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FEP Medical Policy Manual

FEP 7.01.29 Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Effective Policy Date: October 1, 2023

Original Policy Date: December 2011

Related Policies:

1.01.09 - Transcutaneous Electrical Nerve Stimulation
1.01.24 - Interferential Current Stimulation
2.01.21 - Temporomandibular Joint Disorder

Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Description

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Percutaneous electrical nerve stimulation (PENS), percutaneous neuromodulation therapy (PNT), and restorative neurostimulation therapy (ReActiv8) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. Percutaneous electrical nerve stimulation is performed with needle electrodes while PNT uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue. ReActiv8 is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

OBJECTIVE

The objective of this evidence review is to determine whether treatment with percutaneous electrical nerve stimulation, percutaneous neuromodulation therapy, or restorative neurostimulation therapy improves the net health outcome in patients with chronic musculoskeletal or neuropathic pain conditions.

POLICY STATEMENT

Percutaneous electrical neurostimulation is considered **investigational**.

Percutaneous neuromodulation therapy is considered **investigational**.

Restorative neurostimulation therapy (ReActiv8) is considered **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 2002, the Percutaneous Neuromodulation Therapy™ (Vertis Neuroscience) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The labeled indication is: "... for the symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment in the management of post-surgical pain and post-trauma pain."

In 2006, the Deepwave Percutaneous Neuromodulation Pain Therapy System (Biowave) was cleared for marketing by FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to the Vertis neuromodulation system and a Biowave neuromodulation therapy unit. The Deepwave system includes a sterile single-use percutaneous electrode array that contains 1014 microneedles in a 1.5-inch diameter area. The needles are 736 µm (0.736 mm) in length; the patch is reported to feel like sandpaper or Velcro.

In 2020, the ReActiv8 (Mainstay Medical) was FDA approved through the Premarket Approval (PMA) process (PMA P190021) for individuals with intractable chronic low back pain associated with multifidus dysfunction for whom available low back pain treatments do not provide sufficient or durable symptom relief.[2,]

FDA product codes: NHI, QLK.

RATIONALE

Summary of Evidence

For individuals who have chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia) who receive Percutaneous electrical nerve stimulation (PENS), the evidence includes primarily small controlled trials and 2 systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Two systematic reviews have not revealed consistent benefit from PENS in musculoskeletal pain disorders. One review concluded that PENS could decrease pain intensity but not related disability, while the other found no significant differences between PENS and transcutaneous electrical nerve stimulation (TENS) in mitigation of pain. These conclusions are uncertain due to important methodological limitations in individual trials included in these reviews, such as high heterogeneity with regard to application methods. In the highest quality trial of PENS conducted to date in chronic low back pain, no difference in outcomes was found between the active (30 minutes of stimulation with 10 needles) and the sham (5 minutes of stimulation with 2 needles) treatments. Smaller trials, which have reported positive results, are limited by unclear blinding and short-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions (eg, knee osteoarthritis) who receive percutaneous neuromodulation therapy (PNT), the evidence consists of a randomized controlled trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. The single trial is limited by lack of investigator blinding, unclear participant blinding, and short-term follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic pain conditions including low back pain who receive restorative neurostimulation therapy (ReActiv8), the evidence includes 1 sham-controlled RCT (N = 204), 1 prospective single-arm trial (N = 53), and a case series (N = 44). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In the RCT, there was no difference between groups on the primary endpoint of treatment response at 120 days, defined as the composite of 30% or greater reduction in VAS and no increase in pain medications (57.1% intervention vs 46.6%

sham; p =.1377). Prespecified secondary analyses of primary outcome data favored the intervention group, but clinical significance is unclear. An uncontrolled follow-up phase of the RCT reported continued improvement in pain scores through 3 years but results are at high risk of bias due to lack of a control group and high attrition. Nonrandomized studies are limited by lack of blinding, no sham control, high attrition. and small sample sizes. Additional evidence from longer-term sham-controlled RCTs is needed. 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 Academy of Neurology et al

The American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation reaffirmed 2011 evidence-based guidelines on the treatment of painful diabetic neuropathy in 2016.[46,] The guidelines concluded that, based on a class I study, electrical stimulation is probably effective in lessening the pain of diabetic neuropathy and improving quality of life and recommended that PENS be considered for the treatment of painful diabetic neuropathy (level B). The guidelines were retired and replaced in 2022 with a guideline dedicated to oral and topical treatment of painful diabetic polyneuropathy.[47,] In these updated guidelines, there is no mention of any electrical stimulation strategies for pain.

American College of Physicians and American Pain Society

Joint practice guidelines on the diagnosis and treatment of low back pain from the American College of Physicians and the American Pain Society in 2007 indicated uncertainty over whether PENS should be considered a novel therapy or a form of electroacupuncture.[48,] The guidelines concluded that PENS is not widely available. The guidelines also concluded that transcutaneous electrical nerve stimulation has not been proven effective for chronic low back pain. These guidelines were updated in 2017 and authors stated that evidence was insufficient to determine harms associated with PENS thus, no recommendation was made.[49,]

American Society of Anesthesiologists et al

The 2010 practice guidelines for chronic pain management from the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine indicated that subcutaneous peripheral nerve stimulation might be used in the multimodal treatment of patients with painful peripheral nerve injuries who have not responded to other therapies (category B2 evidence, observational studies).[50,]

National Institute for Health and Care Excellence

In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS.[51,] It concluded that the "Current evidence on the safety of [PENS] for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term."

In September 2022, NICE published guidance on neurostimulation of lumbar muscles with the ReActiv8 system for refractory non-specific chronic low back pain.[52,]

The guidance was based on a rapid review conducted in July 2021 and included the following statements:

- "Evidence on the efficacy and safety of neurostimulation of lumbar muscles for refractory non-specific chronic low back pain is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."
- "Further research should include suitably powered randomised controlled trials comparing the procedure with current best practice with appropriate duration. It should report details of patient selection and long-term outcomes."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services currently has the following national coverage policy on PENS[53,]:

"Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator.

Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator....

B. Percutaneous Electrical Nerve Stimulation (PENS)

This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

[I]t is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the [transcutaneous electrical nerve stimulation] on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage".

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

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to not medically necessary. Reference 18 URL updated. Related policies added
December 2013	Replace policy	Policy updated with literature review, references 12, 13, 16 & 17 added and references re-ordered. No change to policy statement or summary
September 2014	Replace policy	Policy updated with literature review. Policy statement unchanged.
September 2015	Replace policy	Policy updated with literature review; no references added. Policy statement unchanged.
June 2017	Replace policy	Policy updated with literature review through January 26, 2017; some references removed. Minor edits to the Policy section; policy statement unchanged
September 2018	Replace policy	Policy updated with literature review through April 9, 2018; no references added. Policy statement unchanged except "not medically necessary, corrected to "investigational, due to FDA 510(k) clearance.
September 2019	Replace policy	Policy updated with literature review through April 9, 2018; no references added. Policy statement unchanged.
September 2020	Replace policy	Policy updated with literature review through April 24, 2020; no references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through April 28, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through May 5, 2022; references added. Policy statements unchanged.
September 2023	Replace policy	Policy updated with literature review through June 7, 2023; references added. New indication and investigational policy statement added for restorative neurostimulation therapy (Reactiv8). Policy statements for percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy separated out for clarity; intent unchanged. Title changed to reflect new indication.