MEDICAID POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
07/26/2016	07/26/2017	07/26/2016

Policy Name	Policy Number
Implantable Spinal Cord Stimulator (SCS) Devices	MM-0076

Policy Type		
☒ Medical	☐ Administrative	☐ Payment

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A. SUBJECT

Implantable Spinal Cord Stimulator (SCS) Devices

B. BACKGROUND

Totally implantable spinal cord stimulator (SCS) systems for pain relief are approved and regulated by the United States FDA as Class III devices through the Premarket Approval (PMA) process. Implantation of a thoracic or lumbar dorsal column SCS for any indication requires a short-term SCS trial. CareSource considers the use of intra-operative motor evoked potentials (MEP) and somatosensory evoked potentials (SSEP) experimental and investigational for implantation of spinal cord stimulators.

C. DEFINITIONS

- **Beneficial clinical response:** CareSource considers an adequate beneficial clinical response from a temporarily implanted electrode trial to occur when a member experienced significant pain reduction (50 % or more by before / after VAS pain scores) with a 3- to 7-day trial of percutaneous spinal stimulation. CareSource considers implantation of a permanent spinal cord stimulator (SCS) medically necessary for members who meet criteria in this policy who have experienced a beneficial clinical response with significant pain reduction. (A trial of percutaneous spinal stimulation is considered medically necessary for members who meet clinical criteria in this policy, in order to predict whether an SCS will induce significant pain relief). A prior authorization is required before a trial of temporarily implanted electrodes. A prior authorization is also required before a permanent SCS is placed, and medical records substantiating a beneficial clinical response to a trial must be submitted.

- **Conservative therapy**: Conservative therapy is a multimodality plan of care. Start and end dates documented in the medical record substantiate duration of treatment. Multimodality care plans include BOTH of the following:
    - Active conservative therapies such as physical therapy, occupational therapy, a physician supervised home exercise program (HEP), or chiropractic care
        - Home Exercise Program (HEP): includes two components that are both required to meet CareSource policy for completion of conservative therapy:
            - Information provided for an exercise prescription and/or plan documented in the medical record AND follow up documented in the medical record with member with information provided regarding completion of, or inability to complete 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")
    - Inactive conservative therapies such as rest, ice, heat, medical devices, acupuncture, TENS unit, prescription medications.
        - 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.
            - A TENS unit is a Transcutaneous Electrical Nerve Stimulator is a durable medical equipment device dispensed by prescription. It 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
- **Licensed mental health provider:** Each licensed mental health provider must have licensure from the state of member's residence, or an adjacent contiguous state, and not have a financial relationship with a device manufacturer nor a corporation affiliated with device manufacturers.

D. POLICY

I. Criteria

A prior authorization is required both for a trial of SCS and a second prior authorization is required for implantation of a permanent SCS.

A. CareSource covers a short-term trial of a lumbar or thoracic spinal cord stimulator (SCS) as medically necessary when **ALL** of the following are present:

1. Failed back surgery syndrome (FBSS) **OR** Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)
2. **ALL** of the following conservative therapy criteria are met:

2.1 ACTIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record that includes at least **ONE of the following:**

a. The patient has received ACTIVE conservative therapy lasting for six (6) MONTHS or more within the past twelve (12) months with start and end dates in the medical record substantiating the duration of treatment including **ONE of the following:**

(1) Physical therapy
(2) Occupational therapy
(3) A physician supervised home exercise program (HEP) as defined in CareSource policy

(4) 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:
   (1) At least moderate pain with significant functional loss at work or home
   (2) Severe pain unresponsive to outpatient medical management
   (3) Inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s)

2.2 PASSIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record lasting for six (6) MONTHS or more within the past twelve (12) months with start and end dates in the medical record substantiating the duration of treatment that includes at least **ONE of the following:**
   a. rest
   b. ice
   c. heat
   d. medical devices (DME such as braces, walkers, crutches)
   e. acupuncture
   f. TENS unit use as defined in CareSource policy
   g. prescription pain medications

3. Surgical intervention is not indicated. Surgical consultation with a neurosurgeon or orthopedic spine surgeon may be indicated.
4. An evaluation by a licensed mental health provider (e.g., a 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 outcomes of an SCS or substantiate a contraindication to SCS placement.
5. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation

B. CareSource covers a short-term trial of a lumbar or thoracic spinal cord stimulator (SCS) as medically necessary for last resort treatment of moderate to severe (5 or more on a 10-point VAS scale as documented on >3 visits in the medical record) chronic neuropathic pain of certain origins (i.e., lumbosacral arachnoiditis, phantom limb/stump pain, peripheral neuropathy, post-herpetic neuralgia, intercostal neuralgia, cauda equina injury, incomplete spinal cord injury, or plexopathy) that is refractory to 12 or more months of standard multi-agent therapy (including opioids, tricyclic antidepressants, and anticonvulsants) and multimodality conservative therapy, **AND** other interventional pain treatments as documented **by ALL of the following** criteria:
   1. Member has undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation (Note: screening must include psychological evaluation by a licensed mental health provider as well as physical evaluations)
   2. Member does not have any untreated existing drug addiction problems (as per American Society of Addiction Medicine (ASAM) guidelines)
   3. Member has obtained clearance from a psychiatrist or psychologist
   4. ACTIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record that includes at least **ONE of the following:**
      4.1 The patient has received ACTIVE conservative therapy lasting for six (6) MONTHS or more within the past twelve (12) months with start and end dates in

the medical record substantiating the duration of treatment including **ONE of the following:**
a. physical therapy
b. occupational therapy
c. a physician supervised home exercise program (HEP) as defined in CareSource policy
d. chiropractic care

4.2 Or, the medical record documents at least **ONE of the following** exceptions to the 6 MONTHS ACTIVE conservative therapy requirement in the past 6 months:
a. at least moderate pain with significant functional loss at work or home
b. severe pain unresponsive to outpatient medical management
c. inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s)

5. PASSIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record lasting for six (6) MONTHS or more within the past twelve (12) months with start and end dates in the medical record substantiating the duration of treatment that includes at least **ONE of the following:**
5.1 rest
5.2 ice
5.3 heat
5.4 medical devices
5.5 acupuncture
5.6 TENS unit use as defined in CareSource policy
5.7 prescription pain medications
6. There is documented pathology, i.e., an objective basis for the pain complaint.

C. CareSource covers a short-term trial of a lumbar or thoracic spinal cord stimulator (SCS) for chronic critical limb ischemia (CLI) as medically necessary when **ALL of the following criteria** are met:
1. ACTIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record that includes at least **ONE of the following:**
1.1 The patient has received ACTIVE conservative therapy lasting for six (6) MONTHS or more within the past twelve (12) months with start and end dates in the medical record substantiating the duration of treatment including **ONE of the following:**
a. physical therapy
b. occupational therapy
c. a physician supervised home exercise program (HEP) as defined in CareSource policy
d. chiropractic care
OR

1.2 the medical record documents at least **ONE of the following** exceptions to the 6 MONTHS ACTIVE conservative therapy requirement in the past 6 months:
a. at least moderate pain with significant functional loss at work or home
b. severe pain unresponsive to outpatient medical management
c. inability to tolerate non-surgical, non-injection care due to co-existing medical condition(s)

2. PASSIVE conservative therapy as part of a multimodality comprehensive approach is addressed in the patient's care plan with documentation in the medical record lasting for six (6) MONTHS or more within the past twelve (12) months with start and end

dates in the medical record substantiating the duration of treatment that includes at least **ONE of the following:**
2.1 rest
2.2 ice
2.3 heat
2.4 medical devices
2.5 acupuncture
2.6 TENS unit use as defined in CareSource policy
2.7 prescription pain medications

3. An evaluation by a licensed mental health provider (e.g., a 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 outcomes of a SCS or substantiate a contraindication to SCS placement.
4. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation

D. CareSource covers a short-term trial of a lumbar or thoracic spinal cord stimulator (SCS) for the treatment of pain secondary to chronic stable angina pectoris as medically necessary for myocardial ischemia when **ALL** of the following criteria are met:
1. The member 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)
2. Member has had optimal pharmacotherapy for at least one month. Optimal pharmacotherapy includes the maximal tolerated dosages of at least 2 of the following anti-anginal medications: long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists
3. Member'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)
4. Reversible ischemia is documented by symptom-limited treadmill exercise test
5. An evaluation by a mental health provider (e.g., a 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 outcomes of an SCS or contraindicate its placement
6. Beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation

E. CareSource covers the replacement of a lumbar or thoracic spinal cord stimulator (SCS) and/or battery/generator replacement, as medically necessary for an individual who meets ALL of the above criteria for the diagnosis requiring implantation, and the existing stimulator and/or battery/generator replacement are/is no longer under warranty and cannot be repaired. 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. Note: Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life. With all prior authorization requests, device interrogation reports must be submitted with interpretation records from the medical records.

