

Spinal Cord Electrical Stimulator (Spinal cord stimulator (SPS) and Dorsal Motor Ganglion Stimulator (DMG), Surgical 69

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<u>Coverage Policy</u>	Surgical 69
<u>Version</u>	6

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Spinal Cord Electrical Stimulator (Spinal cord stimulator (SPS) and Dorsal Motor Ganglion Stimulator (DMG).

Description & Definitions:

A **Dorsal column stimulator** is a device which stimulates nerves by tiny electrical impulses via small electrical wires implanted on the dorsal area of the spinal cord to interrupt pain signals to the brain.

A **Spinal cord stimulator** is a device which uses implanted electrodes to deliver electrical stimulation in the epidural space of the spinal column to disguise signals of pain to the brain.

Spinal Cord Stimulation (also known as dorsal column stimulation or neuromodulation): a reversible therapy applied for neuropathic pain with techniques that include multi-output implanted pulse generators and a choice of electrodes, some of which can be placed percutaneously. A traditional dorsal column stimulator (i.e., non-high-frequency) generally produces a pulse width between 20-1000 µs and frequencies between 2 and 1200 Hz. Some devices allow adjustment of the settings, including burst- and/or continuous-mode stimulation.

High-frequency spinal cord stimulation, (also referred to as kilohertz frequency spinal cord stimulation or HF10): a type of spinal cord stimulation (SCS) providing a higher frequency than traditional spinal cord stimulator systems. It uses low-amplitude, high-frequency, and short-duration pulses.

Dorsal root ganglion (DRG) stimulation: an emerging method of treatment for neuropathic pain. With DRG stimulation leads are placed percutaneously into the epidural space under fluoroscopic guidance directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine.

- non-high-frequency or high-frequency

Criteria:

Spinal cord electrical stimulators are considered medically necessary for **1 or more of the following**:

- Trial spinal cord electrical stimulators devices for individuals with indications of **all of the following**:
 - Indications of **1 or more of the following**:
 - Failed back surgery syndrome (FBSS) with low back pain and significant radicular pain
 - Intractable pain caused by complex regional pain syndrome (CRPS)
 - Intractable pain caused by phantom limb syndrome that has not responded to medical management
 - Intractable pain caused by plexopathy
 - Intractable pain caused by cauda equina injury
 - Intractable pain caused by incomplete spinal cord injury
 - Inoperable chronic ischemic limb pain from peripheral vascular disease
 - Neuropathic pain due to Diabetes or inoperable critical limb ischemia
 - Chronic back pain or neck pain with **ALL of the following**:
 - Individual with chronic back or neck pain who are considered inoperable
 - Documentation of at least 12 months of trial and failure of standard therapy (including non-steroidal anti-inflammatory drugs, tricyclic antidepressants, and anticonvulsants)
 - Individual with intractable angina has angiographically documented significant coronary artery disease with **ALL of the following**:
 - Individual not suitable for revascularization procedures such as coronary artery bypass grafting or percutaneous transluminal coronary angioplasty
 - Individual has had optimal pharmacotherapy for at least one month including maximal tolerated dosages of **2 or more of the following**:
 - Anti-anginal medications
 - Long-acting nitrates
 - Beta-adrenergic blockers
 - Calcium channel antagonists
 - Individual's angina pectoris is New York Heart Association Functional Class III or Class IV
 - Reversible ischemia is documented by symptom-limited treadmill exercise test
 - Documentation of unresponsive trial of conservative therapies such as medications, physical therapy, surgery, psychological therapy or other modalities for at least 6 months
 - Documentation of no active substance abuse issues
 - Documentation of proper patient education, discussion, and disclosure including an extensive discussion of the risks and benefits of this therapy
 - Individual has the ability to understand and operate the device
 - Favorable psychological evaluation, absence of untreated psychiatric comorbidity, or current treatment in multidisciplinary pain management program
 - No cardiac pacemaker or implantable defibrillator
 - No coagulopathy, anticoagulant or antiplatelet therapy, or thrombocytopenia (ie, platelet count of less than 75,000/mm³ (75 x10⁹/L))
 - No current or chronic infection
- **Implanted spinal cord or dorsal motor ganglion electrical stimulators** with indications of **ALL of the following**:
 - Indications of **1 or more of the following**:
 - Failed back surgery syndrome (FBSS) with low back pain and significant radicular pain
 - Intractable pain caused by complex regional pain syndrome (CRPS)

