02-61000-03

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Subject: Electrical Nerve Stimulation

DESCRIPTION:

Percutaneous electrical nerve stimulation (PENS) is similar in concept to transcutaneous electrical nerve stimulation, but differs in that needles are inserted either around or immediately adjacent to the nerves serving the painful area, and then stimulated. PENS is generally reserved for those who fail to get pain relief from transcutaneous electrical nerve stimulation. PENS is also distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. In PENS, the location of stimulation is determined by proximity to the pain.

Percutaneous neuromodulation therapy (PNT) is a variant of PENS in which fine filament electrode arrays are placed near the area causing pain. Some use the terms PENS and PNT interchangeably. It is proposed that PNT inhibits pain transmission by creating an electrical field that hyperpolarizes C fibers, thus preventing action potential propagation along the pain pathway.

Another type of neuromodulation, peripherally implanted nerve stimulators (also known as peripheral subcutaneous field stimulation, or peripheral nerve field stimulation) purport to treat chronic pain by targeting the peripheral nerve causing the chronic pain directly. An electrical current is transmitted via an electrode that has been implanted around the selected peripheral nerve. It is thought the electrical current blocks or disrupts the normal transmission of pain signals. The electrodes are connected by a wire to the peripherally implanted neurostimulator. An external generator (similar to a remote control device) controls the degree of stimulation the individual receives.

Percutaneous electrical nerve field stimulation (PENFS) (auricular neurostimulation) targets branches of cranial Nerves V, VII, IX and X, and the occipital nerves. It has been proposed as a treatment for functional abdominal pain associated with irritable bowel syndrome (IBS) in children and adolescents (IB-Stim®); treatment of pain associated with opioid withdrawal (Bridge, Drug Relief V1, Morph Device); treatment of chronic intractable pain due to diabetic peripheral neuropathy (First Relief); post-cesarean section pain (Primary Relief); and treatment of pain after cardiac surgery (Primary Relief).

Remote electrical neuromodulation (REN) is purported to offer an alternative to pharmacologic interventions for acute migraine and/or prevention of migraines. The Nerivio® REN device is cleared for use by the Food and Drug Administration (FDA) and is worn on the upper arm. It stimulates the peripheral nerves to induce conditioned pain modulation (CPM). The conditioned pain in the arm induced by the Nerivio REN device is believed to reduce the perceived migraine pain intensity. Control of the REN device is accomplished through Bluetooth communication between the device and a smartphone or tablet. For acute treatment, at onset of migraine or aura and no later than within 1 hour of onset, the user initiates use of the device through their mobile application. When used for preventive treatment, the device should be used every other day, controlled by the individual through their smartphone or tablet application.

Restorative neurostimulation is described as a novel form of stimulation for refractory chronic mechanical low back pain (CLBP), targeting impaired neuromuscular control and degeneration of the multifidus muscle. The ReActiv8® Restorative Neurostimulation System targets underlying multifidus muscle dysfunction by delivering electrical pulses through proprietary self-anchoring lead technology placed adjacent to the medial branch of the dorsal ramus.

POSITION STATEMENT:

Percutaneous electrical nerve stimulation/percutaneous neuromodulation **meets the definition of medical necessity** when **ALL** of the following are met:

- Pain relief from TENS was not obtained due to presence of physical barriers to electrical conduction (e.g., obesity, scar tissue)
- Used for a trial period of 7 days to test the effectiveness of electrical stimulation (by PENS/PNS) to relieve pain*
- Used for one of the following:
    - Pain related to musculoskeletal conditions
    - Pain associated with active injury
    - Pain associated with post-trauma injury

***NOTE:** This diagnostic procedure involves stimulation of peripheral nerves by a needle electrode inserted through the skin. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

Percutaneous peripheral implantable nerve stimulators, including but not limited to the Freedom Peripheral Nerve Stimulator (previously the StimQ PNS), Nalu Peripheral Neurostimulation System, Neuspera Nuity Neurostimulation System (NNS), the StimRouter Neuromodulation System, and the Sprint PNS System are considered **experimental or investigational**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

Remote Electrical Neuromodulation (REN) (e.g., Nerivio®)

Acute treatment

Remote electrical neuromodulation for acute migraine is considered **experimental or investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Preventive treatment: Initiation of Use

Remote electrical neuromodulation (REN [e.g. Nerivio]) for the prevention of migraine **meets the definition of medical necessity** in individuals when the following criteria are met:

- Individual is 18 years of age or older; **AND**
- Headaches meet the International Classification of Headache Disorders (ICHD-3) diagnostic criteria for migraine with or without aura; **AND**
- The REN device will be used in the following clinical scenario:
    - For the prevention of migraine in individuals with 6 to 24 headache days (defined as a calendar day with headache regardless of severity or duration) per 28-day period in each of

the 3 months
preceding use of the REN device); **AND**

- 1 of the following additional criteria must also be met:
  - Insufficient response, contraindication, or intolerance to 2 or more guideline-recommended preventive headache medications (e.g., anticonvulsants, antihypertensives, antidepressants, CGRP inhibitors); **OR**
  - Pregnancy, breastfeeding, or planning to conceive; **OR**
  - At risk for or have a history of medication overuse headache; **OR**
  - At risk for drug-drug interactions with medications for comorbid conditions.

