Spinal Cord Stimulation, Implanted

Policy Number: HS-115

Original Effective Date: 7/16/2009


APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

American Association of Neurological Surgeons

Spinal cord stimulation (SCS) is a pain relief technique that delivers a low-voltage electrical current continuously to the spinal cord to block the sensation of pain. SCS is the most commonly used implantable neurostimulation technology for management of pain syndromes. SCS is a widely accepted FDA-approved medical treatment for chronic pain of the trunk and limbs (back, legs and arms). Three SCS device types include:

- Conventional systems require little effort on the patient’s part for maintenance. However, a minor surgical procedure is required to replace the power source when it runs out.
- Radiofrequency systems are designed to sustain therapy over long periods at the highest output level.
Because of its high power capabilities, the RF system is suitable for the most challenging cases in which there is complex, multi-extremity pain. With this type of system, the patient must wear an external power source to activate stimulation.

- Rechargeable systems are the newest type of SCS device. The patient is responsible for recharging the power source when it runs low. A rechargeable system typically lasts longer than a conventional system. Eventually a minor surgical procedure may be required to replace the power source if the time between recharges becomes impractical.

Patients being considered for SCS should ideally meet the following criteria:

- Pain is not associated with malignancy
- Poor response to conservative treatment for a minimum of six months
- Revision surgery not an option or would have a low chance of success
- No pacemaker or other medical contraindications
- No major psychiatric disorders, including somatization
- Willingness to stop inappropriate drug use prior to implantation
- No related litigation
- Ability to give informed consent for the procedure

In addition the member should have a mental health evaluation by a psychiatrist or psychologist to determine any relative contraindications. Mental competency and understanding of the nature, extent and possible complications of the surgery, and ability to participate in pain management strategies are needed to ensure a successful outcome of surgery.

A clinical assessment is appropriate to screen for relative contraindicated conditions. If psychological testing is used as a component of the assessment, a total of 2 hours of psychological testing will be approved. For additional information, please reference HS: 203 Use and Approval of Psychological Testing.

Relative contraindicated diagnoses include:

- a. Active drug abuse
- b. Active suicidal ideation
- c. Self-destructive or suicidal behavior (e.g., ideation, plan, attempt)
- d. Borderline personality disorder
- e. Schizophrenia
- f. Psychotic disorder
- g. Uncontrolled depression
- h. Somatic Symptom Disorder (with Predominant Pain)
- i. Defined non-compliance with previous medical care
- j. Psychiatric hospitalizations in past year

Current outpatient psychotherapy, including medications, should also be reviewed with respect to the member’s length of stability, frequency of follow up visits, and/or the need for possible titration or reevaluation of the current medication regimen prior to the surgical procedure.

Information should be obtained from the member’s provider(s) regarding the member’s emotional stability, coping skills, psychological resources and ability to manage life stressors, impulse control issues and compulsions, as well as the client’s capacity to follow directions and adhere to self-management guidelines. The impact of surgery should also be discussed in terms of symptom resolution and potential exacerbation. Medication issues post-surgery should be taken into consideration as some medications may affect pain thresholds and management.

If a member is a suitable candidate for SCS, often the first step is to implant a device on a trial basis. During the trial phase, a lead or leads are implanted temporarily and are connected to a trial spinal cord stimulator. The trial stimulator is programmed with one or more stimulation programs customized to the specific areas of the member’s pain. The trial phase can be beneficial for the following reasons:
• Allows member/provider to analyze whether SCS effectively relieves pain
• Provides member/provider with assessment period to determine which type of SCS technology works best
• Enables the member/provider to evaluate different stimulation settings and programs

If the SCS trial provides adequate pain relief, then a permanent system may be implanted. SCS is a reversible therapy, so even though it is called permanent, treatment can be discontinued at any time and the implanted parts turned off or removed.

Neurological Treatment Uses for SCS include: Arachnoiditis, Complex Regional Pain Syndrome (CRPS), Failed-Back Surgery Syndrome (FBSS), Post-Laminectomy Syndrome (lumbar or cervical), or Nerve Damage, Neuropathy or Neuritis.

