MEDICAL POLICY – 7.01.574

Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain of Peripheral Nerve Origin

Effective Date: Nov. 1, 2019
Last Revised: July 9, 2019
Replaces: N/A

RELATED MEDICAL POLICIES:
1.01.507 Electrical Stimulation Devices
7.01.20 Vagus Nerve Stimulation
7.01.29 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
7.01.69 Sacral Nerve Neuromodulation/Stimulation
7.01.125 Occipital Nerve Stimulation
7.01.139 Peripheral Subcutaneous Field Stimulation
7.01.522 Gastric Electrical Stimulation
7.01.546 Spinal Cord and Dorsal Root Ganglion Stimulation
8.01.58 Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Peripheral nerves are the nerves that connect the brain and the spinal cord to the body. One way of trying to control pain that arises from peripheral nerves calls for implanting a device that sends low levels of electricity to stimulate part(s) of the nerve. This electrical current is thought to interfere with how the nerve transmits pain signals. Stimulating part(s) of a peripheral nerve to try to treat pain is investigational. That means this technique needs more study to see if it is safe and effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
# Policy Coverage Criteria

## Procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implantable peripheral nerve stimulation</strong></td>
<td>A trial or permanent placement of an implantable peripheral nerve stimulator for the management of chronic pain of peripheral nerve origin is investigational for all indications.</td>
</tr>
</tbody>
</table>

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
</tr>
<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension</td>
</tr>
<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
</tbody>
</table>

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Related Information

**Example of patient components for the Bioness® StimRouter™**

- **StimRouter Lead**: The StimRouter Lead is flexible and approximately 15 cm (6 inches) in length. The lead has a stimulation end and a receiver end. The stimulation end is implanted near or at the targeted peripheral nerve and the receiver end is implanted near the skin surface. The receiver end receives the stimulation signal from the external pulse transmitter (EPT) and then sends the signal through the lead to the stimulation end.

- **StimRouter External Pulse Transmitter (EPT)**: The StimRouter EPT generates the stimulation signal and transmits the signal through the StimRouter Electrode to the StimRouter Lead. The EPT snaps onto the StimRouter Electrode and responds to wireless commands from the Patient Programmer.

- **StimRouter Electrode**: The StimRouter Electrode features: Two gel pads that adhere the StimRouter Electrode to the skin. The gel pads also transmit the stimulation signal from the EPT to the receiver end of the lead.
  - The StimRouter Electrode is disposable and can be reused by the same patient as long as the gel pads are intact and can fully adhere to the skin or for a maximum of four days of use.

- **Patient Programmer**: The Patient Programmer communicates wirelessly with the EPT (external pulse transmitter). The Patient Programmer is used to turn stimulation on and off, to adjust the stimulation intensity and to select a stimulation program.
**Contraindications:** Patients who have any active implanted devices such as an implanted demand cardiac pacemaker, implantable cardioverter defibrillator (ICD), other implanted active devices, or any metallic implant in the immediate area intended for implant.


**Evidence Review**

**Description**

Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation therapy in which electrodes are surgically placed next to a selected peripheral nerve considered to be the source of chronic pain. (Peripheral nerves are nerves located outside of the brain and spinal cord). In this type of treatment, the electrode(s) delivers electrical impulses to the affected nerve. This electrical current is thought to then disrupt the normal transmission of pain signals leading to reduced levels of pain.
Background

Peripheral nerve stimulation is similar to spinal cord stimulation in that it is typically a two-step process. Initially, a temporary electrode is temporarily implanted for a trial period, usually less than 5 days. The electrode is connected to an external device, and if it successfully reduces the pain by at least 50%, then either a multi-electrode lead is permanently implanted and connected to a pulse generator placed in the body or the electrode responds to a hand-held, wireless external pulse transmitter that patients control according to their pain management needs via a patient programmer.

Implantable peripheral nerve stimulation differs from other electrical stimulation therapies in that the origin of pain is from a peripheral nerve and the electrical impulses are delivered directly to the nerve versus the surrounding tissues or spine.

