



An Independent Licensee of the Blue Cross and Blue Shield Association

Kansas City

Peripheral Subcutaneous Field Stimulation

Policy Number: 7.01.139

Origination: 7/2013

Last Review: 9/2014

Next Review: 1/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for peripheral subcutaneous field stimulation. This is considered investigational.

Please note that this is a type of electrical stimulation that is considered a benefit exclusion in many health plan contracts.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Peripheral subcutaneous field stimulation is **investigational**.

Description of Procedure or Service

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. Also being investigated is PSFS 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, 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

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 spinal cord stimulation 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 spinal cord stimulation devices that have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic pain (see separate policy).

Rationale

The literature on peripheral subcutaneous field stimulation (PSFS) was searched through February 19, 2014. Relevant literature identified includes 1 randomized, crossover study, 1 small comparative trial that evaluated combined PSFS and spinal cord stimulation (SCS), 2 large retrospective case series from outside of the U.S., and a number of small case series.

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 (RCTs) 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 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 PSFS: 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 the 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 2013 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 months' follow-up after implantation in the average pain VAS, Oswestry Disability Questionnaire, Beck Depression Inventory, and the Short Form-12 Health Survey. Significant reductions in opioid, nonsteroidal anti-inflammatory, and anticonvulsant 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 ($p \leq 0.001$).

Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients and disability and depression improved.

Sator-Katzenschlager et al reported in 2010 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%).

In 2011, Verrills et al reported on a series of 100 patients treated with 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 Clinical Trials

A search of online site ClinicalTrials.gov on February 19, 2014 found 2 open randomized studies using PSFS in combination with spinal cord stimulation for the treatment of chronic low back and leg pain due to failed back surgery syndrome in 450 patients (NCT01990287) and in 90 patients (NCT01776749).

Summary

In peripheral subcutaneous field stimulation (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. Evidence on PSFS is limited, consisting of 1 small randomized, crossover study, 1 small uncontrolled trial that evaluated combined PSFS and spinal cord stimulation, 2 large retrospective case series, and a number of small case series. The single RCT compared different methods of PSFS and did not include a control or active comparison group; therefore this study offers little evidence on efficacy beyond that of a prospective, uncontrolled study. Case series report that self-reported pain is reduced following treatment with PSFS. However, case

series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of the outcome measures. Prospective controlled trials comparing PSFS with placebo or alternate treatment modalities are needed to determine the efficacy of this treatment for chronic pain. Therefore, PSFS is considered investigational.

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.”

Medicare National Coverage

No national coverage determination (NCD) was identified. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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* 2013; 16(6):565-75.
2. Kloimstein H, Likar R, Kern M et al. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. *Neuromodulation* 2013.
3. Mironer YE, Hutcheson JK, Satterthwaite JR et al. Prospective, two-part study of the interaction between spinal cord stimulation and peripheral nerve field stimulation in patients with low back pain: development of a new spinal-peripheral neurostimulation method. *Neuromodulation* 2011; 14(2):151-4; discussion 55.
4. Verrills P, Rose R, Mitchell B et al. Peripheral Nerve Field Stimulation for Chronic Headache: 60 Cases and Long-Term Follow-Up. *Neuromodulation* 2013.
5. Sator-Katzenschlager S, Fiala K, Kress HG et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. *Pain Pract* 2010; 10(4):279-86.
6. Verrills P, Vivian D, Mitchell B et al. Peripheral nerve field stimulation for chronic pain: 100 cases and review of the literature. *Pain Med* 2011; 12(9):1395-405.
7. National Institute for Health and Care Excellence. IPG451 Peripheral nerve-field stimulation for chronic low back pain: guidance. 2013. Available online at: <http://guidance.nice.org.uk/IPG451/Guidance/pdf/English>

Billing Coding/Physician Documentation Information

- | | |
|--------------|---|
| 0282T | Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; for trial, including removal at the conclusion of trial period |
| 0283T | Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar; permanent, with implantation of a pulse generator |
| 0284T | Revision or removal of pulse generator or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed |
| 0285T | Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed |

Additional Policy Key Words

N/A

Policy Implementation/Update Information

7/1/13	New policy; considered investigational.
1/1/14	No policy statement changes.
9/1/14	No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.