

Policy: MP021

Section: Medical Benefit Policy

Subject: Dorsal Column Stimulation

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Dorsal Column Stimulation

II. Purpose/Objective:

To provide a policy of coverage regarding Dorsal Column Stimulation

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Spinal cord stimulation, also known as dorsal column stimulation, blocks pain conduction pathways to the brain. The neurostimulator electrodes used for this purpose are implanted percutaneously in the epidural space via a special needle. Some members may require an open laminectomy for electrode placement. After the electrodes are implanted, the member is provided with an external neurostimulator on a trial basis for up to 4 weeks. If during the trial, it is determined that the stimulation is not effective or is unacceptable to the member, the electrodes are removed. If the trial proves successful, a spinal neurostimulator and pulse generator that are activated through a radiofrequency device, are inserted subcutaneously and are connected to the implanted electrodes.

INDICATIONS: REQUIRES PRIOR PLAN AUTHORIZATION. The authorization must be requested and approved prior to the implantation of the electrodes for the trial period.

Relief of chronic intractable lumbar or thoracic pain under the following circumstances:

- Lumbosacral arachnoiditis that has not responded to medical management including physical therapy. (Presence of arachnoiditis is usually documented by presence of high levels of proteins in the CSF and/or by myelography or MRI.)
- Nerve root injuries, post-surgical or post traumatic including that of post laminectomy syndrome (failed back syndrome)
- Complex regional pain syndrome I & II
- Diabetic peripheral neuropathy (DPN)
- Phantom limb syndrome that has not responded to medical management
- End stage peripheral vascular disease, when the member cannot undergo revascularization or when revascularization has failed to relieve painful symptoms and the pain has not responded to medical management
- Post-herpetic neuralgia
- Plexopathy
- Intercostal neuralgia that did not respond to medical management and nerve blocks
- Cauda equina injury
- Incomplete spinal cord injury.

NOTE: Services related to component reimplantation or replacement in members previously approved for the implantation, or members having had the implantation prior to enrollment in the Plan, and who otherwise meet criteria for coverage, do not require prior authorization.

CRITERIA FOR COVERAGE: All must be met

- The implantation of the stimulator is used only as a late resort (if not a last resort) for members with chronic intractable pain and;
- Documented failure or contraindication to physical therapy or chiropractic care. There must be documentation of a minimum of 4 weeks of physical therapy or chiropractic care at least 2 times per week for the four weeks (minimum of 8 visits) within one year of the request for injections. The therapy MUST be associated with the body area that will be treated with the requested injections. A home exercise program is not an adequate substitute for formal physical therapy or chiropractic care. If the provider indicates the member cannot do physical therapy or chiropractic care due to pain, the provider must submit documentation from an evaluating physical therapist or chiropractor dated within 4 weeks of the request indicating the member cannot tolerate therapy services. Please note that one visit for injection to allow the member to attend therapy is not considered medically necessary. Please also note that completion of less than the minimum number of therapy or chiropractor visits due to non-compliance is not an acceptable alternative to this requirement in the absence of documentation the member was unable to tolerate therapy services; and
- Documented failure or contraindication to pharmacologic therapy. There must be documentation of the use of at least three (3) classes of medications from the following list of medication classes must be submitted for review: NSAIDs, opiates, non-opioid analgesics, anti-epileptic medications used for treatment of chronic pain, antidepressant medications used for treatment of chronic pain, ASA or ASA derivatives, muscle relaxants, steroids, such as prednisone or Medrol or documented contraindication to each of these drug classes; and
- Documented failure of more conservative invasive methods, such as epidural steroid injections or facet injections, if applicable; and
- The member has completed a spine evaluation and surgical intervention is recommended by the spine evaluator and;
- All facilities, equipment, and personnel required for the proper diagnosis, treatment, training, and follow-up of the members must be available and;
- Demonstration of pain relief with a temporarily implanted electrode must precede permanent implantation.

LIMITATIONS:

For PA Medicaid: Dorsal Column Stimulation for the treatment of chronic stable angina pectoris may be considered through a Program Exception on a per case basis

Please note both the trial and permanent implantation require prior authorization. The permanent implantation cannot be prior authorized until the trial has been completed and response as noted above has been documented.

For permanent implantation, there must be documented improvement of at least 50% or greater in symptoms with a trial.

