NO. 91634

PERIPHERAL NERVE STIMULATION

Effective: 06/01/2026
Committee Review: 05/2026
Last Updated: 05/2026

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Policy scope: This policy addresses the use of electrical nerve stimulation on peripheral nerves to treat pain, including the following modalities:

- Transcutaneous electrical nerve stimulation (TENS) devices
- Transcutaneous Electrical Acupoint Stimulation (TEAS)
- Percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) devices
- Permanently implanted peripheral nerve stimulation and peripheral nerve field stimulation devices
- Tonic Motor Activation (TOMAC) peroneal nerve stimulation therapy for restless leg syndrome (RLS) – Commercial, Medicaid

Related policies:

- For the use of electrical stimulation to treat other conditions (e.g., incontinence, skin ulcers) or the use of electrical stimulation on non-peripheral nerves (e.g., brain, spinal cord/dorsal column, dorsal root ganglion), see ***Priority Health Medical Policy No. 91468 – Stimulation Therapy and Devices.***
- For hypoglossal nerve stimulation for the treatment of obstructive sleep apnea, see ***Priority Health Medical Policy No. 91333 –Sleep Apnea: Obstructive and Central***
- For gastric pacing (gastric pacemaker) and gastric electrical stimulation for treatment of gastroparesis, see ***Priority Health Medical Policy No. 91572 – Gastroparesis Testing and Treatment.***

- For Tonic Motor Activication (ToMAc) peroneal nerve stimulation therapy for restless leg syndrome (RLS) for Medicare, see ***Priority Health Medical Policy No. 91648 – Tonic Motor Activation (ToMAc) Peroneal Nerve Stimulation for Restless Leg Syndrome (i.e., Nidra™) – Medicare Advantage***.
- For transcranial magnetic stimulation for treatment of depression, see ***Priority Health Provider Manual: Transcranial magnetic stimulation (TMS).***

I. MEDICAL NECESSITY CRITERIA

A. Transcutaneous electrical nerve stimulators (TENS)

1. Use of TENS for any diagnosis for a two-month trial does not require prior authorization.
    a. Subsection
        i. Subsection
2. Authorization of TENS beyond the two-month initial trial for any diagnosis (except those listed in "3" below) requires documentation of at least two of the following:
    a. Increased physical activity
    b. Decreased pain
    c. Decreased use of analgesics
3. Use of TENS for the following low back diagnoses does NOT require prior authorization:
    a. Intervertebral disc degeneration
    b. Spinal instabilities
    c. Sacrococcygeal disorders
    d. Dorsopathies
    e. Low back pain
    f. Dorsalgia
4. Transcutaneous electrical nerve stimulators (TENS) include the following (not an all-inclusive list):
    a. **iRelieve Microcurrent Pain Relief System** (Fast Track Technologies, Inc.)
    b. **StimOn™ Pain Relief System** (Gimer Medical Co., Ltd.)
    c. **TrueRelief** (TrueRelief)
    d. **BioWaveGo** (Biowave Corporation)

    The above devices have been classified by the **U.S. Food and Drug Administration (FDA)** as *Stimulator, Nerve, Transcutaneous, For Pain Relief (Classification Product Code GZJ)*

5. Limitations/Exclusions: The following TENS and TENS-related devices are considered experimental, investigational, or unproven:
    a. The **Monarch eTNS®** [external trigeminal nerve stimulation] System (NeuroSigma Inc.) for treatment of **attentiondeficit/hyperactivity disorder (ADHD)**

B. Transcutaneous Electrical Acupoint Stimulation (TEAS)

1. Prescription TEAS devices (e.g., prescription version PrimaBella™ or ReliefBand devices) are medically necessary for the treatment of

hyperemesis gravidarum that is unresponsive to other conservative medical therapy (e.g., change in diet, ginger capsules, vitamin B6).
2. Over-the-counter (OTC) disposable TEAS devices, which are used for the treatment of motion sickness, are not considered to be medically necessary.

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

1. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of PENS or PNT as a treatment option for any indication. Therefore, Priority Health considers the use of PENS or PNT NOT medically necessary for ANY indication.
2. Percutaneous electrical nerve stimulation (PENS) devices include the following (not an all-inclusive list):
    a. **Sprint® PNS** (SPR Therapeutics, Inc.)
    The FDA has assigned the PENS classification to SPRINT. SPRINT PNS is unique in that it acts as a temporary, 60-day treatment intended to provide durable symptom relief after device removal.
    b. **Smartpatch PNS** (SPR Therapeutics, Inc.)
    c. **Primary Relief, ANSIStim-PP, First Relief** (DyAnsys, Inc.)
    d. **Deepwave Percutaneous Neuromodulation Pain Therapy System** (Biowave Corporation)
    e. **Vertis PNT** (Vertis Neuroscience, Inc.)

The above devices have been classified by the **U.S. Food and Drug Administration (FDA)** as Stimulator, Nerve, Electrical, Percutaneous (Pens), For Pain Relief (Classification Product Code NHI).

- Sparrow Ascent (Spark Biomedical, Inc.) and other devices/stimulators/systems that target nerves in the auricular region and are indicated to reduce symptoms associated with opioid withdrawal.

The above devices have been classified by the **U.S. Food and Drug Administration (FDA)** as percutaneous nerve stimulator for opioid withdrawal (Classification Product Code PZR).

D. Percutaneous Electrical Nerve Field Stimulation (PENFS)

1. IB-Stim (NeurAxis) may be considered medically necessary when ALL of the following criteria are met:
    a. Age 8-21
    b. Chronic abdominal pain fulfilling criteria for any of the abdominal pain-related functional gastrointestinal disorders (IBS, functional dyspepsia, abdominal migraine, functional abdominal pain, or functional abdominal pain syndrome) based on the Rome IV version of the Questionnaire on Pediatric Gastrointestinal Symptoms
    c. Organic causes of abdominal pain have been ruled out
    d. Failure of at least one form of conservative management (hypnotherapy, cognitive behavioral therapy, soluble dietary fiber supplement, lactobacillus rhamnosus supplement [probiotics])

e. Failure of at least two medications used to treat abdominal pain, with at least one being hyoscyamine or dicyclomine, unless contraindicated
f. Only one course of treatment with auricular neurostimulation will be considered medically necessary. There is insufficient evidence in peer-reviewed literature to support repeat treatments.

IB-Stim is the only auricular neurostimulation device that will be considered medically necessary. All other auricular neurostimulation devices are considered experimental and investigational due to lack of published peer-reviewed evidence.

E. Permanently Implanted Peripheral Nerve Stimulators

1. Restorative neurostimulation

   The FDA granted Premarket Approval (PMA) for the **ReActiv8® Implantable Neurostimulation System** (Mainstay Medical Ltd.) on June 16, 2020. Priority Health considers this treatment modality/device unproven and not medically necessary due to insufficient evidence of efficacy.

