02-61000-03

Original Effective Date: 09/15/02

Reviewed: 04/25/24

Revised: 05/15/24

Subject: Percutaneous Electrical Nerve Stimulation (PENS)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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).

Summary and Analysis of Evidence: Beltran-Alacreu et al (2022) evaluated the effectiveness of PENS compared to transcutaneous electrical nerve stimulation (TENS) on the reduction of musculoskeletal pain. This systematic review and meta-analysis included a total of 9 RCTs in the qualitative analysis, with 7 in the quantitative analysis. Overall, there was low-quality evidence for increased pain intensity reduction with PENS over TENS, but the difference found was not deemed to be clinically significant. When only studies with low risk of bias were meta-analyzed, there was a moderate quality of evidence that there is no difference between TENS and PENS for pain intensity. Six out of the 9 studies presented high risk for the blinding of participants, and 7 out of 9 were high risk for blinding of personnel. Beyond these 2 items, the risk of bias in the included trials was either low or unclear. Protocols and parameters for the application of PENS and TENS were heterogenous across all trials. In 2013, the National Institute for Health and Care Excellence (NICE) published guidance on PENS (Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]). It concluded that "(c)urrent evidence on the safety of [PENS] for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term." Yokoyama et al (2004) compared percutaneous electrical nerve stimulation PENS) with transcutaneous electrical nerve stimulation (TENS) for long-term pain relief in chronic low back pain. The authors concluded “(a) cumulative analgesic effect was observed in patients with chronic low back pain (LBP) after repeated percutaneous electrical nerve stimulation (PENS), but this effect gradually faded after the treatment was terminated. Results indicate that although PENS is effective for chronic LBP, treatments need to be continued to sustain analgesia.”

Restorative neurostimulation therapy with the ReActiv8 system has been evaluated in 1 multicenter, sham controlled RCT enrolling 204 individuals with chronic, refractory low back pain (ReActiv8-B, NCT02577354). Control group participants received treatment with the ReActiv8 system set to deliver low-level stimulation. The primary endpoint was the difference in proportions of responders in the treatment and control groups. Response was defined as the composite of 30% or greater reduction in VAS and no increase in pain medications, assessed at 120 days. At 120 days, there was no difference between groups on the primary endpoint of treatment response or the individual components of the primary endpoint. The controlled phase was only 120 days. In the longer-term, uncontrolled follow-up phase of the trial, there was continued improvement in VAS scores over time in those who were assessed, but the lack of a control group and high attrition limits drawing conclusions from these results. Data was available for 86.3% of participants at 1 year, 79% of participants at 2 years, and 63.7% of participants at 3 years. An uncontrolled follow-up phase of the RCT reported continued improvement in pain scores through 3 years but results are at high risk of bias due to lack of a control group and high attrition. In September 2022, NICE published guidance on neurostimulation of lumbar muscles (Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain [IPG739]) with the ReActiv8 system for refractory non-specific chronic low back pain. The guidance was based on a rapid review conducted in July 2021 and included the following statements: "(e)vidence on the efficacy and safety of neurostimulation of lumbar muscles for refractory non-specific chronic low back pain is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research." It also stated that "(f)urther research should include suitably powered randomized controlled trials comparing the procedure with current best

practice with appropriate duration. It should report details of patient selection and long-term outcomes."

Wong et al (2023) conducted an evidence review on the effectiveness of peripheral nerve field stimulation on chronic low back pain and persistent spinal pain syndrome. A total of 15 studies were included, including 4 randomized controlled trials (RCTs), 9 observational studies, and 2 case series. For patients receiving PNFS, a significant decrease in back pain intensity and analgesic consumption, together with a significant improvement in physical functioning, was observed upon implant of the permanent system. The authors stated "PNFS, when used alone or in combination with SCS, appears to be effective in managing back pain. However, high-quality evidence that supports the long-term analgesic efficacy and safety is still lacking. Hence, RCTs with a larger patient population and of a longer follow-up duration are warranted." In 2013, NICE issued guidance on peripheral subcutaneous field stimulation for chronic low back pain (Peripheral nerve-field stimulation for chronic low back pain [IPG451]), which stated "(c)urrent evidence on the efficacy of peripheral nerve-field stimulation for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device.

