



Implanted Peripheral Nerve Stimulators

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:	LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
--	---

Enterprise Policy

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 determination 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

Implanted peripheral nerve stimulators (PNS), also known as Peripheral Nerve Field Stimulation (PNFS), are used to electrically stimulate peripheral nerves (PN) to relieve severe intractable pain. The PNS 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, which is defined as at least 50% reduction in reported pain levels. Following a successful trial, permanent subcutaneous electrodes are placed in the area of maximum pain and are connected to an implantable receiver. The patient controls the amount of stimulation using an external transmitter.

Criteria

Commercial

Prior authorization is required.

The evaluation of medical necessity for placement of a permanent peripheral nerve stimulator requires a two (2)-step process:

1. The evaluation for medical necessity for a Peripheral Nerve Stimulators (PNS) trial; and
2. The evaluation of medical necessity for the permanent implantable PNS.

Indications for trial:

PacificSource considers a trial period for PNS medically necessary when **ALL** of the following criteria are met:

1. Member is 18 years of age or older; and
2. Member has at least one of the following conditions:
 - 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 (such as 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. A comprehensive behavioral health evaluation is completed by a master's level or higher behavioral health professional that specifically assesses for the presence of somatic symptom disorder (and related disorders as described in the DSM 5) and recommends or agrees with PNS trial;
 6. No severe or progressive neurological disorder or history of seizures;
 7. Patient capable of operating stimulating device;
 8. No pacemakers or other implanted electrical devices, brain stimulators, some types of dental implants that contain metal, aneurysm clips metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments;
 9. No history of coagulopathy, severe thrombocytopenia and/or currently on anticoagulant or antiplatelet therapy; and
 10. No current or chronic infection.

Indications for Implantation of PNS

Implantable Peripheral Nerve Stimulators (PNS) (permanent nerve stimulators) may be indicated when the following is present:

1. The member has met all the above PacificSource trial criteria or would have met the trial criteria (if member had a trial before having PacificSource coverage);
2. The PNS trial period was at least 24 hours long with a documented reduction in pain by at least 50%; and
3. No contraindications for implantation per the above trial criteria.

Medicaid

PacificSource Community Solutions (PCS) follows Oregon Health Plan (OHP) Oregon Administrative Rules (OARs) 410-141-3820 to 3825 & 410-120-1200 for coverage of Implanted Peripheral Nerve Stimulator.

Medicare

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

Experimental/Investigational/Unproven

PacificSource considers peripheral nerve stimulation, which includes PNS, PNFS and PSFS, experimental, investigational or unproven for all other indications because its effectiveness has not been established.

Definitions

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.

Coding Information

- 64553 Percutaneous implantation of neurostimulator electrode array; cranial nerve
- 64555 Percutaneous implantation of neurostimulator electrode array peripheral nerve (excludes sacral nerve)
- 64575 Incision for 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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- 64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
- 95970 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- 95972 complex spinal cord, or peripheral neurostimulator pulse generator/transmitter with intraoperative or subsequent programming, first hour
- 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, non-rechargeable, includes extension
- L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
- L8688 Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
- L8689 External recharging system for battery (internal) for use with implantable neurostimulator
- L8695 External recharging system for battery (external) for use with implantable neurostimulator, replacement only

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=IAAABAAAA&>

Deer, TR., et al. (2010) Prospective clinical study of a new implantable peripheral nerve stimulation device to treat chronic pain. *Clin J Pain*. 2010 Jun;26(5):359-72. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 06/30/2020, 4/2/2021.

<http://www.ncbi.nlm.nih.gov/pubmed/20473041>

Gronseth, G. et al (2008) Practice Parameter: The diagnostic evaluation and treatment of trigeminal neuralgia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology and the European Federation of Neurological Societies. *Neurology* October 7, 2008 71(15); 1183-1190. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 6/30/2020, 4/2/2021.

<http://www.neurology.org/content/71/15/1183.full.pdf+html>.

Hayes Search & Summary. Peripheral Nerve Stimulation for Treatment of Back Pain. Winifred Hayes, Lansdale, PA. Accessed 4/30/2019, 4/2/2021.

Kloimstein, H. et al (2014) Peripheral nerve field stimulation (PNFS) in chronic low back pain: a prospective multicenter study. *Neuromodulation*. 2014 Feb;17(2):180-7. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 6/30/2020, 4/2/2021.

<http://www.ncbi.nlm.nih.gov/pubmed/24320718>

Mobbs R J et al (2005). Peripheral nerve stimulation for the treatment of chronic pain. *Journal of Clinical Neuroscience* 14 (2007) 216–221. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 6/30/2020, 4/2/2021.

<https://www.neuromodulation.com/PNS#:~:text=Peripheral%20nerve%20stimulation%2C%20frequently%20referred,the%20brain%20or%20spinal%20cord>).

National Institute for Health and Care Excellence (NICE). Interventional procedure guidance [IPG450] Percutaneous electrical nerve stimulation for refractory neuropathic pain. Published March 2013. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 6/30/2020, 4/2/2021.

<http://www.nice.org.uk/guidance/IPG450>

Rasskazoff, SY et al (2012) An update on peripheral nerve stimulation. *Peripheral neuromodulation for pain. Journal of Clinical Neuroscience* 2009; 16:1259-61

Sharma M et al (2014) Surgical Options for Complex Craniofacial Pain. Neurosurg Clin N Am. 2014 Oct;25(4):763-775. doi: 10.1016/j.nec.2014.07.001. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 6/30/2020, 4/2/2021.

<http://www.ncbi.nlm.nih.gov/pubmed/25240663>

Shaw A. et al (2014) Novel Tunneling System for Implantation of Percutaneous Nerve Field Stimulator Electrodes: A Technical Note. Neuromodulation. 2014 Aug 14. doi: 10.1111/ner.12224. Accessed 10/16/2017, 9/26/2018, 9/4/2019, 6/30/2020, 4/2/2021.

<http://www.ncbi.nlm.nih.gov/pubmed/25123149>

Appendix

Policy Number:

Effective: 7/1/2020

Next review: 6/1/2022

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): NCD 160.7, LCD L34328

Commercial Ops: 6/2021

Government Ops: 6/2021