Other electrical stimulation therapies:

- Spinal cord stimulation delivers electrical impulses to the spine.
- Transcutaneous electrical nerve stimulation (TENS) delivers electrical impulses to the surface of the skin at the site of pain.
- Percutaneous electrical nerve stimulation (PENS) delivers electrical impulses via needle electrodes inserted into the skin around or immediately adjacent to the nerves serving the painful area. The stimulation devices used in percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted.
- Percutaneous neuromodulation therapy (PNT) delivers electrical impulses through very thin filament electrode arrays inserted directly into the deep tissues near the area causing the pain.
- Peripheral subcutaneous field stimulation (PSFS) delivers electrical impulses via electrodes placed subcutaneously under the skin over the area of maximal pain. In peripheral nerve field stimulation, a field of pain is targeted rather than specific nerves.

Chronic pain of peripheral nerve origin is experienced by many; however, its etiology is not clearly known, making treatment of this type of pain challenging. Currently available treatment strategies are often insufficient to treat chronic pain of peripheral nerve origin, prompting a renewed interest in the use of neuromodulation techniques in the treatment of chronic pain of peripheral nerve origin that is refractory to first-line treatments such as analgesics, antidepressants, anticonvulsants, and physical therapy.
Peripheral nerve stimulation was first introduced in the mid-1960s. Since that time, it has been investigated in the treatment of low back pain, headaches, median nerve neuropathy, ilio-inguinal neuralgia, trigeminal neuralgia, and complex regional pain syndrome and approved for use in Europe and Australia. It is however, considered “off-label” in the United States.¹

Summary of Evidence

For individuals with chronic pain of peripheral nerve origin, the evidence includes a randomized controlled trial (RCT), an open label trial, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life and treatment-related morbidity. The single randomized controlled trial, which used a crossover design, did not compare peripheral nerve stimulation (PNS) with alternatives. Improvement in pain was statistically significant between the randomized groups and again in the partial crossover period. Efficacy was evaluated for 3 months. Safety was assessed through one-year follow-up with no serious adverse events related to the device.³ However, the results need confirmation in larger sample sizes and additional RCTs with longer follow-up to draw conclusions on safety and efficacy.

The open label study had methodological limitations including, a small sample size of 8 patients with carpal tunnel syndrome, and no mention of follow-up after the device was explanted after five days of treatment.²

Case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of pain outcomes. Prospective controlled trials comparing PNS to alternative treatment modalities are needed to determine the efficacy of PNS for chronic pain of peripheral nerve origin. There are no evidence-based clinical practice guidelines that recommend the use of implantable peripheral nerve stimulation for treatment of chronic pain of peripheral nerve origin. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02873312</td>
<td>Overactive Bladder Treatment Using StimRouter Neuromodulation System: A Prospective Randomized Trial</td>
<td>180</td>
<td>Dec 2019</td>
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<tr>
<td>NCT03093935</td>
<td>StimRouter™ for Pain Management in Post-Stroke Shoulder Pain (PSSP)</td>
<td>50</td>
<td>Sep 2020</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

* Denotes industry-sponsored trial

**Medicare National Coverage**

Medicare has a national coverage determination for Electrical Nerve Stimulators (160.7) for implanted peripheral nerve stimulators since 1995.4


Peripheral nerve stimulation (PNS) may be covered for relief of chronic intractable pain for patients with conditions known to be responsive to this form of therapy, and only after attempts to cure the underlying conditions and appropriate attempts at medication management, physical therapy, psychological therapy and other less invasive interdenominational treatments. As with spinal nerve stimulators, severe neuropathic pain is typically well suited for successful responses to PNS. There may be rare selected situations where both spinal cord stimulators and peripheral neurostimulators are used together.

**Regulatory Status**

In February 2015 the U.S. Food and Drug Administration (FDA) granted 510 (k) marketing clearance for the StimRouter™ Neuromodulation System (Bioness®). (K142432). It is not intended to treat pain in the craniofacial region.

In March 2016, the FDA determined the StimQ Peripheral Nerve Stimulator (PNS) System (StimQ LLC) was substantially equivalent to predicate devices (K152178). It is not intended to treat pain in the craniofacial region.


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/01/19</td>
<td>New policy, approved July 9, 2019, effective November 1, 2019. Add to Surgery section. Implantable peripheral nerve stimulation for the treatment of chronic pain of peripheral nerve origin is investigational.</td>
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U.S. Department of Health and Human Services
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Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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