7.01.139	Peripheral Subcutaneous Field Stimulation		
Original Policy Date:	July 31, 2015	**Effective Date:**	June 1, 2023
Section:	7.0 Surgery	**Page:**	Page 1 of 11

Policy Statement

I. Peripheral subcutaneous field stimulation is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

- N/A

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.

Related Policies

- Occipital Nerve Stimulation
- Spinal Cord and Dorsal Root Ganglion Stimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 Blue Shield of California Medical Policy: Spinal Cord and Dorsal Root Ganglion Stimulation). 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

Background

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.

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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Chronic Neuropathic Pain

Clinical Context and Therapy Purpose

The purpose of peripheral subcutaneous field stimulation in individuals who have chronic neuropathic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with chronic neuropathic pain.

Interventions

The therapy being considered is 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.

Comparators

The following therapies are currently being used to make decisions about peripheral subcutaneous field stimulation: pharmacotherapy, exercise or physical therapy, and cognitive-behavioral therapy.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity.

As a chronic condition, follow-up of at least 6 weeks to 12 months would be desirable to assess outcomes in chronic neuropathic pain.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

One crossover RCT compared levels of peripheral subcutaneous field stimulation. McRoberts et al (2013) reported on a randomized, crossover trial of different types of peripheral subcutaneous field stimulation in 44 patients with chronic back pain. In the first phase of the trial, patients rotated through 4 levels of peripheral subcutaneous field stimulation: minimal, subthreshold, low frequency, and standard stimulation.[1,] Of 30 patients who completed the first phase, 24 reported that pain was significantly reduced by at least 50% in all of the stimulation groups and were considered responders. In phase 2, a permanent peripheral subcutaneous field stimulation system was placed in 23 responders. During the 52 weeks over which these patients were followed, reported mean visual analog scale scores, present pain index, and total scores on the Short-Form McGill Pain Questionnaire were significantly improved from baseline at all follow-up visits (p<.001). Because this trial did not include a control group, the methodologic strength of these results is similar to that of an uncontrolled study.

Johnson et al (2021) conducted a 2-part study comprised of a double-blind, sham controlled RCT followed by an open-label mechanistic study to determine the impact of external non-invasive peripheral electrical nerve stimulation (ENPENS) in adults with chronic moderate to severe peripheral nerve injury pain.[2,] Patients were randomized to either active ENPENS or sham for 3 months (minimum 10 minutes daily). The primary outcome was change in average pain intensity (on a 0 to 10 Likert scale) after ENPENS or sham. Seventy-six patients were randomized (38 per group), with 65 (31 active, 34 sham) included in the intention-to-treat analysis. After adjusting for baseline scores, pain scores were 0.3 units lower in the active group, but not significantly different from the sham group (p=.30). Nineteen patients continued on to the open-label ENPENS mechanistic study after the RCT. In the open-label phase, primary outcomes of mechanical pain sensitivity (p=.006) and mechanical allodynia (p=.043) significantly improved, indicating reduced sensitivity to pain with low-frequency nerve stimulation. Results from the RCT failed to reach significance and the results from the open-label portion were limited by the small sample size and lack of a comparator group.

Ilfeld et al (2021) published the results of a randomized, sham-controlled, pilot study of peripheral nerve stimulation (PNS) for the treatment of postoperative pain in individuals receiving foot, ankle, knee, or shoulder surgery.[3,] Subjects were randomized to 14 days of electrical PNS stimulation (n=32) or sham stimulation (n=34). The dual primary outcomes were cumulative opioid consumption and mean daily pain scores within the first 7 postoperative days. Both outcomes met superiority thresholds with median opioid consumption of 5 mg versus 48 mg (estimated ratio of geometric means, 0.20; 97.5% CI, 0.07 to 0.57; p<.001) and average pain intensity of 1.1 versus 3.1 (difference in means, -1.8; 97.5% CI, -2.6 to -0.9; p<.001) as assessed by the Brief Pain Inventory-Short Form (BPI-SF) in treatment and sham groups, respectively. Differences in average pain, worst pain, and pain as assessed by the Defense and Veterans Pain Rating Scale were not significantly different between groups following completion of the treatment period on postoperative days 15 and 30.

