BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.139 Peripheral Subcutaneous Field Stimulation

Effective Policy Date: July 1, 2022

Original Policy Date: June 2013

Related Policies:

1.01.09 - Transcutaneous Electrical Nerve Stimulation
7.01.29 - Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Peripheral Subcutaneous Field Stimulation

Description

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.

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

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 evidence review 7.01.25).

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 The single 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. 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. 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

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[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

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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. 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. 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
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 March 1, 2022.

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.

Date	Action	Description
June 2022	Replace policy	Policy updated with literature review through March 1, 2022; references added. Policy statement unchanged.