

Clinical Policy: Spinal Cord, Peripheral Nerve, and Percutaneous Electrical Nerve Stimulation

Reference Number: PA.CP.MP.117

Plan Effective Date: 01/2018

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[Coding Implications](#)

[Revision Log](#)

Description

Peripheral nerve stimulation (PNS) is intended to decrease chronic and acute pain by stimulating peripheral nerves with leads placed adjacent or parallel to the affected nerve.¹⁸ PNS can be used in a trial of pain relief effectiveness, or for permanent placement. In peripheral nerve field stimulation (PNFS), leads are placed in the region in which the pain is felt, stimulating smaller peripheral nerves and nerve endings.¹⁸ PNFS is useful when one nerve does not clearly service the painful area.

Percutaneous electrical nerve stimulation (PENS) uses fine needles as electrodes, which are placed in the soft tissues or muscles at dermatomal levels consistent with pain or local pathology. It is similar to transcutaneous electrical nerve stimulation but bypasses the local skin resistance and delivers electrical current closer to the affected tissues. Percutaneous electrical nerve field stimulation (PENFS) is a variation of PENS that targets an area of pain instead of targeting a specific nerve.

The dorsal column stimulator (DCS), or spinal column stimulator (SCS) is a device that allows for electrical stimulation of the dorsal aspect of the spinal cord nerves in an effort to relieve pain in patients with a variety of chronic pain disorders. In most cases, neuropathic pain responds poorly to standard pharmacological and surgical therapies and can last indefinitely with increasing severity over time. It may result in severe disability. Stimulation in this area interferes with the conduction of pain impulses through adjacent sensory pathways and may stimulate endorphins. The technique does not alter the underlying pathological process. However, in selective patients with persistent and intractable pain of nerve origin, approximately 50 percent of patients will have pain relief, thereby decreasing the need for analgesic medication and at times obviating the need for further surgical procedures.

Note: For other types of peripheral nerve stimulation, please refer to:

- PA.CP.MP.40 Gastric Electrical Stimulation
- PA.CP.MP.137 Fecal Incontinence Treatments
- PA.CP.MP.133 Posterior Tibial Nerve Stimulation for Voiding Dysfunction
- PA.CP.MP.12 Vagus Nerve Stimulation
- PA.CP.MP.203 Diaphragmatic/Phrenic Nerve Stimulation

Policy/Criteria

- I. It is the policy of PA Health and Wellness[®] (PHW) that there is insufficient evidence to support the efficacy of peripheral nerve stimulation *or* peripheral nerve field stimulation for any indication.
- II. It is the policy of PHW[®] that percutaneous electrical nerve stimulation (PENS) is **medically necessary** when meeting all the following:

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- A. Diagnosis of diabetic neuropathy or diagnosis of neuropathic pain;
- B. Failed to adequately respond to a trial of at least three conventional treatments, unless contraindicated, and any of the following:
 - 1. Anticonvulsants (e.g., pregabalin);
 - 2. Antidepressants (e.g., amitriptyline, and duloxetine);
 - 3. Opioids (e.g., morphine sulphate and tramadol);
 - 4. Other pharmacological agents (e.g., capsaicin and isosorbide dinitrate spray);
- C. Request is for up to four weeks of PENS;
- D. PENS is not being used to treat low back pain.

III. It is the policy of PHW that there is insufficient evidence to support the efficacy of percutaneous electrical nerve field stimulation (PENFS) for any indication, including irritable bowel syndrome (IBS).

