not have a surgically correctable lesion (excludes CRPS).
G. Documentation of an evaluation by a mental health provider within six months of a stimulator trial request (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) that confirms no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a spinal cord stimulator or contraindicate its placement.
H. All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, training, and follow-up of the patient are available.
I. NOTE: A repeat trial is **not medically necessary** if the initial trial failed, unless failure was due to mechanical causes, such as device failure.

II. Indications for **permanent** spinal cord implantation**:**
Documentation in the medical records indicates that **all of the following** criteria have been met:
A. The individual meets **all** of the criteria for a stimulator trial. See I. A – I, above.

B. Individual has completed a trial of at least three days duration.
C. Documented following the stimulator trial demonstrating **all of the following**:
   1. At least a 50% reduction of **one of the following**:
      a. The target pain locus, *or*
      b. Analgesic medication use
   2. Documented evidence of improved function.

III. Indications for **revision or removal**:
Documentation in the medical record indicates **one of the following**:
A. Stimulator hardware complication (e.g., lead migration, infection, painful generator site)
B. Stimulator response complications (e.g., loss of effectiveness, intolerance, development of new neurologic deficits)
C. Planned procedure where stimulators are contraindicated (e.g., magnetic resonance imaging, automatic implantable cardioverter defibrillator).

**DORSAL ROOT GANGLION STIMULATION**

NOTE: Prior authorization **is required** for dorsal root ganglion stimulation.

IV. Indications for dorsal root ganglion stimulation as an alternative to dorsal column stimulation:
Documentation in the medical record indicates all **of the following**:
A. Individual has moderate-to-severe chronic intractable pain of the lower limbs from complex regional pain syndrome (CRPS) types I or II, *and*
B. Criteria for spinal cord stimulator trial or implantation has been met (i.e., spinal cord stimulation criteria I or II, above).

DOCUMENT HISTORY

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| Original Effective Date | May 01, 2024 |
| Administrative Updates | |

**Selected References**:

1. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine*. 2009;34(10):1066-77.
2. COST B13 Working Group on Guidelines for Chronic Low Back Pain, Airaksinen O, Brox JI, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J*. 2006;15 Suppl 2:S192-300.
3. Lewis RAW, N. H.; Sutton, A. J., et al. Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses. *Spine J.* 2015;15(6):1461-77.
4. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain physician*. 2013;16(2 Suppl):S49-283.