



Medical Coverage Policy

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Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation

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INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses peripheral nerve stimulation (PNS) and peripheral nerve field stimulation (PNFS) for treatment of pain conditions.

Coverage Policy

Peripheral nerve stimulation (PNS) and peripheral nerve field stimulation (PNFS) are considered experimental, investigational or unproven.

General Background

Peripheral Nerve Stimulation (PNS)

Percutaneous peripheral nerve stimulation (PNS) or percutaneous peripheral nerve stimulation, involves the implantation of electrodes near or on a peripheral nerve that is identified as transmitting pain to a specific area of

the body. This is proposed for the treatment of chronic, refractory pain that is nonresponsive to conservative treatments. Chronic pain conditions for which PNS has been used include: hemiplegic shoulder pain, back pain, carpal tunnel syndrome; causalgia, complex regional pain syndrome, failed back syndrome, fibromyalgia, hemiplegic shoulder pain, brachial plexus injuries, post-trauma pain, subacromial impingement syndrome, post-amputation pain, postherpetic neuralgia, stroke, testicular pain, and trigeminal neuropathy (Wilson, et al., 2014; Stevanato, et al., 2014; Reverberi, et al., 2014; Stidd, 2012; International Neuromodulation Society [INS], 2012/2019). There is insufficient evidence to support the safety and effectiveness of PNS for the treatment of any indication including chronic pain.

PNS systems include a neurostimulator (pulse generator), leads (thin wires with electrodes), a controller (remote control device that allows the patient to control the device), and a programmer that is a remote control device that allows a medical professional to make adjustments to the settings of the pulse generator. The leads are positioned and connected to the generator. The electrodes are not permanently implanted as in spinal cord stimulation. A trial of PNS is indicated prior to permanent implantation of the generator. If the trial is successful (defined as >50% response rate in pain reduction), the generator is permanently implanted in the chest, abdomen or buttocks.

U.S. Food and Drug Administration - PNS

The Sprint Peripheral Nerve Stimulation (PNS) System (SPR Therapeutics, Cleveland, Ohio) received 510(k) approval in 2017 as a class II device. The indications for use include:

- Symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain;
- Symptomatic relief of post-traumatic pain;
- Symptomatic relief of post-operative pain.

The Sprint PNS System is not intended to treat pain in the craniofacial region.

StimQ Peripheral Nerve Stimulator (PNS) (Stimwave Technologies Incorporated, Ft. Lauderdale FL) system received 510(k) approval in 2017 as a class II device. The approval included indications for use: the device is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The StimQ PNS System is not intended to treat pain in the craniofacial region. The StimQ Trial Lead Kit is only used in conjunction with the StimQ Stimulator Receiver Kit. The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

StimRouter Neuromodulation System (Bioness Inc., Valencia, CA) received 510(k) approval in 2015 as a class II device. The device is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as an adjunct to other modes of therapy (e.g., medication). It is not intended to treat pain in the craniofacial region.

Literature Review- PNS

There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of implanted PNS for any indication. Studies are primarily in the form of case reports, retrospective reviews and case series with small patient populations (n=7–15) (Ilfeld, et al., 2019; Gilmore, et al., 2019a; Gilmore, et al., 2018; Wilson, et al., 2014; Wilson et al., 2017; Stevanato, et al., 2014; Reverberi, et al., 2014; Stidd, 2012).

Gilmore et al. (2019c) conducted a double-blinded, randomized, placebo-controlled study with twenty-eight lower extremity amputees with postamputation. The subjects underwent ultrasound-guided implantation of percutaneous PNS leads and were randomized to receive PNS (with SPRINT, SPR Therapeutics), or placebo for 4 weeks. The placebo group then crossed over and all subjects received PNS for four additional weeks. The primary efficacy endpoint evaluated the proportion of subjects reporting ≥50% pain reduction during one to four weeks. A greater proportion of subjects receiving PNS (n=7/12, 58%, p=0.037) demonstrated ≥50% reductions in average postamputation pain during weeks one through four compared with subjects receiving placebo (n=2/14, 14%). Two subjects were excluded from efficacy analysis due to eligibility changes. Greater proportions of PNS subjects also reported ≥50% reductions in pain (n=8/12, 67%, p=0.014) and pain interference (n=8/10, 80%, p=0.003) after 8 weeks of therapy compared with subjects receiving placebo (pain: n=2/14, 14%; pain interference: n=2/13, 15%). Limitations of the study included small number of subjects.

Gilmore et al. (2019b) reported on 12 month outcomes in the cohort in above study (Gilmore, et al., 2019c). it was noted that more participants in group one reported $\geq 50\%$ reductions in average weekly pain at 12 months (67%, 6/9) compared with group two at the end of the placebo period (0%, 0/14, $p=0.001$). in addition, 56% (5/9) of participants in group one reported $\geq 50\%$ reductions in pain interference at 12 months, compared with 2/13 (15%, $p=0.074$) in group two at crossover. Limitations of the study included the small number of subjects at 12 months and the loss of participants to follow-up.