IV. It is the policy of PHW that spinal cord stimulation (SCS) is **medically necessary** for the following indications:

- A. A *trial of SCS for failed back surgery syndrome* when all the following criteria are met:
 - 1. Prior lumbar surgery;
 - 2. Neuropathic pain lasting \geq six months, is refractory and interferes with activities of daily living (ADLs);
 - 3. Not a suitable candidate for or opposes additional surgery;
 - 4. Failure of \geq six months of conventional multidisciplinary medical therapy including all of the following:
 - a. Chiropractic, physical therapy or prescribed home exercise program;
 - b. NSAIDs (non-steroidal anti-inflammatory drugs) unless contraindicated or not tolerated;
 - c. Activity modification;
 - 5. Has demonstrated cognitive ability to manage stimulator;
 - 6. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem;
 - 7. No untreated, existing drug or alcohol dependency for a minimum of 60 days prior to request, as confirmed by lab testing.
- B. A *trial of SCS for complex regional pain syndrome (CRPS)* when all the following criteria are met:
 - 1. Pain is being managed by a pain management specialist with experience treating CRPS and pain/burning has persisted for $>$ six months;
 - 2. Has \geq two of the following symptoms limited to one extremity only:
 - a. Allodynia (pain sensation in response to a typically non-painful stimulus) or hyperalgesia;
 - b. Swelling/tenderness;
 - c. Cyanotic/red/pale digit/extremity;
 - d. Increased sweating;
 - e. Alteration of temperature;
 - f. Persistent loss of motion;
 - g. Trophic skin changes;

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- h. Flexion contractures;
 3. Pain is chronic, refractory, and interferes with ADLs;
 4. Failure of \geq six months of conventional multidisciplinary therapy including all of the following:
 - a. Physical therapy or occupational therapy;
 - b. Anticonvulsant or antidepressant medication;
 - c. Sympathetic block;
 5. Has demonstrated cognitive ability to manage stimulator;
 6. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem;
 7. No untreated, existing drug or alcohol dependency for a minimum of 60 days prior to request, as confirmed by lab testing.
- C. *A trial of SCS for chronic ischemic leg pain due to peripheral vascular disease* when all of the following criteria are met:
1. Chronic, ischemic leg pain due to peripheral vascular disease and one of the following:
 - a. Not a candidate for revascularization;
 - b. Revascularization has failed to relieve painful symptoms and the pain has not responded to medical management;
 2. Pain lasting \geq six months, is refractory and interferes with ADLs;
 3. Has demonstrated cognitive ability to manage stimulator;
 4. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem;
 5. No untreated, existing drug or alcohol dependency for a minimum of 60 days prior to request, as confirmed by lab testing.
- D. *A trial of SCS for the following indications* has **limited evidence** to prove effectiveness of treatment and consideration will be made on a case-by-case basis. Medical necessity will be considered in members/enrollees based on the following information:
1. Chronic, intractable pain due to one of the following:
 - a. Lumbosacral adhesive arachnoiditis secondary to multiple myelographies or lumbar surgeries that has not responded to medical management, including physical therapy (the presence of arachnoiditis is usually documented by the presence of high levels of proteins in the cerebrospinal fluid and/or by myelography or magnetic resonance imaging);
 - b. Nerve root injuries, post-surgical or post traumatic (e.g., avulsion);
 - c. Phantom limb syndrome that has not responded to medical management;
 - d. Post-herpetic neuralgia;
 - e. Plexopathy;
 - f. Polyneuropathy;
 - g. Intercostal neuralgia that did not respond to medical management and nerve blocks;
 - h. Cauda equina injury/syndrome;
 - i. Incomplete spinal cord injury;
 - j. Diabetic peripheral neuropathy;

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- k. Failed neck surgery syndrome (FNSS);
 - l. Chronic, intractable back pain and/or lumbar radiculopathy;
 2. Pain lasting \geq six months, is refractory and interferes with ADLs;
 3. Specific goals have been established between the provider and the member/enrollee that include increased function, ADLs, return to work, and/or quality of life;
 4. Failure of \geq six months of conventional multidisciplinary medical therapy, including any of the following:
 - a. Physical therapy and/or chiropractic care;
 - b. Physician-directed home exercises;
 - c. Oral medications including opioids or non-opioids;
 - d. Life-style changes, including diet, smoking cessation, and/or daily exercise;
 5. Has demonstrated cognitive ability to manage stimulator;
 6. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem;
 7. No untreated, existing drug or alcohol dependency for a minimum of 60 days prior to request, as confirmed by lab testing.
- E. *A trial of SCS for refractory chronic stable angina pectoris* has **limited evidence** to prove effectiveness of treatment and consideration will be made on a case-by-case basis. It should be reserved only for carefully selected members/enrollees, if any. Medical necessity will be considered in members/enrollees based on the following information:
1. Continued angina after percutaneous coronary intervention or coronary artery bypass graft;
 2. Not a candidate for further revascularization;
 3. Angina is NYHA (New York Heart Association) III (less than ordinary physical activity causes symptoms) or IV (symptoms present at rest);
 4. Reversible ischemia documented at least by a symptom-limited treadmill exercise test;
 5. Has had optimal pharmacotherapy for at least one month that includes the maximal tolerated dose of at least two of the following:
 - a. Long-acting nitrates;
 - b. Beta-adrenergic blockers;
 - c. Calcium channel antagonists;
 6. Pain is chronic, refractory, and interferes with ADLs;
 7. Has demonstrated cognitive ability to manage stimulator;
 8. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem;
 9. No untreated, existing drug or alcohol dependency for a minimum of 60 days prior to request, as confirmed by lab testing.
- F. *Permanent placement of a SCS* is **medically necessary** following a trial of spinal cord stimulation for an indication listed above when all of the following criteria are met:
1. Disease specific criteria for spinal cord stimulation are met;
 2. Documented trial of \geq three days;
 3. Documented pain reduction of $>$ 50% from the trial associated with functional improvement;

