

Peripheral Subcutaneous Field Stimulation

Effective: June 1, 2018

Next Review: April 2019

Last Review: April 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

Peripheral subcutaneous field stimulation is electrical stimulation via electrodes implanted under the skin over the area of maximal pain for patients with chronic intractable pain.

MEDICAL POLICY CRITERIA

Peripheral subcutaneous field stimulation is considered **investigational** for all indications.

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

CROSS REFERENCES

1. [Transcutaneous Electrical Modulation Pain Reprocessing](#), Medicine, Policy No. 143
2. [Percutaneous Neuromodulation Therapy \(PNT\)](#), Surgery, Policy No. 44
3. [Occipital Nerve Stimulation](#), Surgery, Policy No. 174
4. [Implantable Peripheral Nerve Stimulation for Chronic Pain of Peripheral Nerve Origin](#), Surgery, Policy No. 205

BACKGROUND

Peripheral subcutaneous field stimulation (PSFS), which may also be called peripheral nerve field stimulation or target field stimulation, is a form of neuromodulation that is intended to treat

chronic neuropathic pain. Implantation is typically a two-step process. An initial trial of percutaneous stimulation is conducted to confirm treatment success, defined as at least 50% pain reduction. Following successful trial stimulation, permanent leads are placed subcutaneously within the area of maximal pain and are connected to an implantable generator. This is a modification of conventional peripheral nerve stimulation (PNS) which involves implantation of an electrical stimulator lead on a peripheral nerve.

The objective of PSFS is to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, which then converge back on the spinal cord. PSFS is being evaluated for occipital or craniofacial stimulation for headache/migraines, craniofacial pain, or occipital neuralgia, and for treatment of low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and post-herpetic neuralgia.

Currently, there is no consensus regarding the indications for PSFS. The inclusion criteria for some studies on PSFS have included a clearly defined, discrete focal area of pain with a neuropathic or combined somatic/neuropathic pain component with characteristics of burning and increased sensitivity, and failure to respond to other conservative treatments including medications, psychological therapies, physical therapies, surgery, and pain management programs.

The mechanism of PSFS is not known. Theories include an increase in endogenous endorphins and other opiate-like substances, modulation of smaller A-delta and C fibers with stimulation of large-diameter A-beta fibers, local stimulation of nerve endings in the skin, local anti-inflammatory and membrane depolarizing effect, or a central action via antegrade activation of A-beta nerve fibers. Complications of PSFS include lead migration or breakage and infection of the lead or neurostimulator.

REGULATORY STATUS

No devices have been approved specifically for PSFS by the U.S. Food and Drug Administration (FDA). PSFS is an off-label use of spinal cord stimulation devices that have been FDA approved for the treatment of chronic pain.

EVIDENCE SUMMARY

The principal outcomes for peripheral subcutaneous field stimulation (PSFS) are pain relief and improved functional level. Both of these outcomes can be influenced by nonspecific effects, placebo response, and natural history of the disease. Therefore, large randomized controlled trials (RCTs) are important to control for the placebo effect and determine its magnitude, and to determine whether any treatment effect from PSFS provides a significant advantage over sham or standard treatments. Appropriate comparison groups would receive sham treatment or conventional medical or surgical treatment.

RANDOMIZED CONTROLLED TRIALS

One small randomized double-blind crossover trial was published in 2013; however, this study did not include a control group or a comparison group of alternative treatment modalities.^[1] The aim of this two-phase study was “to obtain preliminary estimates of the safety and efficacy of PSFS therapy using equipment originally designed for spinal cord stimulation.” In the first phase of the study, patients (n=32) were initially randomized to one of the four stimulation

groups, minimal, subthreshold, low frequency, and standard stimulation. Participants then rotated through all four stimulation groups in four to eight-day intervals. Both the investigator and patient were blinded to the group assigned. Two patients exited the study during phase I due to device/procedure-related adverse effects. “Responders” (n=24), defined as patients in any of the three active stimulation groups reporting $\geq 50\%$ pain reduction, progressed to the second phase of permanent system implant (n=23). One responder did not receive permanent implantation due to non-device/procedure-related adverse effects.

Patients were followed for 52 weeks during which time reported mean visual analog scale (VAS), present pain index, and total scores on the Short Form McGill Pain Questionnaire were significantly improved from baseline at all follow-up visits ($p < 0.001$). Excellent or good pain relief was reported in 16 (69.5%) patients at the 52-week follow-up visit. Opioid use decreased in 10 (43%) patients, remained stable in 8 (35%) patients, and increased in 5 (22%) patients. The most common adverse events were diminished or loss of therapy (n=10) and lead migration (n=7). Four patients had their systems explanted prior to completion of the study.

This study had a number of significant limitations that precluded conclusions, including but not limited to the small number of patients and the lack of an appropriate control group. Because this study did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study. Further data are needed from well-designed RCTs which include large sample sizes and an appropriate control group for comparison.

