07.01.70 Peripheral Subcutaneous Field Stimulation (PSFS)

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Related Policies:

- 07.01.79 Implantable Peripheral Nerve Stimulation and Restorative Neurostimulation for the Treatment of Chronic Pain
- 01.01.35 Non-Implantable Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- 07/01/61 Spinal Cord and Dorsal Root Ganglion Stimulation

Summary

Description

Peripheral subcutaneous field stimulation is a form of neuromodulation intended to treat chronic neuropathic pain. Applications of peripheral subcutaneous field stimulation being evaluated are craniofacial stimulation for headache and migraine, craniofacial pain, or occipital neuralgia. Peripheral subcutaneous field stimulation is also being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and postherpetic neuralgia.

Summary of Evidence

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes 2 RCTs, a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. One RCT, McRoberts et al (2013), which used a crossover design, did not compare peripheral subcutaneous field stimulation with alternatives. Rather, it compared different methods of peripheral subcutaneous field stimulation. Among trial participants, 24 (80%) of 30 patients had at least a 50% reduction in pain with any type of peripheral subcutaneous field stimulation. However, because the RCT did not include a sham group or comparator with a different active intervention, this trial offers little evidence for efficacy beyond that of a prospective, uncontrolled study. An open-label RCT found that peripheral subcutaneous field stimulation plus medical management had a greater rate of pain reduction compared to medical management alone at 9 months follow-up. Secondary outcomes found benefits in several quality-of-life indices over medical management alone. The trial had a high loss to follow-up and was terminated early as a result of recruitment challenges, which impacted the durability and certainty of these findings. Case series are insufficient to evaluate patient outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Larger, prospective controlled trials comparing peripheral subcutaneous field stimulation with placebo or alternative treatment modalities are needed to determine the efficacy of peripheral subcutaneous field stimulation for chronic pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this evidence review is to determine whether use of peripheral subcutaneous field stimulation improves the net health outcome for individuals with chronic neuropathic pain.

PRIOR APPROVAL

Not applicable

POLICY

Peripheral subcutaneous field stimulation is considered **investigational** for all indications because the evidence is insufficient to determine the effects of the technology on net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

Chronic Pain

Chronic, noncancer pain is responsible for a high burden of illness. Common types of chronic pain are lumbar and cervical back pain, chronic headaches, and abdominal pain. All of these conditions can be challenging to treat.

Treatment

Pharmacologic agents are typically the first-line treatment for chronic pain, and several classes of medications are available. These include analgesics (opioid and nonopioid), antidepressants, anticonvulsants, and muscle relaxants. A variety of nonpharmacologic treatments also exist, including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, chiropractic, and therapeutic massage.

Neuromodulation, a form of nonpharmacologic therapy, is usually targeted toward patients with chronic pain refractory to other modalities. Some forms of neuromodulation, such as transcutaneous electrical nerve stimulation and spinal cord stimulation, are established methods of chronic pain treatment. Peripheral nerve stimulation, which involves placement of an electrical stimulator on a peripheral nerve, is also used for neuropathic pain originating from peripheral nerves.

Peripheral Subcutaneous Field Stimulation

Peripheral subcutaneous field stimulation is a modification of peripheral nerve stimulation. In peripheral subcutaneous field stimulation, leads are placed subcutaneously within the area of maximal pain. The objective of peripheral subcutaneous field stimulation 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. Combination spinal cord stimulation plus peripheral subcutaneous field stimulation is also being evaluated.

Similar to spinal cord stimulation or peripheral nerve stimulation, permanent implantation is preceded by a trial of percutaneous stimulation with at least 50% pain reduction. Currently, there is no consensus on the indications for peripheral subcutaneous field stimulation. Criteria for a trial of peripheral subcutaneous field stimulation may include 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 action in peripheral subcutaneous field stimulation is unknown. Theories include an increase in endogenous endorphins and other opiate-like substances; modulation of smaller A delta and C nerve fibers by stimulated 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 peripheral subcutaneous field stimulation include lead migration or breakage and infection of the lead or neurostimulator.

Regulatory Status

Peripheral subcutaneous field stimulation is an off-label use of peripheral nerve stimulation systems that have been approved by the FDA for the treatment of chronic pain by targeting one or more peripheral nerves associated with pain.

RATIONALE

This evidence review was created in December 2015 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Chronic Neuropathic Pain

Clinical Context and Therapy Purpose

The purpose of peripheral subcutaneous field stimulation in individuals who have chronic neuropathic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic neuropathic pain.

Interventions

The therapy being considered is peripheral subcutaneous field stimulation. Peripheral subcutaneous field stimulation is a modification of peripheral nerve stimulation. In peripheral subcutaneous field stimulation,

leads are placed subcutaneously within the area of maximal pain. The objective of peripheral subcutaneous field stimulation 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.

