CareSource

MEDICAL POLICY STATEMENT
KENTUCKY MARKETPLACE

Policy Name		Policy Number	Date Effective
Implantable Spinal Cord Stimulator		MM-0717	08/01/2021-06/30/2022
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

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.

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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 pain that is neuropathic in nature i.e., resulting from actual damage to the peripheral nerves. 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, not damage to 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 on the underlying condition, the patient's pain patterns, the area of body affected, and the amount and intensity of stimulation required. Permanent neurostimulators must be placed in an Ambulatory Surgical Center (ASC) or hospital.

There is evidence that outcomes of SCS are improved if candidates are subject to psychological clearance to exclude from surgery persons with serious mental illness (SMI), psychiatric disturbances, or poor personality factors that are associated with poor outcomes. Literature supports pre-surgical psychological clearance for SCS.

Failed back surgery syndrome (FBSS) and Chronic Regional Pain Syndrome (CRPS) are the 2 most common indications for SCS placement. After randomizing 100 FBSS patients to either SCS plus conventional medical management or conventional medical management alone, the results of the 6-month Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS Trial) found that SCS offered superior pain relief, health-related quality of life, and functional capacity. Other investigators reported that SCS provided adequate pain relief in patients with FBSS with predominant LBP and secondary radicular pain. Harney et al report that there is significant evidence to support the SCS in the management of CRPS.

Non-surgical interventional therapies for LBP were reviewed by the American Pain Society, concluding that there is fair evidence that SCS placement is moderately effective for FBSS with persistent radiculopathy, while acknowledging that device-related complications are common.

In a 20-year literature review, implanted SCS devices showed a favorable, long-term symptomatic effect for patients with refractory angina pain, severe chronic ischemic limb pain secondary to peripheral vascular disease, peripheral neuropathic pain, and chronic LBP. A Cochrane review reports that SCS placement improves outcomes over standard conservative treatment in limb salvage and clinical response for patients with inoperable chronic critical leg ischemia. In addition, evidence supports SCS placement for the refractory neuropathic pain, CRPS, angina pectoris and critical limb ischemia. However, a review in 2009 did not address chronic painful diabetic neuropathy (CPDN), and currently there is inadequate evidence to support the use of SCS for this indication.

A systematic review of medical or surgical treatments in patients in chronic vegetative state (VS) or minimally conscious state (MCS) was evaluated in 16 eligible papers. Case reports of medical management by dopaminergic agents (levodopa, amantadine), zolpidem and median nerve stimulation, or surgical management by deep brain stimulation, extra-dural cortical stimulation, SCS and intra-thecal baclofen have variably improved the level of consciousness in selected cases. The authors concluded that treatments proposed for disorders of consciousness are yet to achieve an "evidence-based treatment". At present, the published case reports of therapeutic responses require substantiation by further clinical studies of sound scientific methodology.

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 to support SCS for these conditions. Studies investigating SCS for various other conditions are limited in number and consist of case reports, small case series and retrospective reviews. Outcomes have been conflicting or have reported no significant improvement with SCS. There is also insufficient evidence in the published peer-reviewed scientific literature to support the safety and efficacy of cervical placement of a spinal cord stimulator for any indication. Studies are primarily in the form of case reports and case series with small, heterogeneous patient populations and short-term follow-ups. Studies comparing cervical placement of SCS compared to other established treatment modalities are lacking. Patient selection criteria and clinical application have not been established.

Professional Society Recommendations:
The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

American College of Physicians (ACP) (2017)
The ACP's recommendations for Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Practice Guideline are as follows:

- Clinicians and patients should select nonpharmacological treatment with superficial heat (moderate-quality evidence), massage, acupuncture, or spinal manipulation (low-quality evidence). If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants (moderate-quality evidence)
- Clinicians and patients should initially select nonpharmacological treatment with exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relation, electromyography biofeedback, low level laser therapy, operant therapy, cognitive behavioral therapy or spinal manipulation.
- In patients with chronic low back pain who have had an inadequate response to nonpharmacological therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients.

C. Definitions

- **Implantable Spinal Cord Stimulator/Dorsal Column Stimulator** - 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.
- **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.
- **Visual Analog Scale (VAS) -** A tool used to measure pain using a numerical straight line scale between 0-10 describing pain from mild, moderate to severe.
- **Conservative Therapy** - is a multimodality plan of care. Multimodality care plans include ALL of the following:
  - **Active Conservative Therapies** - such as physical therapy, occupational therapy, a physician supervised home exercise program (HEP) or chiropractic care.
  - **Inactive Conservative Therapies** - such as rest, ice, heat, medical devices, TENS unit or prescription medications.
- **Transcutaneous Electrical Nerve Stimulator (TENS Unit)** - is 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.

