MEDICAL POLICY

POLICY TITLE	**PERCUTANEOUS ELECTRICAL NERVE STIMULATION (PENS) AND PERCUTANEOUS NEUROMODULATION THERAPY (PNT)**
POLICY NUMBER	**MP 6.050**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2024**

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I. POLICY

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Percutaneous electrical nerve stimulation (PENS) may be considered **medically necessary** for refractory chronic pain, for a period of no longer than 30 days, for either of the following:

- The member is assessing the need for continued treatment with an implanted peripheral nerve stimulator; OR
- The member had an ineffective transcutaneous electrical nerve stimulation (TENS) therapeutic trial. The trial must include all of the following:
  - Monitored by a physician
  - At least 30 days in duration
  - Not to exceed 60 days in duration

The use of PENS for any other condition, including but not limited to the treatment of chronic headaches is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Percutaneous neuromodulation therapy (PNT) is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Refractory chronic pain is defined in this policy as pain that causes significant disruption of function and has not responded to at least 3 months of conservative therapy supervised by a physician, nurse practitioner, or physician assistant, including medication, physical therapy, and/or behavioral therapy.

The correct CPT code to use for percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (ie, 64553-64561) are not appropriate, because percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy use percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in percutaneous electrical nerve stimulation and percutaneous neuromodulation therapy are not implanted, so CPT code 64590 is also not appropriate.

Cross-references:

MP 1.034 Implantable Electrical Nerve Stimulators
MP 2.092 Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation
MP 6.020 Transcutaneous Electrical Nerve Stimulation
MP 6.045 Sympathetic Therapy for the Treatment of Pain
MP 6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP 6.047 Interferential Current Stimulation
MP 6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP 6.049 H-Wave Electrical Stimulation
MP 6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy combine the features of electroacupuncture and transcutaneous electrical nerve stimulation. PENS is performed with needle electrodes while percutaneous neuromodulation therapy uses very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue.

CHRONIC PAIN

A variety of chronic musculoskeletal or neuropathic pain conditions, including low back pain, neck pain, diabetic neuropathy, chronic headache, and surface hyperalgesia, presents a substantial burden to patients, adversely affecting function and quality of life.

Treatment

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.

PENS is similar in concept to transcutaneous electrical nerve stimulation (see MP 6.020) but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area and are then stimulated. PENS is generally reserved for patients who fail to get pain relief from transcutaneous electrical nerve stimulation. PENS 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.

PNT 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.

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. 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.

FDA product code: NHI.

IV. RATIONALE

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Summary of Evidence

For individuals who have chronic pain conditions (eg, back, neck, neuropathy, headache, hyperalgesia) who receive PENS, the evidence includes primarily small controlled trials and a systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. A systematic review concluded that PENS could decrease the level of pain intensity, but not related disability, in musculoskeletal pain disorders. However, the authors determined that the true intervention effect can be markedly different from the estimated effect and there was heterogenicity with regard to application methods, leading to the conclusion that there is still high uncertainty regarding the effectiveness of PENS for musculoskeletal pain. 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.

Considering input from a report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation, the evidence is sufficient 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. 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.

V. DEFINITIONS

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510 (K) refers to a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational for PNT; therefore not covered:

Procedure Codes								
64999								

Covered when medically necessary for PENS:

Procedure Codes								
64999								

ICD-10-CM Diagnosis Code	Description
G89.21	Chronic pain due to trauma
G89.22	Chronic post-thoracotomy pain
G89.28	Other chronic postprocedural pain

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ICD-10-CM Diagnosis Code	Description
G89.29	Other chronic pain
G89.4	Chronic pain syndrome
G90.50	Complex regional pain syndrome I, unspecified
G90.511	Complex regional pain syndrome I of right upper limb
G90.512	Complex regional pain syndrome I of left upper limb
G90.513	Complex regional pain syndrome I of upper limb, bilateral
G90.519	Complex regional pain syndrome I of unspecified upper limb
G90.521	Complex regional pain syndrome I of right lower limb
G90.522	Complex regional pain syndrome I of left lower limb
G90.523	Complex regional pain syndrome I of lower limb, bilateral
G90.529	Complex regional pain syndrome I of unspecified lower limb
G90.59	Complex regional pain syndrome I of other specified site

IX. REFERENCES

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X. POLICY HISTORY

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MP-6.050	**09/08/20 Consensus Review.** No changes to policy statements. References updated.

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	12/3/21 Minor review. PENS now MN with criteria. Updated FEP, background, rationale, coding table, and references
	6/10/22 Admin update. New code 0720T added effective 7/1/22
	12/30/2022 Consensus review. Updated references. 0720T removed as it is housed in MP 2.092
	10/4/2023 Consensus review. Updated references. No changes to coding.

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