Albright-Trainer et al (2022) conducted a randomized controlled feasibility trial of PNS for the management of post-amputation pain.[4,] Sixteen U.S. veterans undergoing major lower limb amputation at a single center received up to 60 days of PNS with the SPRINT system and standard medical therapy (n=8) or standard medical therapy alone (n=8). Standard medical therapy was defined as routine use of opioid and non-opioid pain medications, injections, physical rehabilitative therapies or complementary and alternative therapies. Responders were defined as participants with a at least a 50% reduction in average residual and phantom limb pain over time as assessed by the

Brief Pain Inventory-Short Form (BPI-SF), with greater than 50% improvement considered substantial. At 12 weeks of follow-up, the PNS group experienced a 76% and 100% reduction in average phantom and residual limb pain from baseline compared to 58% and 75% in the control group, respectively. Additionally, only 20% of patients in the PNS group were taking opioids at 12 weeks compared to 38% in the control group. No patients in the PNS group required hospital readmission within 30 days compared to 25% requiring readmission in the control group. Follow up analysis through 12 months is ongoing. No serious study-related adverse events were reported. Follow-up at 12 weeks was missing for 3 individuals in the PNS group (termination due to unrelated medical events [2] and withdrawal of consent [1]) and 1 individual in the control group (withdrawal of consent). The authors concluded that larger studies are warranted to reproduce the encouraging results of their feasibility study and to elucidate optimal timing of PNS therapy, evaluate surgical indications, and optimize patient selection.

Nonrandomized Comparative Study

In another comparative study, Mironer et al (2011) used a 2-part evaluation of combined use of spinal cord stimulation and peripheral subcutaneous field stimulation in patients with low back pain.[5,] In the first part of the study, 20 patients with failed back surgery syndrome or spinal stenosis underwent a trial with both spinal cord stimulation and peripheral subcutaneous field stimulation and selected the type of stimulation they found most efficacious (program 1: spinal cord stimulation alone; program 2: peripheral subcutaneous field stimulation alone; program 3: combined spinal cord stimulation plus peripheral subcutaneous field stimulation). Patients were blinded to the differences among the programs (randomized order of presentation) and were encouraged to try each program for at least 8 hours; 79% of patients preferred the combined use of spinal cord stimulation plus peripheral subcutaneous field stimulation. In the second part of the study, 20 patients were implanted with spinal cord stimulation and peripheral subcutaneous field stimulation electrodes and selected which program they preferred (spinal cord stimulation and peripheral subcutaneous field stimulation used simultaneously, spinal cord stimulation as anode and peripheral subcutaneous field stimulation as cathode, spinal cord stimulation as cathode and peripheral subcutaneous field stimulation as anode). The programs were presented in a random order, and patients were blinded to the differences among the programs offered. Communication between spinal cord stimulation and peripheral subcutaneous field stimulation was reported to provide wider coverage of axial pain, with an overall success rate (>50% pain relief) of 90%. The most effective program was spinal cord stimulation as cathode and peripheral subcutaneous field stimulation as anode.

Case Series

In addition to the controlled studies, a number of case series have been published, several of which included 50 or more patients. Kloimstein et al (2014) reported on a prospective multicenter study of 118 patients treated with peripheral subcutaneous field stimulation for chronic low back pain.[6,] Before patients were implanted with the permanent peripheral subcutaneous field stimulation system, trial stimulation was given for at least 7 days. The permanent stimulation system was implanted in 105 patients. Significant improvements occurred at the 1-, 3-, and 6-month postimplantation follow-ups in average visual analog score pain, Oswestry Disability Questionnaire, Beck Depression Inventory, and 12-Item Short-Form Health Survey scores. Significant reductions in use of opioids, nonsteroidal anti-inflammatory, and anticonvulsant medications were also reported.

Sator-Katzenschlager et al (2010) reported on a retrospective multicenter study of peripheral subcutaneous field stimulation.[7,] A total of 111 patients with chronic focal noncancer pain were treated, including 29 patients with low back pain, 37 with failed back surgery syndrome, 15 with cervical neck pain, and 12 patients with postherpetic neuralgia. The median duration of chronic pain was 13 years, and the median number of previous surgeries was 2.7. For permanent implantation of the leads, patients had to have achieved at least 50% reduction in pain on a numeric rating scale during the trial period. After permanent implantation, pain intensity decreased in 102 (92%) patients. Mean pain intensity decreased from 8.2 at baseline to 4.0 at follow-up, with a concomitant reduction

in consumption for analgesics and antidepressants. Lead dislocation or fracture occurred in 20 (18%) patients.

