Peripheral Subcutaneous Field Stimulation

Policy # 00473
Original Effective Date: 07/15/2015
Current Effective Date: 08/09/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Transcutaneous Electrical Nerve Stimulation is addressed separately in medical policy 00142.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy 00144.

Note: Occipital Nerve Stimulation is addressed separately in medical policy 00253.

Note: Spinal Cord Stimulation is addressed separately in medical policy 00260.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers peripheral subcutaneous field stimulation (PSFS) to be **investigational.***

Background/Overview

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. These 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.

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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, 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 is a modification of peripheral nerve stimulation. In peripheral subcutaneous field stimulation, leads are placed subcutaneously within the area of maximal pain. The objective of peripheral subcutaneous field stimulation 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 spinal cord stimulation plus peripheral subcutaneous field stimulation 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 peripheral subcutaneous field stimulation. Criteria for a trial of peripheral subcutaneous field stimulation 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 peripheral subcutaneous field stimulation 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 peripheral subcutaneous field stimulation include lead migration or breakage and infection of the lead or neurostimulator.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
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.

Rationale/Source

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.

Summary of Evidence

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes a randomized controlled trial (RCT), a 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 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. 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 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

National Institute for Health and Care Excellence
In 2013, the National Institute for Health and Care Excellence (NICE) issued guidance on peripheral subcutaneous field stimulation for chronic low back pain, which stated:

> "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.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
ISRCTN53432663	A randomised, patient-assessor blinded, sham-controlled trial of external non-invasive peripheral nerve stimulation for chronic neuropathic pain following peripheral nerve injury (EN-PENS trial)	76	May 2020
NCT02893267	Multimodal treatment for hemiplegic shoulder pain	132	Dec 2021
NCT03783689[a]	The SNAP trial: SPRINT Peripheral Nerve Stimulation for the treatment of neuropathic post-amputation pain in a randomized, double-blinded, placebo-controlled multicenter trial	126	Oct 2022

NCT: national clinical trial: ISRCTN: International Standard RCT Number.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Peripheral Subcutaneous Field Stimulation", 7.01.139, May 2021.
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. Nov-Dec 2013; 16(6): 565-74; discussion 574-5. PMID 23577773
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. Mar-Apr 2011; 14(2): 151-4; discussion 155. PMID 21992203

4. 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): 180-7. PMID 24320718
5. Sator-Katzenschlager S, Fiala K, Kress HG, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. Pain Pract. Jul-Aug 2010; 10(4): 279-86. PMID 20230450
6. 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
7. Verrills P, Rose R, Mitchell B, et al. Peripheral nerve field stimulation for chronic headache: 60 cases and long-term follow-up. Neuromodulation. Jan 2014; 17(1): 54-9. PMID 24165152
8. 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.

Policy History

Original Effective Date: 07/15/2015
Current Effective Date: 08/09/2021

06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. New policy.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes and CPT coding update
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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07/01/2021 Medical Policy Committee review
07/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 07/2022

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64999
HCPCS	No codes

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ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.