   ReActiv8® has been classified by the U.S. Food and Drug Administration (FDA) as *Stimulator, neuromuscular, Lower Back Muscles, Totally Implanted for Pain Relief (Classification Product Code QLK).*

2. A permanently implanted peripheral nerve stimulator may be considered medically necessary only when ALL of the following criteria are met:
   a. Member has been diagnosed with one or more of the following:
      i. Reflex sympathetic dystrophy
      ii. Causalgia
      iii. Plexus avulsion
      iv. Operative trauma
      v. Entrapment neuropathies
      vi. Injection injuries
   b. There is objective evidence of pathology (e.g., electromyography)
   c. Member is refractory to one or more of the following conservative therapies:
      i. Analgesics
      ii. Physical therapy
      iii. Local injection
   d. Member exhibits no psychological contraindications
   e. Member is not addicted to any drug
   f. Member has completed a successful two-week trial of transcutaneous stimulation (resulting in at least a 50% reduction in pain).
3. Permanently implanted peripheral nerve stimulators include the following (not an all-inclusive list):
   a. **Nalu Neurostimulation System** (Nalu Medical)
   b. **StimRouter Neuromodulation System** (Bioventus)
   c. **Neuspera Neurostimulation System** (Neuspera Medical Inc.)
   d. **StimQ Peripheral Nerve Stimulator** (Stimwave Technologies, Inc.)

The above devices have been classified by the **U.S. Food and Drug Administration (FDA)** as *Stimulator, Peripheral Nerve, Implanted (Pain Relief) (Classification Product Code GZF).*

4. Prior authorization is required.

F. Tonic Motor Activation (TOMAC) peroneal nerve stimulation therapy for restless leg syndrome (RLS)

1. **MEDICARE ADVANTAGE**: See Priority Health medical policy No. 91648 TONIC MOTOR ACTIVATION – MEDICARE ADVANTAGE
2. **COMMERCIAL, MEDICAID**:
   a. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of TOMAC peroneal nerve stimulation therapy as a treatment option for RLS. Therefore, Priority Health considers the use of TOMAC peroneal nerve stimulation therapy NOT medically necessary for RLS.
   b. Tonic Motor Activation (TOMAC) peroneal nerve stimulators include the following (may not be an all-inclusive list):
      i. **Nidra™ NTX100 Tonic Motor Activation (TOMAC) System (Noctrix Health, Inc.).** This Class II device has been classified by the **U.S. Food and Drug Administration (FDA)** as *Stimulator, Nerve, For Restless Legs Syndrome (Classification Product Code QWD).*

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)
NCD 10.2 - Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain NCD 160.7 - Electrical Nerve Stimulators NCD 160.7.1 - Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy NCD 160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) NCD 160.27 - Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	Transcutaneous Electrical Nerve Stimulators (TENS) - L33802, A52520
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	Transcutaneous Electrical Nerve Stimulators (TENS) - L33802, A52520
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

Transcutaneous electrical nerve stimulators (TENS)

Transcutaneous electrical nerve stimulation (TENS) is a therapy that uses low voltage electrical current to provide pain relief. A TENS unit consists of a battery-powered device that delivers electrical impulses through **electrodes placed on the surface of the skin**. The electrodes are placed at or near nerves where the pain is located or at trigger points. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic).

There are two theories about how transcutaneous electrical nerve stimulation (TENS) works. One theory is that the electric current stimulates nerve cells that block the transmission of pain signals, modifying your perception of pain. The other theory is that nerve stimulation raises the level of endorphins, which are the body's natural pain-killing chemical. The endorphins then block the perception of pain.

The **Monarch eTNS [external trigeminal nerve stimulation] System** is designed to provide a nonpharmaceutical treatment option for children with attention-deficit/hyperactivity disorder (ADHD) during sleep without the need for device implantation. The U.S. Food and Drug Administration (FDA) granted a de novo (DEN) classification (DEN180041) for the Monarch eTNS System (NeuroSigma Inc.) under product code QGL (transcutaneous nerve stimulator for ADHD). The Monarch eTNS System is a class II device, regulated under Code of Federal Regulations (CFR) 21 CFR 882.5898. Treatment takes place in the patient's home environment. The Monarch eTNS System is a prescription-only, noninvasive, therapeutic device intended for children ages 7 to 12 years diagnosed with ADHD who are not taking medications. Before the patient goes to sleep at night, a new electrical patch is adhered to clean unbroken skin in the midline of the patient's forehead directly above the eyebrows. The patch is connected to the generator by a conductive wire. The pulse generator, operating on preset parameters—except for amplitude, which can be adjusted in 0.2 milliamp (mA) increments and then locked by the caretaker under direction of the prescribing physician—delivers low-level current via the patch to the patient's right and left supraorbital and supratrochlear branches of the trigeminal nerve. Prescribed duration of use while sleeping ranges from 7 to 9 hours. According to the American Academy of Pediatrics (AAP) Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents*: "To date, there is no long-term safety and efficacy evidence for eTNS [external trigeminal nerve stimulation]. Overall, the current evidence supporting [tx] of ADHD with eTNS is*

sparse and in no way approaches the robust strength of evidence documented for established medication and behavioral [tx] for ADHD; therefore, it cannot be recommended as a [tx] of ADHD without considerably more extensive study on its efficacy and safety"

Transcutaneous Electrical Acupoint Stimulation (TEAS) for hyperemesis gravidarum

Up to 90% of pregnant women experience nausea and vomiting. When prolonged or severe, this is known as hyperemesis gravidarum (HG), which can, in individual cases, be life threatening. The etiology of HG is unknown in most cases, although some biological, physiological and psychological as well as sociocultural factors are thought to be contributory factors. Risk factors for HG include multiple pregnancy, nulliparity, obesity, metabolic disturbances, a history of HG in a previous pregnancy, trophoblastic disorders, psychological disorders (for example, eating disorders such as anorexia nervosa or bulimia) and a history of migration. For initial management, dietary and lifestyle advice is often sufficient to ameliorate symptoms and improve quality of life. TEAS devices emit a low-level electrical current across two small electrodes on their underside, stimulating the median nerve (an acupuncture point).

Percutaneous Electrical Nerve Stimulation (PENS), Percutaneous Neuromodulation Therapy (PNT) and Percutaneous Electrical Nerve Field Stimulation (PENFS)

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

Percutaneous electrical nerve stimulation (PENS) involves the use of thin filiform needle electrodes that are placed percutaneously near a peripheral nerve. It may also involve the use of a needle-like introducer that inserts an electrode near a peripheral nerve. An electrical current drawn from an external pulse generator is delivered to the area, aiming to interfere with pain sensation. PENS devices are temporary and do not require invasive procedures to administer.

Percutaneous electrical nerve field stimulation (PENFS) differs from PENS in that with PENFS, a "field" of pain is targeted, instead of targeting a specific nerve. Non-implanted nerve stimulators for functional abdominal pain relief are a class of devices that stimulate nerves remotely from the source of pain by sending gentle electrical impulses into cranial nerve bundles located in the ear with the intent to relieve functional abdominal pain. This stimulation targets brain areas involved in processing pain and aids in the reduction of functional abdominal pain associated with Irritable Bowel Syndrome. An example of this device is IB-Stim (NeurAxis), which is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS.

In a randomized controlled trial by Kovacic and colleagues (2017), 115 adolescents aged 11-18 years who met Rome III criteria for abdominal painrelated functional gastrointestinal disorders from a single US outpatient gastroenterology clinic were

randomly assigned (1:1) to active treatment (n=60) or sham (n=55) for 4 weeks. Patients were stratified by sex and presence or absence of nausea. Allocation was concealed from participants, caregivers, and the research team. The primary efficacy endpoint was change in abdominal pain scores. Improvement in worst abdominal pain and composite pain score were measured using the Pain Frequency-Severity-Duration (PFSD) scale. Participants with less than 1 week of data and those with organic disease identified after enrollment were excluded from the modified intention-to-treat population. After exclusion of patients who discontinued treatment (n=1 in the PENFS group; n=7 in the sham group) and those who were excluded after randomization because they had organic disease (n=2 in the PENFS group; n=1 in the sham group), 57 patients in the PENFS group and 47 patients in the sham group were included in the primary analysis. Patients in the PENFS group had greater reduction in worst pain compared with sham after 3 weeks of treatment (PENFS: median score 5.0 [IQR 4.0-7.0]; sham: 7.0 [5.0-9.0]; least square means estimate of change in worst pain 2.15 [95% CI 1.37-2.93] Effects were sustained for an extended period (median follow-up 9.2 weeks [IQR 6·4-13·4]) in the PENFS group: median 8.0 (IQR 7.0-9.0) at baseline to 6.0 (5.0-8.0) at follow-up versus sham: 7.5 (6.0-9.0) at baseline to 7.0 (5.0-8.0) at follow-up (p<0.0001). Median PFSD composite scores also decreased significantly in the PENFS group (from 24.5 [IQR 16.8-33.3] to 8.4 [3.2-16.2]) compared with sham (from 22.8 [IQR 8.4-38.2] to 15.2 [4.4-36.8]) with a mean decrease of 11.48 (95% CI 6.63-16.32; p<0.0001) after 3 weeks. These effects were sustained at extended follow-up in the PENFS group: median 24.5 (IQR 16.8-33.3) at baseline to 12 (3.6-22.5) at follow-up, compared with sham: 22.8 (8.4-38.2) at baseline to 16.8 (4.8-33.6) at follow-up (p=0.018). Ten patients reported side-effects (three of whom discontinued the study): ear discomfort (n=6; three in the PENFS group, three in the sham group), adhesive allergy (n=3; one in the PENFS group, two in the sham group), and syncope due to needle phobia (n=1; in the sham group). There were no serious adverse events.

Another study by Santucci and colleagues (2023) compared the efficacy of percutaneous electrical nerve field stimulation to standard medical therapy in adolescents with functional abdominal pain disorders. The records of FAPD patients ages 11-21 years, treated with 4 weeks of PENFS, cyproheptadine or amitriptyline were reviewed. Outcomes were evaluated using validated questionnaires [Abdominal Pain Index (API), Nausea Severity Scale (NSS), and the Functional Disability Inventory (FDI)] at baseline and follow-up within 3 months (FU). Of 101 patients, 48% received PENFS, 31% cyproheptadine and 21% received amitriptyline. Median ages were 17 (15-19), 16 (15-18) and 15 (11- 16) years respectively and the majority were females (75%, 90% and 52% respectively). In the PENFS group, API (p = 0.001), NSS (p = 0.059) and FDI (p = 0.048) were significantly lower at FU. API (p = 0.034) but not NSS and FDI (p > 0.05) decreased significantly at FU in the amitriptyline group. API, NSS and FDI did not change significantly with cyproheptadine at FU (p > 0.05). FU API scores were lower in PENFS vs. cyproheptadine (p = 0.04) but not vs. amitriptyline (p = 0.64). The FDI scores were significantly lower in the amitriptyline vs. cyproheptadine group (p = 0.03). The authors concluded that therapy with PENFS showed improvements in abdominal pain, nausea and disability while amitriptyline showed improvements in abdominal pain within 3 months of treatment. PENFS was more effective than cyproheptadine in improving abdominal pain. Amitriptyline improved disability scores more than cyproheptadine and showed promise for treatment.

In a randomized, double-blinded trial, data from pediatric patients with IBS who participated in a double-blind trial at a tertiary care gastroenterology clinic from June

2015 through November 2016 were evaluated. Patients were randomly assigned to groups that received PENFS (n = 27; median age, 15.3 y; 24 female) or a sham stimulation (n = 23; median age, 15.6 y; 21 female), 5 days/week for 4 weeks. The primary endpoint was number of patients with a reduction of 30% or more in worst abdominal pain severity after 3 weeks. Secondary endpoints were reduction in composite abdominal pain severity score, reduction in usual abdominal pain severity, and improvement in global symptom based on a symptom response scale (-7 to +7; 0 = no change) after 3 weeks. Reductions of 30% or more in worst abdominal pain were observed in 59% of patients who received PENFS vs 26% of patients who received the sham stimulation (P = .024). The patients who received PENFS had a composite pain median score of 7.5 (interquartile range [IQR], 3.6-14.4) vs 14.4 for the sham group (IQR, 4.5- 39.2) (P = .026) and a usual pain median score of 3.0 (IQR, 3.0-5.0) vs 5.0 in the sham group (IQR, 3.0-7.0) (P = .029). A symptom response scale score of 2 or more was observed in 82% of patients who received PENFS vs 26% of patients in the sham group (P ≤ .001). No significant side effects were reported. (Krasaelap et al., 2020)

Guidelines/Position Statements

- The European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)/ North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN): Guidelines for Treatment of Irritable Bowel Syndrome and Functional Abdominal Pain- Not Otherwise Specified in Children Aged 4–18 Years (Groen et al., 2025)
    - “Percutaneous Electrical Nerve Field Stimulation (PENFS) is suggested as a treatment option (Conditional recommendation, Moderate certainty evidence)”

Percutaneous neuromodulation therapy (PNT) is a variant of PENS in which fine filament electrode arrays are placed near the area that is 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.

SPRINT PNS

SPRINT PNS is a temporary stimulator designed to selectively stimulate targeted peripheral nerve fibers for up to 60 days, with the intent of providing durable symptom relief. SPRINT has been studied for use in several indications, including but not limited to chronic knee pain after total knee arthroplasty, chronic shoulder pain, chronic low back pain, and phantom limb pain. SPRINT was formally evaluated at Priority Health’s March 2026 Medical Technology Assessment Committee meeting.

In a randomized, placebo-controlled study by Goree and colleagues (2024), 41 patients with postoperative pain after knee replacement were randomized to receive either active PNS or placebo (sham) stimulation. Subjects and a designated evaluator were blinded to group assignments. Subjects in both groups underwent ultrasound-guided placement of percutaneous fine-wire coiled leads targeting the femoral and sciatic nerves on the leg with postoperative pain. Leads were indwelling for eight weeks, and the primary efficacy outcome compared the proportion of subjects in each group reporting ≥50% reduction in average pain relative to baseline during weeks five to eight. Functional outcomes (6-minute walk test; 6MWT and Western Ontario and McMaster Universities Osteoarthritis

Index) and quality of life (Patient Global Impression of Change) also were evaluated at end of treatment (EOT). Results concluded that a greater proportion of subjects in the PNS groups (60%; 12/20) than in the placebo (sham) group (24%; 5/21) responded with ≥50% pain relief relative to baseline (p = 0.028) during the primary endpoint (weeks 5-8). Subjects in the PNS group also walked a significantly greater distance at EOT than did those in the placebo (sham) group (6MWT; +47% vs -9% change from baseline; p = 0.048, n = 18 vs n = 20 completed the test, respectively).

Gutierrez and colleagues evaluated the use of SPRINT PNS in chronic shoulder pain with a single-center retrospective chart review. In this study, data were extracted from the electronic medical records of patients who had previously undergone percutaneous PNS treatment for chronic shoulder pain. The authors found that overall, 84 % (49/58) of patients reported substantial (≥50 %) pain relief at the end of treatment. The records for 2 patients did not include patient-reported percent pain relief. The average indwelling period for leads (i.e., treatment period) was 57 days. Findings on treatment effectiveness were consistent when the patient population was stratified by cause of pain, duration living with pain, and presence of pain-modifying comorbidities. Stimulation paradigms were identified and categorized by the nerve target and stimulation frequency (e.g., motor stimulation, sensory stimulation, or bimodal stimulation).

In a randomized, double-blind, placebo-controlled trial with 12 months of follow up, 28 traumatic lower extremity amputees with residual and/or phantom limb pain were randomized to receive 8 weeks of PNS (group 1) or 4 weeks of placebo followed by a crossover 4 weeks of PNS (group 2). Percutaneous leads were implanted under ultrasound guidance targeting the femoral and sciatic nerves. During follow-up, changes in average pain and pain interference were assessed using the Brief Pain Inventory-Short Form and comparing with baseline. Results showed that significantly more participants in group 1 reported ≥50% reductions in average weekly pain at 12 months (67%, 6/9) compared with group 2 at the end of the placebo period (0%, 0/14, p=0.001). Similarly, 56% (5/9) of participants in group 1 reported ≥50% reductions in pain interference at 12 months, compared with 2/13 (15%, p=0.074) in group 2 at crossover. Reductions in depression were also statistically significantly greater at 12 months in group 1 compared with group 2 at crossover. (Gilmore et al., 2019)

D’Souza and colleagues conducted a systematic review and meta-analysis of analgesic outcomes with implantable PNS systems, with results up to 24 months. Eligible studies included adults with chronic pain treated with an implantable PNS system, and pain intensity was assessed at baseline and follow-up time points. The primary outcome was change in pain intensity from baseline to 6 months after PNS implantation. Secondary outcomes included changes in pain intensity at 3, 12 and 24 months after PNS implantation. A total of 106 studies comprising 9272 patients were included. PNS was associated with large, statistically significant reductions in pain intensity from baseline to all time points: 3 months (Hedges' g 2.92; 95% CI 2.62 to 3.21), 6 months (Hedges' g 3.08; 95% CI 2.68 to 3.48), 12 months (Hedges' g 2.68; 95% CI 2.30 to 3.05) and 24 months (Hedges' g 2.08; 95% CI 1.68 to 2.48) (all p<0.001). However, the certainty of evidence as assessed by the Grading of Recommendations Assessment, Development and Evaluation criteria was rated as low for the primary outcome, due to pooling from observational studies, risk of bias, and heterogeneity (statistical, clinical and methodological). Subgroup analyses revealed no differences by study design or device type, while smaller effect sizes were reported in industry-funded studies and those with

declared conflicts of interest. The largest effect sizes were observed in pelvic and upper extremity pain, whereas the smallest in truncal pain. It is worth noting that this meta-analysis evaluated analgesic outcomes for all implantable PNS systems and was not specific to SPRINT PNS.

Permanently implanted peripheral nerve stimulators

Restorative neurostimulation

The FDA granted Premarket Approval (PMA) for **the ReActiv8® Implantable Neurostimulation System (Mainstay Medical Ltd.).** This device is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3 as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who have failed therapy including pain medications and physical therapy and are not candidates for spine surgery.

ReActiv8® was formally evaluated by Priority Health's **Medical Technology Assessment Committee (MTAC)** on August 30, 2023. It is the company's position that there is insufficient evidence in the published peer reviewed scientific literature to support the efficacy of restorative neurostimulation for the treatment of chronic low back pain. Additional larger studies comparing restorative neurostimulation to standard of care and current alternative treatments are needed to demonstrate safety and efficacy for this modality. Therefore, Priority Health considers this device/treatment modality unproven and not medically necessary due to insufficient evidence of efficacy.

Peripheral nerve stimulation

Peripheral nerve stimulation (PNS) involves surgical insertion of an electrode along a specific peripheral nerve determined to be responsible for regional pain. The electrode is connected to a lead that is tunneled to a receiver unit located within a subcutaneous pocket. Electrical impulses generated by a stimulator attached to the skin overlying the receiver are transmitted along the electrode to the peripheral nerve, thereby blocking or masking pain sensation. A therapeutic trial may be attempted by placement of a temporary electrode to determine if nerve stimulation leads to significant therapeutic analgesia - by at least 50 %. Individuals that experience significant pain relief may then be eligible for permanent implantation.

Peripheral Nerve Field Stimulation (PNFS)

Subcutaneous stimulation (peripheral nerve field stimulation/PNFS) is a novel neuromodulation modality that has increased in its utilization during the past decade. It consists of introducing a lead in the subdermal level to stimulate the small nerve fibers in that layer. Unlike other neuromodulation techniques including direct peripheral nerve stimulation, spinal cord stimulation (SCS), or deep brain stimulation, the precise target is not identified.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline

The European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN)/ North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN)	Guidelines for Treatment of Irritable Bowel Syndrome and Functional Abdominal Pain- Not Otherwise Specified in Children Aged 4–18 Years (Groen et al., 2025)
American Society of Pain and Neuroscience (ASPN)	Consensus Guidelines from the American Society of Pain and Neuroscience for the Use of 60-Day Peripheral Nerve Stimulation Therapy: A NEURON Living Guideline Project (2025)
American Society of Pain and Neuroscience (ASPN)	Consensus Guidelines for the Use of Peripheral Nerve Stimulation in the Treatment of Chronic Pain and Neurological Diseases (2025)
American Society of Interventional Pain Physicians (ASIPP)	Comprehensive Evidence‐Based Guidelines for Implantable Peripheral Nerve Stimulation in the Management of Chronic Pain (2024)
International Society for the Advancement of Spine Surgery (ISASS)	ISASS Statement: Restorative Neurostimulation for Chronic Mechanical Low Back Pain Resulting From Neuromuscular Instability (2023)
International Neuromodulation Society (INS)	Neurostimulation Appropriateness Consensus Committee (NACC) Recommendations (most recent update 2023)
National Institute for Health and Care Excellence (NICE)	Percutaneous Electrical Nerve Stimulation for Refractory Neuropathic Pain (IPG450 / HealthTech Guidance) (2013)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
iRelieve Microcurrent Pain Relief System (Fast Track Technologies, Inc.)	K212618	9/14/2022
SPRINT® Peripheral Nerve Stimulation (PNS) System (SPR Therapeutics, Inc.)	K211801	10/13/2021
StimRouter® Neuromodulation System (Bioventus)	K142432	2/20/2015

Nalu Neurostimulation System (Nalu Medical, Inc.)	K183579	3/29/2019
IB Stim® (Innovative Health Solutions, Inc.)	DEN180057	8/09/2019
Monarch® eTNS System (NeuroSigma, Inc.)	DEN180041	4/19/2019
ReActiv8® Implantable Neurostimulation System (Mainstay Medical Ltd.)	P190021	6/16/2020
StimOn™ Pain Relief System (Gimer Medical Co., Ltd.)	K213802	8/26/2022
TrueRelief® TENS Device (TrueRelief, LLC)	K202186	3/23/2021
BioWaveGO® (BioWave Corporation)	K210202	2/24/2021
SmartPatch® PNS (SPR Therapeutics, Inc.)	K161154	7/23/2016
Primary Relief® / ANSIStim PP / First Relief® (DyAnsys, Inc.)	K213188	1/31/2022
Deepwave Percutaneous Neuromodulation Pain Therapy System (BioWave Corporation)	K061166	8/15/2006
Vertis PNT® System (Vertis Neuroscience, Inc.)	K022241	9/11/2002
Sparrow® Ascent System (Spark Biomedical, Inc.)	K251246	8/25/2025
Nidra™ NTX100 Tonic Motor Activation (TOMAC) System (Noctrix Health, Inc.)	DEN220059	4/17/2023

VI. CODING

TENS

Transcutaneous Electrical Stimulator (TENS)

ICD-10 Codes that may apply:

- *No prior auth required for this indication*

No prior auth for first 2 months trial for any indication for commercial and Medicaid.

Prior auth required for Medicare for all indications from 1st months rental

B02.0	Zoster encephalitis
B02.23	Postherpetic polyneuropathy
B02.29	Other postherpetic nervous system involvement
E08.40 – E08.42	Diabetes mellitus due to underlying condition with neurological complications

E09.40 – E09.42	Drug or chemical induced diabetes mellitus with neurological complications
E10.40 – E10.49	Type 1 diabetes mellitus with neurological complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.65	Type 1 diabetes mellitus with hyperglycemia
E11.40 - E11.49	Type 2 diabetes mellitus with neurological complication
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.65	Type 2 diabetes mellitus with hyperglycemia
E13.40	Other specified diabetes mellitus with diabetic neuropathy, unspecified
E13.41 - E13.49	Other specified diabetes mellitus with neurological complication
G54.8	Other nerve root and plexus disorders
G55	Nerve root and plexus compressions in diseases classified elsewhere
G57.70 - G57.72	Causalgia of lower limb
G57.80 - G57.82	Other specified mononeuropathies of left lower limb
G57.90 - G57.92	Unspecified mononeuropathy of lower limb
G58.8	Other specified mononeuropathies
G58.9	Mononeuropathy, unspecified
G59	Mononeuropathy in diseases classified elsewhere
G89.0	Central pain syndrome
G89.21 – G89.29	Chronic pain
G89.4	Chronic pain syndrome
G90.50 - G90.59	Complex regional pain syndrome I
G99.0	Autonomic neuropathy in diseases classified elsewhere
M43.20 - M43.28	Fusion of spine
M43.8x9	Other specified deforming dorsopathies, site unspecified
M51.36◆	Other intervertebral disc degeneration, lumbar region
M51.37◆	Other intervertebral disc degeneration, lumbosacral region
M53.2x7◆	Spinal instabilities, lumbosacral region
M53.2x8◆	Spinal instabilities, sacral and sacrococcygeal region
M53.3◆	Sacrococcygeal disorders, not elsewhere classified
M53.80	Other specified dorsopathies, site unspecified
M53.84	Other specified dorsopathies, thoracic region
M53.85	Other specified dorsopathies, thoracolumbar region
M53.86◆	Other specified dorsopathies, lumbar region

M53.87◆	Other specified dorsopathies, lumbosacral region
M53.88◆	Other specified dorsopathies, sacral and sacrococcygeal region
M53.9	Dorsopathy, unspecified
M54.5◆	Low back pain
M54.89◆	Other dorsalgia
M54.9◆	Dorsalgia, unspecified

CPT/HCPCS Codes:

97014	Application of a modality to one or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
A4558	Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES)
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

Not Medically Necessary

0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
A4541	Monthly supplies for use of device coded at E0733
A4542	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
A4543	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist

E0721 Transcutaneous electrical nerve stimulatory, stimulates nerves in the auricular region

E0737 Transcutaneous tibial nerve stimulator, controlled by phone application

E0743 External lower extremity nerve stimulator for restless legs syndrome, each

Transcutaneous Electrical Acupoint Stimulation (TEAS) for hyperemesis gravidarum

ICD-10 Codes that may support medical necessity:

O21.0 Mild hyperemesis gravidarum

O21.1 Hyperemesis gravidarum with metabolic disturbance

O21.2 Late vomiting of pregnancy

O21.8 Other vomiting complicating pregnancy

O21.9 Vomiting of pregnancy, unspecified

CPT/HCPCS Codes:

E0765 FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting

PENS

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

64567 Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

Not Medically Necessary

97813 Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient

97814 Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

64999 Unlisted procedure, nervous system *(Explanatory notes must accompany claims billed with unlisted codes.)*

C9807 Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023) (Covered for Medicare and Medicaid)