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4. The same brand and model of the generator device used for the trial is used for permanent placement.
- V. It is the policy of PHW that there is insufficient evidence to support the efficacy of dorsal root ganglion (DRG) stimulation.

Background

Peripheral nerve stimulation (PNS)

Evidence supporting peripheral nerve stimulation (PNS) is limited. According to a systematic review by Xu et al., there is a lack of high-quality randomized control trials to recommend PNS for most pain management indications.¹⁹ They cited wide variations in experimental design, research protocol, and heterogeneity of study population as limitations preventing a meta-analysis.¹⁹ Xu et al. stated that PNS had level I and Level II evidence supporting its efficacy for migraine/chronic headache.¹⁹ However, the large multicenter randomized clinical trial (RCT) included in the systematic review, conducted by Dodick et al. studying the effect of PNS for migraine headache, also noted adverse events among 70% of the study sample, with 48% of the patients with adverse events requiring hospitalization or further surgical intervention to treat the complication.²⁰ An additional systematic literature review noted moderate to strong evidence for peripheral nerves stimulation, but surveyed the literature as a whole for an array of pain indications, noting that further research could help “further refine appropriate populations and pain diagnoses.”²⁶ Hayes notes that there is insufficient evidence to evaluate the efficacy of peripheral nerve stimulation for back pain, or chronic neck pain.¹⁸

Peripheral nerve field stimulation (PNFS)

Hayes notes two available RCTs addressing PNFS for chronic low back pain, stating they were of low quality due to inability to blind patients and/or researchers, low sample sizes, and short follow-up periods.²⁷ An additional RCT evaluated subcutaneous PNFS combined with spinal cord stimulation (SCS) for refractory low back pain, concluding that PNFS significantly decreased pain compared to SCS alone.²⁸ Study limitations included industry ties amongst investigators and small sample sizes.²⁸ There were too few high-quality studies to support the safety or efficacy of PNFS for other indications.

Percutaneous electrical nerve stimulation (PENS)

The American Academy of Neurology’s 2011 guideline on treatment of painful diabetic neuropathy gives a B-grade recommendation for PENS as a treatment modality. They note one class I trial comparing PENS to sham treatment, yielding a 42% reduction in pain according to the visual analog scale.²² The National Institute for Clinical Health and Care Excellence (NICE) also recommends PENS for refractory neuropathic pain, noting evidence of short-term efficacy and no significant safety concerns. NICE guidelines cite evidence from two RCTs with 64 and 50 patients, respectively, demonstrating significant reduction in pain and favorable safety profiles.²⁵

Percutaneous electrical nerve field stimulation (PENFS)

PENFS is a variation of PENS that targets a general area of pain as opposed to a specific nerve. PENFS is emerging as a promising noninvasive auricular neurostimulation therapy to treat disorders of gut-brain interaction (DGBI) with study populations including children and

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adolescents.^{31,34,35} Although study findings are promising, additional studies are needed before PENFS can be routinely recommended for children and adolescents with functional abdominal pain (FAP).³⁵

