Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Electrical Nerve Stimulation Devices is addressed separately in medical policy 00142.

Note: Temporomandibular Joint Dysfunction is addressed separately in medical policy 00583.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers percutaneous electrical neurostimulation (PENS) to be **investigational.***

Based on review of available data, the Company considers percutaneous electrical nerve field stimulation (PENFS) to be **investigational.***

Based on review of available data, the Company considers percutaneous neuromodulation therapy (PNT) to be **investigational.***

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 (ie, 64553, 64555, and 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.

Background/Overview

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.

Percutaneous electrical neurostimulation (PENS)
Percutaneous electrical nerve stimulation is similar in concept to transcutaneous electrical nerve stimulation (TENS) 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 (PNT)
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.

Irritable Bowel Syndrome
Irritable bowel syndrome (IBS) is estimated to affect 5% to 10% of the population globally, and accounts for between 2.4 and 3.5 million physician visits in the United States each year. Up to two-thirds of patients with IBS are female, and it is most common in patients less than 50 years of age. The cause of IBS remains unknown, but is believed to be due to a dysfunction in gut-brain interaction. Symptoms of IBS can include diarrhea, constipation, or both. Abdominal pain and bloating are also common IBS symptoms. These symptoms decrease patient quality of life and create a significant healthcare burden. The American College of Gastroenterology (ACG) recommends that patients diagnosed with IBS are categorized by subtypes: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), IBS with mixed symptoms (IBS-M), or IBS without abnormal stools (IBS-U).

Treatment of Irritable Bowel Syndrome

First-line treatment of patients with IBS generally involves dietary changes. If dietary changes fail to achieve therapeutic goals, there are numerous pharmacotherapeutic options for patients with IBS. Pharmacologic treatment is based on the IBS subtype, and the predominance of either constipation or diarrhea (Table 1). Notably, many IBS treatments are not Food and Drug Administration (FDA)-approved for children or adolescents. The American College of Gastroenterology recommends that gut-directed psychotherapy such as cognitive-behavior therapy and gut-directed hypnotherapy may be beneficial for global IBS symptoms.

Table 1. Pharmacologic Treatment of Irritable Bowel Syndrome

IBS-D	IBS-C	Abdominal Pain
Antidiarrheal agents (e.g., loperamide)	Laxatives (e.g., polyethylene glycol)	Antispasmodics (e.g., dicyclomine, hyoscyamine, peppermint oil)
Mu-opioid receptor agonist (eluxadoline for refractory patients only)	Chloride channel activator (lubiprostone)	TCA
5-HT3 receptor antagonist (alosetron or ondansetron)	Guanylate cyclase agonists (linaclotide or plecanatide)	SSRI
Antibiotic (rifaximin)	Sodium/hydrogen exchanger 3 (tenapanor)	

HT: hydroxytryptamine (serotonin); IBS-C: irritable bowel syndrome with constipation; IBS-D: irritable bowel syndrome with diarrhea; SSRI: selective serotonin reuptake inhibitor; TCA: tricyclic antidepressant.

Percutaneous Electrical Nerve Field Stimulation (PENFS)

Because there are few pharmacologic treatments for children and adolescents with IBS, nonpharmacologic options are commonly explored. Percutaneous electrical nerve field stimulation (PENFS) is a potential treatment option for these patients. PENFS involves a non-implantable device which stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal or neuropathic pain conditions or for patients with opioid withdrawal. The IB-Stim device is a type of PENFS that is intended for use only in patients with IBS. The device is disposable and battery-operated. Key components of the device include a percutaneous electrical nerve field stimulator placed behind the ear which connects to a multi-wire electrode array consisting of 4 leads. The electrodes have thin needles and attach to the ear at points (preauricular, lobule, and superior crus) where cranial nerve peripheral branches are located just beneath the skin. A pen light included

with the device is used to visualize the neurovasculature features and aid in proper electrode placement.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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.

FDA product codes: NHI, QLK.