Peripherally Implanted Nerve Stimulator

ICD-10 Codes that <u>may</u> apply:

G54.8 Other nerve root and plexus disorders

G54.9 Nerve root and plexus disorder, unspecified

G55 Nerve root and plexus compressions in diseases classified elsewhere

G56.40 - G56.42 Causalgia of upper limb

G56.80 - G56.82 Other specified mononeuropathies

G57.70 - G57.72 Causalgia of lower limb

G57.80 - G57.82 Other specified mononeuropathies

G58.0 Intercostal neuropathy

G58.7 Mononeuritis multiplex

G58.8 Other specified mononeuropathies

G89.0 Central pain syndrome

G89.21 Chronic pain due to trauma

G89.22 Chronic post-thoracotomy pain

G89.28 Other chronic postprocedural pain

G89.29 Other chronic pain

G89.4 Chronic pain syndrome

G90.50 - G90.59 Complex regional pain syndrome I

M53.80 Other specified dorsopathies, site unspecified

M53.84 Other specified dorsopathies, thoracic region

M53.85 Other specified dorsopathies, thoracolumbar region

M53.9 Dorsopathy, unspecified

M54.5 Low back pain

M54.89 Other dorsalgia

M54.9 Dorsalgia, unspecified

CPT/HCPCS Codes:

64555 Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)

64575 Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)

64590 Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

64595 Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array (No Auth)

64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming (No Auth)
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional (No Auth)
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional. (No Auth)
A4438	Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1883	Adapter/ extension, pacing lead or neurostimulator lead
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type

L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8689	External recharging system for battery (internal) for use with implantable neurostimulator
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access Evicore guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access EviCore, InterQual, or TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.

- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

1. Hayes, Inc. Evolving Evidence Review. **ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for Chronic Low Back Pain.** Hayes, Inc.; May 20, 2022.
2. Hayes, Inc. Health Technology Assessment. **Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain**. Hayes, Inc.; September 21, 2018.
3. Hayes, Inc. Health Technology Assessment. **Percutaneous Electrical Nerve Stimulation for Treatment of Low Back Pain**. Hayes, Inc.; January 10, 2019.
4. Hayes, Inc. Health Technology Assessment. **Peripheral Nerve Field Stimulation for Treatment of Chronic Low Back Pain**. Hayes, Inc.; April 22, 2021.
5. Hayes, Inc. Health Technology Assessment. **Percutaneous Peripheral Nerve Stimulation for Treatment of Chronic Pain**. Hayes, Inc.; May 5, 2022.
6. Hayes, Inc. Evolving Evidence Review. **SPRINT PNS System (SPR Therapeutics) for Chronic Pain**. Hayes, Inc.; August 3, 2021.
7. Hayes, Inc. Evolving Evidence Review. **Monarch eTNS System (NeuroSigma Inc.) for Treatment of Attention-Deficit/Hyperactivity Disorder in Children**. Hayes, Inc.; February 9, 2023.
8. Electrical Nerve Stimulators. National Coverage Determination (NCD) 160.7. Centers for Medicare & Medicaid Services (CMS).
9. Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy. National Coverage Determination (NCD) 160.7.1. Centers for Medicare & Medicaid Services (CMS).
10. Billing and Coding: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT). Local Coverage Article (LCA) A56062. Wisconsin Physicians Service Insurance Corporation. Centers for Medicare & Medicaid Services (CMS).
11. Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain. National Coverage Determination (NCD) 10.2. Centers for Medicare & Medicaid Services (CMS).
12. Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP). National Coverage Determination (NCD) 160.27. Centers for Medicare & Medicaid Services (CMS).
13. Transcutaneous Electrical Nerve Stimulators (TENS). National Coverage Determination (NCD) 280.13. Centers for Medicare & Medicaid Services (CMS).
14. Transcutaneous Electrical Nerve Stimulators (TENS). Local Coverage Determination (LCD) L33802. CGS Administrators, LLC. Centers for Medicare & Medicaid Services (CMS).

15. Transcutaneous Electrical Nerve Stimulators (TENS) - Policy Article. Local Coverage Article (LCA) A52520. CGS Administrators, LLC. Centers for Medicare & Medicaid Services (CMS).
16. Alberta Heritage Foundation for Medical Research (AHFMR). ReliefBand. Techscan. Edmonton, AB: Alberta Heritage Foundation for Medical Research (AHFMR); March 2000.
17. Alkaissi A, Stalnert M, Kalman S. Effect and placebo effect of acupressure (P6) on nausea and vomiting after outpatient gynaecological surgery. Acta Anaesthesiol Scand. 1999; 43(3):270-274.
18. Allen TK, Habib AS. P6 stimulation for the prevention of nausea and vomiting associated with cesarean delivery under neuraxial anesthesia: A systematic review of randomized controlled trials. Anesth Analg. 2008; 107(4):1308-1312.
19. American College of Obstetrics and Gynecology (ACOG). Nausea and vomiting of pregnancy. ACOG Practice Bulletin No.52. Washington, DC: ACOG; April 2004.
20. Arnberger M, Stadelmann K, Alischer P, et al. monitoring of neuromuscular blockade at the P6 acupuncture point reduces the incidence of postoperative nausea and vomiting. Anesthesiology. 2007; 107(6):903-908.
21. Ardeshiri A, Shaffrey C, Stein KP, Sandalcioglu IE. **Real-World Evidence for Restorative Neurostimulation in Chronic Low Back Pain-a Consecutive Cohort Study**. *World Neurosurg*. 2022;168:e253-e259. doi:10.1016/j.wneu.2022.09.104
22. Beltran-Alacreu H, Serrano-Muñoz D, Martín-Caro Álvarez D, Fernández-Pérez JJ, Gómez-Soriano J, Avendaño-Coy J. **Percutaneous Versus Transcutaneous Electrical Nerve Stimulation for the Treatment of Musculoskeletal Pain. A Systematic Review and Meta-Analysis**. *Pain Med.* 2022;23(8):1387-1400. doi:10.1093/pm/pnac027
23. Chakravarthy K, Lee D, Tram J, et al. **Restorative Neurostimulation: A Clinical Guide for Therapy Adoption.** *J Pain Res*. 2022;15:1759-1774. Published 2022 Jun 20. doi:10.2147/JPR.S364081
24. Coloma M, White PF, Ogunnaike BO, et al. Comparison of acustimulation and ondansetron for the treatment of established postoperative nausea and vomiting. Anesthesiology. 2002; 97(6):1387-1392.
25. 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*. 2018;21(1):48-55. doi:10.1111/ner.12741
26. Deer TR, Esposito MF, McRoberts WP, et al. **A Systematic Literature Review of Peripheral Nerve Stimulation Therapies for the Treatment of Pain**. *Pain Med*. 2020;21(8):1590-1603. doi:10.1093/pm/pnaa030
27. Ezzo JM, Richardson MA, Vickers A, et al. Acupuncture-point stimulation for chemotherapy-induced nausea or vomiting. Cochrane Database Syst Rev. 2006 ;(2):CD002285.
28. Fan CF, Tanhui E, Joshi S, et al. Acupressure treatment for prevention of postoperative nausea and vomiting. Anesth Analg. 1997; 84(4):821-825.
29. Frey UH, Scharmann P, Löhlein C, Peters J. P6 acustimulation effectively decreases postoperative nausea and vomiting in high-risk patients. Br J Anaesth. 2009; 102(5):620-625.
30. Gilligan C, Burnside D, Grant L, et al. **ReActiv8 Stimulation Therapy vs. Optimal Medical Management: A Randomized Controlled Trial for the Treatment of Intractable Mechanical Chronic Low Back Pain (RESTORE Trial Protocol)**. *Pain Ther*. 2023;12(2):607-620. doi:10.1007/s40122-023-00475-4

