MEDICAL POLICY

POLICY TITLE	PERIPHERAL SUBCUTANEOUS FIELD STIMULATION (PSFS)
POLICY NUMBER	MP 1.141

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**9/1/2024**

I. POLICY

Peripheral subcutaneous field stimulation is **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP 1.069 Spinal Cord and Dorsal Root Ganglion Stimulation
MP 2.092 Percutaneous Electrical Nerve Field Stimulation
MP 6.020 Transcutaneous Electrical Nerve Stimulation, Cranial Electrotherapy Stimulation, Auricular Electrostimulation, and External Trigeminal Nerve Stimulation (Formerly Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation)
MP 6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION /BACKGROUND

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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.

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 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.

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). FDA determined that this device was substantially equivalent to existing devices for use in pain management. PSFS is also 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. 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.

IV. RATIONALE

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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 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.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, therefore not covered:

Procedure Codes								
64999								

IX. REFERENCES

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2. *Johnson S, Marshall A, Hughes D, et al. Mechanistically informed non-invasive peripheral nerve stimulation for peripheral neuropathic pain: a randomised double-blind sham-controlled trial. J Transl Med. Nov 06 2021; 19(1): 458. PMID 34742297*

3. *Johnson S, Marshall A, Hughes D, et al. Mechanistically informed non-invasive peripheral nerve stimulation for peripheral neuropathic pain: a randomised double-blind sham-controlled trial. J Transl Med. Nov 06 2021; 19(1): 458. PMID 34742297*
4. *Johnson S, Marshall A, Hughes D, et al. Mechanistically informed non-invasive peripheral nerve stimulation for peripheral neuropathic pain: a randomised double-blind sham-controlled trial. J Transl Med. Nov 06 2021; 19(1): 458. PMID 3474229*
5. *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*
6. *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*
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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):1395-1405. PMID 21812906*
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11. *Johnson S, Marshall A, Hughes D, et al. Mechanistically informed non-invasive peripheral nerve stimulation for peripheral neuropathic pain: a randomised double-blind sham-controlled trial. J Transl Med. Nov 06 2021; 19(1): 458. PMID 34742297*
12. *National Institute for Health and Care Excellence (NICE). Peripheral nerve-field stimulation for chronic low back pain [IPG451]. 2013*
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14. *Kaye AD, Ridgell S, Alpaugh ES, et al. Peripheral Nerve Stimulation: A Review of Techniques and Clinical Efficacy. Pain Ther. 2021;10(2):961-972. doi:10.1007/s40122-021-00298-1*
15. *Xu J, Sun Z, Wu J, et al. Peripheral Nerve Stimulation in Pain Management: A Systematic Review. Pain Physician. 2021;24(2):E131-E152.*
16. *Copenhaver, D., et al. Interventional therapies for chronic pain. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; Updated April 16, 2024.. Literature review current through March 2024.*
17. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.139. Peripheral Subcutaneous Field Stimulation. May, 2023*

X. POLICY HISTORY

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MP 1.141	**11/02/2020 Consensus Review.** No change to policy statement. References updated.
	03/31/2021 Consensus Review. No change to policy statement. Coding reviewed.
	04/25/2022 Consensus Review. Updated cross references, FEP, and references. No changes to coding.
	06/202023 Consensus Review. No change to policy statement. References updated. No change to coding.
	04/29/2024 Consensus Review. No change to policy statement. Regulatory status and references updated. Coding reviewed with no coding changes.

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