PENFS Devices

In 2019, the IB-Stim device (previously known as Neuro-Stim; Innovative Health Solutions, Inc.) was cleared for marketing by the FDA through the de novo 513(f)(2) process (DEN180057). Both the IB-Stim and the similar NSS-2 BRIDGE device (Innovative Health Solutions, Inc.) are derivatives of the Electro Auricular Device (Navigant Consulting, Inc.). The IB-Stim device is indicated for patients 11 to 18 years of age with functional abdominal pain associated with IBS when combined with other IBS therapies. It is intended to be used for 120 hours per week up to 3 consecutive weeks. The First Relief v1 (DyAnsys, Inc.) device was deemed substantially equivalent to the IB-Stim device in 2020. FDA product code: QHH.

The IB-Stim device (Innovative Health Solutions (IHS), Inc. Versailles, IN) received de novo FDA approval in 2018. According to the FDA, the device is “intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS)”. It is intended for use for up to 120 hours per week for up to 3 consecutive weeks; no safety data are available for longer-term use. The disposable, battery-powered device involves a stimulator that is placed behind the ear and percutaneous electrodes that are placed near the nerve branches in the ear. A pen light is used to aid in the placement of the electrodes. Electrical stimulation is delivered to branches of the cranial nerves V, VII, IX and X and the occipital nerves.

IHS also markets the NSS-2 Bridge Device, which received de novo approval by the FDA in 2017 “as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial

Nerves V, VII, IX and X, and the occipital nerves identified by transillumination". Device use is limited to 120 hours, after which it is disposable.

S.T. Genesis, Sperenza Therapeutics (Boca Raton, FL) is also described as a device that applies stimulation to branches of cranial nerves V, VII, IX, and X and the occipital nerve, and that aids in the reduction of opioid withdrawal symptoms.

The FDA cleared the Drug Relief®‡ device, DyAnsys, Inc.(San Mateo, CA) through the 510(k) process in 2018. The FDA stated that the device can be "used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of cranial nerves V, VII, IX and X, and the occipital nerves identified by transillumination." DyAnsys, Inc. also has FDA 510(k) clearance for the PENFS device under the name First Relief®‡ v.1 that is intended 'to be used up to 120 hours per week up to 3 consecutive weeks, through application to cranial nerves V, VII, IX and X and the occipital nerves identified to trans-illumination, as an aid in the reduction of pain when combined with other treatments for IBS."

Another PENFS device, the Sparrow Ascent®‡, was cleared by the FDA under the 510(k) process in 2023. It was originally cleared under the name the Sparrow Therapy System and cited the NSS-2 Bridge as a predicate device. According to FDA documents, the Sparrow Ascent, "is intended to be used in patients experiencing opioid withdrawal in conjunction with standard symptomatic medications and other therapies for opioid withdrawal symptoms under the supervision of trained clinical personnel".

Non-Implantable PNT Devices

An electrical stimulation device identified as Percutaneous Neuromodulation Therapy™‡ Nerve Stimulation System (Vertis Neuroscience, Inc, Vancouver, WA) received FDA 510(k) clearance in 2002. The clearance order stated that the therapy is "indicated for symptomatic relief and management of chronic or intractable pain and/or as an adjunctive treatment for the management of post-surgical pain and post-trauma pain." Its primary indication is for low back pain and spinal pain. The procedure involves the insertion of pairs of electrodes into the skin of the lower back area with the intent of stimulating nerve fibers that lie in the deep tissues. Treatments may be given several times a week, typically for about 30 minutes at a time.

The Axon Therapy®‡ Peripheral Nerve Stimulation System for Chronic Pain Relief (NeuraLace Medical, San Diego, CA).) received FDA 510k clearance in 2021. The device is indicated for pain relief in adults with chronic, intractable, post-traumatic or post-surgical pain. The system targets sensory nerve fibers with focused magnetic pulses. It is intended to be used in a clinical setting (e.g. pain management clinic or physical therapy clinic) and involves a series of 15-20 minute sessions.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Description

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) 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.

Percutaneous electrical nerve field stimulation involves the transmission of electrical impulses to cranial nerve bundles in the ear targeting brain areas involved in processing pain. In the case of patients with irritable bowel syndrome, nerves processing pain for the abdominal region are targeted.

