Clinical Coverage Guidelines – Spinal Cord & Occipital Nerve Stimulation for Chronic Pain

Effective Date: 03/01/12*
Policy Number: OCA: 3.50
Product Applicability:
☑ MassHealth ☑ Commonwealth Care ☑ Commercial

Summary: Spinal cord stimulation is considered medically necessary based upon clinical criteria and requires preauthorization. Occipital nerve stimulation is considered experimental and investigational for all indications.

Description of Item or Service:
Occipital nerve stimulation (ONS): Electrical stimulation to the occipital nerve in an attempt to prevent migraines and other headaches in patients who have not responded to medications. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

Spinal Cord Stimulation (SCS) or Dorsal column stimulation: Electrical stimulation of the spinal nerves with electrodes that are implanted in the epidural space of the spinal column used as a treatment of last resort for chronic pain to block pain conduction pathways to the brain. Spinal cord stimulation consists of the following components: The lead or electrodes that deliver the electrical stimulation to the spinal cord, the extension wire that conducts the electrical stimulation from the power source to the electrode and the power source (battery) that generates the electrical stimulation.

Clinical Guideline Statement:
1. Occipital nerve stimulation is considered experimental and investigational for all indications.

2. Spinal cord stimulation requires prior authorization and may be considered medically necessary for the following conditions when the patient selection criteria have been met and the patient has experienced a 50% or more reduction in...
pain after a three to seven day trial of percutaneous stimulation. The patient must be refractory to all other pain therapies. Clinical indications include but are not limited to:

- Failed back surgery syndrome with low back pain and significant radicular pain
- Complex regional pain syndrome (reflex sympathetic dystrophy)
- Inoperable chronic ischemic limb pain secondary to peripheral vascular disease

3. The patient must meet all of the following criteria for the clinical indications described above:

- There is documented pathology, i.e., an objective basis for the pain complaint, and
- Other more conservative methods of pain management have been tried and failed, and
- The patient does not have any untreated existing substance abuse problems, and
- The patient has obtained psychiatric clearance, and
- The patient has predominantly radiating extremity pain, and
- The patient experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation. (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet the above-listed criteria, in order to predict whether a dorsal column stimulator will induce significant pain relief.)

4. Spinal cord stimulation may be considered medically necessary for the management of intractable angina in patients who are not surgical candidates and whose pain is unresponsive to all standard therapies when all of the following criteria are met:

- The patient has angiographically documented significant coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA), and
- The patient’s angina pectoris is New York Heart Association (NYHA) Functional Class III (patients are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain) or Class IV (symptoms of cardiac insufficiency or angina are present at rest; symptoms are increased with physical activity), and
- Reversible ischemia is documented by symptom-limited treadmill exercise test, and
- The patient has had optimal pharmacotherapy for at least one month. Optimal pharmacotherapy includes the maximal tolerated dosages of at least two of the following anti-anginal medications: long-acting nitrates,
beta-adrenergic blockers, or calcium channel antagonists; and
- The patient experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation.

5. Medical Contraindications for spinal cord stimulation include but are not limited to:
- Uncontrolled bleeding disorder at time of implantation
- Systemic or local sepsis
- Presence of implanted pacemaker or defibrillator
- Failure of percutaneous trial of stimulation

Additional Definitions:
Complex Regional Pain Syndrome:
- **Type I or Reflex Sympathetic Dystrophy:** A regional pain syndrome that usually develops after tissue or bone injury. Examples of associated tissue trauma may include shoulder or limb injury, myocardial infarction and stroke. Typically, pain and swelling in the distal extremity occur within weeks to three months after the precipitating event. The pain is described as throbbing, burning and aching in quality, joints are tender and the involved area is warm with increased sweating and hair growth. Three to six months later, the skin appears thin, shiny and cool. Nine to twelve months later, flexion contractures and atrophy of the skin develops.
- **Type II or Causalgia:** A regional pain syndrome that usually develops after injury to a peripheral nerve characterized by a triad of burning pain, autonomic dysfunction and trophic changes. The pain usually begins 24 hours after the onset of injury worsened by any sensory stimulation. Vascular changes include either vasodilatation that causes a warm sensation or vasoconstriction that causes coldness and mottling of the skin. Trophic changes include dry, scaly skin, loss of hair growth and alteration in sweating.

Failed Back Syndrome (FBS) or (Post Laminectomy Syndrome): Back pain that persists after one or more surgical procedures on the lumbosacral spine. The etiology of failed back syndrome is unknown but the basic belief is that scar tissue forms near the nerve roots applying pressure to the nerves causing intractable pain. Several factors may contribute to this syndrome, including selection of inappropriate patients for surgery, surgical complications, irreversible nerve injury and psychosocial problems. Patients with FBS may suffer from recurrent disc herniation, lumbosacral postoperative fibrosis and/or arachnoiditis, epidural scarring, an injured nerve root, dorsal compartment syndrome and/or lateral spinal stenosis. Pain may arise from viscera, blood vessels, nerves, bones of the spine and pelvis, muscles and/or joints. The pain associated with FBS remains typically refractory, difficult to control and unlikely to respond to further reconstructive surgery.
Neuropathic Pain: A complex chronic pain state that develops after injury to any level of the peripheral or central nervous system that results in impairment of pain sensation. Neuropathic pain typically has an unusual burning, tingling or electric shock-like sensation and may be triggered by very light touch. Examples of syndromes that cause neuropathic pain may include diabetic neuropathy, postherpetic neuralgia, phantom limb pain, failed back syndrome, complex regional pain syndrome, spinal cord injury, arachnoiditis, and syringomyelia.