F. CareSource does not cover implantation of a lumbar or thoracic spinal cord stimulator (SCS) for any other indication because it is considered experimental, investigational or unproven.
G. CareSource does not cover cervical placement of a spinal cord stimulator (SCS) for any indication because it is considered experimental, investigational or unproven. Its effectiveness has not been established for cervical trauma, disc herniation, failed cervical spine surgery syndrome presenting with arm pain, neck pain, cervicogenic headache, gliomas, migraine, radiation-induced brain injury, stroke or any other indication (other than CRPS).
H. CareSource considers spinal cord stimulation experimental and investigational for all other indications not mentioned above because its effectiveness for other indications has not been established. This includes treatment of persons in a chronic vegetative or minimally conscious state, chronic cancer-related pain, chronic pelvic pain (chronic abdominal pain, chronic visceral pain), gait disorders including spinocerebellar ataxia, irritable bowel syndrome, Parkinson's disease, sleep disorders, Sphincter of Oddi dysfunction, types of chronic non-malignant non-neuropathic pain not mentioned above, and ventricular fibrillation and ventricular tachycardia.
I. CareSource considers high-frequency spinal cord stimulators an equal effective alternative to standard spinal cord stimulators for the medically necessary indications listed above. Replacement of a functioning standard spinal cord stimulator with a high-frequency spinal cord stimulator is considered not medically necessary.
J. CareSource considers removal of an SCS medically necessary even where installation would not have been indicated.
K. CareSource considers a spinal cord stimulator patient programmer medically necessary for members who meet criteria for a dorsal column stimulator.
L. CareSource considers up to 16 leads medically necessary for a trial and implantation of a dorsal column stimulator.
M. CareSource considers the use of intra-operative motor evoked potentials (MEP) and somatosensory evoked potentials (SSEP) experimental and investigational for implantation of spinal cord stimulators.
N. CareSource considers that SCS is specifically contraindicated for individuals with cardiac pacemakers and/or defibrillators.

Patients with indwelling implanted spinal cord stimulators or pain pumps should have a device interrogation report submitted with medical records for a prior authorization request for proposed interventional pain injections. If a device is not functioning properly, an escalation in pain may warrant evaluation and management of the implanted device. [21]

II. Spinal Cord Stimulation for Chronic Pain:
Dorsal column spinal cord stimulators (SCS), also known as spinal cord stimulators, are most commonly implanted for chronic pain related to failed back surgery syndrome.[1, 2] Implanting an SCS for control of pain a reversible, non-destructive treatment option procedure and therefore an option for patients experiencing other interventions or failing medications like chronic opioids with addiction potential. The failure in earlier trials[1] of spinal stimulation emphasized importance of carefully selecting patients to achieve success. A patient should meet the following criteria [1-5] before permanent implantation of an SCS is considered: (a) multimodality conservative methods of pain management have been tried and failed; (b) the patient has exhausted all surgical options; (c) the patient has predominantly radiating extremity pain; and (d) the patient experienced significant pain reduction with a trial of percutaneous spinal stimulation.
Spinal cord stimulation requires a two-phase surgical procedure to place an electrode into the epidural space of the dorsal spinal column. After connecting an electrode to a battery-

powered pulse generator that is surgically implanted, electrical impulses are generated by the device and conveyed to electrodes where a paresthesia, or "tingling" sensation, which is perceived to favorably alter the patient's perception of pain. In phase one, an electrode is inserted with fluoroscopic guidance to guide to the desired level in the spinal column, under local anesthesia. Testing with the temporary electrode is performed as an outpatient to measure the effectiveness and determine adequate positioning. If at least a 50% reduction in pain is reported, the patient returns for permanent electrodes and a generator device. In phase two, the patient is kept awake but sedated, to verify that a permanent implantable SCS provides adequate parasthetic sensation over the affected area. A connector wire is tunneled under the skin and connected to permanent electrodes and to an implantable pulse generator which is inserted into a surgically prepared pocket in the abdomen.

