FEP Medical Policy Manual

FEP 7.01.139 Peripheral Subcutaneous Field Stimulation

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2013

Related Policies:

1.01.09 - Transcutaneous Electrical Nerve Stimulation
7.01.29 - Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Peripheral Subcutaneous Field Stimulation

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether use of peripheral subcutaneous field stimulation improves the net health outcome for patients with chronic neuropathic pain.

POLICY STATEMENT

Peripheral subcutaneous field stimulation is **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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..

RATIONALE

Summary of Evidence

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes 2 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 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. 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 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.

SUPPLEMENTAL INFORMATION

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.[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
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 [9,]:

"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.

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 February 8, 2024.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2013	New policy	
June 2014	Replace policy	Policy updated with literature review, adding references 1, 2, 4 and 7.The policy statement is unchanged.
June 2015	Replace policy	Policy updated with literature review; no references added; reference 2 updated. Policy statements unchanged.
June 2016	Replace policy	Policy updated with literature review through February 12, 2016; no references added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Regulatory status section updated. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through February 11, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through February 10, 2021; no references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through March 1, 2022; references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through March 8, 2023; references added. Policy statement unchanged.
June 2024	Replace policy	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.