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

EFFECTIVE DATE: September 1, 2015

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, Medicaid and MinnesotaCare members, 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 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. Arachnoiditis is inflammation of the middle layer meninges, the membrane layers covering the brain and spinal cord. Arachnoiditis can occur as a complication of procedures such as myelograms, spinal operations, epidural steroid injections, and injury to the spine.

B. 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.

C. Failed back surgery syndrome (FBSS) is the development of new, persistent, intractable back pain following a surgical intervention. The pain persists following medical management and may continue to worsen due to a buildup of scar tissue around spinal nerve roots. It is normally accompanied by persistent tissue pain and muscle spasm. The term refers to a condition of continuing pain, and it is not meant to imply that surgery was compromised.

D. Intercostal neuralgia is an uncommon pain condition involving the intercostal nerves, which supply the muscles between the ribs. Individuals with intercostal neuralgia experience bands of pain around the rib cage, which is usually intermittent and spasmodic.

E. 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),
Spinal Cord Stimulation of the Dorsal Column for Treatment of Pain
Medica Policy No. III-DEV.23

F. **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.

G. **Phantom limb syndrome**, a relatively common event, is the perception of sensations, often including pain, in a limb or stump following limb amputation.

H. **Post herpetic neuralgia** is a complication of shingles, caused by reaction to the herpes zoster virus. It affects nerve fibers and skin and the burning pain can be severe enough to interfere with sleep and appetite. Most symptoms of shingles resolve over time, but if pain persists after the rash and blisters have cleared, the condition is called postherpetic neuralgia. The risk of post herpetic neuralgia increases with age and primarily affects people older than 60.

I. **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.

J. **Spinal cord stimulation** (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
   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).

K. **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).

L. **Vascular claudication** displays as a cramping pain in the calves, thighs, or buttocks. It is caused by impaired blood flow to the legs due to atherosclerosis. It is sometimes confused with pain arising from spinal stenosis.
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. 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).
   B. 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.
   C. Documentation of optimal management of any previously diagnosed mental or neurobehavioral condition(s).
   D. 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. - D., 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.

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 is no longer operational.

COVERAGE ISSUES

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), peripheral neuropathy, phantom limb syndrome, post herpetic neuralgia, post-cervical spine surgery, and spinal cord injury.
6. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's plan document.
7. If it appears that the Medical Necessity and Coverage Criteria 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.

<table>
<thead>
<tr>
<th>DOCUMENT HISTORY</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Endorsement Date</td>
<td>June 2014</td>
</tr>
<tr>
<td>Subsequent Endorsement Date(s)</td>
<td>06/2015</td>
</tr>
</tbody>
</table>

Effective Date: September 1, 2015
References

Pre-06/2015 Medical Technology Assessment Committee (MTAC) and Medical Policy Committee (MPC):
Spinal Cord Stimulation of the Dorsal Column for Treatment of Pain
Medica Policy No. III-DEV.23


06/2015 MPC:


