



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

Policy # 00144

Original Effective Date: 11/29/2004

Current Effective Date: 05/13/2024

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.

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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.

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PENFS Devices

PENFS devices are non-implantable and stimulate nerves remotely from the source of pain with the intent to relieve pain, such as functional abdominal pain associated with irritable bowel syndrome. Device is disposable and percutaneous electrodes are placed near the cranial nerve branches in the ear.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2002, the Percutaneous Neuromodulation Therapy^{TM†} (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 μ m (0.736 mm) in length; the patch is reported to feel like sandpaper or Velcro. FDA product code: NHI.

PENFS Devices

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

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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 similar to the NSS-2 Bridge. It 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.

Non-Implantable PNT Devices

An electrical stimulation device identified as Percutaneous Neuromodulation Therapy^{TM†} 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.

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 federal regulations, other plan medical policies, and accredited national guidelines.

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Percutaneous electrical neurostimulation (PENS)

Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) combine the features of electroacupuncture and transcutaneous electrical nerve stimulation (TENS). 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.

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. Two 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 heterogeneity 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 (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.

Percutaneous neuromodulation therapy (PNT)

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PNT is described as a variation of PENS developed as a treatment for chronic or intractable pain. Four cross-over RCTs were conducted by one group of investigators (two studies by Ghoname, 1999; Hamza, 1999; White, 2001). Results of these studies suggest that PNT reduces low back pain and disability due to this pain; however, the randomized crossover studies also provided evidence that these benefits were temporary since pain reoccurred between treatment sessions and during 1-week periods in which treatment was stopped before a change in treatment conditions.

In a single-blinded study, Kang and colleagues (2007) randomized 70 individuals with knee OA to PNT stimulation (at the highest tolerable intensity) or placement of electrodes without stimulation (sham intervention). Individuals in the sham group were informed that they would not perceive the normal “pins and needles” with this new device. Individuals received a single treatment and were followed up for 1 week. The neuromodulation group had 100% follow-up; 7 of 35 (20%) individuals from the sham group dropped out. VAS pain scores improved immediately after active (from 5.4 to 3.2) but not sham (5.6 to 4.9) treatments. VAS scores (4.6 vs. 5.2) were not significantly different for the 2 groups at 48 hours after treatment. Changes in the WOMAC scale were significantly better for the category of stiffness (1 point change vs. 0 point change) but not for pain or function at 48 hours. Measures of satisfaction in the study participants were significantly higher in the neuromodulation group (77% vs. 11% good to excellent) at up to 1-week follow-up. Interpretation is limited by the discrepancy between participant satisfaction ratings and 48-hour VAS pain scores, and the differential loss to follow-up in the 2 groups. These results raise questions about the effectiveness of the blinding and the contribution of short-term pain relief and placebo effects to these results. Questions also remain about the duration of the treatment effects since the study reported only short-term follow-up.

Percutaneous electrical nerve field stimulation (PENFS)

PENFS to Treat Chronic Abdominal Pain

PENFS has been evaluated in a single double-blind sham-controlled RCT (Kovacic, 2017). The study enrolled 115 adolescents aged 11 to 18 years with chronic abdominal pain who met ROME III criteria for a functional abdominal disorder (irritable bowel syndrome [IBS], functional dyspepsia, abdominal migraine, functional abdominal pain or functional abdominal pain syndrome). In addition, individuals needed to have an average abdominal pain score of 3 or higher (on a 10-point scale) and a minimum of 2 days per week of pain. Participants received either active (n=60) or sham

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(n=55) stimulation with the Neuro-Stim device (now known as the IB-Stim device, Innovative Health Solutions). The device was placed behind the ear each week for 4 weeks during clinic visits, and individuals were instructed to keep the device on for 5 days and then remove it for the last 2 days of the week. The sham devices were manufactured identically to the active devices, but without electrical charge. While the investigators claimed that both active stimulation and sham were below sensation threshold, they noted that some individuals could potentially experience an auricular sensation after device placement. At the end of week 3, 75% of individuals in the PENFS group thought they had the active device and 46% of individuals in the sham group thought they had the active device. Participants completed Pain Frequency-Severity-Duration (PFSD) questionnaires (maximum possible score=70) at visits after the first 3 weeks of treatment and at a follow-up visit at 8 to 12 weeks. The primary outcome was change in abdominal pain scores (change in worst pain intensity and a composite PFSD score). Global symptom improvement was assessed as a secondary endpoint using the Symptom Response Scale (SRS). Individuals were followed for a median of 9.2 weeks after the last week of treatment.

A total of 104 of the 115 participants (90%) were included in the primary analysis: 57 in the active PENFS group, and 47 in the sham group. One participant in the PENFS group and 7 in the sham group discontinued treatment. Between baseline and week 3, the worst pain score showed statistically significantly greater improvement in the PENFS group compared with the sham group (difference between groups 2.15 points, $p<0.0001$). However, there was no significant difference between the PENFS group and sham group in the proportion of participants who had an improvement of 30% or more in worst pain ($p=0.47$) or usual pain ($p=0.11$) from baseline to extended follow-up. The median PFSD composite scores decreased significantly more in the PENFS versus sham treatment group (difference between groups, 11.48 points, $p<0.0001$) at week 3. At extended follow-up, both the median worst pain score ($p=0.019$) and the composite PFSD score ($p=0.018$) improved significantly more in the PENFS group compared with the sham treatment group. SRS scores reflected improvements in the PENFS group at 3 weeks versus the sham group ($p=0.0003$), no significant difference between groups was observed at the extended follow-up. The authors noted that the study did not assess changes in bowel habits, considered the most bothersome IBS symptom, and only focused on pain reduction. Reported side effects were similar in the 2 groups and there were no serious adverse effects.

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Several secondary analyses of the Kovacic (2017) RCT have been published. Krasaelap and colleagues (2020) reported on 50 participants with IBS (27 from the PENFS group and 23 in the sham group). They found that significantly more individuals in the active treatment group had at least a 30% or more reduction in worst abdominal pain than individuals in the sham group at 3 weeks (59% versus 26%, $p=0.024$). Kovacic (2020) examined the association between treatment efficacy and a pre-treatment physiological measure known as vagal efficiency (VE), which was defined as the change in heart rate per unit change in respiratory sinus arrhythmia). The authors found a statistically significant association between low VE and pain reduction in the treatment group and no significant associations in the sham or high-VE groups.

While initial findings of the Kovacic (2017) RCT are promising, additional studies are necessary to confirm the results of the study, determine the optimal setting and duration of treatment, and determine the optimal target population. Given the chronic nature of abdominal pain-related functional gastrointestinal disorders, a longer assessment period is also needed to establish the durability of efficacy. Furthermore, the clinical significance of the purported effects of the PENFS is difficult to assess based on current findings.

PENFS to Reduce Symptoms of Opioid Withdrawal or Reduce Opioid Use

Results of a retrospective analysis of 73 individuals who were voluntarily treated with the Bridge device was published in 2018 by Miranda and Taca. Eligibility criteria included age at least 18 years old, meeting DSM-IV criteria for opioid dependence and voluntary presentation at an outpatient drug treatment clinic. The primary outcome measure was reduction in Clinical Opioid Withdrawal Scale (COWS) scores. The COWS scale ranges from 0 to 48 and symptoms are categorized as follows: 5-12, mild; 13-24, moderate; 25-36 moderately severe; >36, severe. Most individuals received Bridge placement in the clinic and were sent home within approximately the first hour, when symptoms of withdrawal were relieved. They were instructed to leave the device on for 5-days. Prior to Bridge placement, the mean COWS score was 20.1 (SD, 6.1). By 60 minutes after placement, the mean score was 3.1 (SD, 3.4). No rescue medication was used during the first 60 minutes after device placement and no antipsychotic narcotic or benzodiazepine medications were given during the 5 days of device use. A total of 28 of 73 individuals (38%) used an antiemetic. A total of 33 of 73 individuals (45%) had data available after 5 days of treatment. In this group, the mean COWS score before receiving the first dose of naltrexone was 0.6. No adverse events were reported in any

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participant. Limitations of the study are the lack of a comparison group, a large amount of missing data at 5 days, and no long term data to evaluate health outcomes such as sustained abstinence.

In 2021, Ahmed and colleagues published data on use of the Bridge device to reduce post-surgical opioid use after Roux-en-Y gastric bypass. The analysis included 8 individuals who received the Bridge device and 10 individuals who underwent similar surgery and did not receive the Bridge device. For those using the Bridge device, it was placed on the individual's ear in the post-anesthesia care unit. The device remained in place and active for 5 days. The primary study outcome was opioid requirement (oral morphine equivalent [OME], in milligrams), 24 hours after surgery. At 24 hours, the OME was 15.19 (SD, 15.02) in the Bridge group and 38.15 (SD, 38.32) in the comparison group. Although use in the Bridge group was lower, the difference between groups was not statistically significant ($p=0.063$). The difference between groups in OME was also not statistically significant at 24-48 hours post-operatively. In addition, there were no statistically significant differences in the rate of post-operative nausea and vomiting, time to oral intake or time to hospital discharge.

Supplemental Information

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 et al

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

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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."

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:

"Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator.

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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 TENS 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 unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04243915	Effectiveness of Percutaneous Neuromuscular Electrical Stimulation on Lumbar Multifidus in Combination With a Protocol of Motor Control Exercises in Patients With Chronic Low Back Pain	64	Jun 2024



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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

NCT: national clinical trial.

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Louisiana

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

Policy # 00144

Original Effective Date: 11/29/2004

Current Effective Date: 05/13/2024

Policy History

Original Effective Date: 11/29/2004

Current Effective Date: 05/13/2024

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
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

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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.
04/10/2024	Medical Policy Implementation Committee approval. Policy statements separated out for clarity; intent unchanged.

Next Scheduled Review Date: 04/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of

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descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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, 0766T, 0767T, 64999 Delete codes effective 01/01/2024: 0768T, 0769T Add codes effective 01/01/2024: 64596, 64597, 64598
HCCPS	L8678 Delete codes effective 09/01/2023: K1018, K1019 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



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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

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