Comparators

The following therapies are currently being used to make decisions about peripheral subcutaneous field stimulation: pharmacotherapy, exercise or physical therapy, and cognitive-behavioral therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity.

As a chronic condition, follow-up of at least 6 weeks to 12 months would be desirable to assess outcomes in chronic neuropathic pain.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

One crossover RCT compared levels of peripheral subcutaneous field stimulation. McRoberts et al (2013) reported on a randomized, crossover trial of different types of peripheral subcutaneous field stimulation in 44 patients with chronic back pain. In the first phase of the trial, patients rotated through 4 levels of peripheral subcutaneous field stimulation: minimal, subthreshold, low frequency, and standard stimulation. Of 30 patients who completed the first phase, 24 reported that pain was significantly reduced by at least 50% in all of the stimulation groups and were considered responders. In phase 2, a permanent peripheral subcutaneous field stimulation system was placed in 23 responders. During the 52 weeks over which these patients were followed, reported mean visual analog scale scores, present pain index, and total scores on the Short-Form McGill Pain Questionnaire were significantly improved from baseline at all follow-up visits ($p<.001$). Because this trial did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study.

One multi-center RCT compared peripheral subcutaneous field stimulation plus medical management to medical management alone for chronic back pain due to failed back surgery.[1] The study had an open-label design and randomized 116 participants 1:1 to either peripheral subcutaneous field stimulation plus medical management (n=56) or a medical management control group (n=60). Discontinuation was high

prior to the 9-month follow-up, with 18 (32%) in the field stimulation and 24 (40%) in the control group; follow-up at the 36-month visit was only available for a single participant in the peripheral subcutaneous field stimulation arm and 3 participants in the control group. This poor rate of long-term follow-up was primarily due to selective early termination of the trial due to recruitment difficulties. The primary endpoint was the response rate which the authors defined as a ≥50% reduction in back pain intensity on the visual analogue scale (VAS). At 9 months, the response rate was significantly higher for combined subcutaneous field stimulation plus medical management (33.9%; 95% CI, 21.5% to 46.3%) compared to medical management alone (1.7%; 95% CI 0% to 4.9%; p<.0001) as an intention to treat (ITT) analysis with similar findings on per-treatment and modified ITT analyses. The mean absolute change from baseline VAS pain score to nine months follow-up was -33.3 mm in the field stimulation group (standard deviation [SD], 24.5) compared to -2.7 mm (SD,16.0; p<.0001) in the control group. Significant treatment effects were also seen for secondary outcomes on the Oswestry Disability Index, EuroQol quality of life five dimensions (EQ-5DL-5L), and patient global impression of change, which favored combined treatment with peripheral subcutaneous field stimulation plus medical management (p<.001). Forty-nine subjects experienced 1 or more adverse events (29 [52.7%] in the field stimulation arm vs. 20 [33.3%] in the control arm), with the most common etiology classified as an “other” (defined as non-biological, hardware, therapy, human factors, or medication events). Device-related events amongst implanted patients included 4 (5.0%) device or implant-related infections, 3 (3.8%) lead fractures, and 2 (2.5%) lead dislocation/migrations. Despite early positive findings through 9 months, the trial was limited by a lack of blinding, high loss to follow-up, an absence of longer-term follow-up due to early termination, potential bias in the selection of the comparison group as participants had 6 or more months of prior medication management without a response as an enrollment criterion, and an omission of power calculations.

Nonrandomized Comparative Study

In another comparative study, Mironer et al (2011) used a 2-part evaluation of combined use of spinal cord stimulation and peripheral subcutaneous field stimulation in patients with low back pain. In the first part of the study, 20 patients with failed back surgery syndrome or spinal stenosis underwent a trial with both spinal cord stimulation and peripheral subcutaneous field stimulation and selected the type of stimulation they found most efficacious (program 1: spinal cord stimulation alone; program 2: peripheral subcutaneous field stimulation alone; program 3: combined spinal cord stimulation plus peripheral subcutaneous field stimulation). Patients were blinded to the differences among the programs (randomized order of presentation) and were encouraged to try each program for at least 8 hours; 79% of patients preferred the combined use of spinal cord stimulation plus peripheral subcutaneous field stimulation. In the second part of the study, 20 patients were implanted with spinal cord stimulation and peripheral subcutaneous field stimulation electrodes and selected which program they preferred (spinal cord stimulation and peripheral subcutaneous field stimulation used simultaneously, spinal cord stimulation as anode and peripheral subcutaneous field stimulation as cathode, spinal cord stimulation as cathode and peripheral subcutaneous field stimulation as anode). The programs were presented in a random order, and patients were blinded to the differences among the programs offered. Communication between spinal cord stimulation and peripheral subcutaneous field stimulation was reported to provide wider coverage of axial pain, with an overall success rate (>50% pain relief) of 90%. The most effective program was spinal cord stimulation as cathode and peripheral subcutaneous field stimulation as anode.