Pain: The International Association for the Study of Pain defines pain as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" and defines chronic pain as “That which persists beyond the normal time of healing”. Chronic pain is defined by the American Society of Anesthesiologists as “Persistent or episodic pain of a duration or intensity that adversely affects the function or well being of the patient, attributable to any nonmalignant etiology”. Pain that is present for three to six months or longer and has not been relieved by standard medical management is also used to define chronic pain.

Applicable Coding: Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Spinal Cord Stimulation</th>
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<tbody>
<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
</tr>
<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
</tr>
<tr>
<td>63661</td>
<td>Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<tr>
<td>63662</td>
<td>Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
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<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63664</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
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<tr>
<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<tr>
<td>63688</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
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<tr>
<th>CPT Codes</th>
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This guideline provides information on BMC HealthNet Plan clinical criteria and claims adjudication processing guidelines. The use of this guideline is not a guarantee of payment and will not determine how a specific claim(s) will be paid. Reimbursement is based on member benefits and eligibility, medical necessity review, where applicable, coordination of benefits, adherence to Plan policies, clinical coding criteria, and the BMC HealthNet Plan agreement with the rendering or dispensing provider. Reimbursement policies may be amended at BMC HealthNet Plan’s discretion. BMC HealthNet Plan will always use the most recent CPT and HCPCS coding guidelines. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including NCQA.
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Limitations:
- Spinal cord stimulation is considered experimental and investigational for the management of patients with chronic, malignant pain, other chronic non-malignant pain (e.g., headache, cephalgia, occipital neuralgia, intercostal neuralgia, trigeminal neuralgia, phantom limb syndrome, inguinal pain, and post-herpetic neuralgia), and spasticity because its effectiveness for these indications has not been established.
- Cervical Spinal Cord (SCS) stimulation for the treatment of patients with cervical trauma or disc herniation, presenting with arm pain, neck pain, or cervicogenic headache, as experimental and investigational because its effectiveness for these indications has not been established.
- Occipital nerve stimulation is considered experimental and investigational for all indications investigational because its effectiveness has not been established.

Clinical Background Information:
Spinal cord stimulation was developed in the late 1960’s and refined in the 1980’s and is used to treat a variety of pain disorders that are difficult to manage successfully. The most common disorders that are treated with spinal cord stimulation are neurological or neurogenic in origin such as spinal cord injuries, brachial plexus injuries and phantom limb pain. Vascular cases are related to diabetes and arteriosclerosis and musculoskeletal cases are mostly related to failed back syndrome. The neurophysiology of pain relief after spinal cord stimulation is unknown but may be related to the blockage of pain conduction pathways to the brain. Spinal cord stimulation should not be a first-line treatment but may be considered only after failure of all other pain management regimes. Spinal cord stimulation involves the use of electrical stimulation on the spinal column by the implantation of electrodes in the epidural space along the spinal column. Implantation is typically a two-step process. Initially, the electrode is temporarily implanted in the epidural space allowing for a trial period of stimulation. The trial typically lasts for a period of three to seven days. Following the trial, the electrodes are permanently implanted once effectiveness has been confirmed by at least a 50% reduction in pain. Complications of spinal cord stimulation can include: infection, hematoma, leakage of cerebrospinal fluid, lead migration, spasm and device failure.

Occipital nerve stimulation has been proposed for patients with intractable headache that can not be managed by alternative treatments. The procedure involves implanting electrodes under the skin in the suboccipital region of the scalp. The electrodes deliver electrical impulses near the occipital nerves through insulated wires, which are tunneled under the skin. Usually a trial of stimulation is done for several days to assess the response to pain before permanent implantation. At the current time Occipital nerve stimulation is considered experimental and investigational for all indications investigational because its effectiveness has not been established.
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References:


Institute for Clinical Systems Improvement (ICSI). Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI);
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http://www.guidelines.gov/content.aspx?id=15525&search=spinal+cord+stimulation+and+chronic+pain


**Policy History**

**Original Effective Date:** 12/06/05

*Effective date for Commercial is 01/01/12*

**Date of Review/Revision:**
02/06/07: Annual review, updated template and references
02/19/08: Annual review, revised clinical criteria, revisions effective July 1, 2008
01/27/09: Annual review, no changes to the clinical criteria, updated codes
12/21/09: Annual review, no changes to the clinical criteria, updated references
12/01/10: Annual review, updated references, no changes to criteria
12/01/11: Annual review, added occipital nerve stimulation for migraines is experimental, updated title, summary, clinical criteria, background information, references and coding sections

**Last Review Date:**
12/01/11

**Next Review Date**
12/01/12
Approval Dates

Regulatory Approval: N/A

Internal Approval:
12/06/05: Initial approval by Q&CMC
02/06/07: Q&CMC
02/19/08: MPCTAC
02/26/08: UMC
03/12/08: QIC
01/27/09: MPCTAC & UMC
02/25/09: QIC
12/23/09: MPCTAC
02/24/10: QIC
12/28/10: MPCTAC
01/26/11: QIC
12/12/11: MPCTAC
12/20/11: QIC

Authorizing entity
QIC

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses the Plan’s determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. The Plan has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered or not covered, this conclusion is not based upon the terms of a member’s particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all services that are determined to be medically necessary will necessarily be covered services under the terms of a member’s benefit plan. Members and their providers need to consult the applicable benefit plan document (e.g., Evidence of Coverage) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this medical policy and the benefit plan document, the provisions of the benefit plan document will govern. In addition, this policy and the benefit plan document are subject to applicable state and federal laws that may mandate coverage for certain services and supplies.