For individuals who have chronic neuropathic pain who receive peripheral subcutaneous field stimulation, the evidence includes 4 RCTs , a nonrandomized comparative study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. McRoberts et al (2013) compared different methods of peripheral subcutaneous field stimulation. Among trial participants, 24 of 30 patients had at least a 50% reduction in pain with any type of peripheral subcutaneous field stimulation. However, because the RCT did not include a sham group or comparator with a different active intervention, this trial offers little evidence for efficacy beyond that of a prospective, uncontrolled study. Another RCT (Johnson et al, 2021) compared sham to external non-invasive peripheral electrical nerve stimulation, but found no significant differences in pain scores between groups after intervention. A third small, pilot RCT (Ilfeld et al, 2021) found significantly reduced opioid consumption and mean daily pain scores within the first 7 postoperative days in subjects receiving foot, ankle, knee, or shoulder surgery. However, differences in average pain, worst pain, and Defense and Veterans Pain Rating Scale scores were not significantly different between treatment and sham groups following completion of the treatment period on postoperative days 15 and 30. A fourth small, pilot feasibility RCT (Albright-Trainer et al, 2022) compared peripheral nerve stimulation with standard medical care to standard medical care alone in veterans undergoing lower extremity amputation. Greater reductions in average phantom limb pain, residual limb pain, and daily opioid consumption were reported through 3 months with the addition of peripheral nerve stimulation. Case series are insufficient to evaluate patient outcomes due to the variable nature of pain and the subjective nature of pain outcome measures. Larger, prospective controlled trials comparing peripheral subcutaneous field stimulation with placebo or alternative treatment modalities are needed to determine the efficacy of peripheral subcutaneous field stimulation for chronic pain.

There are few pharmacologic treatment options for children and adolescents with IBS. Non-pharmacologic options are commonly explored. Percutaneous electrical nerve field stimulation (PENFS) (auricular neurostimulation) is a potential treatment option for these individuals.The evidence for PENFS with IB Stim® includes 2 randomized, double-blind, sham-controlled trials. PENFS has proven to be an effective and safe treatment for children and adolescents with functional abdominal pain disorders. PENFS with IB-Stim® showed an 81% improvement in overall symptoms, and approximately 59% of test

subjects showed at least a 30% reduction in their worst pain (Kovacic et al, 2017; Krasaelap et al, 2020). The evidence for PENFS (auricular neurostimulation) for all other indications is insufficient.

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/implanted nerve stimulators, including but not limited to the ReActiv8 Implantable Neurostimulation System, StimQ Peripheral Nerve Stimulator (PNS) system, 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.

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 11-18
- 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 9 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)
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
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

HCPCS Coding

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:

TENS (transcutaneous electric nerve stimulation): a small battery powered electronic device used for the treatment of pain. An electrode attaches to the skin near the painful area and sends a signal to the brain that competes with "pain signals" from the painful area, resulting in less perception of pain by the brain. These devices do not treat the cause of the pain, but decreases the brain's sensation of the pain.

PENS (percutaneous electric nerve stimulation): similar to TENS except that instead of electrodes attached to the skin, a needle is inserted into the site of pain.

PNT (percutaneous neuromodulation therapy): a variant of PENS in which up to 10 fine filament electrodes are temporarily placed at specific anatomical landmarks in the back.

RELATED GUIDELINES:

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

OTHER:

Indexing terms:

Percutaneous Neuromodulation Therapy™ system
Deepwave® Percutaneous Neuromodulation Pain Therapy System

REFERENCES:

1. Albright-Trainer B, Phan T, Trainer RJ, Crosby ND, Murphy DP, Disalvo P, Amendola M, Lester DD. Peripheral nerve stimulation for the management of acute and subacute post-amputation pain: a randomized, controlled feasibility trial. Pain Manag. 2022 Apr;12(3):357-369. doi: 10.2217/pmt-2021-0087. Epub 2021 Nov 11.
2. 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 Dec;168:e253-e259. doi: 10.1016/j.wneu.2022.09.104.
3. Babygirija R, Sood M, Kannampalli P, Sengupta JN, Miranda A. Percutaneous electrical nerve field stimulation modulates central pain pathways and attenuates post-inflammatory visceral and somatic hyperalgesia in rats. Neuroscience. 2017 Jul 25;356:11-21. doi: 10.1016/j.neuroscience.2017.05.012. Epub 2017 May 17.
4. 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 Aug 1;23(8):1387-1400. doi: 10.1093/pm/pnac027.
5. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.29 - Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy, 08/23.
6. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.139 - Peripheral Subcutaneous Field Stimulation, 05/23.
7. Bora G, Atkinson SN, Pan A, Sood M, Salzman N, Karrento K. Impact of auricular percutaneous electrical nerve field stimulation on gut microbiome in adolescents with irritable bowel syndrome: A pilot study. J Dig Dis. 2023 May;24(5):348-358. doi: 10.1111/1751-2980.13203. Epub 2023 Aug 9.
8. Castillo DF, Denson LA, Haslam DB, Hommel KA, Ollberding NJ, Sahay R, Santucci NR. The microbiome in adolescents with irritable bowel syndrome and changes with percutaneous electrical nerve field stimulation. Neurogastroenterol Motil. 2023 Jul;35(7):e14573. doi: 10.1111/nmo.14573. Epub 2023 Apr 24.
9. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7) (08/07/95).
10. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) (06/19/06).
11. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2) (04/01/03).
12. Chakravarthy K, Lee D, Tram J, et al. Restorative Neurostimulation: A Clinical Guide for Therapy Adoption. J Pain Res. 2022 Jun 20;15:1759-1774. doi: 10.2147/JPR.S364081.
13. Chogle A, El-Chammas K, Santucci N, Grimm M, Dorfman L, Graham K, Kelly DR, Dranove JE, Rosen R, Nurko S, Croffie J, Balakrishnan K, Chiou EH, Zhang L, Simpson P, Karrento K. A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut-brain interaction. J Pediatr Gastroenterol Nutr. 2024 Mar 7. doi: 10.1002/jpn3.12174. Epub ahead of print.
14. Chogle A, Visnagra K, Janchoi J, Tran T, Davis R, Callas N, Ornelas E. Prospective study of the effect of auricular percutaneous electrical nerve field stimulation on quality of life in children with pain related disorders of gut-brain interaction. Front Pain Res (Lausanne). 2023 Sep 8;4:1223932. doi: 10.3389/fpain.2023.1223932.
15. Chou R, Qaseem A et al. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society. Ann Intern Med. 2007;147:478-491.

16. Chow RM, Lee RY, Rajput K. Peripheral Nerve Stimulation for Pain Management: A Review. Curr Pain Headache Rep. 2023 Sep;27(9):321-327. doi: 10.1007/s11916-023-01143-0. Epub 2023 Jul 31. PMID: 37523121.
17. ClinicalTrials.gov. NCT03783689: The SNAP Trial: SPRINT® Peripheral Nerve Stimulation for the Treatment of Neuropathic Post-Amputation Pain (SNAP). SPR Therapeutics, Inc. (September 2019).
18. ClinicalTrials.gov. NCT03255200: ReActiv8 Post Market Surveillance Registry (ReActiv8-C) (MainStay Medical) (March 2023).
19. ClinicalTrials.gov. NCT04803214: ReActiv8 Stimulation Therapy vs Optimal Medical Management: A Randomized Evaluation (RESTORE) (MainStay Medical) (March 2023).
20. ClinicalTrials.gov. NCT02577354: ReActiv8 Implantable Neurostimulation System for Chronic Low Back Pain (ReActiv8-B) (MainStay Medical) (March 2023).
21. Cohen S, Gilmore C, et al. Percutaneous Peripheral Nerve Stimulation for Pain Reduction and Improvements in Functional Outcomes in Chronic Low Back Pain. Mil Med. 2019 Mar 1;184(Suppl 1):537-541. doi: 10.1093/milmed/usy310. PMID: 30901473.
22. Corriveau M, Lake W, Hanna A. Nerve Stimulation for Pain. Neurosurg Clin N Am. 2019 Apr;30(2):257-264. doi: 10.1016/j.nec.2018.12.008. PMID: 30898276.
23. 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 Jan;21(1):48-55. doi: 10.1111/ner.12741. Epub 2017 Dec 15.
24. Deer T, Pope J, et al. Prospective, Multicenter, Randomized, Double-Blinded, Partial Crossover Study to Assess the Safety and Efficacy of the Novel Neuromodulation System in the Treatment of Patients With Chronic Pain of Peripheral Nerve Origin. Neuromodulation. 2016 Jan;19(1):91-100. doi: 10.1111/ner.12381. PMID: 26799373.
25. ECRI TARGET database. Percutaneous neuromodulation therapy (PNT) for low-back pain. Target report 877. April 2005.
26. First Coast Service Options, Inc. (FCSO). Local Coverage Determination (LCD): Noncovered Services (L33777) (10/01/15) (Retired 07/01/20).
27. Gilligan C, Burnside D, Grant L, Yong RJ, Mullins PM, Schwab F, Mekhail N. 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 Apr;12(2):607-620. doi: 10.1007/s40122-023-00475-4. Epub 2023 Feb 14.
28. Gilligan C, Volschenk W, Russo M, Green M, et al. Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction. Neuromodulation. 2023 Jan;26(1):98-108. doi: 10.1016/j.neurom.2022.08.457. Epub 2022 Sep 27.
29. Gilligan C, Volschenk W, Russo M, et al; ReActiv8-B investigators. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. 2021 Oct 1;162(10):2486-2498. doi: 10.1097/j.pain.0000000000002258.
30. Gilligan C, Volschenk W, Russo M, et al; ReActiv8-B Investigators. 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. 2021 Dec 18:S1094-7159(21)06386-8. doi: 10.1016/j.neurom.2021.10.011. Epub ahead of print.
31. 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. 2022 Sep 26:S1094-7159(22)01254-5. doi: 10.1016/j.neurom.2022.08.457. Epub ahead of print.