31. 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.* 2021;162(10):2486-2498. doi:10.1097/j.pain.0000000000002258
32. Gilligan C, Volschenk W, Russo M, et al**. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial.** *Neuromodulation*. 2023;26(1):87-97. doi:10.1016/j.neurom.2021.10.011
33. 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*. 2023;26(1):98-108. doi:10.1016/j.neurom.2022.08.457
34. Gralla RJ. Antiemetic therapy. Semin Oncol. 1998; 25(5):577-583.
35. Habib AS, Itchon-Ramos N, Phillips-Bute BG, et al. Transcutaneous acupoint electrical stimulation with the ReliefBand for the prevention of nausea and vomiting during and after cesarean delivery under spinal anesthesia. Anesth Analg. 2006;102(2):581-584.
36. Ho CM, Hseu SS, Tsai SK, Lee TY. Effect of P-6 acupressure on prevention of nausea and vomiting after epidural morphine for post-cesarean section pain relief. Acta Anaesthesiol Scand. 1996; 40(3):372-375.
37. Jewell D, Young G. Interventions for nausea and vomiting in early pregnancy. Cochrane Database Syst Rev. 2003 ;(4):CD000145.
38. Johnson MI, Paley CA, Jones G, Mulvey MR, Wittkopf PG. **Efficacy and safety of transcutaneous electrical nerve stimulation (TENS) for acute and chronic pain in adults: a systematic review and meta-analysis of 381 studies (the meta-TENS study).** *BMJ Open*. 2022;12(2):e051073. Published 2022 Feb 10. doi:10.1136/bmjopen-2021-051073
39. Lagos LR, Arribas-Romano A, Fernández-Carnero J, González-Zamorano Y, Laguarta Val S. **Effects of percutaneous and transcutaneous electrical nerve stimulation on endogenous pain mechanisms in patients with musculoskeletal pain. A systematic review and meta-analysis [published online ahead of print, 2022 Sep 20]**. *Pain Med*. 2022;pnac140. doi:10.1093/pm/pnac140
40. Lee A, Done ML. The use of nonpharmacologic techniques to prevent postoperative nausea and vomiting: A meta-analysis. Anesth Analg. 1999; 88(6):1362-1369.
41. Lee A, Fan LT. Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting. Cochrane Database Syst Rev. 2009 ;(2):CD003281.
42. Lorio M, Lewandrowski KU, Coric D, Phillips F, Shaffrey CI. **International Society for the Advancement of Spine Surgery Statement: Restorative Neurostimulation for Chronic Mechanical Low Back Pain Resulting From Neuromuscular Instability** [published online ahead of print, 2023 Aug 10*]. Int J Spine Surg*. 2023;8525. doi:10.14444/8525
43. Miller KE, Muth ER. Efficacy of acupressure and acustimulation bands for the prevention of motion sickness. Aviat Space Environ Med. 2004; 75(3):227-234.
44. Mitchell B, Deckers K, De Smedt K, et al. **Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain.** *Neuromodulation*. 2021;24(6):1024-1032. doi:10.1111/ner.13477
45. Pearl ML, Fischer M, McCauley DL, et al. Transcutaneous electrical nerve stimulation as an adjunct for controlling chemotherapy-induced nausea and vomiting in gynecologic oncology patients. Cancer Nurs. 1999; 22(4):307-311.

46. Plaza-Manzano G, Gómez-Chiguano GF, Cleland JA, Arías-Buría JL, Fernández-de-Las-Peñas C, Navarro-Santana MJ. **Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis**. *Eur J Pain*. 2020;24(6):1023-1044. doi:10.1002/ejp.1559.
47. Rosen T, de Veciana M, Miller HS, et al. A randomized controlled trial of nerve stimulation for relief of nausea and vomiting in pregnancy. Obstet Gynecol. 2003; 102(1):129-135.
48. Russo M, Deckers K, Eldabe S, et al. **Muscle Control and Non-specific Chronic Low Back Pain.** *Neuromodulation*. 2018;21(1):1-9. doi:10.1111/ner.12738
49. Sayed D, Grider J, Strand N, et al. **The American Society of Pain and Neuroscience (ASPN) Evidence-Based Clinical Guideline of Interventional Treatments for Low Back Pain** [published correction appears in J Pain Res. 2022 Dec 24;15:4075-4076]. *J Pain Res*. 2022;15:3729-3832. Published 2022 Dec 6. doi:10.2147/JPR.S386879
50. Shaffrey C, Gilligan C. **Effect of Restorative Neurostimulation on Major Drivers of Chronic Low Back Pain Economic Impact**. *Neurosurgery*. 2023;92(4):716-724. doi:10.1227/neu.0000000000002305
51. Shenkman Z, Holzman RS, Kim C, et al. Acupressure-acupuncture antiemetic prophylaxis in children undergoing tonsillectomy. Anesthesiology. 1999; 90(5):1311-1316.
52. Shiao SY, Dune LS. Metaanalyses of acustimulations: Effects on nausea and vomiting in postoperative adult patients. Explore (NY). 2006; 2(3):202-215.
53. Slotnick RN. Safe, successful nausea suppression in early pregnancy with P-6 acustimulation. J Reprod Med. 2001; 46(9):811-814.
54. Tieppo Francio V, Westerhaus BD, Carayannopoulos AG, Sayed D. **Multifidus Dysfunction and Restorative Neurostimulation: A Scoping Review** [published online ahead of print, 2023 Jul 13]. *Pain Med*. 2023;pnad098. doi:10.1093/pm/pnad098
55. 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*. 2021;10(2):1451-1465. doi:10.1007/s40122-021-00307-3
56. Thomson S, et al. **Restorative neurostimulation for chronic mechanical low back pain – Three year results from the United Kingdom post market clinical follow-up registry**. *British Journal of Pain*. 2023; Vol. 0(0) 1–10. doi: 10.1177/20494637231181498
57. Treish I, Shord S, Valgus J, et al. Randomized double-blind study of the Reliefband as an adjunct to standard antiemetics in patients receiving moderately-high to highly emetogenic chemotherapy. Support Care Cancer. 2003; 11(8):516-521.
58. University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Evaluation and management of nausea and vomiting in early pregnancy (less than or equal to 20 weeks gestation). Austin, TX: University of Texas at Austin, School of Nursing; May 2002.
59. White PF, Hamza MA, Recart A, et al. Optimal timing of acustimulation for antiemetic prophylaxis as an adjunct to ondansetron in patients undergoing plastic surgery. Anesth Analg. 2005; 100(2):367-372.
60. White PF, Issioui T, Hu J, et al. Comparative efficacy of acustimulation (ReliefBand) versus ondansetron (Zofran) in combination with droperidol for preventing nausea and vomiting. Anesthesiology. 2002; 97(5):1075-1081.
61. Wolraich ML, Hagan JF Jr, Allan C, et al. **Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder**

