MEDICAL POLICY STATEMENT
Ohio Marketplace

Policy Name & Number	Date Effective
Implantable Spinal Cord Stimulator-OH MP-MM-0718	08/01/2022-02/28/2023
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Archived

Table of Contents

A. Subject....2
B. Background....2
C. Definitions....3
D. Policy....3
E. Conditions of Coverage....7
F. Related Polices/Rules....7
G. Review/Revision History....7
H. References....7

A. Subject

Implantable Spinal Cord Stimulator

B. Background

Spinal cord (dorsal column) stimulation (SCS) is a pain relief technique that delivers a low-voltage electrical current to the spinal cord to block the sensation of pain. This technique is best suited for neuropathic pain. Common indications include, but are not limited to, failed back surgery syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, and peripheral neuropathy. SCS is generally not effective in treating nociceptive pain (resulting from irritation of the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury).

Two stages are involved in SCS implantation. In both stages, a physician, guided by an x-ray, places a lead into the epidural space located within the bony spinal canal.

The first stage consists of a short trial (e.g., 3-14 days) with a temporary percutaneous implantation of neurostimulator electrode(s) and external generator for assessing the patient's suitability for ongoing treatment with a permanent surgically implanted nerve stimulator. During the trial phase, one or two leads are placed via an epidural needle in the appropriate position. This can be done under light sedation in an office setting if all the sterility, equipment, professional training and support personnel required for the proper surgery and follow up of the patient are available. If at least 50% pain relief is achieved during the trial phase, the temporary system may be transitioned to a permanent system. Performance and documentation of an effective trial is a prerequisite for permanent nerve stimulation.

In the permanent implantation stage, there are two different SCS systems routinely used. The first system uses percutaneous insertion of electrodes into the epidural space and subcutaneous connection to a neurostimulator. The second system involves the implantation of paddle-type leads into the epidural space after laminectomy and subcutaneous connection to a neurostimulator. Neurostimulators may be either Implantable Pulse Generators (IPGs), which use either a non-rechargeable or a rechargeable internal battery, or radio frequency devices, which receive energy in the form of radio frequency pulses from an external device powered by a rechargeable battery. The appropriate SCS system with up to 16 contacts/electrodes will depend upon the underlying condition, the patient's pain patterns, the area of body affected, and the amount and intensity of stimulation required. Surgery for implantation of a permanent neurostimulator must be performed in an Ambulatory Surgical Center (ASC) or hospital.

Lumbar or thoracic dorsal column SCS has been proposed for the treatment of numerous other conditions (e.g., diabetic neuropathies, phantom limb pain, movement disorders, ataxia, and brain lesions), however there is insufficient evidence in the peer-reviewed published literature to support SCS for these conditions. There is also insufficient evidence to support the safety and efficacy of cervical placement of a spinal cord stimulator for any indication.

Archived

C. Definitions

- **Conservative Therapy** - A multimodality plan of care. Multimodality care plans include both active and inactive conservative therapies.
  - **Active Conservative Therapies** - Include physical therapy, occupational therapy, a physician supervised home exercise program (HEP), and/or chiropractic care.
  - **Inactive Conservative Therapies** - Include rest, ice, heat, medical devices, TENS unit, and/or prescription medications.
- **High-frequency Spinal Cord Stimulation** - Provides a higher frequency than traditional SCS, operating at a frequency of 10,000 Hz as opposed to traditional SCS operating in a 40 – 60 Hz range.
- **Implantable Spinal Cord Stimulator/Dorsal Column Stimulator** - A pain relief technique that delivers a low voltage electrical current to the spinal cord to block the sensation of pain.
- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** - A durable medical equipment device dispensed by prescription. Its use, frequency, duration, and start dates must be documented in the medical record to be considered part of conservative therapy during the period of prior authorization request.
- **Visual Analog Scale (VAS)** - A tool used to measure pain using a numerical straight line scale between 0-10 describing pain from mild to severe.

D. Policy

I. Implantable Spinal Cord Stimulator

A. CareSource considers a preliminary trial (3-14 days) for implantable spinal cord stimulators for the treatment of chronic pain medically necessary when **ALL** the following criteria are met:

1. The member has one of the following diagnoses:
   a. Failed back surgery syndrome (FBSS);
   b. Complex regional pain syndrome (CRPS) or reflex sympathetic dystrophy (RSD);
   c. Neuropathic pain that is moderate to severe (5 or more on a 10 point Visual Analog Scale (VAS) scale); or
   d. Inoperable limb ischemia secondary to peripheral vascular disease;
2. Pain pathology is documented;
3. Surgical intervention is not indicated;
4. Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation;
5. Patient has undergone a psychological evaluation by a licensed mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) that reveals no evidence of an inadequately controlled mental or behavioral health problem that would negatively impact the success of a SCS or contraindicate its placement, including:
   a. Alcohol abuse;
   b. Drug abuse;

