LifeWise
Health Plan of Washington

MEDICAL POLICY – 7.01.139

Peripheral Subcutaneous Field Stimulation

BCBSA Ref. Policy:	7.01.139
Effective Date:	July 1, 2024
Last Revised:	Jan. 1, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.125	Occipital Nerve Stimulation
7.01.588	Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

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Introduction

Peripheral subcutaneous field stimulation (PSFS) uses small amounts of electricity to try to treat pain. Small electrodes are placed under the skin near the area of pain. The electrodes are connected by wires to a battery pack that generates electrical signals. The generator is usually also placed under the skin. The goal is to use small bursts of electricity to interrupt the pain signals carried by the nerves. PSFS is unproven (investigational). Studies comparing PSFS with other forms of pain treatment are needed to find out how well PSFS works for chronic pain.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Peripheral subcutaneous field stimulation	**Peripheral subcutaneous field stimulation (e.g., SPRINT peripheral nerve stimulation system) is considered investigational.**

Coding

Code	Description
CPT	
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64999	Unlisted procedure, nervous system
HCPCS	
C9807	Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023) (New code effective 1/1/2025)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

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.

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. They include analgesics (opioid and non-opioid), 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, another form of nonpharmacologic therapy, is usually targeted toward individuals 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

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. Combined spinal cord stimulation 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.

Summary of Evidence

For individuals who have chronic neuropathic pain who receive PSFS, the evidence includes two 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 PSFS with alternatives. Rather, it compared different methods of PSFS. Among trial participants, 24 (80%) of 30 individuals had at least a 50% reduction in pain with any type of PSFS. 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. An open-label RCT found that peripheral subcutaneous field stimulation plus medical management had a greater rate of pain reduction compared to medical management alone at 9 months follow-up. Secondary outcomes found benefits in several quality-of-life indices over medical management alone. The trial had a high loss to follow-up and was terminated early as a result of recruitment challenges, which impacted the durability and certainty of these findings. Case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Larger, prospective controlled trials comparing PSFS with placebo or alternative treatment modalities are needed to determine the efficacy of PSFS for chronic pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

No ongoing or unpublished clinical trials of peripheral subcutaneous field stimulation were identified.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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.[8] 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

Recommendations	LOE	DOR
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, the NICE issued guidance on peripheral subcutaneous field stimulation for chronic low back pain which stated[9]:

> 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Peripheral subcutaneous field stimulation is an off-label use of peripheral nerve stimulation systems that have been approved by the FDA for the treatment of chronic pain by targeting one or more peripheral nerves associated with pain.

References

1. 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. 2013; 16(6): 565-74; discussion 574-5. PMID 23577773
2. Eldabe SS, Taylor RS, Goossens S, et al. A Randomized Controlled Trial of Subcutaneous Nerve Stimulation for Back Pain Due to Failed Back Surgery Syndrome: The SubQStim Study. Neuromodulation. Jul 2019; 22(5): 519-528. PMID 29704437
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. 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. 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. 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
9. 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 May 15, 2024.

History

Date	Comments
05/13/13	New policy. Policy created with literature search through February 13, 2013; considered investigational.
05/12/14	Annual Review. Policy updated with literature review through February 19, 2014. References 1, 2, 4, 7 added; others renumbered/removed. Policy statement unchanged.
05/27/15	Annual Review. Policy updated with literature review through February 22, 2015; no references added; reference 2 updated. Policy statements unchanged.
01/29/16	Minor update. Added HCPCS code L8679.
07/01/16	Annual Review, approved June 14, 2016. Policy updated with literature review through February 12, 2016; no references added. Policy statement unchanged.
07/01/17	Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; no references added. Added CPT code 64999. Policy statement unchanged.
01/01/18	Coding update, removed CPT codes 0282T, 0283T, 0284T, and 0285T as the codes were terminated 1/1/17.
07/01/18	Annual Review, approved June 5, 2018. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Regulatory status section updated. Policy statement unchanged.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through February 2020; references updated. Policy statement unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 10, 2021; no references added. Policy statement unchanged. Added CPT code 64555.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 1, 2022; references added. Policy statement unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through March 8, 2023; references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/04/23	Updated related policy. Policy 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy was renumbered to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy.

Date	Comments
01/01/24	Coding update. Added HCPCS code L8680.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through February 8, 2024. References were added, and several references were removed that did not pertain to peripheral subcutaneous field stimulation. Policy statement unchanged.
01/01/25	Coding update. Added new HCPCS code C9807.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.