Medical Coverage Policy | Peripheral Subcutaneous Field Stimulation

EFFECTIVE DATE: 04|01|2017
POLICY LAST REVIEWED: 05|20|2026

OVERVIEW
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 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Peripheral subcutaneous field stimulation, PSFS, is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Peripheral subcutaneous field stimulation, PSFS, is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

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

Neuromodulation is another form of nonpharmacologic 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 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. Moreover, it is important to distinguish direct peripheral nerve stimulation from other indirect and nonspecific neuromodulation techniques. Direct peripheral nerve stimulation targets specific peripheral nerves and requires image guidance (fluoroscopy or ultrasound) and advanced procedural skills for proper lead placement and to minimize complications such as lead fracture or migration. In contrast, peripheral nerve field stimulation (ie, peripheral subcutaneous field stimulation) places leads in subcutaneous tissue to provide diffuse stimulation over painful areas; percutaneous electrical nerve stimulation (PENS) delivers temporary stimulation to subcutaneous

nerves; and transcutaneous electrical nerve stimulation (TENS) uses surface skin electrodes to relieve pain without targeting specific nerves.

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 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 action in PSFS is not known. Theories include an increase in endogenous endorphins and other opiate-like substances, modulation of smaller A delta and C nerve 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.

For individuals who have chronic neuropathic pain who receive PSFS, the evidence includes 2 randomized controlled trials (RCTs), a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT, McRoberts et al (2013), 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 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. An open-label RCT found that PSFS plus medical management had a greater rate of pain reduction compared to medical management alone at 9 months follow-up. Secondary outcomes found benefits in several quality-of-life indices over medical management alone. The trial had a high loss to follow-up and was terminated early as a result of recruitment challenges, which impacted the durability and certainty of these findings. Case series are insufficient to evaluate patient outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Larger, 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 that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

There is no specific CPT code for this treatment. Report using unlisted CPT code 64999 (Unlisted procedure, nervous system).

RELATED POLICIES:

Lysis of Epidural Adhesions
Nerve Graft with Radical Prostatectomy
Occipital Nerve Stimulation – Insertion
Sphenopalatine Ganglion Block for Headache
Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
Pulsed Radiofrequency for the Treatment of Chronic Pain

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