Archived

c. Depression; and
d. Psychosis;

6. The patient has documentation, including dates of service, addressing ACTIVE conservative therapy as part of a multimodality comprehensive plan of care in the medical record, including one of the following:
   a. The patient has received ACTIVE conservative therapy lasting for 6 months or more within the past 12 months including **at least ONE** of the following:
      01. Physical therapy;
      02. Occupational therapy;
      03. A physician supervised home exercise program (HEP), including the following two requirements:
         (1). An exercise prescription and/or plan documented in the medical record; and
         (2). A follow up documented in the medical record regarding completion of a HEP (after suitable 6 week period), or inability to complete a HEP due to a stated physical reason i.e. increased pain, inability to physically perform exercises. (Patient inconvenience or noncompliance without explanation does not constitute “inability to complete”);
      04. Chiropractic care; or
   b. The medical record documents **at least ONE** of the following exceptions to the 6 months ACTIVE conservative therapy requirement in the past 6 months:
      01. At least moderate pain with significant functional loss at work or home;
      02. Severe pain unresponsive to outpatient medical management; or
      03. Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s);
7. The patient has documentation, including dates of service, addressing INACTIVE conservative therapy as part of a multimodality comprehensive plan of care in the medical record, as follows:
   a. The patient has received INACTIVE conservative therapy lasting for 6 months or more within the past 12 months including **at least ONE** of the following:
      01. Rest;
      02. Ice;
      03. Heat;
      04. Medical devices (DME such as braces, walkers, crutches);
      05. TENS unit;
         (1). If a TENS unit is part of the care plan, the frequency of use, and duration of use with dates must be documented in the medical record. General statements in the medical record such as “Patient has a TENS unit” do not document use, and will not suffice to meet this policy criterion.

Archived

06. Pain medications (prescription or over the counter) (e.g., non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen). Opioid narcotics are not required for consideration.

B. CareSource considers a permanently placed SCS for the treatment of chronic pain medically necessary when the patient has met **ALL** the criteria above (A. 1-7) and at least a 50% reduction in pain was achieved during the trial period and is documented in the medical record.

C. CareSource considers a preliminary trial (3-14 days) for implantable spinal cord stimulators for the treatment of chronic stable angina pectoris medically necessary when **ALL** the following criteria are met:
   1. Patient's angina pectoris is a Class III or Class IV on the New York Heart Association and Canadian Cardiovascular Society Functional Classifications (refer to table, below);
   2. Failure to obtain satisfactory improvement of symptoms with optimal pharmacological treatment, including use of antianginal medications such as long acting nitrates, beta-adrenergic blockers, and calcium-channel antagonists;
   3. Patient is not a candidate for revascularization procedure (coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA));
   4. Patients has undergone a psychological evaluation by a licensed mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) that reveals no evidence of an inadequately controlled mental or behavioral health problem that would negatively impact the success of a SCS or contraindicate its placement, including:
      a. Alcohol abuse;
      b. Drug abuse;
      c. Depression; and
      d. Psychosis.

D. CareSource considers a permanently placed SCS for the treatment of chronic stable angina medically necessary when the patient has met **ALL** the criteria above (C. 1-4) and at least a 50% reduction in pain was achieved during the trial period and documented in the medical record.

New York Heart Association and Canadian Cardiovascular Society Functional Classifications

Functional Capacity	**Objective Assessment**
Class I: Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	**A:** No objective evidence of cardiovascular disease.
Class II: Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	**B:** Objective evidence of minimal cardiovascular disease.

Archived

Class III: Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.	**C:** Objective evidence of moderately severe cardiovascular disease.
Class IV: Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	**D:** Objective evidence of severe cardiovascular disease.

II. Contraindications
Implantable spinal cord stimulators are contraindicated in members with ANY of the following:
A. Active infection or sepsis.
B. Coagulopathy.
C. Major psychiatric disorders, including somatization.
D. Active and untreated substance use disorder.
E. Presence of other implanted programmable devices that may result in miscommunication between the devices impacting pump function (e.g., cardiac pacemaker, defibrillator).

III. Exclusions
CareSource considers spinal cord stimulators experimental and investigational for ANY of the following:
A. The use of intra-operative motor evoked potentials (MEP) and somatosensory evoked potentials (SSEP).
B. Cervical placement of an SCS for any indication.
C. All other indications not mentioned above because its effectiveness for other indications has not been established, including (but not limited to):
1. Members in a chronic vegetative or minimally conscious state.
2. Chronic cancer-related pain.
3. Chronic pelvic pain (e.g., chronic abdominal pain, chronic visceral pain).
4. Gait disorders including spinocerebellar ataxia.
5. Irritable bowel syndrome.
6. Parkinson's disease.
7. Sleep disorders.
8. Sphincter of Oddi dysfunction.
9. Types of chronic non-malignant non-neuropathic pain not mentioned above.
10. Ventricular fibrillation and ventricular tachycardia.

