



Brain, Spinal Cord, and Peripheral Nerve Stimulators

LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon
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Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

Deep brain stimulation is a neurosurgical procedure that uses implanted electrodes and electrical stimulation to deliver electrical impulses to specific areas of the brain, depending on the symptoms to be addressed. A burr hole is drilled into the patient's skull and introduces a lead wire into the brain. A neurostimulator is placed subcutaneously in the chest or abdominal wall and the stimulator is activated and programmed to adjust the voltage, frequency, and polarity settings to achieve the best possible outcome.

Spinal cord stimulators (dorsal column and dorsal root ganglion stimulators) uses electrical stimulation to treat multiple indication. **See criteria outlined in Carelon Interventional Pain Management Guideline**

Peripheral Nerve Stimulators (also known as Peripheral Nerve Field Stimulation) are used to electrically stimulate peripheral nerves to relieve severe intractable pain. The Peripheral Nerve Stimulators consists of an implanted receiver, electrodes, and an external transmitter. Implantation is a 2-step process. An initial trial using a temporary electrode is performed to confirm treatment success. If successful pain reduction is reported during this trial, it may be followed by the second phase of permanent implantation.

Criteria

Commercial

Prior authorization is required

I. Implanted Spinal Cord Stimulators (including dorsal column and dorsal root ganglion)

PacificSource considers Implanted Spinal Cord Stimulators, Revisions, and needed Replacements to be medically necessary when the criteria outlined in Carelon Interventional Pain Management Guideline is met.

II. Deep brain stimulation

PacificSource considers deep brain stimulation medically necessary when the following criteria is met:

A. MCG criteria: Neurosurgery or Procedure GRG: GRG: SG-NS (ISC GRG)

III. Implanted Peripheral Nerve Stimulator

A. PacificSource considers Sacral Nerve Stimulation medically necessary when the following criteria is met:

1. MCG criteria: Implanted Electrical Stimulator ACG: A-0645 (AC)

B. PacificSource considers Implanted Peripheral Nerve Stimulators to be medically necessary in a two-phase implementation when **ALL** of the following criteria is met:

1. For Temporary (Trial) Implanted Peripheral Nerve Stimulator:

a. Member is 18 years of age or older

b. Member has at least **ONE** of the following diagnoses:

- Failed back syndrome
- Complex Regional Pain Syndrome
- Craniofacial Pain Syndromes
- Entrapment Neuropathies (Nerve Compression Syndrome or Compression Neuropathy)
- Herpetic Neuropathy
- Intractable Neuropathic Pain
- Plexus avulsion
- Reflex sympathetic dystrophy
- Trigeminal neuralgia

c. Failed conservative management over a six-month period, including **at least three (3)** of the following categories of pharmacotherapy:

- Topical Treatments (e.g., capsaicin and lidocaine)
- Opioids
- Antidepressants

- Anti-epileptic (anticonvulsant) drugs
 - d. Members with neuropathic pain must have tried a stellate ganglion or sympathetic block
 - e. Evaluation and clearance by a mental health provider which revealed no evidence of a behavioral health diagnosis or diagnosis that are not adequately managed (e.g., alcohol or drug dependence, depression, psychosis)
2. PacificSource considers Permanent Peripheral Nerve Stimulator to be medically necessary when **ALL** of the following criteria is met:
- a. The member has met **ALL** the above trial criteria
 - b. The Peripheral Nerve Stimulator trial period was at least 24 hours long with a documented reduction in pain by at least 50%
 - c. Absent of any contraindications listed in Section C
- C. Contraindications** for Temporary **AND** Permanent Peripheral Nerve Stimulator, but not limited to the following:
1. No severe or progressive neurological disorder or history of seizures
 2. No pacemakers, other implanted electrical devices, or brain stimulators
 3. Some types of implanted metal object (e.g., dental implants, aneurysm clips, metallic prostheses, metal pins and rods, heart valves, and cochlear implants, permanent eyeliner, implanted delivery pump, or shrapnel fragments)
 4. No history of coagulopathy, severe thrombocytopenia and/or currently on anticoagulant or antiplatelet therapy
 5. Certain anatomical conditions (e.g., severe spondylolisthesis with stenosis, Scoliosis that creates difficulty with lead steering, previous surgery with epidural scarring)

IV. Revision

PacificSource may consider revision(s) of all, or parts of, an existing Peripheral Nerve Stimulator medically necessary after the device has been placed, to allow for proper functioning of the device.

V. Replacement

PacificSource considers replacement of all, or parts of, an existing Peripheral Nerve Stimulator medically necessary when **ALL** of the following is met:

- A.** Device is malfunctioning
- B.** Device cannot be repaired
- C.** Device is no longer under warranty

Medicaid

PacificSource Community Solutions follows the hierarchical process detailed in the "Clinical Criteria Used in UM Decisions" policy when determining coverage for treatment with brain, spinal cord, and peripheral nerve stimulators. PCS evaluates services based on the relevant coverage guidelines, limitations, and restrictions specified in the OHP Prioritized List of Health Services and its guidelines, as well as any applicable Oregon Administrative Rules (OARs).

