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:	**4/1/2025**

I. POLICY

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Percutaneous electrical nerve stimulation (PENS) 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

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 (i.e., 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 Vagus Nerve, Peripheral Nerve, and Phrenic Nerve Stimulators
MP 2.092 PENFS, CES, Auricular Electrostimulation, and External Trigeminal Nerve Stimulation
MP 6.020 Transcutaneous Electrical Nerve Stimulation
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

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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. 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 or 2019.

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 (e.g., 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. 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 (e.g., 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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. 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' medical policies are developed to assist in administering a member's benefits. These medical policies 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 PENS and PNT; therefore, not covered:

Procedure Codes								
64999								

IX. REFERENCES

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1. *Centers for Disease Control and Prevention (CDC). By the Numbers: Diabetes in America. Updated March 2022*
2. *Food & Drug Administration. 2020. ReActiv8 Implantable Neurostimulation System. Approval Order.*
3. *Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. Jan 2005; 113(1-2): 9-19. PMID 15621359*
4. *Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain. Feb 2008; 9(2): 105-21. PMID 18055266*
5. *Gewandter JS, Dworkin RH, Turk DC, et al. Research design considerations for chronic pain prevention clinical trials: IMMPACT recommendations. Pain. Jul 2015; 156(7): 1184-1197. PMID 25887465*
6. *Plaza-Manzano G, Gómez-Chiguano GF, Cleland JA, et al. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. Eur J Pain. Jul 2020; 24(6): 1023-1044. PMID 32171035*
7. *Beltran-Alacreu H, Serrano-Muñoz D, Martín-Caro Álvarez D, et al. Percutaneous Versus Transcutaneous Electrical Nerve Stimulation for the Treatment of Musculoskeletal Pain. A Systematic Review and Meta-Analysis. Pain Med. Aug 01 2022; 23(8): 1387-1400. PMID 35167691*
8. *Ghoname EA, Craig WF, White PF, et al. Percutaneous electrical nerve stimulation for low back pain: a randomized crossover study. JAMA. Mar 03 1999; 281(9): 818-23. PMID 10071003*
9. *Ghoname ES, Craig WF, White PF, et al. The effect of stimulus frequency on the analgesic response to percutaneous electrical nerve stimulation in patients with chronic low back pain. Anesth Analg. Apr 1999; 88(4): 841-6. PMID 10195535*
10. *Hamza MA, Ghoname EA, White PF, et al. Effect of the duration of electrical stimulation on the analgesic response in patients with low back pain. Anesthesiology. Dec 1999; 91(6): 1622-7. PMID 10598602*
11. *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*
12. *Topuz O, Ozfidan E, Ozgen M, Ardic F. Efficacy of transcutaneous electrical nerve stimulation and percutaneous neuromodulation therapy in chronic low back pain. J Back Musculoskeletal Rehabil. 2004;17:127-133.*
13. *Yokoyama M, Sun X, Oku S, et al. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. Anesth Analg. Jun 2004; 98(6): 1552-1556. PMID 15155304*
14. *Weiner DK, Perera S, Rudy TE, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain. Nov 30 2008; 140(2): 344-357. PMID 18930352*

15. *Perez-Palomares S, Olivan-Blazquez B, Magallon-Botaya, et al. Percutaneous electrical nerve stimulation versus dry needling: effectiveness in the treatment of chronic low back pain. J Musculokeletal Pain. 2010;18:23-30.*
16. *Weiner DK, Rudy TE, Morone N, et al. Efficacy of periosteal stimulation therapy for the treatment of osteoarthritis-associated chronic knee pain: an initial controlled clinical trial. J Am Geriatr Soc. Oct 2007; 55(10): 1541-7. PMID 17908057*
17. *Weiner DK, Moore CG, Morone NE, et al. Efficacy of periosteal stimulation for chronic pain associated with advanced knee osteoarthritis: a randomized, controlled clinical trial. Clin Ther. Nov 2013; 35(11): 1703-20.e5. PMID 24184053*
18. *da Graca-Tarragó M, Deitos A, Patrícia Brietzke A, et al. Electrical Intramuscular Stimulation in Osteoarthritis Enhances the Inhibitory Systems in Pain Processing at Cortical and Cortical Spinal System. Pain Med. May 01 2016; 17(5): 877-891. PMID 26398594*
19. *Elbadawy MA. Effectiveness of Periosteal Stimulation Therapy and Home Exercise Program in the Rehabilitation of Patients With Advanced Knee Osteoarthritis. Clin J Pain. Mar 2017; 33(3): 254-263. PMID 27513639*
20. *Dunning J, Butts R, Henry N, et al. Electrical dry needling as an adjunct to exercise, manual therapy and ultrasound for plantar fasciitis: A multi-center randomized clinical trial. PLoS One. 2018; 13(10): e0205405. PMID 30379937*
21. *da Graca-Tarragó M, Lech M, Angoleri LDM, et al. Intramuscular electrical stimulus potentiates motor cortex modulation effects on pain and descending inhibitory systems in knee osteoarthritis: a randomized, factorial, sham-controlled study. J Pain Res. 2019; 12: 209-221. PMID 30655690*
22. *León-Hernández JV, Martín-Pintado-Zugasti A, Frutos LG, et al. Immediate and short-term effects of the combination of dry needling and percutaneous TENS on post-needling soreness in patients with chronic myofascial neck pain. Braz J Phys Ther. Jul 11 2016; 20(5): 422-431. PMID 27410163*
23. *Sumen A, Sarsan A, Alkan H, et al. Efficacy of low level laser therapy and intramuscular electrical stimulation on myofascial pain syndrome. J Back Musculoskelet Rehabil. 2015; 28(1): 153-8. PMID 25061034*
24. *Medeiros LF, Caumo W, Dussán-Sarria J, et al. Effect of Deep Intramuscular Stimulation and Transcranial Magnetic Stimulation on Neurophysiological Biomarkers in Chronic Myofascial Pain Syndrome. Pain Med. Jan 2016; 17(1): 122-35. PMID 26408420*
25. *Botelho L, Angoleri L, Zortea M, et al. Insights About the Neuroplasticity State on the Effect of Intramuscular Electrical Stimulation in Pain and Disability Associated With Chronic Myofascial Pain Syndrome (MPS): A Double-Blind, Randomized, Sham-Controlled Trial. Front Hum Neurosci. 2018; 12: 388. PMID 30459575*
26. *Dunning J, Butts R, Young I, et al. Periosteal Electrical Dry Needling as an Adjunct to Exercise and Manual Therapy for Knee Osteoarthritis: A Multicenter Randomized Clinical Trial. Clin J Pain. Dec 2018; 34(12): 1149-1158. PMID 29864043*
27. *Yoshimizu M, Teo AR, Ando M, Kiyohara K, Kawamura T. Relief of chronic shoulder and neck pain by electro-acupuncture and transcutaneous electrical nervous stimulation: A randomized crossover trial. Med Acupunct 2012;24(2):97103.*

