BENEFIT COVERAGE POLICY

Title: BCP-73 Spinal Cord (Dorsal Column) Stimulation for Pain Management

Effective Date: 10/01/2019

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Health Plan considers spinal cord stimulators/dorsal column stimulators (SCS/DCS) medically necessary for the management of members with chronic pain and who meet the criteria listed below in the Clinical Determination Guidelines.

Services for spinal cord/dorsal column stimulators require authorization/approval prior to the health service being provided.

For all non-network covered services to be paid at the network benefit level except for emergency/urgent services, prior approval is required.

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions. Pain Management services received from Non-Network providers may not be covered.

2.0 Background:

Dorsal column stimulators (DCS), also known as spinal cord stimulators or neuromodulation, are most commonly used for the management of failed back surgery syndrome. The use of DCS for controlling chronic low back pain (LBP) is a non-destructive, reversible procedure, thus, it is an attractive alternative for patients who may be facing or have already experienced neuroablative procedures or opioid medications.

Dorsal column stimulation is a therapy for chronic pain with organic origins and has not been shown to benefit problems which are largely behavioral or psychiatric. There is evidence that outcomes of DCS are improved if candidates are subject to psychological clearance to exclude from surgery persons with serious mental disabilities, psychiatric disturbances, or poor personality factors that are associated with poor outcomes.

National Institute for Health and Clinical Excellence's guideline on spinal cord stimulation for chronic neuropathic or ischemic pain (2008) recommended DCS for patients who continue to experience chronic neuropathic pain (e.g., failed back surgery syndrome after lumbar spine surgery and complex

regional pain syndrome) for at least six months despite trying conventional approaches to pain management. Patients should have had a successful trial of the therapy before a spinal cord stimulator is implanted.

Dorsal column stimulators have also been shown to be effective in the treatment of patients with angina pectoris patients who fail to respond to standard pharmacotherapies and are not candidates for surgical interventions. Patients should undergo a screening trial of percutaneous DCS of three to seven days. If they achieve significant pain reduction (more than 50%), the system is then implanted permanently. For this procedure, epidural electrodes are generally placed at an upper thoracic or lower cervical spinal level. Although the exact mode of action of DCS in alleviating anginal pain is unclear, it has been suggested that its beneficial effects are achieved through an increase in oxygen supply to the myocardium in addition to its analgesic effect.

3.0 Clinical Determination Guidelines:

A. This procedure initially involves a short-term trial (e.g., three to seven days) of percutaneous, temporary spinal cord stimulation, prior to the subcutaneous, permanent implantation of the spinal cord stimulation device, to determine if the spinal cord stimulator device provides sufficient pain relief to deem it medically necessary.

B. Spinal cord/dorsal column stimulators (SCS/DCS) are covered when used for FDA approved indications as follows:

   1. Non-malignant pain – covered for management of chronic, intractable, non-malignant pain when the following criteria are met:

      a. Failed back surgery syndrome (FBSS) with low back pain and significant radicular pain; OR

      b. Complex regional pain syndrome (CRPS, also known as reflex sympathetic dystrophy); OR

      c. Last resort treatment for moderate to severe (5 or more on a 10-point VAS scale) chronic neuropathic pain of certain origins:

         i. Diabetic neuropathy, or

         ii. Lumbosacral arachnoiditis or radiculopathies, or

         iii. Phantom limb/stump pain, or

         iv. Peripheral neuropathy, or

         v. Inoperable chronic ischemic limb pain due to peripheral vascular disease, or

         vi. Post-herpetic neuralgia, or

         vii. Intercostal neuralgia, or

         viii. Cuada equina injury, or

         ix. Incomplete spinal cord injury.

   2. Angina – covered for the management of intractable angina in patients who are not surgical candidates and whose pain is unresponsive to all standard therapies when the following criteria are met:

      a. Patient has angiographically documented significant coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting (CABG) or percutaneous transluminal coronary angioplasty (PTCA), OR

      b. Patient's angina pectoris is New York Heart Association (NYHA) Functional Class III (patients are comfortable at rest; less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain) or Class IV (symptoms of cardiac insufficiency or angina are present at rest; symptoms are increased with physical activity), OR

c. Patient has had optimal pharmacotherapy for at least one month. Optimal pharmacotherapy includes the maximal tolerated dosages of at least two of the following anti-anginal medications: long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists; OR

d. Criteria for exclusion from coverage of DCS in treating intractable angina pectoris include any of the following:

i. Myocardial infarction or unstable angina in the previous three months, or

ii. Significant valve abnormalities as demonstrated by echocardiography, or

iii. Somatic disorders of the spine leading to insurmountable technical problems in treatment with DCS.