A prospective, multicenter, randomized, double-blind, partial crossover study was conducted to assess safety and efficacy of the StimRouter System for use in the treatment of severe, intractable pain of peripheral nerve origin associated with posttraumatic or postsurgical neuralgia, exclusive of the craniofacial region (Deer, et al., 2016). Ninety-four patients were randomized to treatment group ($n=45$) or control group ($n=49$). Primary outcomes included pain relief and safety, measured by average pain at rest using a numerical rating scale (NRS) followed for three months, and safety, determined by assessment of adverse events (AEs) during the one-year study period. Treatment group received electrical stimulation from the StimRouter System and stable dosing of pain medications, while the Control group received no therapeutic stimulation and a stable dose of pain medications. At three months with patients receiving active stimulation achieved indicated higher response rate of 38% vs. the 10% rate found in the Control group ($p = 0.0048$). Improvement in pain was between the randomized groups, the Treatment group achieved a mean pain reduction of 27.2% from baseline to month three compared to a 2.3% reduction in the Control group ($p<0.0001$). Safety, assessed throughout the trial and with follow-up to one year, demonstrated no serious adverse events related to the device. For safety follow-up, 15 did not participate in the six- and 12-month follow-up and 33 patients at 12 month follow-up, representing an attrition of 51%.

Peripheral nerve field stimulation (PNFS)

Peripheral nerve field stimulation (PNFS), also known as subcutaneous peripheral field stimulation, is a recent 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. This technique is different from peripheral nerve stimulation (PNS), in which specific peripheral nerves are targeted. In peripheral nerve field stimulation, a field of pain is targeted rather than specific nerves. The electrodes are placed in the skin either through an open or percutaneous approach. Imaging guidance is included, when performed. The electrode is placed subcutaneously at the site of maximum pain rather than at the site of the nerve. This technique also referred to as subcutaneous target stimulation (STS) or peripheral nerve field stimulation (PNFS) involves a temporary trial period in which an electrode is placed subcutaneously by open or percutaneous approach, is secured in place with suture, and is then attached to a generator for approximately two to 14 days. A trial is considered successful if there is at least 50% pain reduction. Following a successful temporary trial the device is implanted.

U.S. Food and Drug Administration (FDA) - PNFS:

FDA approval for specific PNFS devices was not found on the FDA site. However, PNFS can be carried out using leads and electrodes that are primarily designed for spinal cord stimulation and may be considered an off-label use of these devices.

Literature Review- (PNFS)

Randomized controlled clinical trial data, and meta-analyses are lacking in the published, peer-reviewed scientific literature and there is insufficient evidence to determine safety and effectiveness of this therapy. Published peer-reviewed clinical trial data is primarily limited to case series and prospective and retrospective reviews and studies with small number of subjects (McRoberts, et al., 2013; Petersen, et al., 2014; Verrills, et al., 2011; Mitchell, et al., 2016).

Ishak et al. (2018) reported on a study to assess the usefulness, safety, and efficacy of subcutaneous peripheral nerve field stimulation (SPNS), in patients with chronic low back pain (CLBP). Twenty-six consecutive patients with CLBP were prospectively included in the study. Two electrodes were implanted vertically at a depth of 1 cm into the subcutaneous tissue, ≤ 10 cm from the region of maximum pain. Trial neurostimulation was performed in all patients for 14 days. A successful outcome was defined as at least 50% pain relief and to monitor the effects of permanent neurostimulation, the Visual Analog Scale (VAS), the Oswestry Disability Index (ODI), and quality of life (EQ-5D-3L) were scored preoperatively and at 6-month and 24-month follow-ups. Thirteen patients

responded to trial stimulation and had a permanent neurostimulator implanted. The use of pain medication, including opioid analgesics, was reduced in 92% of patients after 24 months. VAS, ODI, and EQ-5D-3L scores were improved in these patients at the 24-month follow-up. The complication rate was 23% (3/13 patients). In non-responders, the VAS and ODI at 24 months dropped as well but the decrease was less pronounced compared to responders and did not lead to decrease in pain medication. The study was limited by small number of participants and large prospective, randomized, controlled studies are needed to confirm findings.

Professional Societies/Organizations

The American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine published practice guidelines for chronic pain management (2010). The guidelines noted regarding subcutaneous peripheral nerve stimulation, that studies with observational findings indicate that subcutaneous peripheral nerve stimulation can provide pain relief for assessment periods ranging from four months to two years (Category B2 evidence).

Category B2 evidence: the literature contains noncomparative observational studies with associative (e.g., relative risk and correlation) or descriptive statistics.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs) National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7) 8/7/1995. The NCD is broader in scope than the Coverage Policy. Refer to the CMS NCD table of contents link in the reference section.
- Local Coverage Determinations (LCDs): Peripheral Nerve Stimulation. (L34328) (2019). The Coverage Policy is broader in scope than the LCD. Refer to the CMS LCD table of contents link in the reference section.

Use Outside of the US

European Federation of Neurological Societies (EFNS): EFNS guidelines on neurostimulation therapy for neuropathic pain evaluate the evidence for techniques including PNS and concluded that they could not draw any conclusion for PNS (Crucchu, et al., 2007). A 2016 update to these guidelines by the European Academy of Neurology examined central neurostimulation therapy in chronic pain conditions and noted that the recommendations were restricted to central neurostimulation because trials on peripheral stimulations are characterized by a great heterogeneity of methods (Crucchu, et al., 2016).

National Institute for Health and Care Excellence (NICE): NICE (2013) published guidance regarding peripheral nerve field stimulation for chronic low back pain. NICE recommendations note that evidence on efficacy is very limited, in both quality and quantity. Likewise, evidence on safety is also limited and there is a risk of complications from any implanted device. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven for peripheral nerve stimulation (PNS) and peripheral nerve field stimulation (PNFS):

CPT®* Codes	Description
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

HCPCS Codes	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
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, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.

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