Peripheral Subcutaneous Field Stimulation

Description

Peripheral subcutaneous field stimulation (PSFS, also called peripheral nerve field stimulation or target field stimulation) is a form of neuromodulation that is intended to treat chronic neuropathic pain. One application of PSFS that is being evaluated is occipital or craniofacial stimulation for headache/migraines, craniofacial pain, or occipital neuralgia. PSFS is also being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and post-herpetic neuralgia.

Background

Chronic, non-cancer 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. Medications are typically the first line treatment for chronic pain, and several classes of medications are available. These include analgesics (opioid and non-opioid), antidepressants, anticonvulsants, and muscle relaxants. There are also a variety of non-pharmacologic treatments, including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, chiropractic, massage.

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

Peripheral Subcutaneous Field Stimulation: PSFS is a modification of peripheral nerve stimulation. In PSFS, leads are placed subcutaneously within the area of maximal pain. 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. Combined spinal cord stimulation and PSFS is also being evaluated.

Similar to SCS or peripheral nerve stimulation, permanent implantation is preceded by a percutaneous stimulation trial with at least 50% pain reduction. Currently, there is no consensus regarding the
indications for PSFS. Criteria for a PSFS trial 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 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. PSFS is an off-label use of SCS devices that
have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic pain
(see policy No. 7.01.25).

Related Policies

7.01.25 Spinal Cord Stimulation

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification,
Advanced Benefit Determination, etc.) and/or post-service claims.

Peripheral subcutaneous field stimulation is investigational.

Rationale

Case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the
subjective nature of the outcome measures. Randomized controlled trials with adequate blinding are
needed to control for the variable natural history of pain, as well as for the expected placebo effect in
research on pain treatment.

McRoberts et al (2013) reported on a randomized, crossover trial of different types of PSFS in 44
patients with chronic back pain. This study did not include a control group or a comparison group of
alternative treatment modalities. In the first phase of the study, patients rotated through 4 different
levels of trial PFSF: minimal, subthreshold, low frequency, and standard stimulation. (1) Of the 30
patients who completed phase 1, 24 reported their pain was significantly reduced by at least 50% in any
of the stimulation groups and were considered responders to PSFS. In phase 2, a permanent PSFS
system was then placed in 23 of the responders. 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).
Because this study did not include any control group, the methodologic strength of these results is
similar to that of an uncontrolled study.
In 2014 Kloimstein et al 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 7 days. The permanent stimulation system was implanted in 105 patients. Significant improvements occurred at 1, 3 and 6 month follow-up after implantation in the average pain VAS, Oswestry Disability Questionnaire, Becks Depression Inventory, and 12-Item Short-Form Health Survey. Significant reductions in use of opioid, nonsteroidal anti-inflammatory and anti-convulsant medications also occurred.

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

Other large case series have been identified. In 2013, Verrills et al reported on PSFS for chronic headache conditions. (4) 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≤0.001). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients and disability and depression improved.

Sator-Katzenschlager et al (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 post herpetic 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%).

In 2011, Verrils et al 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. (6) 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.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in March 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements
In 2013 the National Institute for Health and Care Excellence issued guidance on PSFS (7) the guidance indicates:

“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.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Summary of Evidence
The evidence for peripheral subcutaneous field stimulation (PSFS) in individuals who have chronic neuropathic pain includes 1 randomized controlled trial (RCT), 1 nonrandomized comparative study, and case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The single RCT, which used a crossover design, did not compare PSFS to alternatives. Rather, this study compared different methods of PSFS. Among study participants, 24 (80%) of 30 patients had at least 50% reduction in pain with any type of PSFS. However, because the RCT did not include a sham group or comparator with a different active intervention, this study offers little evidence for efficacy beyond that of a prospective, uncontrolled study. In addition, case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Prospective controlled trials comparing PSFS with placebo or alternative treatment modalities are needed to determine the efficacy of this treatment for chronic pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare National Coverage
There is no national coverage determination (NCD).
References


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<td>June 2013</td>
<td>New Policy</td>
<td>Policy updated with literature review, adding references 1, 2, 4 and 7. The policy statement is unchanged.</td>
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<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; no references added; reference 2 updated. Policy statements unchanged.</td>
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<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review through February 12, 2016; no references added. Policy statement unchanged.</td>
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Keywords

PNFS
Peripheral nerve field stimulation
Peripheral subcutaneous field stimulation
Peripheral target stimulation
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective July 15, 2016.

Signature on File

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