EXCLUSIONS:

Spinal Cord Stimulation for the treatment of members with cervical trauma, disc herniation, or failed cervical spine surgery syndrome, presenting with arm pain, neck pain, or cervicogenic headache, chronic pain associated with malignancy, is considered **experimental, investigational or unproven** and therefore **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

For Commercial and Medicare Business Segments:

Spinal Cord Stimulation as a treatment for chronic stable angina pectoris is considered **experimental, investigational or unproven** and therefore **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

CODING ASSOCIATED WITH: Dorsal Column Stimulation

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 63650 Percutaneous implantation of neurostimulator electrode array, epidural
- 63655 Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
- 63661 Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
- 63662 Removal of spinal neurostimulator electrode percutaneous plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
- 63663 Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy
- 63664 Revision including replacement, when performed of spinal neurostimulator electrode percutaneous plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
- 63685 Incision and subcutaneous placement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
- 63688 revision or removal of implanted spinal neurostimulator pulse generator or receiver

- 95970 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971 simple brain, spinal cord, or peripheral (ie, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972 complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
- C1767 generator neurostimulator (implantor) non-rechargeable
- C1778 lead, neurostimulator
- C1787 patient programmer, neurostimulator
- C1816 receiver and/or transmitter neurostimulator (implantable)
- C1820 generator, neurostimulator (implantable), non-frequency, with rechargeable battery and charging system
- C1822 generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
- C1897 lead neurostimulator test kit (implantable)
- 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
- L8989 external recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Practice Guidelines for Chronic Pain Management: A Report by the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section, *Anesthesiology*, Vol 86(4), April 1997, pp. 995-1004.
 Watkins ES, Koeze TH, " Spinal Cord Stimulation and Pain Relief", *British Medical Journal*, Vol 307(6902), 21 Aug. 1993, p 462.
 Kumar K, Toth C, Nath RK, Laing P, "Epidural Spinal Cord Stimulation for Treatment of Chronic Pain – Some Predictors of Success. A 15-year Experience", *Surgical Neurology*, 50(2), Aug 1998, pp110-120.
 Stojanovic MP, "Stimulation Methods for Neuropathic Pain Control", *Current Pain and Headache Reports*, Vol 5(2), Apr 2001, pp 130-137.

Barolat G, Singh-Sahni K, Staas WE, Shatin D, Ketcik B, Allen K, "Epidural Spinal Cord Stimulation in the Management of Spasms in Spinal Cord Injury: A Prospective Study", *Stereotactic & Functional Neurosurgery*, Vol 64(3), 1995, pp 153-164.

Barolat G, "Spinal Cord Stimulation for Chronic Pain Management", *Archives of Medical Research*, Vol 31(3), May-Jun 2000, pp 258-262.

Kavar B, Rosenfeld JV, Hutchinson A, "The Efficacy of Spinal Cord Stimulation for Chronic Pain", *Journal of Clinical Neuroscience*, Vol 7(5), Sept 2000, pp 409-413.

Villavicencion AT, Leveque JC, Rubin L, Bulsara K, Gorecki JP, "Laminectomy Versus Percutaneous Electrode Placement for Spinal Cord Stimulation", *Neurosurgery*, Vol 46(2), Feb 2000, pp 399-405.

Winifred S. Hayes, Hayes Inc. Online, [Spinal Cord Stimulation for the Treatment of Pain](#), Feb 6, 2002.

Winifred S. Hayes, Hayes Inc. Online, [Spinal Cord Stimulation for Relief of Neuropathic Pain](#), May 2003.

Winifred S. Hayes, Hayes Inc. Online, [Spinal Cord Stimulation for the Treatment of Intractable Angina](#), April 30, 2003. Updated Mar. 27, 2005.

Lanza GA, Sestito A, Sgueglia GA, Infusino F, Papucci F, Visocchi M, Ierardi C, Meglio M, Bellocchi F, Crea F, "Effect of Spinal Cord Stimulation on Spontaneous and Stress-induced Angina and 'Ischemia-like' ST-segment Depression in Patients with Cardiac Syndrome X", *European Heart Journal*, Vol 26, January 2005, pp 983-989.

UpToDate Online, [New Medical and Invasive Therapies for Angina Pectoris](#), accessed August 21, 2005.

UpToDate Online. New Therapies for Angina Pectoris. Current as of May 31, 2008. Accessed on August 21, 2008.

Leon, MB, Kornowski, R, Downey, WE et al. A blinded randomized, placebo-controlled trial of percutaneous laser myocardial revascularization to improve angina symptoms in patients with severe coronary artery disease. *J Am Coll Cardiol* 2005;46:1812.

