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

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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 uses fine needles as electrodes, which are placed in the soft tissues or muscles at dermatomal levels consistent with pain or pathology 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.

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
NOTE: It is the policy of Pennsylvania Health and Wellness® that there is insufficient evidence to support the efficacy of peripheral nerve stimulation (PNS) *or* peripheral nerve field stimulation (PNFS), for any indication. PNS, PNFS and PENS are not equivalent technologies. There is limited evidence for efficacy and high level of adverse events reported for PNS and PNFS. (See Background section of this policy for more detailed discussion).

Note: *All requests for the following indications requires a Medical Director review on a case-by-case basis.*

Requests for PNS and PNFS.

I. It is the policy of Pennsylvania Health and Wellness® that percutaneous electrical nerve stimulation (PENS) is **medically necessary** when meeting all the following:
- A. Diagnosis of diabetic neuropathy or 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.

II. It is the policy of Pennsylvania Health and Wellness® 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 ≥ 6 months, is refractory and interferes with activities of daily living (ADLs);
  3. Patient is not a candidate for additional surgery;
  4. Patient has failed ≥ 6 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. Patient 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 > 6 months;
  2. The patient has ≥ 2 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;
     h. Flexion contractures;

3. Pain is chronic, refractory, and interferes with ADLs;
4. Patient has had ≥ 6 months of failed conventional multidisciplinary therapy including all of the following:
   a. Physical therapy or occupational therapy;
   b. Anticonvulsant or antidepressant medication;
   c. Sympathetic block;
5. Patient has demonstrated cognitive ability to manage stimulator;
6. Patient has no inadequately treated major psychiatric disorders;
7. Patient is willing to cease any inappropriate drug use prior to implantation.
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.

C. *A trial of SCS* for *chronic ischemic leg pain due to peripheral vascular disease* when all of the following criteria are met:
   1. Patient has chronic, ischemic leg pain due to peripheral vascular disease and one of the following:
      a. The patient cannot undergo revascularization;
      b. Revascularization has failed to relieve painful symptoms and the pain has not responded to medical management;
   2. Pain lasting ≥ 6 months, is refractory and interferes with ADLs;
   3. Patient 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.

Note: *All requests for the following indications requires a Medical Director review on a case-by-case basis.*

Medical necessity will be considered in patients based on the following information:

1. Patient has 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 cerebro spinal 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 neuropathy;
k. Failed neck surgery syndrome (FNSS);
l. Chronic back pain;

2. Pain lasting ≥ 6 months, is refractory and interferes with ADLs;
3. Patient has failed ≥ 6 months of conventional multidisciplinary medical therapy;
4. Patient has demonstrated cognitive ability to manage stimulator;
5. Psychological evaluation and clearance by a qualified mental health professional reveals no evidence of an inadequately controlled mental health problem;
6. 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 patients, if any.

Note: *All requests for the following indications requires a Medical Director review on a case-by-case basis.*

Medical necessity will be considered in patients based on the following information:

1. Patient has continued angina after percutaneous coronary intervention or coronary artery bypass graft;
2. Patient is not a candidate for further revascularization;
3. Patient's 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. Patient has had optimal pharmacotherapy for at least one month that includes the maximal tolerated dose of at least 2 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. Patient 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 ≥ 3 days;
3. Documented pain reduction of > 50% from the trial associated with functional improvement;
4. The same device used for the trial is used for permanent placement.

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]

Spinal cord stimulation

Spinal cord stimulation (SCS) is currently used to treat a wide variety of inoperable and intractable chronic pain syndromes, including failed back surgery syndrome and 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 6 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.

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 6-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.

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 2021, 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	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
64999	Unlisted procedure, nervous system
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
95970	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 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 (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 simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
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

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

HCPCS Codes	Description
L8679	Implantable neurostimulator, pulse generator, any type

HCPCS Codes	Description
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

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
B02.29	Other postherpetic nervous system involvement
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly) neuropathy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly) neuropathy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
G03.1	Chronic meningitis
G09	Sequelae of inflammatory diseases of central nervous system
G54.0-G54.9	Nerve root and plexus disorders
G56.40-G56.42	Causalgia of upper limb
G56.80-G56.82	Other specified mononeuropathies of upper limb
G56.90-G56.93	Unspecified mononeuropathies of upper limb
G57.70-G57.73	Causalgia of lower limb
G57.80-G57.93	Other specified mononeuropathies of lower limb
G90.50-G90.59	Complex regional pain syndrome I (CRPSI)
I20.1	Angina pectoris with documented spasm
I70.221-I70.229	Atherosclerosis of native arteries of extremities with rest pain
I73.9	Peripheral vascular disease, unspecified
M54.10	Radiculopathy, site unspecified
M54.12	Radiculopathy, cervical region

ICD-10-CM Code	Description
M54.13	Radiculopathy, cervicothoracic region
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region
M54.30-M54.32	Sciatica
M79.2	Neuralgia and neuritis, unspecified
M96.1	Postlaminectomy syndrome, not elsewhere classified
R20.3	Hyperesthesia
S34.3XX*	Injury of cauda equine
S14.2XX*	Injury of nerve root of cervical spine
S24.2XX*	Injury of nerve root of thoracic spine
S34.21X*	Injury of nerve root of lumbar spine
S34.22X*	Injury of nerve root of sacral spine
T87.9	Unspecified complications of amputation stump

*Add 7th digit A-S

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 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.l. 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. ***Note:*** *All requests for the following indications requires a Medical Director review on a case-by-case basis.* Added to D & E.	6/29/2022	

Reviews, Revisions, and Approvals	Review Date	Approval Date

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