BlueCross BlueShield of Alabama

Name of Policy:
Peripheral Subcutaneous Field Stimulation

Policy #: 526
Category: Medical

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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. Applications of PSFS being evaluated are 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 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 (SCS), 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 SCS plus 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.

Policy:

Peripheral subcutaneous field stimulation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused *because of a coverage determination.*

Key Points:

The most recent literature review was updated through February 05, 2018.
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.

Chronic Neuropathic Pain

No sham- or active pain treatment-controlled RCTs evaluating peripheral subcutaneous field stimulation (PSFS) were identified. One crossover RCT 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. Of 30 patients who completed the first phase, 24 reported that pain was significantly reduced by at least 50% in any

of the stimulation groups and were considered responders to PSFS. In Phase II, a permanent PSFS system was placed in 23 responders. During the 52 weeks over which these patients were followed, reported mean visual analog scale (VAS) 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 comparative evaluation of combined use of spinal cord stimulation (SCS) and PSFS in patients with low back pain; it was reported by Mironer et al in 2011. 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 and 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 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, 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. In 2014, Kloimstein et al reported on a prospective multicenter study of 118 patients treated with PSFS for chronic low back pain. 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 follow-ups after implantation in average pain VAS, 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. 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 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% 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.

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. 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) with 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. Analgesic 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.

In 2014, Verrills et al reported on PSFS for chronic headache conditions. 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 peripheral subcutaneous field stimulation (PSFS), the evidence includes 1 randomized controlled trial (RCT), 1 nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT, which used a crossover design, did not compare PSFS to 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 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. 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.

Practice Guidelines and Position Statements

In 2013 the National Institute for Health and Care Excellence issued guidance peripheral subcutaneous field stimulation for chronic low back pain. The guidance stated:

> "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.

Key Words:
Peripheral subcutaneous field stimulation, PSFS

Approved by Governing Bodies:
No devices have been approved by the U.S. Food and Drug Administration (FDA) specifically for peripheral subcutaneous field stimulation (PSFS). PSFS an off-label use of SCS devices has been approved by FDA for the treatment of chronic pain. *(See policy #328-Spinal Cord Stimulation)*

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:
CPT Codes:

There are no specific CPT codes for peripheral subcutaneous field stimulation.

64999	unlisted procedure, nervous system

Previous Coding:
CPT Codes:

0282T	Percutaneous of 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 **(Deleted 12/31/16)**
0283T	Percutaneous of 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 **(Deleted 12/31/16)**
0284T	Revision or removal of pulse generator or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed **(Deleted 12/31/16)**
0285T	Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed **(Deleted 12/31/16)**

References:

1. Kloimstein H, Likar R, Kern M et al. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. Neuromodulation 2013.
2. 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.
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. National Institute for Health and Care Excellence. IPG451 Peripheral nerve-field stimulation for chronic low back pain: guidance. 2013. Available online at: guidance.nice.org.uk/IPG451/Guidance/pdf/English. Last accessed February, 2014.
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, Rose R, Mitchell B et al. Peripheral Nerve Field Stimulation for Chronic Headache: 60 Cases and Long-Term Follow-Up. Neuromodulation 2013.
7. 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.

Policy History:

Medical Policy Panel, March 2013
Medical Policy Group, March 2013 **(2)** New policy
Medical Policy Administration Committee, April 2013
Available for comment April 18 through June 5, 2013
Medical Policy Panel, March 2014
Medical Policy Group, March 2014 **(1):** Update to Key Points and References; no change to policy statement
Medical Policy Panel, March 2015
Medical Policy Group, March 2015 **(6):** Update to Key Points; no change to policy statement
Medical Policy Panel, April 2016
Medical Policy Group, April 2016 **(6):** Update to Description and Key Points; no change to policy statement.
Medical Policy Group, December 2016: 2017 Annual Coding Update. Created previous coding section and moved deleted CPT codes 0282T - 0285T to this section; added existing CPT code 64999 to current coding.
Medical Policy Panel, April 2017
Medical Policy Group, April 2017 **(6)**: Update to Description and Key Points: no change to policy statement.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(6)**: Updates to Key Points.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Crss and Blue Shield's administration of plan contracts.