Preventive treatment: Continuation of Use

Continued use of the REN device and/or accessories for the prevention of migraine is **meets the definition of medical necessity** in individuals when the following criteria are met:

- Compliance with ongoing use; **AND**
- Documentation of clinical benefit*.

Remote Electrical Neuromodulation (REN) (e.g., Nerivio®)- Children and Adolescents

Remote electrical neuromodulation for the prevention of migraine meets the definition of medical necessity in individuals when the following criteria are met:

- Individual is 8-17 years of age; **AND**
- Headaches meet the International Classification of Headache Disorders (ICHD-3) diagnostic criteria for migraine with or without aura; **AND**
- The REN device will be used in the following clinical scenario:
  - For the prevention of migraine in individuals with 6 to 24 headache days (defined as a calendar day with headache regardless of severity or duration) per 28-day period in each of the 3 months preceding use of the REN device).

Remote electrical neuromodulation for prevention of migraine outside of the above criteria is considered **experimental or Investigational**. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Note: Nerivio is contraindicated in patients with uncontrolled epilepsy and patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device. Nerivio has not been evaluated in patients with congestive heart failure, severe cardiac or cerebrovascular disease, pregnancy, or patients under the age of 8 years.

*Documentation of clinical benefit for continuation of use may include a clinician attestation regarding any of the following outcomes:

- Improvements in pain relief or freedom, particularly for acute use;
- Reduction in headache frequency, duration, or severity;
- Reduction in functional disability;
- Reduction in absenteeism;

- Reduction in concomitant headache medications.

Based on observed outcomes of pivotal studies of Nerivio and study duration recommendations from the International Headache Society concerning migraine neuromodulation trial designs, assessment for clinical benefit is reasonable after a minimum of 8-12 weeks for preventive treatment.

Restorative neurostimulation (e.g., ReActiv8® Restorative Neurostimulation System) is considered **experimental or investigational**. There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and eficiacy.

Percutaneous electrical nerve field stimulation (PENFS) with IB-STIM® **meets the definition of medical necessity** in children and adolescents when **ALL** of the following are met:

- Age 8-21
- Diagnosed with a ROME IV criteria* defined-functional gastrointestinal disorder (functional abdominal pain, functional abdominal pain syndrome, irritable bowel syndrome, functional dyspepsia, or abdominal migraine) with symptoms present for at least 3 months
- Organic gastrointestinal disease (e.g., neoplasm, infection, etc.) has been ruled out
- Failed treatment with diet modification and probiotics
- Failed at least 3 months of treatment with acid suppressors**, antispasmodics***, and neuromodulators****
- Device will be used up to 120 hours per week, up to 3 consecutive weeks, not to exceed 4 weeks
- Will be applied to healthy, intact skin
- None of the following contraindications are present:
    - Cardiac pacemakers
    - Hemophilia
    - Psoriasis vulgaris

****Acid suppression** (includes H2-blockers and PPIs)

*****Antispasmodics** (includes hyoscyamine, dicyclomine erythromycin/linaclotide, prucalopride)

******Neuromodulators** (includes amitriptyline/nortriptyline/gabapentin)

Percutaneous electrical nerve field stimulation (PENFS) for all other indications is considered **experimental or investigational**. There is insufficient published clinical evidence to support safety and effectiveness.

***ROME Foundation**

ROME IV Diagnostic Criteria Disorders of Gut-Brain Interaction (DGBI)

H. CHILDHOOD FUNCTIONAL GI DISORDERS: CHILD/ADOLESCENT

H2. FUNCTIONAL ABDOMINAL PAIN DISORDER

H2a. Functional Dyspepsia

Diagnostic criteria:

Must include one or more of the following bothersome symptoms at least 4 times a month for at least 2 months prior to diagnosis:

1. Postprandial fullness
2. Early satiation
3. Epigastric pain or burning not associated with defecation
4. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

Functional dyspepsia subtypes:

H2a1. Postprandial distress syndrome includes bothersome postprandial fullness or early satiation which prevents finishing a regular meal. Supportive features include upper abdominal bloating, postprandial nausea, or excessive belching.

H2a2. Epigastric pain syndrome which includes all of the following: bothersome (severe enough to interfere with normal activities) pain or burning localized to the epigastrium. The pain is not generalized or localized to other abdominal or chest regions and is not relieved by defecation or passage of flatus. Supportive criteria can include (a) burning quality of the pain but without a retrosternal component, and (b) commonly induced or relieved by ingestion of a meal but may occur while fasting.

