PREMERA HMO

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MEDICAL POLICY – 7.01.139

Peripheral Subcutaneous Field Stimulation

BCBSA Ref. Policy:	7.01.139
Effective Date:	July 1, 2023
Last Revised:	Jan. 1, 2024
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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EVIDENCE REVIEW | REFERENCES | HISTORY

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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
64999	Unlisted procedure, nervous system
HCPCS	
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each

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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 four 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. 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 three months with the addition of peripheral nerve stimulation. Case series are insufficient to evaluate pain outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. 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

Some currently ongoing and 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			
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.

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 U.S. professional society, an international society with U.S. 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 2**.

Table 2. 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

Recommendations	LOE	DOR
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[12]:

> 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

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. PSFS is also an off-label use of spinal cord stimulation devices that have been approved by the FDA 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.

References

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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
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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 May 3, 2023.

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.

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