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 post-herpetic 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.

BENEFIT APPLICATION

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

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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). 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 Food and Drug Administration for the treatment of chronic pain.

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 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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

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<th>Date</th>
<th>Action</th>
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<tr>
<td>June 2013</td>
<td>New policy</td>
<td>Policy updated with literature review, adding references 1, 2, 4 and 7.</td>
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<tr>
<td>June 2014</td>
<td>Replace policy</td>
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<td>June 2015</td>
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