Neuropathic pain is generated and perpetuated by the nervous system itself, without any ongoing stimuli from injury. Examples of this type of pain include diabetic neuropathy, postherpetic neuralgia, phantom limb pain, trigeminal neuralgia, failed back surgery syndrome (FBSS), and complex regional pain syndrome (CRPS) Type I. In most cases, neuropathic pain responds poorly to standard pharmacological and surgical therapies, can last indefinitely with an increasing severity over time, and often results in severe disability. Spinal cord stimulation (SCS) for the treatment of neuropathic pain involves surgical implantation of electrodes in the epidural space. In theory, passage of electrical currents through the spinal column disrupts the transmission of pain signals in stimulated spinal nerves and may activate pain inhibitory mechanisms. After a trial period to ensure that SCS provides sufficient pain relief, an adjustable, battery-powered pulse generator is implanted surgically and connected to the electrodes. This assessment focuses primarily on neuropathic pain associated with FBSS and on CRPS Type 1.5

Temporary Percutaneous Electrode Placement5,6,7,8

During the first phase of the spinal cord stimulation (SCS) implantation procedure, a local anesthetic is given, and an electrode unit is inserted via a Tuohy needle into the epidural space. Fluoroscopy is used to guide the placement of electrodes to the desired level in the spinal column so that paresthesias will cover the anatomical region that is the source of neuropathic pain. For the next 1 to 3 days, extensive testing with the temporary electrode is performed to measure effectiveness and determine adequate positioning. Some members are released from the hospital on the second day and permitted to test the temporary unit at home for a period of 2 days to several months. After a report of at least 50% reduction in pain, the member is returned to surgery for implantation of a permanent pulse generator.

Permanent Electrode Placement and Implantation of the Pulse Generator5,6,7,8

During the second phase of the SCS implantation procedure, permanent electrode placement is performed in a surgical suite under a combination of local anesthetic and intravenous sedation. The member is kept awake during the procedure to help guide electrode placement and to ensure that SCS provides adequate paresthetic coverage over the affected area. Internalization of the SCS unit is preceded by the connection of the lead to an extension wire tunneled subcutaneously to an implantable pulse generator, which is inserted in a surgically prepared subcutaneous pocket in the abdominal wall. Electrodes may be implanted percutaneously, but those implanted via laminotomy or minilaminectomy generally result in fewer technical problems (e.g., lead migration), exhibit superior paresthesia coverage, and require half the power expenditure. After implantation and an x-ray to confirm the position of the electrode, members are discharged from the hospital; however, they return to an outpatient clinic for suture removal after the incisions are sufficiently healed (Hayes, 2009).

SCS is endorsed by the American Academy of Pain Medicine, the American Society of Interventional Pain Physicians, Institute for Clinical Systems Improvement and the National Institute for Health and Clinical Excellence.5,10,11,12
POSITION STATEMENT

Applicable To:
- Medicaid – Hawaii
- Medicare – California (Easy Choice), Hawaii

NOTE: For all other lines of business, please refer to the current contracted vendor for Musculoskeletal Management requests.

Coverage

Spinal cord stimulation of the dorsal column is considered medically necessary for the relief of chronic (greater than six months) intractable pain caused by the following conditions:

- Lumbosacral arachnoiditis that has not responded to medical management including physical therapy (NOTE: Presence of arachnoiditis is usually documented by presence of high levels of proteins in the cerebrospinal fluid and/or by myelography or magnetic Resonance Imaging); OR,
- Post-surgical or post-traumatic nerve root injuries, including post-laminectomy syndrome (failed back surgery syndrome [FBSS]); OR,
- Complex regional pain syndrome I and II; OR,
- Phantom limb syndrome that has not responded to medical management; OR,
- 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; OR,
- Post-herpetic neuralgia; OR,
- Plexopathy; OR,
- Intercostal neuralgia that did not respond to medical management and nerve blocks; OR,
- Cauda equine injury; OR,
- Incomplete spinal cord injury.

Spinal cord stimulation of the dorsal column is considered medically necessary for the relief of chronic intractable pain caused by the above conditions if ALL of the following criteria are met:

- The implantation is used as a last resort for members with chronic intractable pain; AND,
- Other treatment modalities (pharmacological, surgical, physical) have been tried for a minimum of six months and did not prove satisfactory or are considered unsuitable or contraindicated for the given member; AND,
- Further surgical intervention is not indicated; AND,
- Psychological evaluation has been obtained and there is documentation clearly stating the pain is not psychologic in origin, and psychological contraindications are present; AND,
- Member understands the risks, benefits, and alternatives to the procedure as well as post-operative care needs; AND,
- No contraindications to implantation exist such as sepsis or coagulopathy; AND,
- There has been a clear demonstration of pain relief (50% reduction) on a 3 to 7 day trial with a temporarily implanted electrode preceding permanent implantation.

Per CMS9,10 Local Coverage Determinations for Hawaii and South Carolina specify that reimbursement is allowed for placement of a maximum of 2 leads or 16 “contacts”, and for 2 SCS trials per anatomic spinal region per patient per lifetime. If a trial fails, a repeat trial is not appropriate unless there are extenuating circumstances that lead to trial failure. Appropriate medical documentation to support a repeat trial can be sent on appeal.

