

FEP 7.01.139 Peripheral Subcutaneous Field Stimulation

Effective Date: July 15, 2018

Related Policies:

7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Peripheral Subcutaneous Field Stimulation

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.

FDA REGULATORY STATUS

No devices have been approved by the U.S. Food and Drug Administration specifically for peripheral subcutaneous field stimulation (PSFS). PSFS is an off-label use of spinal cord stimulation devices that have been approved by the Food and Drug Administration for the treatment of chronic pain.

POLICY STATEMENT

Peripheral subcutaneous field stimulation is **investigational**.

BENEFIT APPLICATION

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

RATIONALE

Summary of Evidence

For individuals who have chronic neuropathic pain who receive PSFS, the evidence includes a randomized controlled trial, a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single randomized controlled trial, 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 patients had at least a 50% reduction in pain with any type of PSFS. However, because the randomized controlled trial 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. 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 PSFS with placebo or alternative treatment modalities

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are needed to determine the efficacy of PSFS for chronic pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

The National Institute for Health and Care Excellence issued guidance (2013) on peripheral subcutaneous field stimulation for chronic low back pain, which stated:

“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.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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2. 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):151-154; discussion 155. PMID 21992203
3. 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):180-187. PMID 24320718
4. 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):279-286. PMID 20230450
5. 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):1395-1405. PMID 21812906
6. 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):54-59. PMID 24165152
7. 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 9, 2018.

POLICY HISTORY

Date	Action	Description
June 2013	New Policy	
June 2014	Update Policy	Policy updated with literature review, adding references 1, 2, 4 and 7. The policy statement is unchanged.
June 2015	Update Policy	Policy updated with literature review; no references added; reference 2 updated. Policy statements unchanged.
June 2016	Update Policy	Policy updated with literature review through February 12, 2016; no references added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through February 5, 2018; no references added. Policy statement unchanged.

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