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Medical Policy Manual Surgery, Policy No. 205

Implantable Peripheral Nerve Stimulation for Chronic Pain of Peripheral Nerve Origin

Effective: January 1, 2019

Next Review: January 2019
Last Review: December 2018

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Implantable peripheral nerve stimulation (PNS) for chronic pain of *peripheral nerve origin* is a type of neuromodulation therapy that involves the surgical implantation of electrodes that target *peripheral nerves considered to be the origin of pain*. This procedure differs from other forms of PNS, because the origin of pain is from a peripheral nerve and the electrical impulses are delivered to the nerve versus surrounding tissues or the spine.

MEDICAL POLICY CRITERIA

Notes:

- This policy only applies to the initial placement of the device. This policy does not apply to revision(s) or replacement(s) after the device has been placed.
- This policy only addresses implantable peripheral nerve stimulation (PNS) (e.g., StimRouter) for chronic pain of peripheral nerve origin. Please refer to the Cross References below for other specific neuromodulation or stimulation therapies.

Implantable peripheral nerve stimulation (PNS) for chronic pain of peripheral nerve origin is **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83
2. Spinal Cord and Dorsal Root Ganglion Stimulation, Surgery, Policy No. 45
3. Deep Brain Stimulation, Surgery, Policy No. 84
4. Occipital Nerve Stimulation, Surgery, Policy No. 174
5. Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. 44
6. Peripheral Subcutaneous Field Stimulation, Surgery, Policy No. 188

BACKGROUND

Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation that delivers electrical impulses *directly to a nerve*.

Implantable PNS therapies have been around since the 1960's.[1] There are several implantable PNS neuromodulation therapies that use electrical stimulation for pain.[2] Examples include, but are not limited to: occipital nerve stimulation (ONS) and spinal cord stimulation (SCS).The StimRouter, an implantable PNS system is being marketed specifically for chronic pain *of peripheral nerve origin* i.e. upper/lower limb pain, entrapment syndromes, intercostal neuralgias and other peripheral injuries or diseases.[3] Although SCS addresses pain in the truck and limbs, the electrodes for SCS deliver electrical stimulation to the spine versus directly to the peripheral nerve pain site like the StimRouter.[4]

PNS systems vary from other electrical stimulation therapies.

- Transcutaneous electrical nerve stimulation (TENS) delivers impulses below the skin, to alleviate pain.
- Percutaneous electrical nerve stimulation (PENS) is similar to TENS, except PENS requires electrodes to be inserted into the skin.
- Percutaneous neuromodulation therapy (PNT) is similar to PENS. PNT is an electrical stimulation therapy in which *10 fine filament electrodes* are temporarily placed in the deep tissues *near the area causing pain* (with or without radiating lower extremity pain).
- Peripheral subcutaneous field stimulation (PSFS) is electrical stimulation via electrodes implanted *under the skin over the area of maximal pain* for patients with chronic intractable pain.

REGULATORY STATUS

The Bioness® StimRouter™ received FDA 510K approval in February 2015.[5]

EVIDENCE SUMMARY

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain can be a subjective outcome associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect and determine if an implanted peripheral nerve stimulation (PNS) system for chronic pain of peripheral nerve origin provides a significant advantage over placebo.

Treatment with an implanted PNS system to treat chronic pain of peripheral nerve origin must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an implanted peripheral nerve stimulation (PNS) system to treat chronic pain of peripheral nerve origin should be compared to other forms of conservative therapy such as rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

Systematic Reviews

There were no systematic reviews identified.

Randomized Controlled Trials

Deer (2015) published a multicenter, randomized, double-blinded, partial crossover study addressing the safety and efficacy of the StimRouter™ neuromodulation system for 94 patients with chronic pain of peripheral nerve origin (upper or lower extremity or truck).[6] The patients were assigned to the StimRouter™ group (n=45) or the control group (n=49). Efficacy was evaluated for three months and safety for one year. Primary outcomes included pain relief and safety. At three months the StimRouter™ group reported 27.2% pain reduction vs. the control group 2.3%. Fifty-one percent of patients did not follow-up at one year. No serious adverse events were reported related to the device. A significant limitation of the study is the small sample size and large loss to follow-up.

Nonrandomized Studies

Deer and Rosenfeld (2010) published the results of a single-center open-label study in which eight patients with carpal tunnel syndrome were evaluated for pain relief from the StimRouter™. Pain evaluation occurred before implant, during implant and after explant. The authors concluded the StimRouter™ was effective and safe for pain reduction from carpal tunnel syndrome, but the study had methodological limitations including a small sample size and no mention of follow-up after the StimRouter™ was explanted after five days of treatment.

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of implanted percutaneous neuromodulation therapy for the treatment of pain of peripheral nerve origin.

SUMMARY

There is not enough research to show that an implantable percutaneous neuromodulation stimulation (PNS) system for treatment of chronic pain of peripheral nerve origin improves health outcomes. There are no evidence-based clinical practice guidelines that recommend the use of an implantable PNS system for treatment of chronic pain of peripheral nerve origin. Therefore, the use of an implantable PNS system for treatment of chronic pain of peripheral nerve origin is considered investigational.

REFERENCES

1. Society, In. Peripheral Nerve Stimulation. 2012 [cited 10/18/2017]; Available from: http://www.neuromodulation.com/PNS

2. Society, In. Neuromodulation Therapies - Patient Information. 2012 [cited 10/18/2017]; Available from: http://www.neuromodulation.com/therapies
3. Bioness. StimRouter. 2017 [cited 10/18/2017]; Available from: http://stimrouter.com/
4. Bioness. Control Your Pain, Live Your Life. 2017 [cited 10/18/2017]; Available from: http://www.stimrouter.com/dtcinquiries/?utm_source=PPC&utm_medium=Ads&utm_campaign=WP_StimRouter_Brand&gclid=EAIaIQobChMI5Nf3y_H61gIVwSWBCh0C6A8JEAAYASAAEgLRRfD_BwE
5. (FDA), USFaDA. StimRouter Neuromodulation System. 2015 [cited 10/17/2017]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142432.pdf
6. Deer, T, Pope, J, Benyamin, R, et al. Prospective, Multicenter, Randomized, Double-Blinded, Partial Crossover Study to Assess the Safety and Efficacy of the Novel Neuromodulation System in the Treatment of Patients With Chronic Pain of Peripheral Nerve Origin. *Neuromodulation : journal of the International Neuromodulation Society*. 2016 Jan;19(1):91-100. PMID: 26799373

CODES

Codes	Number	Description
CPT	~~64550~~	~~Application of surface (transcutaneous) neurostimulator (eg, TENS unit)~~ (Deleted 1/1/2019)
	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
	64999	Unlisted procedure, nervous system
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulsewidth, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	;with simple spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter, t programming by physician or other qualified health care professional
	95972	;with complex spinal cord, or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	95973	;complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

	~~95974~~	~~;complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour~~ (Deleted 1/1/2019)
	~~95975~~	~~;complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)~~ (Deleted 1/1/2019)
	95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	95977	;with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	~~95978~~	~~Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour~~ (Deleted 1/1/2019)
	~~95979~~	~~,complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour (List separately in addition to code for primary procedure)~~ (Deleted 1/1/2019)
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	C1778	Lead, neurostimulator (implantable)
	L8680	Implantable neurostimulator electrode, each
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

Date of Origin: *January 2018*