Case Series

In addition to the controlled studies, a number of case series have been published, several of which included 50 or more patients. Kloimstein et al (2014) reported on a prospective multicenter study of 118 patients treated with peripheral subcutaneous field stimulation for chronic low back pain. Before patients were implanted with the permanent peripheral subcutaneous field stimulation system, trial stimulation was given for at least 7 days. The permanent stimulation system was implanted in 105 patients. Significant

improvements occurred at the 1-, 3-, and 6-month postimplantation follow-ups in average visual analog score pain, Oswestry Disability Questionnaire, Beck Depression Inventory, and 12-Item Short-Form Health Survey scores. Significant reductions in use of opioids, nonsteroidal anti-inflammatory, and anticonvulsant medications were also reported.

Sator-Katzenschlager et al (2010) reported on a retrospective multicenter study of peripheral subcutaneous field stimulation. A total of 111 patients with chronic focal noncancer 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% reduction in pain on a numeric rating scale during the trial period. After permanent implantation, pain intensity decreased in 102 (92%) patients. Mean pain intensity decreased from 8.2 at baseline to 4.0 at follow-up, with a concomitant reduction in consumption for analgesics and antidepressants. Lead dislocation or fracture occurred in 20 (18%) patients.

Verrills et al (2011) reported on a series of 100 patients treated with peripheral subcutaneous field stimulation for chronic neuropathic pain. Indications included chronic pain occurring among varying regions: occipital/craniofacial (n=40), lumbosacral (n=44), thoracic (n=8), groin/pelvis (n=5), or abdominal (n=3). 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, assessed at a mean of 8.1 months after implantation (range, 1 to 23 months), included a combination of numeric pain scores, self-report questionnaires, and patient medical histories. For the entire cohort, pain decreased from 7.4 at baseline to 4.2 at follow-up. Pain scores improved by 75% or more in 34% of patients and by 50% or more in 69% of patients. Analgesia use decreased in 40% of patients after peripheral subcutaneous field stimulation. Adverse events were reported in 14% of patients and included unpleasant sensations, lead erosions, and lead or battery migration.

Verrills et al (2014) also reported on peripheral subcutaneous field stimulation for chronic headache conditions. After a trial stimulation period, 60 patients underwent permanent implantation of the peripheral subcutaneous field stimulation system and were followed for an average of 12.9 months (range, 3 to 42 months). Ten patients required revision of the implant system. Significant reductions in pain from baseline were reported ($p \leq .001$). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients, and reductions in degree of disability and depression were noted.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians published guidelines in 2024 on implantable peripheral nerve stimulation, but the guidelines do not address subcutaneous field stimulation.

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience published consensus clinical guidelines for the use of implantable peripheral nerve stimulation in the treatment of chronic pain based on a review of the literature through March 2021. Recommendations for best practices are listed in the table below.

Table of American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	DOR
Head and Neck		
Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatment have failed. The average effect size for relief of migraine symptoms is modest to moderate.	I	B
There is presently insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain	II-3	C
Upper Extremities		
PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain.	I	B
PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief.	II-2	B
Low Back and Trunk		
Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone.	I	B
There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain.	II-2	B
There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia.	III	C
Lower Extremities		
PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief.	I	B

Recommendations	LOE	DOR
PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief.	I	B
CRPS		
As a less-invasive modality compared to SCS therapy, PNS may be offered to patients with CRPS Type I/II or peripheral causalgia, and may be associated with modest improvement in pain intensity and functional outcomes. However, high-quality evidence is limited and other neuromodulation interventions such as dorsal root ganglion SCS are recommended.	III	C
Other Considerations		
PNS carries a low-to-intermediate risk for bleeding complications and depends on the proximity of the targeted nerve to critical vessels and invasiveness of PNS implantation.	III	I

CRPS: complex regional pain syndrome; DOR: degree of recommendation; LOE: level of evidence; PNS: peripheral nerve stimulation; SCS: spinal cord stimulator.

National Institute for Health and Care Excellence

In 2013, NICE issued guidance on peripheral subcutaneous field stimulation for chronic low back pain, which stated:

"Current evidence on the efficacy of peripheral nerve-field stimulation 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."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	64999	Unlisted procedure, nervous system
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Outpatient/Inpatient	

POLICY HISTORY

Date	Action	Action
July 2025	Annual Review	Policy Renewed
June 2024	Annual Review	Policy Revised
June 2023	Annual Review	Policy Revised
November 2022	Annual Review	Policy Renewed
November 2021	Annual Review	Policy Renewed
November 2020	Annual Review	Policy Revised
November 2019	Annual Review	Policy Revised
November 2018	Annual Review	Policy Revised
November 2017	Annual Review	Policy Revised
November 2016	Annual Review	Policy Renewed
December 2015		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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