The IB-Stim (NeurAxis Inc.) is a PENFS designed to relieve functional abdominal pain and is cleared by the U.S. Food and Drug Administration (FDA) for the treatment of abdominal pain in adolescents with irritable bowel syndrome (IBS). According to a Hayes review, clinical studies suggest no or unclear support for the use of IB-Stim in the treatment of IBS in adolescents, and there are no professional guidelines that currently offer recommendations for PENFS in this population. In the Hayes review, only one fair quality trial was identified, and IB-Stim was not compared to other active treatments and did not report clear benefits in patient outcomes compared to sham past three to four weeks of study follow up.³¹

Spinal cord stimulation (SCS)

SCS is currently used to treat a wide variety of inoperable and intractable chronic pain syndromes, including failed back surgery syndrome and complex regional pain syndrome (CRPS). In patients with failed conservative and surgical treatment of lower-limb ischemia, SCS increases skin blood flow, decreases pain, and improves quality of life. Four studies used inferential statistics and found pain reduction to be significant. At least 50% pain reduction at follow-up was found in 78%, 80%, and 85% of patients in the three studies that reported this data. Follow-up ranged from six to 35 months.

According to recent systematic reviews, the most favorable results have been observed in patients with peripheral vascular disease, complex regional pain syndrome, and peripheral neuropathy (e.g., diabetic or causalgic origin). Of interest, the pain relief achieved with SCS in patients with complex regional pain syndrome is possible without vasodilation. The vasodilation found with SCS is attributed to an inhibitory effect on sympathetically maintained vasoconstriction. Diabetic patients with peripheral arterial occlusive disease who present with intractable pain have also been successfully treated with SCS, except those who have severe autonomic neuropathy. Recently, SCS has been successfully used to treat intractable angina pectoris and chronic mesenteric ischemia.

Spinal cord stimulation is proposed as a late or last resort treatment for chronic pain due to stable angina pectoris. Although most of the research reviewed used subjective outcome measures and some studies lacked prospective design, adequate sample size, and control groups, SCS was shown to alleviate pain and reduce myocardial ischemia in many of the study patients for whom pain relief was previously unobtainable. SCS has also been shown to reduce service utilization in aggregate among recipients. Side effects, while not infrequent, are rarely serious and can usually be resolved by the realignment or replacement of the device. Evidence indicates that the analgesic effect of SCS in angina does not mask the warning pain of myocardial infarction. Patients who have been treated with SCS have not been shown to be at increased risk for morbidity or mortality compared with their peers. Although a minority of patients receiving a trial of SCS ultimately experience prolonged pain relief, the significance of the alleviation of pain and suffering among those who do cannot be underestimated. Therefore, spinal cord stimulation for chronic stable angina pectoris secondary to demonstrable myocardial ischemia in patients who are refractory to treatment should be considered.

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Slangen et al., performed a multicenter randomized clinical trial in 36 painful diabetic peripheral neuropathy (PDPN) patients with severe lower limb pain not responding to conventional therapy.¹³ The authors concluded treatment success was shown in 59% of patients with PDPN who were treated with SCS over a six month period, although this treatment is not without risks. Two-year outcomes of the same study reported clinically significant improvements in pain and sleep in 53% of patients. Additionally, a randomized controlled trial of 60 patients, conducted by de Vos and colleagues, found that pain due to PDPN was significantly reduced from baseline at 6 months, and quality of life was improved.

Dorsal Root Ganglion (DRG) Stimulation

Hayes notes that currently there is insufficient evidence to determine the effectiveness and safety of DRG stimulation for adults with CRPS. According to Hayes, there is limited evidence suggesting that DRG stimulation for CRPS may result in successful outcomes for pain, quality of life, and mood, but conclusions could not be made due to the limited quantity of evidence, individual study limitations such as small sample sizes, and limited follow up. Additional high quality comparative studies are recommended to evaluate the benefits and risks of DRG stimulation for CRPS.⁸

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT Codes That Do Not Support Coverage Criteria

CPT® Codes	Description
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

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CPT Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Incision and subcutaneous placement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585	Revision or removal of peripheral neurostimulator electrode array
64590*	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595*	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
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
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
64999	Unlisted procedure, nervous system
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
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 (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	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 complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse

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	generator/transmitter programming by physician or other qualified health care professional
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CPT Codes That Support Coverage Criteria