NONRANDOMIZED TRIALS

Kloimstein (2014) reported on a prospective study of 118 patients treated with PSFS for chronic low back pain.^[2] Before patients were implanted with the permanent PSFS system, a trial of stimulation was given for at least seven days. The permanent stimulation system was implanted in 105 patients. Significant improvements occurred at one, three and six months’ follow-up after implantation in the average pain VAS, Oswestry Disability Questionnaire, Becks Depression Inventory, and the Short Form-12 health survey. Significant reductions in opioid, nonsteroidal anti-inflammatory and anti-convulsant medications also occurred.

Verrills (2014) reported on PSFS for chronic headache conditions.^[3] After a trial stimulation period, 60 patients underwent permanent implantation of the PSFS system and were followed for an average of 12.9 ± 9.4 months (range, 3-42 months). Ten patients required revision of the implant system. Significant reductions in pain were reported ($p \leq 0.001$). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients and disability and depression improved.

Verrills (2011) reported on a series of 100 patients treated PSFS for chronic neuropathic pain. Indications included chronic pain in occipital/craniofacial (n=40), lumbosacral (n=44), thoracic (n=8), groin/pelvis (n=5), or abdominal (n=3) regions.^[4] Selection criteria included a clearly defined, discrete focal area of pain with a neuropathic component or combined somatic neuropathic pain component with characteristics of burning and increased sensitivity, and failure to respond to other conservative treatments including medications, psychological therapies, physical therapies, surgery, and pain management programs. Outcomes were assessed at a mean of 8.1 months after implantation (range, 1-23 months) with a combination of numerical pain scores, patient answered questionnaires, and patient medical histories. For the entire cohort, pain decreased from 7.4 at baseline to 4.2 at follow-up. About 34% of patients had at least a 75% improvement in pain scores and 69% improved by at least 50%.

Analgesic use decreased in 40% of patients following PSFS. Adverse events were reported in 14% of patients, including unpleasant sensations, lead erosions and lead or battery migration.

Sator-Katzenschlager (2010) reported a retrospective multicenter study of the use of PSFS.^[5] A total of 111 patients with chronic pain were treated, including 29 patients with low back pain, 37 with failed back surgery syndrome, 15 with cervical neck pain, and 12 patients with postherpetic neuralgia. The median duration of chronic pain was 13 years and the median number of previous surgeries was 2.7. For permanent implantation of the leads, patients had to have achieved at least 50% improvement in pain on a numerical rating scale during the trial period. After permanent implantation, pain intensity decreased in 102 patients (92%). Mean pain intensity decreased from 8.2 at baseline to 4.0 at follow-up with a reduction in consumption for analgesics and antidepressants. Lead dislocation or fracture occurred in 20 patients (18%).

PRACTICE GUIDELINE SUMMARY

The National Institute for Health and Care Excellence issued guidance in 2013 on peripheral subcutaneous field stimulation for chronic low back pain.^[6] The guidance stated: “Current evidence on the efficacy of peripheral nerve-field stimulation (PNFS) for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. 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.”

SUMMARY

There is not enough research to show that peripheral subcutaneous field stimulation (PSFS) improves health outcomes for any indication. No clinical guidelines based on research recommend PSFS. Therefore, the use of PSFS is considered investigational for all indications.

REFERENCES

1. McRoberts, WP, Wolkowitz, R, Meyer, DJ, et al. Peripheral nerve field stimulation for the management of localized chronic intractable back pain: results from a randomized controlled study. *Neuromodulation : journal of the International Neuromodulation Society*. 2013 Nov-Dec;16(6):565-74; discussion 74-5. PMID: 23577773
2. Kloimstein, H, Likar, R, Kern, M, et al. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. *Neuromodulation : journal of the International Neuromodulation Society*. 2014 Feb;17(2):180-7. PMID: 24320718
3. Verrills, P, Rose, R, Mitchell, B, Vivian, D, Barnard, A. Peripheral nerve field stimulation for chronic headache: 60 cases and long-term follow-up. *Neuromodulation : journal of the International Neuromodulation Society*. 2014 Jan;17(1):54-9. PMID: 24165152
4. Verrills, P, Vivian, D, Mitchell, B, Barnard, A. Peripheral nerve field stimulation for chronic pain: 100 cases and review of the literature. *Pain Med*. 2011 Sep;12(9):1395-405. PMID: 21812906

5. Sator-Katzenschlager, S, Fiala, K, Kress, HG, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. *Pain practice : the official journal of World Institute of Pain*. 2010 Jul-Aug;10(4):279-86. PMID: 20230450
6. Peripheral nerve-field stimulation for chronic low back pain: guidance [IPG451]. [cited 4/17/2018]; Available from: <https://www.nice.org.uk/guidance/ipg451>
7. BlueCross BlueShield Association Medical Policy Reference Manual "Peripheral Subcutaneous Field Stimulation." Policy No. 7.01.139

CODES

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system
HCPCS	L8679	Implantable neurostimulator, pulse generator, any type

Date of Origin: April 2013