Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Peripheral Subcutaneous Field Stimulation

Policy #: 526
Latest Review Date: April 2023
Category: Medical
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage*

Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

POLICY:

Blue Advantage will treat **peripheral subcutaneous field stimulation** as a **non-covered** benefit and as **investigational.**

Blue Advantage 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 Advantage administers benefits based on the members' contract and 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.

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, 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.

Treatment

Pharmacologic agents are typically the first-line treatment for chronic pain, and several classes of medications are available. They include analgesics (opioid and non-opioid), antidepressants, anticonvulsants, and muscle relaxants. Varieties of non-pharmacologic treatments also exist, including physical therapy, exercise, cognitive-behavioral interventions, acupuncture, chiropractic, and therapeutic massage.

Neuromodulation, a form of non-pharmacologic 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.

KEY POINTS:
The most recent literature review was updated through March 8, 2023.

Summary of Evidence
For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes 4 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 peripheral subcutaneous field stimulation with alternatives. Rather, it compared different methods of peripheral subcutaneous field stimulation. Among trial participants, 24 (80%) of 30 patients had at least a 50% reduction in pain with any type of peripheral subcutaneous field stimulation. 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. Another RCT by Johnson et al (2021) compared sham to external non-invasive peripheral electrical nerve stimulation, but found no significant differences in pain scores between groups after intervention.

A third small, pilot RCT by Ilfeld et al (2021) found significantly decreased opioid consumption and mean daily pain scores within the first 7 postoperative days in subjects undergoing foot, ankle, knee, or shoulder surgery. However, differences in average pain, worst pain, and Defense and Veterans Pain Rating Scale scores were not significantly different between treatment and sham groups following completion of the treatment period on postoperative days 15 and 30.

A fourth small, pilot feasibility RCT by Albright-Trainer et al (2022) compared peripheral nerve stimulation with standard medical care to standard medical care alone in veterans receiving lower extremity amputation. Greater reductions in average phantom limb pain, residual limb pain, and daily opioid consumption were reported through 3 months with the addition of peripheral nerve stimulation. 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 peripheral subcutaneous field stimulation with placebo or alternative treatment modalities are needed to determine the efficacy of peripheral subcutaneous field stimulation for chronic pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Society of Pain and Neuroscience

In 2022, the American Society of Pain and Neuroscience published consensus clinical guidelines for the use of implantable peripheral nerve stimulation in the treatment of chronic pain based on a review of the literature through March 2021. Recommendations for best practices are listed below in Table 1.

Table 1. American Society of Pain and Neuroscience Best Practices Peripheral Nerve Stimulation Guidelines

Recommendations	LOE	DOR
Head and Neck		
Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatment has failed. The average effect size for relief of migraine symptoms is modest to moderate.	I	B
There is presently insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain	II-3	C
Upper Extremities		
PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain.	I	B

PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief.	II-2	B
Low Back and Trunk		
Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone.	I	B
There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain.	II-2	B
There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia.	III	C
Lower Extremities		
PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief.	I	B
PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief.	I	B
CRPS		
As a less-invasive modality compared to SCS therapy, PNS may be offered to patients with CRPS Type I/II or peripheral causalgia, and may be associated with modest improvement in pain intensity and functional outcomes. However, high-quality evidence is limited and other neuromodulation interventions such as dorsal root ganglion SCS are recommended.	III	C

Other Considerations		
PNS carries a low-to-intermediate risk for bleeding complications and depends on the proximity of the targeted nerve to critical vessels and invasiveness of PNS implantation.	III	I

CRPS: complex regional pain syndrome; DOR: degree of recommendation; LOE: level of evidence; PNS: peripheral nerve stimulation; SCS: spinal cord stimulator.

The National Institute for Health and Care Excellence (NICE)
In 2013, NICE 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, SPRINT® Peripheral Nerve Stimulation System

APPROVED BY GOVERNING BODIES:
In July 2018, the U.S. Food and Drug Administration (FDA) cleared the SPRINT Peripheral Nerve Stimulation System (SPR Therapeutics, Inc.) for marketing through the 510(k) process (K181422). FDA determined that this device was equivalent to existing devices for use in pain management. FDA has approved PSFS an off-label use of SCS devices for the treatment of chronic pain. (See policy #328-Spinal Cord Stimulation)

The U.S. Food and Drug Administration (FDA) has not approved a device specifically for peripheral subcutaneous field stimulation (PSFS). PSFS is an off-label use of spinal cord stimulation devices or peripheral nerve stimulation devices (e.g. the SPRINT® PNS System) that have been FDA approved for the management of pain.

In October 2022, the indications for use were clarified to note that the system is not intended to be placed in the region innervated by the cranial and facial nerves.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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

64999	unlisted procedure, nervous system

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POLICY HISTORY:

Adopted for Blue Advantage, April 2013
Available for comment April 18 through June 5, 2013
Medical Policy Group, March 2014
Medical Policy Group, March 2015
Medical Policy Group, April 2016
Medical Policy Group, December 2016
Medical Policy Group, April 2017
Medical Policy Group, May 2018
Medical Policy Group, May 2019
Medical Policy Group, May 2020
Medical Policy Group, April 2021
Medical Policy Group, April 2022
Medical Policy Group, April 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.