32. Hayes, Inc. Hayes Medical Technology Directory. Electrical Stimulation of the Occipital Nerve for the Treatment of Occipital Neuralgia and Cervicogenic Headache. Lansdale, PA: Hayes, Inc., 12/13/06.

33. Hayes, Inc. Revolving Evidence Review. ReActiv8 Implantable Neuromuscular Stimulation System (Mainstay Med Ltd.) for Chronic Low Back Pain. ©2022 Hayes (May 2022).

34. He DP, Zhang J, Bai ZF. Percutaneous Electrical Nerve Stimulation for Chronic Knee Pain: A Randomized, Sham-controlled Trial. Altern Ther Health Med. 2019 Mar;25(2):30-34. PMID: 29101777.

35. Ilfeld BM, Plunkett A, Vijjeswarapu AM, Hackworth R, Dhanjal S, Turan A, Cohen SP, Eisenach JC, Griffith S, Hanling S, Sessler DI, Mascha EJ, Yang D, Boggs JW, Wongsarnpigoon A, Gelfand H; PAINfRE Investigators. Percutaneous Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study. Anesthesiology. 2021 Jul 1;135(1):95-110. doi: 10.1097/ALN.0000000000003776.

36. Johnson S, Marshall A, Hughes D, Holmes E, Henrich F, Nurmikko T, Sharma M, Frank B, Bassett P, Marshall A, Magerl W, Goebel A. Mechanistically informed non-invasive peripheral nerve stimulation for peripheral neuropathic pain: a randomised double-blind sham-controlled trial. J Transl Med. 2021 Nov 6;19(1):458. doi: 10.1186/s12967-021-03128-2. Erratum in: J Transl Med. 2023 Apr 29;21(1):289.

37. Karrento K, Venkatesan T, Zhang L, Pawela L, Simpson P, Li BUK. Percutaneous Electrical Nerve Field Stimulation for Drug-Refractory Pediatric Cyclic Vomiting Syndrome. J Pediatr Gastroenterol Nutr. 2023 Sep 1;77(3):347-353. doi: 10.1097/MPG.0000000000003876. Epub 2023 Jun 26. PMID: 37364137.

38. Kloimstein H,, Likar R, et al. Peripheral nerve field stimulation (PNFS) in chronic low back pain: a prospective multicenter study. Neuromodulation. 2014 Feb;17(2):180-7. doi: 10.1111/ner.12139. Epub 2013 Dec 9. PMID: 24320718 .

39. Kovacic K, Hainsworth K, Sood M, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. Lancet Gastroenterol Hepatol. 2017 Oct;2(10):727-737. doi: 10.1016/S2468-1253(17)30253-4. Epub 2017 Aug 18. PMID: 28826627.

40. Krasaelap A, Sood MR, Li BUK, Unteutsch R, Yan K, Nugent M, Simpson P, Kovacic K. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. Clin Gastroenterol Hepatol. 2020 Aug;18(9):1987-1994.e2. doi: 10.1016/j.cgh.2019.10.012. Epub 2019 Oct 14. PMID: 31622740.

41. McRoberts WP, Wolkowitz R, et al. Peripheral nerve field stimulation for the management of localized chronic intractable back pain: results from a randomized controlled study. Neuromodulation. 2013 Nov-Dec;16(6):565-74; discussion 574-5. doi: 10.1111/ner.12055. Epub 2013 Apr 11. PMID: 23577773.

42. Miranda A. Opinion: Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. Front Pain Res (Lausanne). 2024 Jan 11;5:1279946. doi: 10.3389/fpain.2024.1279946.

43. 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 Aug;24(6):1024-1032. doi: 10.1111/ner.13477. Epub 2021 Jul 9.

44. National Guideline Clearing House. Guideline Summary NGC-8519. Pain (chronic). Work Loss Data Institute; 2008. Last updated 2011.

45. National Institute for Health and Care Excellence (NICE). Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain [IPG739]. 2022. Accessed at https://www.nice.org.uk/.

46. National Institute for Health and Care Excellence (NICE). Percutaneous electrical nerve stimulation for refractory neuropathic pain [IPG450]. 2013. Accessed at https://www.nice.org.uk/.

