



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 <input type="checkbox"/> Washington
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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

Spinal cord stimulators, also known as dorsal column stimulation, involves the use of low-level epidural electrical stimulation of the spinal cord dorsal column, creating a paresthesia to alter the perception of pain. Spinal Cord Stimulators has been used in a wide variety of chronic refractory pain conditions, including complex regional pain syndrome, failed back surgery syndrome, critical limb ischemia, which is a non-destructive and reversible procedure. Spinal Cord Stimulators are indicated for cervical, thoracic, and lumbar spine.

Dorsal root ganglion stimulators are a more specific implanted Spinal Cord Stimulators that may be used to treat pain that starts in a lower part of the body (e.g., foot, knee, hip, and groin). Dorsal root ganglions are spinal structures densely populated with sensory nerves that transmit information to the brain via the spinal column.

Both Spinal Cord Stimulator and Dorsal root ganglion stimulator implantation requires a surgical procedure, conducted in two phases initiated with a trial period of Spinal Cord / Dorsal Root Ganglion Stimulators with a temporarily implanted lead. If successful pain reduction is reported during this trial, it may be followed by the second phase of permanent implantation.

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 with electrodes that are placed around a peripheral nerve 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. Spinal Cord Stimulators; including Dorsal Root Ganglion Stimulators

PacificSource considers Spinal Cord and Dorsal Root Ganglion Stimulators to be medically necessary in a two-phase implementation when the following criteria is met:

A. For Temporary (Trial) Spinal Cord Stimulators:

1. Member has chronic neuropathic or ischemic pain due to at least **ONE** of the following diagnoses:
 - a. Complex regional pain syndrome
 - b. Failed back surgery syndrome
 - c. Critical limb ischemia

OR

B. For Temporary (Trial) Dorsal Root Ganglion Stimulators

1. The member has moderate to severe chronic intractable pain of the lower limbs due to diagnosis of complex regional pain syndrome (CRPS)

AND

C. ALL of the below criteria is met for both Spinal Cord Stimulators and Dorsal Root Ganglion Stimulators:

1. Imaging reports correlate with pain complaint or rules out other sources of pain (e.g., abnormal MRI);
2. Evidence of objective neurological impairment (e.g., abnormal reflexes, muscle weakness, segmental sensory loss, neurogenic bowel or bladder, long tract abnormalities)
3. Member has failed 12 or more months of conservative treatment modalities (e.g., pharmacological, surgical, physical therapy, cognitive therapy)
4. Evaluation and clearance by a mental health provider which revealed no evidence of a behavioral health diagnosis or a diagnosis that is not adequately managed (e.g., alcohol or drug dependence, depression, psychosis)
5. Absent of any contraindications listed below in Section E

D. PacificSource considers Permanent Spinal Cord Stimulators and Dorsal Root Ganglion Stimulators medically necessary when **ALL** of the following criteria is met:

1. The member has met **ALL** the above trial criteria
2. Member experienced significant pain reduction (reduced by at least 50%) with the trial of spinal stimulation
3. Absent of any contraindications listed below in Section E

E. **Contraindications** for Temporary **AND** Permanent Spinal Cord or Dorsal Root Ganglion Stimulators, 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)

II. **Implanted Peripheral Nerve Stimulator**

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

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

1. Member is 18 years of age or older
2. Member has at least **ONE** of the following diagnoses
 - a. Failed back syndrome
 - b. Complex Regional Pain Syndrome
 - c. Craniofacial Pain Syndromes
 - d. Entrapment Neuropathies (Nerve Compression Syndrome or Compression Neuropathy)
 - e. Herpetic Neuropathy
 - f. Intractable Neuropathic Pain
 - g. Plexus avulsion
 - h. Reflex sympathetic dystrophy
 - i. Trigeminal neuralgia
3. Failed conservative management over a six-month period, including at least **3** of the following categories of pharmacotherapy:
 - a. Topical Treatments (e.g., capsaicin and lidocaine).
 - b. Opioids.

- c. Antidepressants.
 - d. Anti-epileptic (anticonvulsant) drugs.
 - 4. Members with neuropathic pain must have tried a stellate ganglion or sympathetic block.
 - 5. 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).
- B. PacificSource considers **Permanent Peripheral Nerve Stimulator** to be medically necessary when **ALL** of the following criteria is met:
 - 1. The member has met **ALL** the above trial criteria
 - 2. The Peripheral Nerve Stimulator trial period was at least 24 hours long with a documented reduction in pain by at least 50%
 - 3. 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)

III. Revision

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

IV. Replacement

PacificSource considers replacement of all, or parts of, an existing Spinal Cord Stimulator, Dorsal Root Ganglion Stimulator, or 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 Guideline Note 178 of the OHP Prioritized List of Health Services for Spinal Cord Stimulation.

PacificSource Community Solutions (PCS) follows Oregon Health Plan (OHP) Oregon Administrative Rules (OARs) 410-141-3820 to 3830, 410-151-0000 to 0003, and 410-120-1200 for coverage of Implanted Peripheral Nerve Stimulator.

PacificSource Community Solutions (PCS) follows Guideline Note 173 of the Oregon Health Plan (OHP) Prioritized List of Health Services for coverage of the associated CPT code 64555 to have insufficient evidence of effectiveness.

Medicare

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

PacificSource Medicare follows National Coverage Determination (NCD) 160.7 and Local Coverage Determination (LCD) L34328 for peripheral nerve stimulation.

Experimental/Investigational/Unproven

PacificSource considers dorsal column stimulation to be experimental, investigational, or unproven for all other indications including, but not limited to the following:

- Cancer-related pain
- Nociceptive pain
- Post -herpetic neuralgia
- Refractory angina pectoris
- Visceral pain

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

PacificSource considers Spinal Cord Stimulation for the treatment of diabetic peripheral neuropathy to be experimental, investigational, or unproven

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

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:

- 63650 Percutaneous implantation of neurostimulator electrode array, epidural
- 63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
- 63663 Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed

- 63664 Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
- 63685 Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
- 63688 Revision or removal of implanted spinal neurostimulator pulse generator or receiver, with detachable connection to electrode array
- 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

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

New and Emerging Technologies – Coverage Status

References

Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electrical Nerve Stimulators (106.7) <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&DocID=160.7&SearchType=Advanced&bc=IAAAABAAAA&>

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Appendix

Policy Number:

Effective: 9/1/2021

Next review: 6/1/2025

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): NCD 160.7, LCD L34328, Oregon Administrative Rules 410-141-3820 through 3830, 410-151-0000 through 410-151-0003, & 410-120-1200. Guideline Notes 173 and 178 of the Oregon Health Plan (OHP) Prioritized List of Health Services.

Commercial OPs: 5/2024

Government OPs: 5/2024