CODING

Covered CPT® Codes
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 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, when performed
63664  Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685  Insertion or replacement 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 (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971  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 spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
95973+  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); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour
+List separately in addition to code for primary procedure, i.e. Use 95973 in conjunction with 95972.
95980  Electronic analysis of implanted neurostimulator pulse generator system (eg, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative with programming.
95981  Electronic analysis of implanted neurostimulator pulse generator system (eg, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming.
95982  Electronic analysis of implanted neurostimulator pulse generator system (eg, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming.

Note: 63660 deleted for 2010. To Report, see 63661 – 63664.

Covered HCPCS Codes
C1767  Generator, neurostimulator (implantable), non-rechargeable
C1778  Lead, neurostimulator (implantable)
C1787  Patient programmer, neurostimulator
C1820  Generator, neurostimulator (implantable), with rechargeable battery and charging system
L8680  Implantable neurostimulator electrode, each
L8681  Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
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, non-rechargeable, includes extension
L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689  External recharging system for implanted neurostimulator, replacement only
L8695  External recharging system for battery (external) for use with implantable neurostimulator

Covered ICD-10-CM Diagnosis Codes

**Primary Diagnosis Code**

G89.18  Other acute postprocedural pain  
G89.21  Chronic pain due to trauma  
G89.22  Chronic post-thoracotomy pain  
G89.28  Other chronic postprocedural pain  
G89.29  Other chronic pain

**Secondary Diagnosis Code**

B02.0  Zoster encephalitis  
B02.22  Postherpetic trigeminal neuralgia  
B02.29  Other postherpetic nervous system involvement  
E08.44  Diabetes mellitus due to underlying condition with diabetic amyotrophy  
E09.44  Drug or chemical induced DM with neurological complications with diabetic amyotrophy  
E10.44  Type 1 diabetes mellitus with diabetic amyotrophy  
E11.44  Type 2 diabetes mellitus with diabetic amyotrophy  
E13.44  Other specified diabetes mellitus with diabetic amyotrophy  
G03.0  Nonpyogenic meningitis  
G03.9  Meningitis, unspecified  
G50.0  Trigeminal neuralgia  
G54.0  Brachial plexus disorder  
G54.1  Lumbosacral plexus disorders  
G54.5  Neuralgic amyotrophy  
G54.6 - G54.7  Phantom limb syndrome  
G54.8  Other nerve root and plexus disorders  
G56.40 - G56.42  Causalgia of upper limb (CRPS II)  
G57.70 - G57.72  Causalgia of lower limb (CRPS II)  
G83.4  Cauda equina syndrome  
G90.50 - G90.59  Complex regional pain syndrome I (CRPS I)  
I73.89  Other specified peripheral vascular diseases  
I79.8  Other disorders of arteries, arterioles and capillaries in diseases classified elsewhere (Code first the underlying disease)  
M96.1  Postlaminectomy syndrome, not elsewhere classified  
S14.151S - S14.159S  Other incomplete lesions of cervical spinal cord  
S24.151S - S24.151S  Other incomplete lesions of thoracic spinal cord

Covered ICD-10-PCS Codes

00HU3MZ-00HU4MZ  M/S, CNS, Insertion, spinal canal, percutaneous, neurostimulator lead  
00PU3MZ-00PU4MZ  M/S, CNS, Removal, spinal canal, percutaneous, neurostimulator lead  
0JH63BZ - 0JH63EZ  M/S, Subcutaneous, Insertion, percutaneous, Stimulator Generator, Single/Multiple Array  
0JH63MZ  M/S, Subcutaneous, Insertion, percutaneous, Stimulator Generator  
0JH83BZ - 0JH83EZ  M/S, Subcutaneous, Insertion, percutaneous, Stimulator Generator, Single/Multiple Array  
0JH83MZ  M/S, Subcutaneous, Insertion, percutaneous, Stimulator Generator  
00WU3MZ-00WU4MZ  M/S, CNS, Revision, percutaneous, Neurostimulator lead

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

**REFERENCES**

2. Doly DM. Psychological factors in spinal cord stimulation therapy: brief review and discussion. Neurosurg Focus. 2006;21(6)


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>11/1/2018, 12/7/2017</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>4/6/2017</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>1/12/2017, 8/6/2015, 8/7/2014</td>
<td>Approved by MPC, additional psych testing criteria and information added.</td>
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<tr>
<td>8/9/2013</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>6/7/2012</td>
<td>Reinstated for markets where CareCore is not a vendor.</td>
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<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
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<td>8/2/2011</td>
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