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 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 (e.g., 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 with irritable bowel syndrome (IBS) who receive percutaneous electrical nerve field stimulation (PENFS), the evidence includes a subgroup analysis of a single randomized controlled

trial (RCT). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT (N=115) included a heterogeneous population of adolescent patients aged 11 to 18 years with pain-related functional gastrointestinal disorders. Treatment was administered for 3 weeks, and reductions in pain were observed with the active device compared with a sham PENFS device at end of treatment and end of follow-up (maximum of 12 weeks). The subgroup of patients with IBS also had improved pain at the end of treatment with the active device compared with the sham device. However, the trial is limited by its small sample size, heterogeneous population of gastrointestinal disorders, lack of bowel habit measurement, and the short duration of follow-up.

ECRI (12/2024) clinical evidence assessment concluded that there is moderate evidence from two double-blind, sham-controlled RCTs showing reduction of 30% or more in worst abdominal pain severity, however, results were primarily based on four weeks of treatment, and long-term efficacy data are lacking. The case series were all prospective pre/post studies but have a high risk of bias because they lack a control group, and patients were not blinded to treatment. Long-term data (i.e., > 5-year follow-up) are needed to enable higher confidence conclusions and to determine whether PENFS benefits are long term. Reviewers also noted that PENFS have not diffused into general practice for treating abdominal pain in patients with IBS and there are no clinical practice guidelines mentioning PENFS for treating IBS.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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

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. 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. 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. 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.

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).

National Institute for Health and Care Excellence
In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS. 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."

American College of Gastroenterology
The American College of Gastroenterology (ACG) updated their recommendations for irritable bowel syndrome (IBS) management in 2021. The ACG recommendations do not include percutaneous electrical nerve field stimulation.

The American Gastroenterological Association
The American Gastroenterological Association (AGA) updated guidelines for both IBS with constipation and IBS with diarrhea in 2022. Neither of these guidelines include recommendations for percutaneous electrical nerve field stimulation.

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:

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"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".

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04442321	Effectiveness of Ultrasound-Guided Percutaneous Electrical Stimulation on Radial Nerve With Exercises in Patients With Lateral Epicondylalgia	60	Sep 2023
NCT04683042	Fibromyalgia TENS in Physical Therapy Study (TIPS): an Embedded Pragmatic Clinical Trial	450	Aug 2024
NCT04428619	Neuromodulation With Percutaneous Electrical Nerve Field Stimulation for Adults With Irritable Bowel Syndrome: A Randomized, Double-Blind, Sham-Controlled Pilot Study	54	Nov 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Centers for Disease Control and Prevention (CDC). By the Numbers: Diabetes in America. Updated March 2022; https://www.cdc.gov/diabetes/health-equity/diabetes-by-the-numbers.html.
2. 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
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
11. 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.
12. 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

13. 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
14. 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.
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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

25. 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
26. 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.
27. 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
28. 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
29. 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.
30. 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
31. 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
32. 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
33. 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
34. 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
35. 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
36. 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
37. Gilligan C, Volschenk W, Russo M, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. Oct 01 2021; 162(10): 2486-2498. PMID 34534176
38. Gilligan C, Volschenk W, Russo M, et al. Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction. Neuromodulation. Jan 2023; 26(1): 98-108. PMID 36175320

