BlueCross BlueShield Federal Employee Program.

# FEP Medical Policy Manual

## FEP 7.01.139 Peripheral Subcutaneous Field Stimulation

**Effective Policy Date: July 1, 2023**

**Original Policy Date: June 2013**

**Related Policies:**

1.01.09 - Transcutaneous Electrical Nerve Stimulation
7.01.29 - Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

## Peripheral Subcutaneous Field Stimulation

### Description

## Description

Peripheral subcutaneous field stimulation is a form of neuromodulation intended to treat chronic neuropathic pain. Applications of peripheral subcutaneous field stimulation being evaluated are craniofacial stimulation for headache and migraine, craniofacial pain, or occipital neuralgia. Peripheral subcutaneous field stimulation is also being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and postherpetic neuralgia.

## OBJECTIVE

The objective of this evidence review is to determine whether use of peripheral subcutaneous field stimulation improves the net health outcome for patients with chronic neuropathic pain.

## POLICY STATEMENT

Peripheral subcutaneous field stimulation is **investigational**.

# POLICY GUIDELINES

None

# BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

# FDA REGULATORY STATUS

In July 2018, the SPRINT Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K181422). The FDA determined that this device was substantially equivalent to existing devices for use in pain management. Peripheral subcutaneous field stimulation is also an off-label use of spinal cord stimulation devices that have been approved by the FDA for the treatment of chronic pain (see evidence review 7.01.25). 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.

# RATIONALE

## Summary of Evidence

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes 4 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 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 reduced opioid consumption and mean daily pain scores within the first 7 postoperative days in subjects receiving 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 undergoing 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.

# SUPPLEMENTAL INFORMATION

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### 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.[11,] 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 have 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.

## National Institute for Health and Care Excellence

In 2013, NICE issued guidance on peripheral subcutaneous field stimulation for chronic low back pain, which stated[12]:

"Current evidence on the efficacy of peripheral nerve-field stimulation 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.

# REFERENCES


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8. 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): 1395-405. PMID 21812906
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11. Strand N, D'Souza RS, Hagedorn JM, et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. J Pain Res. 2022; 15: 2483-2504. PMID 36039168
12. 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 28, 2023.

## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---|---|---|
| June 2013 | New policy | |
| June 2014 | Replace policy | Policy updated with literature review, adding references 1, 2, 4 and 7.The policy statement is unchanged. |
| June 2015 | Replace policy | Policy updated with literature review; no references added; reference 2 updated. Policy statements unchanged. |
| June 2016 | Replace policy | Policy updated with literature review through February 12, 2016; no references added. Policy statement unchanged. |
| June 2018 | Replace policy | Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged. |
| June 2019 | Replace policy | Policy updated with literature review through February 5, 2019; no references added. Regulatory status section updated. Policy statement unchanged. |
| June 2020 | Replace policy | Policy updated with literature review through February 11, 2020; no references added. Policy statement unchanged. |
| June 2021 | Replace policy | Policy updated with literature review through February 10, 2021; no references added. Policy statement unchanged. |
| June 2022 | Replace policy | Policy updated with literature review through March 1, 2022; references added. Policy statement unchanged. |
| June 2023 | Replace policy | Policy updated with literature review through March 8, 2023; references added. Policy statement unchanged. |