Priority Health

MEDICAL POLICY
No. 91634-R4

PERIPHERAL NERVE STIMULATION

Effective Date: November 1, 2025
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Review Dates: 11/22, 5/23, 11/23, 11/24, 8/25
Status: Current

Summary of Changes

Additions:

- Tonic Motor Activation (ToMAc) peroneal nerve stimulation therapy for restless leg syndrome (RLS): Reference to new Medicare-only policy has been added.
- Added new medical necessity criteria for IB-Stim (NeurAxis) auricular stimulation device (Section II. D. Percutaneous Electrical Nerve Field Stimulation (PENFS).
- Added Section III. GOVERNMENTAL REGULATIONS.

Changes:

- Tonic Motor Activation (ToMAc) peroneal nerve stimulation therapy for restless leg syndrome (RLS) is not medically necessary due to insufficient evidence for only the commercial and Medicaid lines of business (Section II. F.).

I. 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 medical 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)*.**

II. POLICY/CRITERIA

A. Transcutaneous electrical nerve stimulators (TENS)

1. Use of TENS for any diagnosis for a two-month trial does not require prior authorization.
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:

    - Intervertebral disc degeneration
    - Spinal instabilities
    - Sacrococcygeal disorders
    - Dorsopathies
    - Low back pain
    - Dorsalgia

4. Transcutaneous electrical nerve stimulators (TENS) include the following (not an all-inclusive list):

    - **iRelieve Microcurrent Pain Relief System** (Fast Track Technologies, Inc.)
    - **StimOn™ Pain Relief System** (Gimer Medical Co., Ltd.)
    - **TrueRelief** (TrueRelief)

- **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:

   - The **Monarch eTNS® [external trigeminal nerve stimulation] System (NeuroSigma Inc.)** for treatment of attention-deficit/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):

   - **Sprint® PNS** (SPR Therapeutics, Inc.)
   - **Smartpatch PNS** (SPR Therapeutics, Inc.)
   - **Primary Relief, ANSIStim-PP, First Relief** (DyAnsys, Inc.)
   - **Deepwave Percutaneous Neuromodulation Pain Therapy System** (Biowave Corporation)
   - **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:
   i. Age 8-21
   ii. 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
   iii. Organic causes of abdominal pain have been ruled out
   iv. Failure of at least one form of conservative management (hypnotherapy, cognitive behavioral therapy, soluble dietary fiber supplement, lactobacillus rhamnosus supplement [probiotics])
   v. Failure of at least two medications used to treat abdominal pain, with at least one being hyoscyamine or dicyclomine, unless contraindicated
   vi. 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:

      - Reflex sympathetic dystrophy
      - Causalgia
      - Plexus avulsion
      - Operative trauma
      - Entrapment neuropathies
      - 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:

      - Analgesics
      - Physical therapy
      - 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):

   - **Nalu Neurostimulation System** (Nalu Medical)
   - **StimRouter Neuromodulation System** (Bioventus)
   - **Neuspera Neurostimulation System** (Neuspera Medical Inc.)

- **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)

MEDICARE ADVANTAGE: See Priority Health medical policy *No. 91648 TONIC MOTOR ACTIVATION – MEDICARE ADVANTAGE*

COMMERCIAL, MEDICAID:

1. 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.

2. Tonic Motor Activation (TOMAC) peroneal nerve stimulators include the following (may not be an all-inclusive list):

   - **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)*.

III. GOVERNMENTAL REGULATIONS

Centers for Medicare & Medicaid Services (CMS)

National Coverage Determinations (NCDs)	
Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain 10.2 *Electrical Nerve Stimulators* 160.7 *Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy* 160.7.1 *Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)* 160.13 *Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)* 160.27	
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, LLC	*Transcutaneous Electrical Nerve Stimulators (TENS)* L33802 A52520
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

IV. MEDICAL NECESSITY REVIEW

☒ Required

- **Medicare**: Prior authorization is required from the start of the rental period.
- **Commercial/Individual, Medicaid**: Use of TENS beyond the two-month initial trial for any diagnosis (except those listed in section II. A. 3. above)
- Permanently implanted peripheral nerve stimulators

☒ Not Required

- **Commercial/Individual, Medicaid**: Use of TENS for any diagnosis for a two-month trial.
- **Commercial/Individual, Medicaid**: Use of TENS for any of the low back diagnoses listed in section II. A. 3. above

☐ Not Applicable

V. APPLICATION TO PRODUCTS

Coverage is subject to 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, 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.***

VI. 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" (p. 13).

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 pain-related 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], p<0.0001). 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 ($P \leq .001$). 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.

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 **Technology Assessment Committee (TAC)** 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.

VII. CODING INFORMATION

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) ***(No Auth)*** (*Not covered for Medicare)*
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes ***(No Auth)***
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care *(Medicare only)* ***(No Auth)***
A4558	Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz ***(No Auth)***
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES) ***(No Auth)***
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient ***(No Auth) (Not covered by Priority Medicaid)***
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) *(Covered for Medicare, Medicaid ONLY)*

<u>Not covered</u>

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 *(Not covered for Priority Health Medicaid/Healthy Michigan Plan members)*

PENS

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

Covered
0720T Percutaneous electrical nerve field stimulation, cranial nerves, without implantation *(covered for Medicare & Commercial)*

Not Covered:
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 may 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

(L codes not separately paid under APC payment arrangements)

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