CareSource

MEDICAL POLICY STATEMENT
INDIANA MEDICAID

Policy Name	Policy Number	Date Effective
Implantable Spinal Cord Stimulator	MM-0704	12/01/2021-08/31/2022

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.

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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 al so 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) (April 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.
- **Conservative Therapy** - is a multimodality plan of care. Multimodality care plans include 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, prescription medications.

D. Policy

I. Implantable Spinal Cord Stimulator

A. Prior authorization (PA) is required and must be requested by providers for all implantable spinal cord stimulators, including the trial stimulation period and permanent spinal cord stimulator placement. Diagnosis for chronic nonmalignant,

neuropathic pain are considered for approval on a case-by-case basis by a pain management consultant, if all other PA criteria are met.

II. Trial Stimulation Period
   A. SCS treatment must be evaluated in a 3-7 day trial stimulation period before permanent plantation. Member's must meet the following clinical criteria for the 3-7 day trial stimulation period:
      1. The implantation of the stimulator is used only as a treatment of last resort for members with chronic intractable, nonmalignant pain.
      2. There is documented pathology, such as an objective basis for the pain complaint.
      3. There must be documentation of failure of at least six (6) months of conservative treatment, including at least three (3) of the following:
         a. Pharmacological therapy;
         b. Surgical management;
         c. Physical therapy;
         d. Psychological therapy;
         e. The member must not be a candidate for further surgical interventions;
         f. An evaluation must be performed by a physician experienced in treating chronic pain, which includes documentation of a psychological evaluation, as well as a consultation from another pain specialist, that indicates the member would benefit from SCS.
         g. The psychological evaluation should reveal no evidence of an inadequately controlled mental health problem (such as alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement.
         h. The member must not have any existing, untreated drug addictions.

III. Permanent SCS Implantation
   A. Following the trial stimulation period, PA will be approved for a permanent implantation after ALL of the following criteria have been met:
      1. All six (6) criteria for a 3-7 day trial implantation period must be met;
      2. The trial implantation must show a 50% reduction in pain for at least 2 days in order to receive approval for permanent implantation. Providers must submit documentation of successful treatment; and
      3. IHCP providers are directed to use the Multidimensional Affect and Pain Scale, the Brief Pain Inventory, and/or the Faces Pain Scale to measure pain levels. Providers are responsible for deciding which pain measurement scale is appropriate for each member

E. Conditions of Coverage

N/A

F. Related Polices/Rules

N/A

G. Review/Revision History

DATE		ACTION
Date Issued	08/12/2019	
Date Revised	05/13/2020 08/26/2020 07/21/2020 07/21/2021	Annual Update: PA exclusions PA is now required for removal/revision of the device. Annual Update: Policy has been revised to follow the *IHCP Surgical Services Provider Reference Module.* Reviewed, no changes
Date Effective	12/01/2021	
Date Archived	08/31/2022	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.

H. References

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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

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