28. *Ng MM, Leung MC, Poon DM. The effects of electro-acupuncture and transcutaneous electrical nerve stimulation on patients with painful osteoarthritic knees: a randomized controlled trial with follow-up evaluation. J Altern Complement Med. Oct 2003; 9(5): 641-9. PMID 14629842*
29. *Tsukayama H, Yamashita H, Amagai H, et al. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: a preliminary study for a pragmatic trial. Acupunct Med. Dec 2002; 20(4): 175-80. PMID 12512791*
30. *Cheng RSS, Pomeranz B. Electrotheraphy of chronic musculoskeletal pain: Comparison of electroacupuncture and acupuncture-like transcutaneous electrical nerve stimulation. Cochrane Library. Clin J Pain 1986;2(3):1439.*
31. *Lehmann TR, Russell DW, Spratt KF, et al. Efficacy of electroacupuncture and TENS in the rehabilitation of chronic low back pain patients. Pain. Sep 1986; 26(3): 277-290. PMID 2946016*
32. *Ghoname EA, White PF, Ahmed HE, et al. Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica. Pain. Nov 1999; 83(2): 193-9. PMID 10534590*
33. *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): 949-54. PMID 11004055*
34. *Hamza MA, White PF, Craig WF, et al. Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain. Diabetes Care. Mar 2000; 23(3): 365-70. PMID 10868867*
35. *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): 311-5. PMID 10759936*
36. *Raphael JH, Raheem TA, Southall JL, et al. Randomized double-blind sham-controlled crossover study of short-term effect of percutaneous electrical nerve stimulation in neuropathic pain. Pain Med. Oct 2011; 12(10): 1515-22. PMID 21883874*
37. *Kang RW, Lewis PB, Kramer A, et al. Prospective randomized single-blinded controlled clinical trial of percutaneous neuromodulation pain therapy device versus sham for the osteoarthritic knee: a pilot study. Orthopedics. Jun 2007; 30(6): 439-45. PMID 17598487*
38. *Bril V, England J, Franklin GM, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. May 17 2011; 76(20): 1758-65. PMID 21482920*
39. *Price R, Smith D, Franklin G, et al. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary: Report of the AAN Guideline Subcommittee. Neurology. Jan 04 2022; 98(1): 31-43. PMID 34965987*
40. *Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. Oct 02 2007; 147(7): 478-91. PMID 17909209*

41. *Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. Apr 04 2017; 166(7): 514-530. PMID 28192789*
42. *Benzon HT, Connis RT, De Leon-Casasola OA, et al. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. Apr 2010; 112(4): 810-33. PMID 20124882*
43. *National Institute for Health and Care Excellence (NICE). Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]. 2013*
44. *Centers for Medicare & Medicaid. National Coverage Determination (NCD) for Assessing Patient's Suitability for ELECTRICAL NERVE STIMULATION Therapy (160.7.1). 2006*
45. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.29, Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy. July 2024*

X. POLICY HISTORY

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MP 6.050	**09/08/2020 Consensus Review.** No changes to policy statements. References updated.
	12/03/2021 Minor Review. PENS now MN with criteria. Updated FEP, background, rationale, coding table, and references
	06/10/2022 Administrative Update. New code 0720T added effective 07/01/22
	12/30/2022 Consensus Review. Updated references. 0720T removed as it is housed in MP 2.092
	10/04/2023 Consensus Review. Updated references. No changes to coding.
	11/04/2024 Minor Review. PENS is no longer MN**.** Updated clinical benefit, cross references, background, rationale and references.

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