Implantable Peripheral Nerve Stimulation for Chronic Pain of Peripheral Nerve Origin

Effective: March 1, 2020

Next Review: January 2021
Last Review: January 2020

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

Note: 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 considered investigational.

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

1. Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. 44
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. 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 1960s.[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 Neuromodulation System™ received FDA 510(k) approval in February 2015[5] and in October 2019.[6]

In March of 2016, the StimQ Peripheral Nerve Stimulator (PNS) System received FDA 510(k) approval.[7]

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 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 trunk).[8] 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**

A multi-center, prospective case series published by Oswald (2019) evaluated outcomes in 39 patients implanted with the StimRouter™ on various isolated mononeuropathies.[9] The authors report 78% of the participants noted an improvement in pain, 72% noted improvement in activity, and 89% experienced a greater than 50% reduction in opioid consumption. This was not a controlled trial and no information comparing these outcomes to outcomes achieved through standard of care was provided. Future RCTs addressing these limitations are required.

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

4. Control Your Pain, Live Your Life. [cited 1/14/2020]; Available from: http://www.stimrouter.com/dtcinquiries/?utm_source=PPC&utm_medium=Ads&utm_campaign=WP_StimRouter_Brand&gclid=EAIaIQobChMI5Nf3y_H61glVwSWBCh0C6A8JEAAYASAEqLRRfD_BwE

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*Date of Origin:* January 2018