in children and adolescents [published correction appears in Pediatrics. March 2020;145(3)]. *Pediatrics*. 2019;144(4):e20192528. doi:10.1542/peds.2019-2528
62. Zarate E, Mingus M, White PF, et al. The use of transcutaneous acupoint electrical stimulation for preventing nausea and vomiting after laparoscopic surgery. Anesth Analg. 2001; 92(3):629-635.
63. Zheng LH, Sun H, Wang GN, et al. Effect of transcutaneous electrical acupoint stimulation on nausea and vomiting induced by patient controlled intravenous analgesia with tramadol. Chin J Integr Med. 2008; 14(1):61-64.
64. Kovacic, K., Hainsworth, K., Sood, M., Chelimsky, G., Unteutsch, R., Nugent, M., Simpson, P., & Miranda, A. (2017). Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. *The lancet. Gastroenterology & hepatology*, *2*(10), 727–737. https://doi.org/10.1016/S2468-1253(17)30253-4
65. Groen, J., Gordon, M., Chogle, A., Benninga, M., Borlack, R., Borrelli, O., Darbari, A., Dolinsek, J., Khlevner, J., Di Lorenzo, C., Person, H., Sanghavi, R., Snyder, J., Thapar, N., Vlieger, A., Sinopoulou, V., Tabbers, M., & Saps, M. (2025). ESPGHAN/NASPGHAN guidelines for treatment of irritable bowel syndrome and functional abdominal pain-not otherwise specified in children aged 4-18 years. *Journal of pediatric gastroenterology and nutrition*, 10.1002/jpn3.70070. Advance online publication. https://doi.org/10.1002/jpn3.70070
66. Santucci, N. R., Sahay, R., El-Chammas, K. I., Graham, K., Wheatley, M., Vandenbrink, M., Hardy, J., & Fei, L. (2023). Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. *Frontiers in pain research (Lausanne, Switzerland)*, *4*, 1251932. https://doi.org/10.3389/fpain.2023.1251932
67. Krasaelap, A., Sood, M. R., Li, B. U. K., Unteutsch, R., Yan, K., Nugent, M., Simpson, P., & Kovacic, K. (2020). Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association*, *18*(9), 1987–1994.e2. https://doi.org/10.1016/j.cgh.2019.10.012

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68. Goree JH, Grant SA, Dickerson DM, Ilfeld BM, Eshraghi Y, Vaid S, Valimahomed AK, Shah JR, Smith GL, Finneran JJ, Shah NN, Guirguis MN, Eckmann MS, Antony AB, Ohlendorf BJ, Gupta M, Gilbert JE, Wongsarnpigoon A, Boggs JW. Randomized Placebo-Controlled Trial of 60-Day Percutaneous Peripheral Nerve Stimulation Treatment Indicates Relief of Persistent Postoperative Pain, and Improved Function After Knee Replacement. Neuromodulation. 2024 Jul;27(5):847-861. doi: 10.1016/j.neurom.2024.03.001. Epub 2024 May 11. PMID: 38739062.
69. Gilmore CA, Ilfeld BM, Rosenow JM, Li S, Desai MJ, Hunter CW, Rauck RL, Nader A, Mak J, Cohen SP, Crosby ND, Boggs JW. Percutaneous 60-day peripheral nerve stimulation implant provides sustained relief of chronic pain following amputation: 12-month follow-up of a randomized, double-blind, placebo-controlled trial. Reg Anesth Pain Med. 2019 Nov 17:rapm-2019-100937. doi: 10.1136/rapm-2019-100937. Epub ahead of print. PMID: 31740443.
70. Gutierrez GJ, Mehta P, Mouch T, Puri S, Caylor JR, Huffman WJ, Crosby ND, Boggs JW. A single-center retrospective chart review of percutaneous PNS for treatment of chronic shoulder pain. Interv Pain Med. 2024 Jul 11;3(3):100419. doi: 10.1016/j.inpm.2024.100419. PMID: 39502900; PMCID: PMC11536284.

71. D'Souza RS, Her YF, Morsi M, Soleymani H, Banks D, Miclau TA, Ekhtiari E, Cho D, Prokop L, Hussain N. Implantable peripheral nerve stimulation for chronic pain: a systematic review and meta-analysis of analgesic outcomes up to 24 months. Reg Anesth Pain Med. 2025 Nov 5:rapm-2025-107160. doi: 10.1136/rapm-2025-107160. Epub ahead of print. PMID: 41193385.
72. Gill B, Tidwell C, Hagedorn JM, Moreira AM, Lawandy M, Boyett B, Schappell J, Latif U, Pritzlaff S, Skaribas I, Kalia H, Sheth S, Schnur M, Li S, Lester D, Ellico T, Naidu R, Russo D, Massey C, Ottestad E, Vorenkamp K, Vucetic H, Pingree MJ, Abejón D, Desai MJ, Dickerson D, Gulati A, Sayed D, Deer TR. Consensus Guidelines from the American Society of Pain and Neuroscience for the Use of 60-Day Peripheral Nerve Stimulation Therapy. A NEURON Living Guideline Project. J Pain Res. 2025 Jun 24;18:3117-3139. doi: 10.2147/JPR.S521788. PMID: 40590046; PMCID: PMC12206896.

SUMMARY OF CHANGES

Clarifications:

- SPRINT PNS is a unique device in that it's intended for temporary (60-day) implantation to provide durable symptom relief. It is considered not medically necessary.
- Updated background and references

Past committee review dates: 11/22, 5/23, 11/23, 11/24, 8/25, 5/26

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