3. Member must meet ALL the following criteria:

a. Other more conservative methods of pain management have been tried and failed (e.g., non-steroidal, anti-inflammatory drugs, tricyclic antidepressants, local or regional nerve blocks, physical therapy, behavioral therapy); AND

b. Patient is not a candidate for further surgical intervention; AND

c. Member has been carefully screened, evaluated and diagnosed by a multidisciplinary pain management team, which includes an evaluation by a mental health provider (e.g., face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a spinal cord stimulator or contraindicate its placement; AND

d. Member can operate the stimulating control device; AND

e. For permanent SCS/DCS device implantation, significant (≥50%) reduction in pain has been demonstrated during the short-term trial use of a percutaneous spinal stimulation. (A trial of spinal cord stimulation requires prior authorization/approval.)

4. Standard supplies for either the trial or implantation of a spinal cord stimulator include:

a. 16 electrodes and 2 percutaneous leads or 1 paddle lead as medically necessary. Spinal cord stimulation using more than this has not been proven more effective than standard spinal cord stimulation.

b. Battery life for spinal cord stimulators can vary depending on the power settings. Most non-rechargeable implanted batteries can last five to seven years while rechargeable batteries can last up to ten years.

5. The replacement of a malfunctioning SCS/DCS and/or battery/generator is considered medically necessary for an individual who meets ALL the above criteria and the existing stimulator and/or battery/generator replacement are/is no longer under warranty.

6. Replacement of a functioning SCS/DCS with a high frequency spinal cord stimulator is considered not medically necessary.

C. Spinal cord stimulation is not a covered benefit for the following as considered experimental, investigational, or unproven:

1. Pain and spasticity related to spinal cord injuries.

2. Radiation-induced brain injury or stroke.

3. Cervicalgia and other syndromes affecting cervical neck region.

4. Migraine headaches.

5. Chronic abdominal pain, pelvic pain, inguinal pain, visceral pain.

6. Rectal pain.

7. Gait disorders including spino-cerebellar ataxia and ataxia due to cerebrovascular disease.
8. Pain secondary to malignancy.
9. Patient fails multidisciplinary screening as detailed above.
10. 3D neural targeting spinal cord stimulation (no specific CPT code).

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO L0001269 Non-Union; 5 = ASO group L0001631; 6 = ASO group L0002011; ASO group L0001269 Union.

COVERED CODES			
Code	**Description**	**Prior Approval**	**COC Reference**
63650	Percutaneous implantation of neurostimulator electrode array, epidural	Y	Benefits and Coverage; Pain Management
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural	Y	Benefits and Coverage; Pain Management
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	N	Benefits and Coverage; Pain Management
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	N	Benefits and Coverage; Pain Management
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	N	Benefits and Coverage; Pain Management
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed	N	Benefits and Coverage; Pain Management
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling	Y	Benefits and Coverage; Pain Management
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver	N	Benefits and Coverage; Pain Management
64999	Unlisted procedure, nervous system	Y	Benefits and Coverage; Professional Fees for Surgical and Medical Services; unless determined to be Experimental/Investigational or Unproven
95970	Electronic analysis of implanted neurostimulator pulse generator system…simple or complex brain, spinal cord, or peripheral… neurostimulator pulse generator/transmitter, w/o programming	N	Benefits and Coverage; Pain Management
95971	… simple spinal cord, or peripheral neurostimulator pulse genera/transmitter,	N	Benefits and Coverage; Pain Management