D. Policy

I. Implantable Spinal Cord Stimulator

A. CareSource considers implantable spinal cord stimulators medically necessary when the cinical criteria in this policy is met.
B. CareSource considers a preliminary trial (3-14 days) for implantable spinal cord stimulators medically necessary for ONE (1) or MORE of the following conditions:
   1. Failed Back Surgery Syndrome (FBSS);
   2. Complex Regional Pain Syndrome (CRPS) or Reflex Sympathetic Dystrophy (RSD);
   3. Moderate to severe (5 or more on a 10 point Visual Analog Scale (VAS) scale); Neuropathic Pain;
   4. Limb Ischemia; or
   5. Chronic Intractable Angina.
C. CareSource considers a preliminary trial (3-14 days) for implantable spinal cord stimulators medically necessary for FBSS, CRPS, RSD, Limb Ischemia and neuropathic pain (moderate to severe) when ALL of the following criteria are met:
   1. Pain pathology is documented
   2. Surgical intervention is not indicated
   3. Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation.
   4. Patients must undergo 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.
   5. 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.
      a. The patient has received ACTIVE conservative therapy lasting for six (6) MONTHS or more within the past twelve (12) months including ONE (1) 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.
            (2) A follow up documented in the medical record regarding completion of a HEP (after suitable six (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
05. The medical record documents at least ONE (1) of the following exceptions to the six (6) MONTHS ACTIVE conservative therapy requirement in the past six (6) months:
(1). At least moderate pain with significant functional loss at work or home;
(2). Severe pain unresponsive to outpatient medical management; or
(3). Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s).

6. 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
a. The patient has received INACTIVE conservative therapy lasting for six (6) MONTHS or more within the past twelve (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 use as defined in CareSource policy;
(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.
06. Pain medications (prescription or over the counter) such as: non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen. Opioid narcotics are not required for consideration.

D. CareSource considers a permanently placed SCS medically necessary when the patient has met ALL of the criteria above (C. 1-6) and at least a 50% reduction in pain was achieved during the trial period and is documented in the medical record.

E. CareSource considers a preliminary trial for implantable spinal cord stimulators medically necessary for Chronic Stable Angina Pectoris when ALL of 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.
2. Failure of 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 (CABG or PTCA)
4. Patients must undergo 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.

F. CareSource considers a permanently placed SCS medically necessary when the patient has met ALL of the criteria above (E. 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.
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. Implantable Spinal Cord Stimulators are not medically necessary for members with ANY of the following contraindications:
   A. Active infection or sepsis;
   B. Coagulopathy;
   C. Major psychiatric disorders, including somatization;
   D. Active and untreated substance abuse disorder; or
   E. Presence of other implanted programmable devices that may result in miscommunication between the devices impacting pump function. For example, patients who have another implanted device, such as a cardiac pacemaker (due to lack of research in patients with other implanted devices).

III. Exclusions: CareSource considers SCS for ANY of the following experimental and investigational:
   A. The use of intra-operative motor evoked potentials (MEP) and somatosensory evoked potentials (SSEP).
   B. Cervical placement of a spinal cord stimulator (SCS) for any indication.
   C. All other indications not mentioned above because its effectiveness for other indications has not been established, including:
      1. Members in a chronic vegetative or minimally conscious state;
      2. Chronic cancer-related pain;
      3. Chronic pelvic pain (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; or
      10. Ventricular fibrillation and ventricular tachycardia.

IV. High Frequency
   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.
      1. Replacement of a functioning standard spinal cord stimulator with a high-frequency spinal cord stimulator is NOT considered medically necessary.

V. Removal and Replacement
   A. CareSource covers the replacement of a lumbar or thoracic spinal cord stimulator (SCS) and/or battery/generator replacement, as medically necessary when:
      1. Existing stimulator and/or battery/generator are no longer under warranty and cannot be repaired.
         a. Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life.
   B. 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.
   C. CareSource considers removal of an SCS medically necessary even where installation would not have been indicated.

E. Conditions of Coverage

F. Related Polices/Rules

G. Review/Revision History

	DATE	ACTION
Date Issued	09/01/2019	
Date Revised	05/13/2020 04/28/2021	Annual Update: PA exclusions added Annual Update: Removed PA language
Date Effective	08/01/2021	
Date Archived	06/30/2022	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.

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

Independent medical review – 5/2019