Winifred S. Hayes, Hayes Inc. Online, [Electrical Spinal Cord Stimulation for the Treatment of Intractable Angina](#), September 18, 2006. Updated September 9, 2007.

Fraker, TD, Fihn SD et al. 2007 chronic angina focused update of the ACC/AHA 2002 Guidelines for the management of patients with chronic stable angina: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines Writing Group to develop the focused update of the 2002 Guidelines for the management of patients with chronic stable angina. [Circulation](#). 2007 Dec 4;116(23):2762-72. Epub 2007 Nov 12.

Garcia-March G, Sanchez-Ledesma MJ, Diaz P, et al. Dorsal root entry zone lesion versus spinal cord stimulation in the management of pain from brachial plexus avulsion. *Acta Neurochir Suppl (Wien)*. 1987;39:155-158.

Simpson BA, Bassett G, Davies K, et al. Cervical spinal cord stimulation for pain: A report of 41 patients. *Neuromodulation*. 2003;6(1):20-26.

British Pain Society. Spinal cord stimulation for the management of pain: recommendations for best clinical practice. Apr 2009. Accessed Oct 2010. Available at URL address: http://www.britishpainsociety.org/book_scs_main.pdf

Hayek SM, Veizi IE, Stanton-Hicks M. Four-limb neurostimulation with neuroelectrodes placed in the lower cervical epidural space. *Anesthesiology*. 2009 Mar;110(3):681-4.

Novitas Solutions. Spinal Cord Stimulation (Dorsal Column Stimulation). LCD (L35450) https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35450&ContrlD=314&ver=14&ContrVer=1&CntrctrSelected=314*1&Cntrctr=314&DocType=Active&c=AgACAAIAAAAAAA%3d%3d

Eldabe, S, Thomson, S, Duarte, R, et al. The Effectiveness and Cost-Effectiveness of Spinal Cord Stimulation for Refractory Angina (RASCAL Study): A Pilot Randomized Controlled Trial. *Neuromodulation : journal of the International Neuromodulation Society*. 2016 Jan;19(1):60-70.

Pan, X, Bao, H, Si, Y, et al. Spinal Cord Stimulation for Refractory Angina Pectoris: A Systematic Review and Meta-analysis. *The Clinical journal of pain*. 2016 Nov 21.

Deer T, Slavin KV, Amirdelfan K, et al. Success Using Neuromodulation with BURST (SUNBURST) Study: Results from a prospective, randomized controlled trial using a novel burst waveform. *Neuromodulation*. 2018;21(1):56-66.

Kallewaard, JJ, Edelbroek, CC, Terheggen, MM, Raza, AA, Geurts, JJ. A Prospective Study of Dorsal Root Ganglion Stimulation for Non-Operated Discogenic Low Back Pain. *Neuromodulation*, 2019 Mar 2.

Rigoard, PP, Basu, SS, Desai, MM, Taylor, RR, Annemans, LL, Tan, YY, Johnson, MM, Van den Abeele, CC, North, RR. Multicolumn Spinal Cord Stimulation for Predominant Back Pain in Failed Back Surgery Syndrome Patients: A Multicenter Randomized Controlled Trial. *Pain*, 2019 Feb 6.

Sivanesan, EE, Bicket, MM, Cohen, SS. Retrospective analysis of complications associated with dorsal root ganglion stimulation for pain relief in the FDA MAUDE database. *Reg Anesth Pain Med*, 2019 Jan 15;44(1)

Mekhail NA, Argoff CE, Taylor RS, et al. High-frequency spinal cord stimulation at 10 kHz for the treatment of painful diabetic neuropathy: design of a multicenter, randomized controlled trial (SENZA-PDN). *Trials*. 2020;21(1):87.

Petersen EA, Stauss TG, Scowcroft JA, et al. Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial. *Diabetes care*. 2022;45(1):e3-e6.

Petersen EA, Stauss TG, Scowcroft JA, et al. Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy: A Randomized Clinical Trial. Supplemental Online Content, Supplement 3. *JAMA neurology*. 2021;78(6):687-698.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/03

Revised: 9/04: 9/05;9/06, 11/09, 11/10, 11/12, 2/15 (criteria); 3/15, 10/16, 10/17 (clarified Medicaid coverage for angina), 1/20 (Removed Coverage for DME statement); 8/22 (add DPN indication)

Reviewed: 9/07, 9/08, 11/11, 11/13, 11/14, 10/18, 10/19, 1/21, 1/22

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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