COVERED CODES			
Code	**Description**	**Prior Approval**	**COC Reference**
	with intraoperative or subsequent programming		
95972	… complex spinal cord, or peripheral neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	N	Benefits and Coverage; Pain Management
A4290	Sacral nerve stimulation test lead, each	Y	Benefits and Coverage; Durable Medical Equipment (DME)
C1767	Generator, neurostimulator (implantable), non-rechargeable	Y	Benefits and Coverage; Prosthetic Devices
C1778	Lead, neurostimulator (implantable)	Y	Benefits and Coverage;, Durable Medical Equipment (DME)
C1787	Patient programmer, neurostimulator	Y	Benefits and Coverage; Durable Medical Equipment (DME)
C1816	Receiver and/or transmitter, neurostimulator (implantable)	Y	Benefits and Coverage; Prosthetic Devices
C1820	Generator, neurostimulator [implantable], with rechargeable battery and charging system	Y	Benefits and Coverage; Prosthetic Devices
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	Y	Benefits and Coverage; Prosthetic Devices
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	Y	Benefits and Coverage; Durable Medical Equipment (DME)
C1897	Lead, neurostimulator test kit (implantable)	Y	Benefits and Coverage; Durable Medical Equipment (DME)
L8679	Implantable neurostimulator; pulse generator, any type	Y	Benefits and Coverage; Prosthetic Devices
L8680	Implantable neurostimulator electrode, each	Y	Benefits and Coverage; Prosthetic Devices
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	Y	Benefits and Coverage; Durable Medical Equipment (DME)
L8682	Implantable neurostimulator radiofrequency receiver	Y	Benefits and Coverage; Durable Medical Equipment (DME)
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	Y	Benefits and Coverage; Durable Medical Equipment (DME)
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement	Y	Benefits and Coverage; Durable Medical Equipment (DME)
L8685	Implantable neurostimulator pulse generator, single array, rechargeable,	Y	Benefits and Coverage; Prosthetic Devices

COVERED CODES			
Code	**Description**	**Prior Approval**	**COC Reference**
	includes extension		
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension	Y	Benefits and Coverage; Prosthetic Devices
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	Y	Benefits and Coverage; Prosthetic Devices
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension	Y	Benefits and Coverage; Prosthetic Devices
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	Y	Benefits and Coverage; Durable Medical Equipment (DME)
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	Y	Benefits and Coverage; Durable Medical Equipment (DME)

ICD-10 DIAGNOSIS CODES (list is not all-inclusive)	
Code	**Description**
A52.11	Tabes dorsalis
B02.21 – B02.29	Zoster [herpes zoster] with other nervous system involvement
G03.9	Meningitis, unspecified [lumbar arachnoiditis]
G11.0 – G11.9	Hereditary ataxia
G54.6 – G54.7	Phantom limb syndrome
G90.50 – G90.59	Complex regional pain syndrome I
I20.0 – I20.9	Angina pectoris
I49.01	Ventricular fibrillation
I73.00 – I73.9	Other peripheral vascular diseases [with chronic ischemic limb pain]
M96.1	Post laminectomy syndrome, not elsewhere classified [failed back surgery syndrome]
R26.0 – R27.9	Abnormalities of gait and mobility and other lack of coordination
S22.000+ - S22.089+	Fracture of thoracic and lumbar vertebra, sacrum and coccyx [must be billed as an incomplete spinal cord injury code]
S32.000+ - S32.2xx+	Subluxation and dislocation of thoracic and lumbar vertebra, sacrum and coccyx
S23.100+ - S23.171+	Incomplete spinal cord lesion
S33.100+ - S33.39x+	Injury of cauda equina
S24.151+ - S24.159+	Tabes dorsalis
S34.121+ - S34.129+	Zoster [herpes zoster] with other nervous system involvement
S34.132+	Meningitis, unspecified [lumbar arachnoiditis]
S34.3xx+	Hereditary ataxia

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 Terms & Definitions:

Complex regional pain syndrome (CRPS) – A type of neuropathic pain which can develop spontaneously or after a stroke, spinal cord injury, surgery, or peripheral trauma. Type I is known as reflex sympathetic dystrophy (RSD) which describes cases with no nerve injury. Type II is called causalgia and refers to cases with distinct nerve injury.

Diabetic peripheral neuropathy – Nerve damage in diabetic patients that affects the toes, feet and hands.

Failed back surgery syndrome (FBSS) – Is not actually a syndrome, it is a very generalized term that is often used to describe a condition of patients who have not had a successful result with back or spine surgery and have experienced continued pain after surgery. Some types of back surgery are far more predictable in terms of alleviating a patient's symptoms than others. The best way to avoid a spine surgery that leads to an unsuccessful result is to stick to operations that have a high degree of success and to make sure that an anatomic lesion that is amenable to surgical correction is identified preoperatively

Implanted pulse generator (IPG) – A small, battery operated power source which is implanted under the skin (around the abdomen or buttocks) or worn externally. The IPG contains the battery and electronics to generate the electrical signals for the stimulation. It is programmed by the clinician using a computer, but on a day-to-day basis the stimulation can be switched "on" and "off" by the patient using a hand-held programmer

Intractable pain – Chronic, non-malignant pain in which the cause cannot be removed or otherwise treated, and no relief or cure has been found after reasonable efforts.