47. National Institute for Health and Care Excellence (NICE). Peripheral nerve-field stimulation for chronic low back pain [IPG451]. 2013. Accessed at https://www.nice.org.uk/.

48. ReActiv8® Payer Dossier. Mainstay Medical.

49. Rome Foundation. Rome IV Diagnostic Criteria for FGIDs (2019). Accessed at https://theromefoundation.org/wp-content/uploads/Rome-Foundation-Diagnostic-Criteria-Booklet-2019.pdf.

50. Santucci NR, Beigarten AJ, Khalid F, El-Chammas KI, Graham K, Sahay R, Fei L, Rich K, Mellon M. Percutaneous Electrical Nerve Field Stimulation in Children and Adolescents With Functional Dyspepsia-Integrating a Behavioral Intervention. Neuromodulation. 2024 Feb;27(2):372-381. doi: 10.1016/j.neurom.2023.07.005. Epub 2023 Aug 16.

51. Santucci NR, King C, El-Chammas KI, et al. Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders. Neurogastroenterol Motil. 2022 Mar 16:e14358. doi: 10.1111/nmo.14358. Epub ahead of print.

52. Santucci NR, Sahay R, El-Chammas KI, Graham K, Wheatley M, Vandenbrink M, Hardy J, Fei L. Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. Front Pain Res (Lausanne). 2023 Sep 19;4:1251932. doi: 10.3389/fpain.2023.1251932.

53. 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. J Pain Res. 2022 Dec 6;15:3729-3832. doi: 10.2147/JPR.S386879. Erratum in: J Pain Res. 2022 Dec 24;15:4075-4076.

54. Shaffrey C, Gilligan C. Effect of Restorative Neurostimulation on Major Drivers of Chronic Low Back Pain Economic Impact. Neurosurgery. 2023 Apr 1;92(4):716-724. doi: 10.1227/neu.0000000000002305. Epub 2023 Feb 14. PMID: 36786565; PMCID: PMC9988326.

55. Stabingas K, Bergman J, Patterson M, Tomycz ND. Peripheral subcutaneous field stimulation for the treatment of spinal cord injury at-level pain: case report, literature review, and 5-year follow-up. Heliyon. 2020 Jul 24;6(7):e04515. doi: 10.1016/j.heliyon.2020.e04515.

56. Thomson S, Chawla R, Love-Jones S, Sharma M, Vajramani G, Williams A, Eldabe S; ReActiv8 PMCF Investigators. Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort. Pain Ther. 2021 Dec;10(2):1451-1465. doi: 10.1007/s40122-021-00307-3. Epub 2021 Sep 3.

57. UpToDate. Functional abdominal pain in children and adolescents: Management in primary care. 2024. Accessed at uptodate.com.

58. UpToDate. Overview of the clinical uses of acupuncture. 2024. Accessed at uptodate.com.

59. UpToDate. Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment. 2023. Accessed at uptodate.com.

60. U.S. Food & Drug Administration (FDA). DE NOVO CLASSIFICATION REQUEST FOR IB-STIM. SUBMISSION NUMBER: DEN180057 (October 2018).

61. Weatherall MW, Nandi D. Percutaneous electrical nerve stimulation (PENS) therapy for refractory primary headache disorders: a pilot study. Br J Neurosurg. 2019 Dec;33(6):608-612. doi: 10.1080/02688697.2019.1671951. Epub 2019 Oct 3. PMID: 31578882.

62. Wong CH, Chan TCW, Wong SSC, Russo M, Cheung CW. Efficacy of Peripheral Nerve Field Stimulation for the Management of Chronic Low Back Pain and Persistent Spinal Pain Syndrome: A Narrative Review. Neuromodulation. 2023 Apr;26(3):538-551. doi: 10.1016/j.neurom.2022.07.011. Epub 2022 Sep 1. PMID: 36058792.

63. Woodbury A, Krishnamurthy LC, Bohsali A, et al. Percutaneous electric nerve field stimulation alters cortical thickness in a pilot study of veterans with fibromyalgia. Neurobiol Pain. 2022 May 17;12:100093. doi: 10.1016/j.ynpai.2022.100093.

64. Yokoyama M, Sun X, Oku S, Taga N, Sato K, Mizobuchi S, Takahashi T, Morita K. Comparison of percutaneous electrical nerve stimulation with transcutaneous electrical nerve stimulation for long-term pain relief in patients with chronic low back pain. Anesth Analg. 2004 Jun;98(6):1552-1556. doi: 10.1213/01.ANE.0000112312.94043.DF.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 04/25/24.

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.