IV. High-Frequency Spinal Cord Stimulators
A. CareSource considers high frequency spinal cord stimulators an equal and effective alternative to standard spinal cord stimulators for the medically necessary indications listed above.
B. Replacement of a functioning standard spinal cord stimulator with a high-frequency spinal cord stimulator is considered NOT medically necessary.

Archived

V. Removal and Replacement

A. CareSource covers the replacement of a lumbar or thoracic SCS and/or battery/generator replacement as medically necessary when the existing stimulator and/or battery/generator are no longer under warranty and cannot be repaired. Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life.

C. Device interrogation reports with interpretation reports in the medical records must be acquired within a minimum 3 months of a prior authorization request and must be submitted with each prior authorization request for replacement.

D. CareSource considers removal of an SCS medically necessary even where installation would not have been indicated.

E. Conditions of Coverage

NA

F. Related Polices/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	09/01/2019	
Date Revised	05/13/2020 04/28/2021 03/21/2022	Annual Update: PA exclusions added Annual Update: Removed PA language. Annual Review: Updated references, re-organized criteria, consolidated background
Date Effective	08/01/2022	
Date Archived	02/28/2023	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Caylor J, Reddy R, Yin S, et al. Spinal cord stimulation in chronic pain: evidence and theory for mechanisms of action. Bioelec Med. 2019;5:12. doi:10.1186/s42234-019-0023-1.
2. Dombovy-Johnson ML, Hunt CL, Morrow MM, et al. Current evidence lacking to guide clinical practice for spinal cord stimulation in the treatment of neuropathic pain in spinal cord injury: a review of the literature and a proposal for future study. Pain Pract. 2020 Mar;20(3):325-335. doi:10.1111/papr.12855.
3. Grider J, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: a systematic review. Pain Phys 2016;19:E33-E54. Retrieved March 21, 2022 from www.painphysicianjournal.com.
4. Hayes Inc. Spinal Cord Stimulation Systems (Product Comparison). (2022 February). Retrieved March 7, 2022 from www.evidence.hayesinc.com.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

Archived

5. Hayes Inc. Health Technology Assessment: Spinal Cord Stimulation for Relief of Neuropathic Pain. (2018 December). Annual review 2022 January. Retrieved March 7, 2022 from www.evidence.hayesinc.com.
6. Henson JV, Varhabhatla NC, Bebic Z, et al. Spinal cord stimulation for painful diabetic peripheral neuropathy: a systematic review. Pain Ther. 2021 Dec;10(2):895-908. doi:10.1007/s40122-021-00282-9.
7. Mailis A, Taenzer P. Evidence-based guideline for neuropathic pain interventional treatments: spinal cord stimulation, intravenous infusions, epidural injections and nerve blocks. Pain Res Manag. 2012 May-Jun;17(3):150-158. doi:10.1155/2012/794325.
8. Manca A, Kumar K, Taylor RS, et al. Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). Eur J Pain 2008 Nov;12(8):1047-1058. doi:10.1016/j.ejpain.2008.01.014.
9. North RB, Kidd DH, Forrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurg. 2005;56(1):98-106. doi:10.1227/01.neu.0000144839.65524.e0.
10. Peng L, Min S, Zejun Z, et al. Spinal cord stimulation for cancer-related pain in adults. Cochrane Database Syst Rev. 2015 Jun;2015(6):CD009389. doi:10.1002/14651858.CD009389.pub3.
11. Sdrulla AD, Guan Y, Raja SN. Spinal cord stimulation: clinical efficacy and potential mechanisms. Pain Prac 2018 Nov;18(8):1048-1067. doi:10.1111/papr.12692.
12. Sun L, Peng C, Joosten E, et al. Spinal cord stimulation and treatment of peripheral or central neuropathic pain: mechanisms and clinical application. Neural Plasticity 2021. doi:10.1155/2021/5607898.
13. Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischemia. Cochrane Database Sys Rev. 2013 Feb;2013(2):CD004001. doi:10.1002/14651858.CD004001.pub3.
14. Waszak PM, Modric M, Paturej A, et al. Spinal cord stimulation in failed back surgery syndrome: review of clinical use, quality of life and cost-effectiveness. Asian Spine J. 2016 Dec;10(6):1195-1204. doi:10.4184/asj.2016.10.6.1195.

Independent medical review – 5/2019

Archived