PacificSource follows the “Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)” criteria for members under 21 and Young Adults with Special Health Care Needs (YSHCN).

Medicare

PacificSource Medicare follows National Coverage Determination (NCD) 160.7 for Electrical Nerve Stimulators.

PacificSource Medicare follows National Coverage Determination (NCD) 160.7 and Local Coverage Determination (LCD) L37360 for peripheral nerve stimulation.

Experimental/Investigational/Unproven

PacificSource considers peripheral nerve stimulation experimental, investigational, or unproven for all other indications.

PacificSource considers the ReActiv8 Implantable Neurostimulation System to be experimental, investigational, or unproven.

PacificSource considers peripheral subcutaneous field stimulation (e.g., Sprint PNS System) to be experimental, investigational, or unproven.

Note: PacificSource Community Solutions (PCS) and PacificSource Medicare require items listed on this policy’s E/I/U list, to be reviewed by medical necessity review guidelines. Please see related policy, “Clinical Criteria Used in UM Decisions” to review criteria hierarchy and “Medical Necessity Reviews” for determination of coverage and medical necessity guidelines.

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

CPT Codes:

- 61863 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
- 61864 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
- 61867 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of Neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode
- 61868 Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, Globus pallidum, subthalamus nucleus, periventricular, periaqueductal gray), with use of intraoperative

microelectrode recording; each additional array (List separately in addition to primary procedure)

- 61880 Revision or removal of intracranial neurostimulator electrodes
- 61885 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
- 61886 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
- 61888 Revision or removal of cranial neurostimulator pulse generator or receiver
- 64553 Percutaneous implantation of neurostimulator electrode array; cranial nerve
- 64555 Percutaneous implantation of neurostimulator electrode array peripheral nerve (excludes sacral nerve)
- 64575 Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
- 64585 Revision or removal of peripheral neurostimulator electrode array
- 64590 Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
- 64595 Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array

HCPCS Codes:

- L8679 Implantable neurostimulator, pulse generator, any type
- L8680 Implantable neurostimulator electrode, each
- L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
- L8682 Implantable neurostimulator radiofrequency receiver
- L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
- L8685 Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
- L8686 Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
- L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
- L8688 Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
- L8689 External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
- L8695 External recharging system for battery (external) for use with implantable neurostimulator, replacement only

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS)

Definitions

Deep brain stimulation- consists of the delivery of electrical impulses to specific areas of the brain, depending on the symptoms to be addressed.

Essential tremors is a progressive neurological movement disorder. It is characterized primarily by an action and postural tremor most often affecting the arms, but it can also affect other body parts.

Fluoroscopy- an x-ray that produces real-time video images for procedural interventions.

Neuropathic pain- numbness, tingling, burning, or shooting pain that is often degenerative resulting from damage, disease, or dysfunction of one or more nerves.

Nociceptive pain- aching, throbbing, dull or sharp pain arising from receptors for tissue injury which are mostly located in the skin and internal organs.

Paresthesia- an abnormal sensation of the body, such as numbness, tingling or burning that is usually felt in the hands, arms, legs, or feet.

Peripheral implantable stimulation (PNS)- is a small electrical device placed next to the peripheral nerves in the subcutaneous tissue. PNS differs from PNFS and PSFS, as it targets a specific nerve, rather than a general area.

Peripheral nerve field stimulation (PNFS)- is a technology proposed for the treatment of chronic cervical, thoracic, or lumbar pain. Electrode leads are placed in subcutaneous tissue around the painful area, and electrical current is applied to create stimulation in the area, or "field" of pain.

Peripheral Subcutaneous Field Stimulation (PSFS)- is a modification of peripheral nerve stimulation and is similar to PNS, except PSFS involves electrical stimulation via electrodes implanted under the skin over the area of maximal pain, rather than targeting the nerve thought to be the origin of the pain, as is done in PNS.

Visceral pain- pain that arises from, in, or around internal organs.

Visual Analogue Scale (VAS)- a measurement instrument for acute and chronic pain, recorded by marking on a 10-cm line that represents a continuum between "no pain" and "worst pain".

Related Policies

Bariatric Surgery

Clinical Criteria Used in UM Decisions

Clinical Resources Used for Medical Necessity Determinations When No Other UM Clinical Criteria or Guideline Exists

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)

Epilepsy Surgery

Gastric Pacing and Gastric Electrical Stimulation (GES) for Gastroparesis

New and Emerging Technologies – Coverage Status

Sleep Disorder Treatment

Thalamotomy

Transcranial Magnetic Stimulation

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Appendix

Policy Number:

Effective: 9/1/2021

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Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): NCD 160.7, LCD L34328, Oregon Administrative Rules 410-141-3820, 410-141-3825, 410-151-0001, 410-151-0002, 410-151-0003, 410-120-1200

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