MEDICAL POLICY

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

Original Issue Date (Created):	**3/1/2012**
Most Recent Review Date (Revised):	**9/8/2020**
Effective Date:	**12/1/2020**

I. POLICY

TOP

Percutaneous electrical neurostimulation or percutaneous neuromodulation is considered investigational as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

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 BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual MP-7.01.29 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation. The FEP Medical Policy manual can be found at: www.fepblue.org

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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 evidence review 1.034) 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. In the highest quality trial of PENS conducted to date, 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 the effects of the technology on health outcomes. For individuals who have chronic pain conditions (eg, knee osteoarthritis) who receive percutaneous neuromodulation therapy, 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 the effects of the technology on health outcomes.

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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross'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 BlueCross' Provider Services or Member Services. Capital BlueCross 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; therefore not covered:

CPT Codes®								
64999								

IX. REFERENCES

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3. *Weiner DK, Rudy TE, Glick RM, et al. Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults. J Am Geriatr Soc. May 2003;51(5):599-608. PMID 12752833*
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6. *Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. JAMA. Mar 3 1999;281(9):818-823. PMID 10071003*

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9. *White PF, Craig WF, Vakharia AS, et al. Percutaneous neuromodulation therapy: does the location of electrical stimulation effect the acute analgesic response? Anesth Analg. Oct 2000;91(4):949-954. PMID 11004055*
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11. *Ahmed HE, White PF, Craig WF, et al. Use of percutaneous electrical nerve stimulation (PENS) in the short-term management of headache. Headache. Apr 2000;40(4):311-315. PMID 10759936*
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WordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAABAAAAAA&. Accessed April 27, 2020.

19. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.29, Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy. June 2020.*

X. POLICY HISTORY

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MP-6.050	**CAC 10/25/11 Adopted BCBSA**. Removed information for PENs from the original policy titled Electrical Stimulation Modalities, and created new separate policy. Changed policy criteria from medically necessary to investigational.
	CAC 10/30/12 Consensus. Changed FEP variation to reference to FEP Medical Policy Manual MP-7.01.29 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation. No change to policy statement. References updated. Code reviewed 10/31/12
	CAC 11/26/13 Consensus review. References updated. No changes to the policy statements. Rationale added.
	CAC 11/25/14 Consensus review. No change to policy statements. References and rationale updated. Coding reviewed 11/07/2014
	CAC 11/24/15 Consensus review. No change to the policy statements. References and rationale updated. Coding reviewed.
	CAC 11/29/16 Consensus review. No change to the policy statement. References updated. Variations reformatted. Coding reviewed.
	12/19/17 Consensus review. No change to the policy statement. Rationale and references updated.
	11/1/18 Consensus Review. No change to the policy statement. Rationale condensed. References updated. Coding reviewed 1/3/19.
	09/26/19 Consensus review. No change to policy statement. Coding reviewed.
	09/08/20 Consensus Review. No changes to policy statements. References updated.

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