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|------------------------------|--------------------------------------------------|------------------------|--------------|
| <b>7.01.139</b>              | <b>Peripheral Subcutaneous Field Stimulation</b> |                        |              |
| <b>Original Policy Date:</b> | July 31, 2015                                    | <b>Effective Date:</b> | June 1, 2018 |
| <b>Section:</b>              | 7.0 Surgery                                      | <b>Page:</b>           | Page 1 of 7  |

### Policy Statement

Peripheral subcutaneous field stimulation is considered **investigational**.

### Policy Guidelines

Implantation of neurostimulator electrode arrays for peripheral subcutaneous field stimulation would be reported with the unlisted CPT code 64999.

**Prior to 2017**, the following category III CPT codes were specific to this treatment:

- **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

### Description

Peripheral subcutaneous field stimulation (PSFS) is a form of neuromodulation intended to treat chronic neuropathic pain. Applications of PSFS being evaluated are craniofacial stimulation for headache and migraine, 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 postherpetic neuralgia.

### Related Policies

- Occipital Nerve Stimulation
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- Spinal Cord and Dorsal Root Ganglion Stimulation
- Transcutaneous Electrical Nerve Stimulation

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

No devices have been approved by the U.S. Food and Drug Administration specifically for peripheral subcutaneous field stimulation (PSFS). PSFS is an off-label use of spinal cord stimulation devices that have been approved by the Food and Drug Administration for the treatment of chronic pain (see Blue Shield of California Medical Policy: Spinal Cord and Dorsal Root Ganglion Stimulation).

## Rationale

### 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. They 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 (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. Combination spinal cord stimulation plus PSFS 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 PSFS. Criteria for a trial of PSFS 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 PSFS 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 PSFS include lead migration or breakage and infection of the lead or neurostimulator.

### Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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 is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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.

### **Neuropathic Pain**

No sham- or active pain treatment-controlled randomized trials evaluating peripheral subcutaneous field stimulation (PSFS) were identified. One crossover randomized controlled trial compared levels of PSFS stimulation. McRoberts et al (2013) reported on a randomized, crossover trial of different types of PSFS in 44 patients with chronic back pain. In the first phase of the trial, patients rotated through 4 levels of trial PSFS: minimal, subthreshold, low frequency, and standard stimulation.<sup>1</sup> 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 to PSFS. In phase 2, a permanent PSFS 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 ( $p < 0.001$ ). Because this trial did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study.

Another comparative study used a 2-part evaluation of combined use of spinal cord stimulation (SCS) and PSFS in patients with low back pain; it was reported by Mironer et al (2011).<sup>2</sup> 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; program 3: combined SCS plus PSFS). 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% percent of patients preferred the combined use of SCS plus 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, SCS as cathode and PSFS as anode). The programs were presented in a random order, and patients were blinded to the differences among the programs offered. 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.

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 PSFS for chronic low back pain.<sup>3</sup> Before patients were implanted with the permanent PSFS 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 opioid, nonsteroidal anti-inflammatory, and anticonvulsant medications were also reported.

Sator-Katzenschlager et al (2010) reported on a retrospective multicenter study of PSFS.<sup>4</sup> 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 PSFS 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).<sup>5</sup> 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, 1-23 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 PSFS. 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 PSFS for chronic headache conditions.<sup>6</sup> After a trial stimulation period, 60 patients underwent permanent implantation of the PSFS system and were followed for an average of 12.9 months (range, 3-42 months). Ten patients required revision of the implant system. Significant reductions in pain from baseline were reported ( $p \leq 0.001$ ). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients, and reductions in degree of disability and depression were noted.

### **Summary of Evidence**

For individuals who have chronic neuropathic pain who receive PSFS, the evidence includes a randomized controlled trial, a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single randomized controlled trial, which used a crossover design, did not compare PSFS with alternatives. Rather, it compared different methods of PSFS. Among trial participants, 24 (80%) of 30 patients had at least a 50% reduction in pain with any type of PSFS. However, because the randomized controlled trial 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. Case series are insufficient to evaluate patient 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 PSFS for chronic pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **Supplemental Information**

#### **Practice Guidelines and Position Statements**

The National Institute for Health and Care Excellence issued guidance (2013) on peripheral subcutaneous field stimulation for chronic low back pain, which stated<sup>7</sup>:

“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.”

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

| NCT No.        | Trial Name                                                                                                                                                                                         | Planned Enrollment | Completion Date |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------|
| <b>Ongoing</b> |                                                                                                                                                                                                    |                    |                 |
| ISRCTN53432663 | A randomised, patient-assessor blinded, sham-controlled trial of external non-invasive peripheral nerve stimulation for chronic neuropathic pain following peripheral nerve injury (EN-PENS trial) | 75                 | Aug 2019        |
| NCT02893267    | Multimodal Treatment for Hemiplegic Shoulder Pain                                                                                                                                                  | 132                | Dec 2021        |

NCT: national clinical trial; ISRCTN: International Standard RCT Number.

### References

- 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*. Nov 2013;16(6):565-575. PMID 23577773
- 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*. Mar-Apr 2011;14(2):151-154; discussion 155. PMID 21992203
- Kloimstein H, Likar R, Kern M, et al. Peripheral nerve field stimulation (PNFS) in chronic low back pain: a prospective multicenter study. *Neuromodulation*. Feb 2014;17(2):180-187. PMID 24320718
- Sator-Katzenschlager S, Fiala K, Kress HG, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. *Pain Pract*. Jul-Aug 2010;10(4):279-286. PMID 20230450
- Verrills P, Vivian D, Mitchell B, et al. Peripheral nerve field stimulation for chronic pain: 100 cases and review of the literature. *Pain Med*. Sep 2011;12(9):1395-1405. PMID 21812906
- Verrills P, Rose R, Mitchell B, et al. Peripheral nerve field stimulation for chronic headache: 60 cases and long-term follow-up. *Neuromodulation*. Jan 2014;17(1):54-59. PMID 24165152
- National Institute for Health and Care Excellence (NICE). Peripheral nerve-field stimulation for chronic low back pain [IPG451]. 2013; <https://www.nice.org.uk/guidance/ipg451>. Accessed March 9, 2018.
- Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.139 (April 2018).

### Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.*

### IE

The following services may be considered investigational.

| Type             | Code  | Description                        |
|------------------|-------|------------------------------------|
| CPT®             | 64999 | Unlisted procedure, nervous system |
| HCPCS            | None  |                                    |
| ICD-10 Procedure | None  |                                    |

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action                                                                                                                                                    | Reason                   |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| 07/31/2015     | Policy title change from Electrical Stimulation for Pain and Other Conditions<br>Policy revision without position change<br>BCBSA Medical Policy adoption | Medical Policy Committee |
| 06/01/2016     | Policy revision without position change                                                                                                                   | Medical Policy Committee |
| 02/01/2017     | Coding update                                                                                                                                             | Administrative Review    |
| 06/01/2017     | Policy revision without position change                                                                                                                   | Medical Policy Committee |
| 06/01/2018     | Policy revision without position change                                                                                                                   | Medical Policy Committee |

## Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*