Verrills et al (2011) reported on a series of 100 patients treated with peripheral subcutaneous field stimulation for chronic neuropathic pain. Indications included chronic pain occurring among varying regions: occipital/craniofacial (n=40), lumbosacral (n=44), thoracic (n=8), groin/pelvis (n=5), or abdominal (n=3).[8,] Selection criteria included a clearly defined, discrete focal area of pain with a neuropathic component 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. Outcomes, assessed at a mean of 8.1 months after implantation (range, 1 to 23 months), included a combination of numeric pain scores, self-report questionnaires, and patient medical histories. For the entire cohort, pain decreased from 7.4 at baseline to 4.2 at follow-up. Pain scores improved by 75% or more in 34% of patients and by 50% or more in 69% of patients. Analgesia use decreased in 40% of patients after peripheral subcutaneous field stimulation. Adverse events were reported in 14% of patients and included unpleasant sensations, lead erosions, and lead or battery migration.

Verrills et al (2014) also reported on peripheral subcutaneous field stimulation for chronic headache conditions.[9,] After a trial stimulation period, 60 patients underwent permanent implantation of the peripheral subcutaneous field stimulation system and were followed for an average of 12.9 months (range, 3 to 42 months). Ten patients required revision of the implant system. Significant reductions in pain from baseline were reported ($p \leq .001$). Additionally, use of analgesics or prophylactic medications was reduced in 83% of patients, and reductions in degree of disability and depression were noted.

A retrospective case series by Warner et al (2020) reported on adults undergoing peripheral nerve stimulation implantation at an academic medical center.[10,] The primary outcomes were changes in numeric rating scale pain scores, opioid use in oral morphine milligram equivalent (MME), and self-reported patient functioning at 6 months post-implantation. A total of 72 patients underwent peripheral nerve stimulation implantation. The most common indication for stimulation was occipital neuralgia (47.3%) followed by lower-extremity neuropathies (16.5%). Peripheral nerve stimulation implantation was associated with a 6-month reduction in pain scores (median baseline score 7 vs median score 4 at 6 months; $p<.001$) and opioid utilization (median 60 MME at baseline vs median 18 MME among those with baseline opioid use [n=25]; $p<.001$). All patients reported improvement in daily functioning, with median improvement of 73% post-implantation.

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.

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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing or unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02893267	Multimodal Treatment for Hemiplegic Shoulder Pain	132	Dec 2023
NCT04341948[a]	Treatment of Post-Operative Pain Following Orthopedic Surgery With SPRINT® Peripheral Nerve Stimulation (PNS) System in a Randomized, Double-Blinded, Placebo-Controlled Trial	150	Apr 2024
NCT04713098	Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacologic Alternative for the Treatment of Postoperative Pain	250	Dec 2024
NCT04246281[a]	A Randomized, Controlled, Multicenter Trial of Percutaneous Peripheral Nerve Stimulation (PNS) for the Treatment of Back Pain (RESET)	230	Dec 2024
Unpublished			
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	104	Sep 2022 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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. Ilfeld BM, Plunkett A, Vijjeswarapu AM, et al. Percutaneous Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study. Anesthesiology. Jul 01 2021; 135(1): 95-110. PMID 33856424
4. Albright-Trainer B, Phan T, Trainer RJ, et al. Peripheral nerve stimulation for the management of acute and subacute post-amputation pain: a randomized, controlled feasibility trial. Pain Manag. Apr 2022; 12(3): 357-369. PMID 34761694
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. 2011; 14(2): 151-4; 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): 180-7. PMID 24320718
7. Sator-Katzenschlager S, Fiala K, Kress HG, et al. Subcutaneous target stimulation (STS) in chronic noncancer pain: a nationwide retrospective study. Pain Pract. 2010; 10(4): 279-86. PMID 20230450
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
9. 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
10. Warner NS, Schaefer KK, Eldrige JS, et al. Peripheral Nerve Stimulation and Clinical Outcomes: A Retrospective Case Series. Pain Pract. Apr 2021; 21(4): 411-418. PMID 33222402

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.

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	64999	Unlisted procedure, nervous system
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/31/2015	Policy title change from Electrical Stimulation for Pain and Other Conditions Policy revision without position change BCBSA Medical Policy adoption
06/01/2016	Policy revision without position change
02/01/2017	Coding update
06/01/2017	Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2023	Policy reactivated. Previously archived from 06/01/2020 to 05/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not

more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	**Peripheral Subcutaneous Field Stimulation 7.01.139** **Policy Statement:** I. Peripheral subcutaneous field stimulation is considered **investigational**.