39. Deckers K, De Smedt K, Mitchell B, et al. New Therapy for Refractory Chronic Mechanical Low Back Pain-Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial. Neuromodulation. Jan 2018; 21(1): 48-55. PMID 29244235
40. Thomson S, Chawla R, Love-Jones S, et al. Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort. Pain Ther. Dec 2021; 10(2): 1451-1465. PMID 34478115
41. Mitchell B, Deckers K, De Smedt K, et al. Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain. Neuromodulation. Aug 2021; 24(6): 1024-1032. PMID 34242440
42. Ardeshiri A, Shaffrey C, Stein KP, et al. Real-World Evidence for Restorative Neurostimulation in Chronic Low Back Pain-a Consecutive Cohort Study. World Neurosurg. Dec 2022; 168: e253-e259. PMID 36184040
43. 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
44. 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
45. 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
46. 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
47. 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
48. National Institute for Health and Care Excellence (NICE). Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]. 2013; https://www.nice.org.uk/guidance/ipg450.
49. National Institute for Health and Care Excellence. 2022 Neurostimulation of lumbar muscles for refractory nonspecific chronic low back pain: Interventional Procedures Guidance. https://www.nice.org.uk/guidance/ipg739.
50. Centers for Medicare & Medicaid. National Coverage Determination (NCD) for Assessing Patient's Suitability for ELECTRICAL NERVE STIMULATION Therapy (160.7.1). 2006; https://www.cms.gov/medicare-coverage- database/details/ncd-details.aspx?NCDId=63&ncdver=2&CoverageSelection=National&KeyWord=Electrical+Nerv

e+Stimulation&Key WordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAABAAAAAA&.
51. IBS Facts and Statistics. International Foundation for Gastrointestinal Disorders. https://aboutibs.org/what-is-ibs/facts-about-ibs/.
52. Definition & Facts for Irritable Bowel Syndrome. National Institute of Diabetes and Digestive and Kidney Diseases. https://www.niddk.nih.gov/health-information/digestive-diseases/irritable-bowel-syndrome/definition-facts. Updated November 2017.
53. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. Am J Gastroenterol. Jan 01 2021; 116(1): 17-44. PMID 33315591
54. Lembo A, Sultan S, Chang L, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. Gastroenterology. Jul 2022; 163(1): 137-151. PMID 35738725
55. Chang L, Sultan S, Lembo A, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. Gastroenterology. Jul 2022; 163(1): 118-136. PMID 35738724
56. IB-STIM. FDA Classification. https://ibstim.com/fda-classification/. Accessed June 26, 2024.
57. Kovacic K, Hainsworth K, Sood M, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. Lancet Gastroenterol Hepatol. Oct 2017; 2(10): 727-737. PMID 28826627
58. Krasaelap A, Sood MR, Li BUK, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. Clin Gastroenterol Hepatol. Aug 2020; 18(9): 1987-1994.e2. PMID 31622740
59. ECRI Clinical Evidence Assessment. Percutaneous Electrical Nerve Field Stimulation for Treating Abdominal Pain in Children with Irritable Bowel Syndrome. December 2024.

Policy History

Original Effective Date: 11/29/2004
Current Effective Date: 05/01/2025

10/05/2004	Medical Director review
10/19/2004	Medical Policy Committee review
11/29/2004	Managed Care Advisory Council approval
06/01/2006	Format revision, including addition of FDA and or other governmental regulatory approval. Coverage eligibility unchanged.
12/01/2006	Medical Director review
12/20/2006	Medical Policy Committee approval. Coverage eligibility unchanged.
12/03/2008	Medical Director review
12/17/2008	Medical Policy Committee approval. No change to coverage eligibility.
10/14/2010	Medical Policy Committee review
10/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/31/2010	Coding updated

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 05/01/2025

10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. No change to coverage.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. No change to coverage. FDA updated.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. No change to coverage.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Added Percutaneous electrical nerve field stimulation (PENFS) as investigational. Added policy guidelines. Coding update
06/08/2022	Coding update
12/06/2022	Coding update
03/19/2023	Coding update
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. No change to coverage.
08/23/2023	Coding update
12/12/2023	Coding update
04/04/2024	Medical Policy Committee review.

Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Policy # 00144
Original Effective Date: 11/29/2004
Current Effective Date: 05/01/2025

04/10/2024	Medical Policy Implementation Committee approval. Policy statements separated out for clarity; intent unchanged.
04/03/2025	Medical Policy Committee review.
04/09/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Body of policy updated.

Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0720T, 64999 Delete codes effective 01/01/2024: 0768T, 0769T Delete codes effective 05/01/2025: 0766T, 0767T, 64596, 64597, 64598
HCPCS	L8678 Delete codes effective 01/01/2024: K1016, K1017
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.