Implantable Peripheral Nerve Stimulation for Chronic Pain of Peripheral Nerve Origin

Effective: April 1, 2021

Next Review: January 2022
Last Review: February 2021

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®, SPRINT®) 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.
Peripheral nerve stimulation (PNS) systems vary from other electrical stimulation therapies.

- Transcutaneous electrical nerve stimulation (TENS) delivers impulses across the skin to alleviate pain. PNS is similar to TENS, except PNS requires electrodes to be inserted under the skin and targets a nerve considered to be the origin of the pain.

- Percutaneous neuromodulation therapy (PNT) is an electrical stimulation therapy in which fine filament electrodes are temporarily placed in the tissues near the area causing pain. PNS is similar to PNT, except PNS requires electrodes to be inserted under the skin and targets a nerve considered to be the origin of the pain.

- Peripheral subcutaneous field stimulation (PSFS) 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. PNS devices (e.g. the SPRINT® PNS System) are sometimes used off-label for PSFS.

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]

REGULATORY STATUS

In July 2018, the SPRINT® Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K181422).[5] The SPRINT® PNS System is not intended to treat pain in the craniofacial region.

In March of 2016, the StimQ Peripheral Nerve Stimulator (PNS) System received FDA 510(k) approval. The StimQ PNS System is not intended to treat pain in the craniofacial region.

**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**

In an industry-sponsored randomized controlled trial (RCT) published by Gilmore (2019), 28 lower-extremity amputees with postamputation pain were randomized to PNS or placebo for four weeks. A significantly greater proportion of subjects receiving PNS (n=7/12, 58%, p=0.037) demonstrated ≥50% reductions in average postamputation pain up to four weeks compared with subjects receiving placebo (n=2/14, 14%). In addition, a significantly greater proportion of PNS subjects reported ≥50% reductions in pain and pain interference after eight weeks of therapy compared with subjects receiving placebo, however the partial crossover design of this study prevents evaluation of placebo effects beyond four weeks. Twelve-month follow-up is ongoing. Overall, the study is limited by a small sample size which limits generalizability.

The results of an RCT of PNS compared to usual care (UC) for hemiplegic shoulder pain was published by Wilson (2016). The study included 25 participants (12 PNS and 12 UC). Although pain reduction with PNS treatment group was reported as significantly greater than the UC group, the per-protocol analysis of 21 participants showed significant reductions in pain in both groups and no significant slope difference between groups during the study. In addition, no significant group differences were observed for secondary outcome measures including pain interference, physical functioning, and global success rates. The authors concluded that additional RCTs are needed to determine treatment effectiveness.

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). 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

Warner (2020) published a retrospective case series of 72 patients who had undergone PNS implantation for treatment of various indications including occipital neuralgia (47%) and lower-extremity neuropathies (17%).[13] Six-month outcomes were assessed by numerical rating scale pain scores, opioid utilization, and self-reported functioning. Infection and device-related complications were also assessed. PNS implantation was associated with reductions in pain scores (p<0.001) and opioid utilization (p<0.001). Postoperative surgical site infection was found in ten percent of patients leading to device removal in five patients. No comparison to standard of care was provided.

A retrospective chart review including data from 240 patients implanted with a PNS, 165 of whom were being treated for complex regional pain syndrome, was published by Chmiela in 2020.[14] Median length of follow-up was 74 months. Pain scores at 12-month follow-up were decreased by an estimated 1.87 points (95% CI: [1.29, 2.46], paired t-test p<0.001). The percentage of patients on chronic opioid therapy decreased over 12 months from 62% to 41%. Of the 126 patients who reported changes in functional status, 64 (51%) reported improvement, 27 (21%) reported worsening, and 35 (28%) did not report any meaningful change. Excluding end-of-life battery replacements, surgical revision was needed in 56 (34%) of patients. Thirteen patients (8%) underwent implantation of a second PNS due to symptomatic expansion outside of the original region and device explant was performed in 32 (19%) of patients.

A multi-center, prospective case series published by Oswald (2019) evaluated outcomes in 39 patients implanted with the StimRouter™ on various isolated mononeuropathies.[15] 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.

Ilfeld (2017) published a review evaluating the safety of lead types in clinical studies of percutaneous neurostimulation of the peripheral nervous system.[16] Forty-three studies were included and of these both coiled (n = 21) and noncoiled (n = 25) leads were studied. The infection rates were estimated to be 0.03 (95% CI 0.01 to 0.13) infections per 1,000 indwelling days for coiled leads and 0.83 (95% CI 0.16 to 4.33) infections per 1,000 indwelling days for noncoiled leads. No information is provided in the publication regarding clinical outcomes other than infection rates and no control group is evaluated.

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™.[17] 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.
Numerous additional case series and case studies been published on PNS for the treatment of conditions including complex regional pain syndrome,[18] chronic shoulder pain,[19] chronic low back pain,[20] peripheral neuralgia[21] oncologic pain,[22] and trigeminal pain.[23] Case studies and small case series generally are not considered in evidence reviews as they do not provide sufficient sample sizes or comparison groups to determine the added benefit of the technology on health outcomes over standard of care for any patient population.

**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**


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**Date of Origin:** January 2018