*For gastric electrical stimulation, refer to PA.CP.MP.40 Gastric Electrical Stimulation

HCPCS Codes That Support Coverage Criteria

HCPCS Codes	Description
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Reviews, Revisions, and Approvals	Review Date	Approval Date
References reviewed and updated.	06/18	
Added Failed Neck Surgery Syndrome to indications under limited evidence criteria (I.D.1.K). Reviewed by specialist.	11/18	
References reviewed and updated. Codes updated	10/19	11/18/2019
Codes & references reviewed and updated, annual review completed. Reviewed by specialist.	2/18/2021	
Annual review completed. References and codes reviewed. Changed “members” to “members/enrollees” throughout policy. Split CPT category G57.80-G57.93 into 2 separate code ranges along with applicable descriptions. Revised I.A.6&7, B.6&7, C.4&5, D.5&6, and E.8&9, to strengthen criteria for psychological evaluation and drug abuse. Changed policy title to include peripheral nerve and percutaneous electrical nerve stimulation. Added note referring to other policies with criteria for specific types of peripheral nerve stimulation. Added policy statement, background, and references regarding peripheral nerve	6/29/2022	

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Reviews, Revisions, and Approvals	Review Date	Approval Date
<p>stimulation and peripheral nerve field stimulation in I. Added criteria, background, and references regarding percutaneous electrical nerve stimulation (PENS). Updated procedure codes. Added “chronic back pain” to criteria I.D.1. Changed “Review Date” in header to “Revision Date” and “Date” in the revision log header to “Revision Date.” References reviewed and updated. Reviewed by specialist. <i>Note: All requests for the following indications requires a Medical Director review on a case-by-case basis.</i> Added to D & E.</p>		
<p>Annual review. Criteria II.A. updated verbiage to include “diagnosis of” neuropathic pain. Added Criteria II.D. regarding PENS not being used to treat low back pain. Updated Criteria III.A.3. to state, “Not a suitable candidate for or opposes additional surgery.” Criteria III.D.1.j. added “peripheral.” Criteria III.D.1.l. updated to say “Chronic, intractable back pain and/or lumbar radiculopathy.” Added Criteria III.D.3. Criteria III.D.4. updated to include examples of conservative therapy. Criteria III.F.4. updated to include “...same brand and model...” Added criteria IV. Regarding insufficient evidence to support dorsal root ganglion (DRG) stimulation. Background updated to include information regarding DRG stimulation for complex regional pain syndrome. Removed ICD-10 codes. References reviewed and updated. Reviewed by internal specialists.</p>	09/2023	
<p>Annual review. Criteria II.A. updated verbiage to include “diagnosis of” neuropathic pain. Added Criteria II.D. regarding PENS not being used to treat low back pain. Updated Criteria III.A.3. to state, “Not a suitable candidate for or opposes additional surgery.” Criteria III.D.1.j. added “peripheral.” Criteria III.D.1.l. updated to say “Chronic, intractable back pain and/or lumbar radiculopathy.” Added Criteria III.D.3. Criteria III.D.4. updated to include examples of conservative therapy. Criteria III.F.4. updated to include “...same brand and model...” Added criteria IV. Regarding insufficient evidence to support dorsal root ganglion (DRG) stimulation. Background updated to include information regarding DRG stimulation for complex regional pain syndrome. Removed ICD-10 codes. Updated description and background with no clinical significance. Coding reviewed. References reviewed and updated. Reviewed by internal specialists.</p>	01/2024	03/20/2024
<p>Annual review. Updated description with no clinical significance or impact on criteria. Background updated with information to support updated criteria regarding PENFS. Added Criteria III. stating that there is insufficient evidence to support the efficacy of PENFS for any indication, including irritable bowel syndrome (IBS). Added CPT</p>	06/2024	07/2024

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Reviews, Revisions, and Approvals	Review Date	Approval Date
code 0720T as not covered. Coding reviewed. References reviewed and updated.		
Annual review. Coding reviewed and descriptions updated as needed. Added codes 64596, 64597, 64598, and L8678. References reviewed and updated.	12/2024	

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CLINICAL POLICY

Spinal Cord, Peripheral Nerve, and Percutaneous Electrical Nerve Stimulation

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