- Intractable pain caused by phantom limb syndrome that has not responded to medical management
- Intractable pain caused by plexopathy
- Intractable pain caused by cauda equina injury
- Intractable pain caused by incomplete spinal cord injury
- Inoperable chronic ischemic limb pain from peripheral vascular disease
- Neuropathic pain due to Diabetes or inoperable critical limb ischemia
- Chronic back pain or neck pain with **ALL of the following**:
 - Individual with chronic back or neck pain who are considered inoperable
 - Documentation of at least 12 months of trial and failure of standard therapy (including non-steroidal anti-inflammatory drugs, tricyclic antidepressants, and anticonvulsants)
- Individual with intractable angina has angiographically documented significant coronary artery disease with **ALL of the following**:
 - Individual not suitable for revascularization procedures such as coronary artery bypass grafting or percutaneous transluminal coronary angioplasty
 - Individual has had optimal pharmacotherapy for at least one month including maximal tolerated dosages of **2 or more of the following**:
 - Anti-anginal medications
 - Long-acting nitrates
 - Beta-adrenergic blockers
 - Calcium channel antagonists
 - Individual's angina pectoris is New York Heart Association Functional Class III or Class IV
 - Reversible ischemia is documented by symptom-limited treadmill exercise test
- Documentation of successful completion of a trial with percutaneous spinal stimulator, after meeting criteria for trial
- Individual has the ability to understand and operate the device
- No cardiac pacemaker or implantable defibrillator
- No coagulopathy, anticoagulant or antiplatelet therapy, or thrombocytopenia (ie, platelet count of less than 75,000/mm³ (75 x10⁹/L))
- No current or chronic infection
- Documentation of no active substance abuse issues
- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain
- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient
- Individuals have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation
- Short trial with percutaneous implantation of neurostimulator electrode(s) in epidural space for assessing patient's suitability for ongoing treatment. (A successful trial should be associated with at least a 50% reduction of target pain, or 50% reduction of analgesic medications, and show some element of functional improvement. (Patients with reflex sympathetic dystrophy may show lower levels of improvement since it takes longer periods for improvement than the typical one to two week trial)).

Spinal Cord Stimulation is considered not medically necessary for any use other than those indicated in clinical criteria, to include but not limited to:

- Repeat trials are not considered medically necessary unless appropriate medical documentation proves there was an extenuating circumstance that led to trial failure
- Cephalgia
- Headache of any etiology
- Inguinal pain
- Occipital neuralgia
- Trigeminal neuralgia
- Spasticity
- Cervical spinal cord stimulation for the treatment of cervical trauma, disc herniation, failed cervical spine surgery syndrome presenting with arm pain, neck pain, and/or cervicogenic headache, radiation-induced brain injury, or stroke
- Implantable epidural spinal cord stimulation (both temporary and permanent) as a treatment of critical limb ischemia as a technique to forestall amputation
- Implantable subcutaneous target stimulator devices (both temporary and permanent) for all indications

Dorsal Column Stimulation is considered not medically necessary for any use other than those indicated in clinical criteria, to include but not limited to:

- Chronic malignant pain
- Other chronic non-malignant neuropathic pain (e.g., cephalgia, diabetic neuropathy, headache, inguinal pain occipital neuralgia, phantom limb syndrome, and trigeminal neuralgia) that does not meet the clinical indications below
- Spasticity
- Critical limb ischemia as a technique to forestall amputation
- Chronic vegetative state or minimally conscious state
- Irritable bowel syndrome

The combined use of dorsal column stimulation and dorsal root ganglion stimulation for the treatment of complex regional pain syndrome or any other indications are not medically necessary.

Coding:

Medically necessary with criteria:

Coding	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
L8680	Implantable neurostimulator electrode, each
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

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2024: March
- 2020: March, April
- 2015: September
- 2013: September
- 2012: August
- 2011: March, May, September
- 2008: October
- 2006: October
- 2005: January
- 2002: September

Reviewed Dates:

- 2023: March
- 2022: April
- 2021: March
- 2018: November
- 2017: January
- 2015: June
- 2014: September
- 2010: September
- 2009: September
- 2008: January
- 2007: December
- 2006: February
- 2004: October
- 2003: October

Effective Date:

- December 2000

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Spinal Cord Stimulation and Dorsal Column Stimulation, SHP Surgical 69, chronic intractable pain, peripheral vascular disease, reflex sympathetic dystrophy, complex regional pain syndrome, radicular pain, low back pain, phantom limb syndrome, plexopathy, cauda equina injury, spinal cord injury, coronary artery disease, angina pectoris, New York Heart Association Functional Class III, New York Heart Association Functional Class IV, Complex regional pain syndrome, CRPS, Failed back surgery syndrome, FBSS, Neuropathic pain, Diabetes, inoperable critical limb ischemia, dorsal motor ganglion electrical stimulators, Spinal cord stimulator (SCS), Dorsal column stimulators (DCS), Dorsal Motor Ganglion Stimulator (DMG), dorsal root ganglion stimulation (DRGS)