TITLE: SPINAL CORD STIMULATION OF THE DORSAL COLUMN FOR TREATMENT OF PAIN

EFFECTIVE DATE: January 15, 2018

This policy was developed with input from specialists in neurology and physical/rehabilitative medicine and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for 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 and Minnesota Health Care Programs, this policy will apply unless those 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 about this Medica utilization management policy 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 reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of spinal cord stimulation of the dorsal column for treatment of pain. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

Definitions

A. 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.

B. Failed back surgery syndrome (FBSS), also known as post laminectomy syndrome, is characterized by 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.

C. Neuropathic pain originates and is perpetuated within the nervous system itself, without ongoing stimulation from an injury. Pain may arise from a primary lesion or from other dysfunction or disease affecting the nervous system. Prevalence of neuropathic pain is estimated to affect approximately eight percent of the population. Neuropathic pain may often respond poorly to standard therapies, can last indefinitely, and can increase in severity over time, often leading to severe disability with markedly reduced quality of life. Examples of neuropathic pain include, but are not limited to, complex regional pain syndrome (CRPS), diabetic neuropathy/polyneuropathy, failed back syndrome (FBS), phantom limb pain, postherpetic neuralgia, post-stroke pain, or trigeminal neuralgia.

D. Peripheral neuropathy/polyneuropathy is a problem with the functioning of the nerves outside the spinal cord. Symptoms of peripheral neuropathy may include numbness, weakness, burning pain (especially at night), and loss of reflexes. Polyneuropathy is the most common form of peripheral neuropathy, and may advance to compromise swallowing, breathing, or eye movements. Diabetic peripheral neuropathy is a type
of nerve damage that occurs when prolonged high blood sugar levels cause permanent injury to nerve fibers, most often affecting nerves in the legs and feet.

E. Spinal cord stimulation utilizes low-voltage electrical impulses to stimulate large spinal nerve fibers, which act to block small nerve fiber responses that would otherwise be interpreted as pain. Electrodes are placed in the epidural space within the spinal column, with the intended outcome of suppressing pain in individuals experiencing severe chronic pain refractory to standard therapy. Implantation of the stimulation device is done in two phases:

1. Phase one is a trial using temporary electrical stimulation. Either percutaneous or surgical implantation of the leads, with an external trailing neurostimulator (aka, pulse generator), can be used for the screening test. The trial is usually performed from 3 to 7 days.
2. Phase two consists of permanent implantation of both the leads and the neurostimulator. If the individual experiences a positive response in symptoms, permanent implantation may result. The neurostimulator is inserted under the skin through a small incision in the upper buttock, and the permanent lead is implanted in the epidural space. Implantation is typically done as an outpatient procedure.

F. Spinal cord stimulation system (aka, dorsal column stimulation system) is composed of the following components:

1. Neurostimulator – a device similar to a pacemaker, which sends electrical pulses to the spine. It is surgically implanted under the skin in the abdomen or upper buttock. Standard spinal cord stimulation applies tonic stimulation to the spinal cord (i.e., regularly spaced, mild electrical pulses [e.g., 1-kHz] of energy), and the individual experiences a tingling sensation (paresthesia) intended to interrupt the transmission of pain signals to the brain. Modifications used to stimulate the spinal cord include, but are not limited to:
   a. High-frequency stimulation (Senza Spinal Cord Stimulation System), which uses higher frequency pulses (e.g., 10-kHz) to interrupt the pain pathway while markedly reducing or eliminating paresthesia.
   b. Burst stimulation, which uses low-energy closely-spaced, but intermittent, pulses of energy with the intent of producing little-to-no paresthesia.
   c. Position-adaptive stimulation, which is designed to automatically adapt stimulation amplitude in response to changes in an individual’s position or activity.
   d. Multicolumn-based stimulation, which applies multiple leads to various spinal cord column locations, with the intent of applying stimulation and paresthesia to a broader area of the spine.
2. Leads - insulated medical wires that deliver neurostimulation to the epidural space near the spine
3. Physician programmer - a computer allowing the clinician to adjust the neurostimulation system and set stimulation levels
4. Handheld programmer - a device similar to a remote control that can be used by the individual to adjust pain relief based on changing pain levels throughout the day (e.g., with changing degrees of activity).