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.[6]

Examples of US Food and Drug Administration (FDA)-approved SCS implantable devices include, but are not be limited to, Protégé, RestoreAdvanced, RestorePrime, Restore Sensor and RestoreUltra Eon, EonC, Eon Mini, Genesis IPG System, Itrel4, Precision Plus SCS System, Precision Spectra, PrimeAdvanced Neurostimulator,. The Restore Sensor SureScan is the first MRI-compatible SCS device approved by the FDA.. The Senza HF-10 SCS is a high-frequency stimulator, the first device to receive FDA approval to treat chronic pain without generating paresthesia.

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.[5] Other investigators reported that SCS provided adequate pain relief in patients with FBSS with predominant LBP and secondary radicular pain.[7, 8] Harney et al report that there is significant evidence to support the SCS in the management of CRPS.[9] 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.[10]

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.[11] 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.[12] In addition, evidence supports SCS placement for the refractory neuropathic pain, CRPS, angina pectoris and critical limb ischemia.[13-15] 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.[16]

III. Spinal Cord Stimulation for Other Indications:

Spinal cord stimulators have also been shown to be effective in the treatment of patients with angina pectoris. For patients with refractory angina pectoris from myocardial ischemia who are not candidates for surgical interventions, implanted SCS are effective in selected patients. If a trial of a temporary SCS is beneficial with a pain reduction of 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. Its beneficial effects are thought to be achieved through an increase in oxygen supply to the myocardium in addition to its analgesic effect.[13, 17]

For cancer pain, investigators evaluated treatment effects and also risks associated with the use of SCS.[18] Analgesic use was largely reduced. The main adverse events were infection of sites of implantation, cerebrospinal fluid (CSF) leakage, pain at the sites of electrodes, dislodgement of the electrodes and system failure, however, the incidence in patients with cancer could not be calculated. Since all trials were non-RCTs, they carried risk of all types of bias. The authors concluded that current evidence is insufficient to establish the role of SCS in treating refractory cancer-related pain. Moreover, they stated that future randomized studies should focus on the implantation of SCS in patients with cancer-related pain.

Inconclusive results in studies for SCS:
Cervical SCS has been used to treat patients with cervical trauma/disc herniation presenting with arm pain, neck pain, and/or cervicogenic headache. However, there is insufficient evidence that cervical SCS is effective for these indications. In a review in 2004, authors concluded that SCS had a positive, symptomatic, long-term effect in cases of refractory angina pain, severe ischemic limb pain secondary to peripheral vascular disease, peripheral neuropathic pain, and chronic low-back pain.[11] Spinal cord stimulation for the treatment of cervical trauma with disc herniation presenting with arm pain, neck pain, and/or cervicogenic headache was not discussed in the review. Results are inconclusive or non-supportive for cervical SCS indications and need to be investigated by well-designed RCTs to determine clinical value.

A systematic review of medical or surgical treatments in patients in chronic vegetative state (VS) or minimally conscious state (MCS) 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.[19] 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.

In a case report, a tripolar SCS provided relief of abdominal and thoracic pain, and improved management of gastro-intestinal tract symptoms.[20] The patient had irritable bowel syndrome (IBS) and was followed-up for 1 year, and his quality of life also was improved via the IBS-Severity Scoring System quality of life tool. The findings of this case study require validation by well-designed randomized, controlled trials. A separate evaluation of 5 cases of chronic pelvic pain had variable presentation (lower abdominal pain rectal) and required different stimulation fields and various leads were used.[21] Inconclusive and limited information are available for standardized and reproducible neuromodulation in visceral pain syndromes. Scientific evaluation by RCT are lacking, and given the heterogeneous nature of visceral pain, patient selection for adequately powered RCTs will be a challenge. Sacral

nerve root neuromodulation for bladder related symptoms have only observational results published.

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.

CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 07/26/2016
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G. 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.