### MEDICAL POLICY

<table>
<thead>
<tr>
<th>POLICY TITLE</th>
<th>PERIPHERAL SUBCUTANEOUS FIELD STIMULATION (PSFS)</th>
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<tbody>
<tr>
<td>POLICY NUMBER</td>
<td>MP 1.141</td>
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| Original Issue Date (Created): | September 24, 2013 |
| Most Recent Review Date (Revised): | September 24, 2013 |
| Effective Date: | February 1, 2014 |

## I. POLICY

Peripheral subcutaneous field stimulation is **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

*Cross-reference:*  
MP-1.069 Spinal Cord Stimulation

## II. PRODUCT VARIATIONS

Key:
- \( [N] \) = No product variation, policy applies as stated  
- \( [Y] \) = Standard product coverage varies from application of this policy, see below

<table>
<thead>
<tr>
<th>Product Variation</th>
<th>Policy Coverage</th>
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<tbody>
<tr>
<td>Capital Cares 4 Kids</td>
<td>( [N] )</td>
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</table>
| Indemnity | \( [N] \)  
| PPO | \( [N] \)  
| HMO | \( [N] \)  
| SeniorBlue HMO | \( [N] \)  
| SeniorBlue PPO | \( [N] \)  
| Indemnity | \( [N] \)  
| SpecialCare | \( [N] \)  
| POS | \( [N] \)  
| FEP PPO* | \( [Y] \) |

* Refer to FEP Medical Policy Manual MP-7.01.139 Peripheral Subcutaneous Field Stimulation. The FEP Medical Policy manual can be found at: [www.fepblue.org](http://www.fepblue.org)

## III. BACKGROUND 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. 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.
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.
IV. RATIONALE

The literature on peripheral subcutaneous field stimulation (PSFS) was searched through February 13, 2013. Relevant literature identified includes 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 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.

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. (1) 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.

Two large case series have been identified. Sator-Katzenschlager et al. reported in 2010 a retrospective multicenter study of the use of PSFS. (2) 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 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. (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 were assessed at a mean of 8.1 months after implantation (range, 1 to 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.

**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 uncontrolled trial that evaluated combined PSFS and spinal cord stimulation (SCS), 2 large retrospective case series, and a number of small case series. These 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 are needed to evaluate the efficacy of this treatment for chronic pain. Therefore, PSFS is considered investigational.

V. **Definitions**

N/A

VI. **Benefit Variations**

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.
VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES


IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, therefore not covered:

<table>
<thead>
<tr>
<th>CPT Codes®</th>
<th>0282T</th>
<th>0283T</th>
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Note: Final page is signature page and is kept on file, but not issued with Policy.
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X. POLICY HISTORY

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