Laminectomy – Surgical procedure to remove a portion of the lamina of the vertebral body.

Neuropathic pain – A complex and chronic pain state that is neurologic in origin. The nerve fibers themselves are damaged, injured or dysfunctional. Neuropathic pain often seems to have no obvious cause, but some common causes can include: diabetic neuropathy, shingles, phantom limb pain, trigeminal neuralgia, spinal surgery, also known as failed back surgery syndrome (FBSS), alcoholism and chemotherapy. Neuropathic pain responds poorly to standard pain therapies, can last indefinitely and even increase over time, and often results in severe disability. See also Complex Regional Pain Syndrome

Paresthesia – A burning, prickling or tingling sensation or numbness that is usually felt in the hands, arms, legs or feet sometimes felt when there is prolonged pressure placed on a nerve.

Percutaneous electrode – A device through which electric current passes. In spinal cord stimulation, an electrode is surgically placed in the epidural space of the spinal column to stimulate spinal nerves

Phantom limb pain/ syndrome – A form of nerve pain (neuropathy, neuralgia, neuritis) appearing to arise from an area of the body that has been surgically or traumatically amputated. 50 – 80% of amputees experience phantom limb pain. It is most commonly seen following amputation of the arm and leg, but may also occur following surgery to remove breasts, eyes, testicles and even internal organs. Common complaints include cramping, burning, shooting or stabbing type pain or a sensation that the amputated limb is in a distorted, painful position.

Radicular pain or radiculitis – Pain experienced along the dermatome (or sensory distribution) of a nerve due to pressure on the nerve root. Also known as sciatica. A common form of radiculitis radiates along the sciatic nerve from the lower spine to the lower back, gluteal muscles, back of the upper thigh, calf and foot as often caused by nerve root compression from a lumbar disc herniation or osteophytes in the lumbar region of the spine.

Reflex sympathetic dystrophy – A form of complex regional pain syndrome, Type I.

Spinal cord stimulator (SCS) – An electrical device which has 4 parts: a pulse generator, electrode(s), lead wires and a hand-held controller.

7.0 References, Citations & Resources:

1. Centers for Medicare and Medicaid Services. National Coverage Determination: Electrical Nerve Stimulators, NCD #160.7. Effective August 7, 1995. Available at: http://www.cms.hhs.gove/mcd/indix_list.asp?list_type=ncd.
2. Hayes Medical Technology Directory, Spinal Cord Stimulation for Relief of Neuropathic Pain, December 21, 2018.
3. MCG Ambulatory Care 22nd Edition, Implanted Electrical Stimulator, Spinal Cord ACG: A-0243, 02/11/19.
4. Medscape, Spinal Cord Stimulation Technique, Aug. 7, 2018. Available at: http://emedicine.medscape.com/article/1980819-technique.

8.0 Associated Documents [For internal use only]:

Standard Operating Procedure (SOP) – MM-03 Benefit Determinations; MM-25 Transition/Continuity of Care; MM-55 Peer-to-Peer Conversations; SOP 007 Algorithm for Use of Criteria for Benefit Determinations.

Desk Level Procedure (DLP) – None.

Letters – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Partial Coverage, Partial Non-Coverage Letter; Specific Exclusion Denial Letter.

Form – Prior Authorization Request Form for Services.

Other – None.

9.0 Revision History

Original Effective Date: 07/12/2006

Last Approval Date: 08/26/2019

Next Revision Date: 08/14/2020

Revision Date	Reason for Revision
December 2015	Revised format, added criteria for angina and ICD-10 codes, CPT/HCPCS codes updated.
February 2016	Definition added for Failed Back Surgery Syndrome
December 2016	Annual review – removed references to Medicaid/DHHS, updated references and resources, added language regarding trial and replacement of implantable device
December 2017	Converted from Medical Policy 007 to Benefit Coverage Policy format.
November 2017	Annual review and approval by QI/MRM 12/13/17 – updated references and code status changes for DME.
April 2018	Initial review by BCC – code status and references updated.
June 2019	Annual review; citations updated, approved by QI/MRM 8/14/19.