Medical Coverage Policy | Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

EFFECTIVE DATE: 02|01|2024
POLICY LAST REVIEWED: 02|07|2024

OVERVIEW
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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Restorative neurostimulation therapy (ReActiv8), Percutaneous electrical neurostimulation (PENS) or percutaneous neuromodulation therapy (PNT) for the treatment of chronic pain conditions is considered medically necessary if pain is effectively controlled by percutaneous stimulation and implantation of electrodes is warranted.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products
Restorative neurostimulation therapy (ReActiv8), Percutaneous electrical neurostimulation (PENS) or percutaneous neuromodulation therapy (PNT) for the treatment of chronic pain conditions is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery or not medically necessary benefits/coverage.

BACKGROUND
A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, present a substantial burden to patients, adversely affecting function and quality of life. Certain racial and ethnic groups are at a higher risk of developing diabetes, which may also put them at higher risk of developing complications from diabetes, such as diabetic neuropathy. According to a 2018 to 2019 National Health Interview Survey and data from the Indian Health Service National Data Warehouse, American Indians and Alaska Natives had the highest reported rate of diagnosed diabetes at 14.5%. This was followed by 12.1% of Black individuals, 11.8% of

Hispanic individuals, 9.5% of Asian individuals, and 7.4% of White individuals having diagnosed diabetes in 2018 or2019.

These chronic pain conditions have typically failed other treatments, and percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) have been evaluated as treatments to relieve unremitting pain.

Percutaneous electrical nerve stimulation is similar in concept to transcutaneous electrical nerve stimulation (TENS) (see evidence review 1.01.09) but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area and are then stimulated. Percutaneous electrical nerve stimulation is generally reserved for patients who fail to get pain relief from TENS. Percutaneous electrical nerve stimulation is also distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. In PENS, the location of stimulation is determined by proximity to the pain.

Percutaneous neuromodulation therapy is a variant of PENS in which fine filament electrode arrays are placed near the area causing pain. Some use the terms PENS and PNT interchangeably. It is proposed that PNT inhibits pain transmission by creating an electrical field that hyperpolarizes C fibers, thus preventing action potential propagation along the pain pathway.

The purpose of restorative neurostimulation therapy in individuals with chronic pain conditions is to provide a treatment option that is an alternative to or an improvement on existing therapies. The ReActiv8 System is an implantable electrical neurostimulation system that stimulates the nerves that innervate the lumbar multifidus muscles.

Medicare Advantage Plans
PENS, 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.

Commercial Products
For individuals who have chronic pain conditions (e.g., back, neck, neuropathy, headache, hyperalgesia) who receive 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 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 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.

CODING

Medicare Advantage Plans and Commercial Products

There is not a specific code for PENS or PNT. Use the unlisted code below

64999 Unlisted procedure, nervous system

RELATED POLICIES

Lysis of Epidural Adhesions
Nerve Graft with Radical Prostatectomy
Occipital Nerve Stimulation – Insertion
Peripheral Subcutaneous Field Stimulation
Pulsed Radiofrequency for the Treatment of Chronic Pain
Sphenopalatine Ganglion Block for Headache
Unlisted Procedures

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Provider Update, April 2024
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Provider Update, September 2020

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