G. Standard therapies used for neuropathic pain include, but are not limited to:

1. Back surgery
2. Neurosurgery
3. Percutaneous neurostimulation therapies (e.g., transcutaneous electrical nerve stimulation [TENS], motor cortex stimulation)
4. Pharmacotherapy (e.g., antidepressants, anticonvulsants, opioids, botulinum toxin)
5. Physical therapy (e.g., acupuncture, spinal manipulation)
6. Psychotherapy or cognitive behavioral therapy (e.g., biofeedback, relaxation techniques).

BENEFIT CONSIDERATIONS

1. Prior authorization is required for both spinal cord stimulation trial and permanent implantation, including reoperation.
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 this policy, including but not limited to: angina pectoris/myocardial ischemia, arachnoiditis, cancer associated pain, chronic visceral abdominal pain, cluster/migraine headache, intercostal neuralgia, lower limb ischemia, (chronic/critical), non-diabetic peripheral neuropathy, phantom limb syndrome, post herpetic neuralgia, post-cervical spine surgery, and spinal cord injury.
5. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's plan document.
6. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed.
MEDICAL NECESSITY CRITERIA

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. Spinal cord stimulator system has received final FDA approval. Examples of FDA approved device systems include, but are not be limited to:
      1. Eon® Neurostimulation System (St. Jude Medical)
      2. Precision™ Spinal Cord Stimulation Systems, now marketed as Precision Plus SCS System (Boston Scientific)
      3. Restore™ Systems (Medtronic)
      4. Senza Spinal Cord Stimulation System (Nevro Corp.).
   B. Individual has a diagnosis of one of the following chronic neuropathic pain conditions of the trunk or limbs:
      1. Complex regional pain syndrome (also known as reflex sympathetic dystrophy, algoneurodystrophy/algodystrophy, causalgia syndrome)
      2. Failed back surgery syndrome (FBSS)
      3. Moderate to severe diabetic peripheral neuropathy, when all of the following criteria have been met:
         a. Pain scale intensity rating of 50% or higher using a standard pain relief inventory assessment tool (e.g., Visual Analog Scale, Numeric Rating Scale, Verbal Rating Scale).
         b. Neuropathic pain refractory to a minimum of 12 months of conservative therapy, including all of the following therapies:
            1) Non-steroidal anti-inflammatory drug [NSAIDS]
            2) Antidepressant
            3) Anticonvulsant.
   C. Documentation of all of the following:
      1. Intractable pain for a minimum of twelve months duration
      2. Failure of standard therapy (i.e., conservative management, standard surgical intervention) or unsuitability of standard therapies
      3. Comprehensive physical examination, including a pain evaluation.
   D. Psychiatric/psychological evaluation has been conducted, and all of the following apply:
      1. Evaluation has been completed within the past 12 months
      2. Continued optimal management of any previously diagnosed (greater than 12 months) mental or neurobehavioral condition(s).
   E. None of the following are present:
      1. Administration of anticoagulant or antiplatelet therapy
      2. Coagulation disorder (e.g., coagulopathy, severe thrombocytopenia)
      3. Current or chronic infection
      4. Implanted cardiac pacemaker or defibrillator
      5. Malignancy-derived pain

II. Indications for permanent spinal cord implantation:
   Documentation in the medical records indicates that all of the following criteria have been met:
   A. Medical necessity criteria is consistent with I.A. - E., above.
   B. Individual has completed a trial using either percutaneous leads or surgically implanted leads with documentation of all of the following:
      1. Trial duration of a minimum of three days
      2. Greater than or equal to 50% reduction in pain using a standard pain relief inventory assessment tool (e.g., Visual Analog Scale, Numeric Rating Scale, Verbal Rating Scale).

III. Indications for reoperation:
   Documentation in the medical record indicates one of the following:
   A. Development of fibrosis surrounding the electrode tip
   B. Electrode misalignment or migration has occurred
C. Infection necessitating removal of the stimulation system
D. Spinal cord stimulator and/or the battery are no longer operational.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>July 1, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPC Endorsement Date(s)</td>
<td>06/2014, 06/2015, 06/2016, 09/2016, 11/2017</td>
</tr>
<tr>
<td>Administrative Updates</td>
<td>05/01/2017</td>
</tr>
</tbody>
</table>

References

Pre-06/2015 Medical Technology Assessment Committee (MTAC) and Medical Policy Committee (MPC):

06/2015 MPC:

07/2016 MTAC and 09/2016 MPC:
46. Feldman EL, McCulloch DK. Treatment of diabetic neuropathy. UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2016.
55. Rosenquist EWL. Overview of the treatment of chronic pain. UpToDate, Basow, DS (Ed), UpToDate, Waltham, MA, 2016.
No new references added.