H2b. Irritable Bowel Syndrome

Diagnostic criteria:

Must include abdominal pain at least 4 days per month over at least 2 months associated with one or more of the following:

1. Related to defecation
2. A change in frequency of stool
3. A change in form (appearance) of stool
4. In children with abdominal pain and constipation, the pain does not resolve with resolution of the constipation (children in whom the pain resolves have functional constipation, not IBS)
5. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition
6. *Criteria fulfilled for at least 2 months prior to diagnosis

H2c. Abdominal Migraine

Diagnostic criteria:

Must include all of the following occurring at least twice:

1. Paroxysmal episodes of intense, acute periumbilical, midline or diffuse abdominal pain lasting 1 hour or more (should be the most severe and distressing symptom)
2. Episodes are separated by weeks to months
3. The pain is incapacitating and interferes with normal activities
4. Stereotypical pattern and symptoms in the individual patient
5. The pain is associated with two or more of the following:

- Anorexia
- Nausea
- Vomiting
- Headache
- Photophobia
- Pallor

6. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition
7. *Criteria fulfilled for at least 6 months prior to diagnosis

H2d. Functional Abdominal Pain – Not Otherwise Specified

Diagnostic criteria:

Must be fulfilled at least 4 times per month and include all of the following:

1. Episodic or continuous abdominal pain that does not occur solely during physiologic events (e.g., eating, menses)
2. Insufficient criteria for irritable bowel syndrome, functional dyspepsia, or abdominal migraine
3. After appropriate evaluation, the abdominal pain cannot be fully explained by another medical condition
4. *Criteria fulfilled for at least 2 months prior to diagnosis

BILLING/CODING INFORMATION:

CPT Coding

64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
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

HCPCS Coding

A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm
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) **(investigational)**
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month (**investigational**)

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, treatment plan, radiology report(s) and diagnostic studies.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology report	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Diagnostic studies (non-lab)	27899-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2); Electrical Nerve Stimulators (160.7); and Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Transcutaneous Electric Nerve Stimulation (TENS), 02-61000-04

OTHER:

None applicable.

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12. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.29 - Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy, 07/25.
13. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.139 - Peripheral Subcutaneous Field Stimulation, 05/25.
14. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.171 - Remote Electrical Neuromodulation for Migraines, 11/25.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 03/26/26.

GUIDELINE UPDATE INFORMATION:

09/15/02	Medical Coverage Guideline Reformatted.
09/15/04	Scheduled review and revision to guideline; consisting of updated references and changed non-covered statement to investigational for electrical stimulation used for motor function disorders.
01/01/05	Annual HCPCS update; consisting of the revision of 64590.
01/01/07	HCPCS coding update consisting of the revision of 64590 and 64595.
07/15/07	Scheduled review, coverage and limitations maintained, Description, Billing/Coding Information, and Reimbursement Information section updated with CPT codes, guideline reformatted, and references updated.
09/15/09	Scheduled review; no change in position statement.
05/15/11	Revision; formatting changes.
09/15/11	Scheduled review; no change in position statement. Updated description section, billing/coding section and references, formatting changes.
05/11/14	Revision: Program Exceptions section updated.
01/01/18	Annual CPT/HCPCS coding update: deleted 64565 from Billing/Coding Information section. Revised Programs Exceptions section. Reformatted guideline.
10/15/19	Scheduled review. Revised description and index terms. Maintained position statement. Updated references.
11/15/19	Revision. Revised description, added coverage statement for peripherally implanted nerve stimulators. Updated references.
08/15/21	Scheduled review. Maintained position statement and updated references.
07/01/22	Quarterly CPT/HCPCS coding update. Added 0720T.
08/15/22	Unscheduled review. Updated references and added E/I coverage statement for percutaneous electrical nerve field stimulation (PENFS).
12/15/22	Revision. Updated references and maintained position statement.
04/01/23	Quarterly CPT/HCPCS coding update. Code L8678 added.
05/15/23	Scheduled review. Maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
09/15/23	Added code 64555.
01/01/24	Annual CPT/HCPCS coding update. Added 64596, 64597, 64598.
05/15/24	Scheduled review. Revised description and position statement (added coverage criteria for IB-Stim®). Updated references.
09/15/24	Revision. Revised description, maintained position statement and updated references.
11/15/24	Revision. Revised description, added coverage statement for remote electrical neuromodulation (REN) (eg, Nerivio®), added code A4540, and updated references.
12/15/24	Revision. Updated age criteria for PENFS with IB-STIM®. Updated references.

01/01/25	Annual CPT/HCPCS coding update. Added C9807.
04/15/25	Revision. Revised description. Updated references for remote electrical neuromodulation (REN) (eg, Nerivio®), peripheral nerve stimulation (PNS) with Nalu, and restorative neurostimulation with Reactiv8. Maintained position statement.
01/01/26	Scheduled review. Policy title, description, position statements, coding and references updated. Annual CPT/HCPCS coding update. Code 64567 added; 0720T deleted.
04/15/26	Revision: Remote electrical neuromodulation position statements added for children and adolescents; restorative neurostimulation and percutaneous peripheral implantable nerve stimulators position statements maintained; references updated.