



Epidural Spinal Cord Stimulator

Spine, Pain and Joint (SPJ) Utilization Management Policy

Effective Date: 06/13/2024

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Policy Statement

Members may be eligible under the plan for lumbar/thoracic spinal cord stimulators when the following criteria are met:

- Failed back surgery syndrome (FBSS) with primarily radicular pain; OR
- Inoperable chronic critical limb ischemia; OR
- Reflex sympathetic dystrophy (RSD)/complex regional pain syndrome (CRPS) of the extremities

Members may not be eligible under the plan for lumbar/thoracic spinal cord stimulators for any indications other than those listed above including, but not limited to the following:

- Chronic visceral abdominal pain
- Pain and ischemia from peripheral vascular disease (PVD)
- Subcutaneous placement of electrical stimulator electrode arrays
- Peripheral nerve stimulation except surgical placement along trigeminal nerve divisions but not it's branches
- Ventral sacral nerve roots (by placing electrodes close to S2, S3, S4 sacral nerve roots) for pain including but not limited to spinal, chronic pelvic, and abdominal pain
- Vagus nerve stimulation for pain
- Hypoglossal nerve stimulation to treat chronic pain states caused by obstructive sleep apnea
- Gastric electrical stimulation for abdominal pain
- P-STIM® (and its substantially equivalent FDA approved medical devices)
- Occipital nerve stimulation for headache and facial pain
- Combined occipital and supra-orbital nerve stimulation for facial pain or headaches including but not limited to migraines
- TENS (transcutaneous electrical nerve stimulation) for chronic low back pain
- Functional electrical stimulation for disuse atrophy or pain caused by gait disorders in spinal cord injured persons
- Neuromuscular Electrical Stimulation (NMES) for the treatment of neurologic or orthopedic (e.g., scoliosis) or other abnormalities including pain
- Interferential therapy
- Pulsed Electrical Stimulation (PES) for pain including osteoarthritis
- Pudendal nerve stimulation for pudendal neuralgia or “cyclist syndrome”
- Microcurrent Electrical Nerve Stimulation (MENS)
- H-wave stimulation
- Percutaneous Neuromodulation Therapy (PNT)
- Scrambler therapy/ Calmare pain therapy
- Transdermal neuromodulation (e.g., Nometex)
- Transcutaneous electrical acupoint stimulation
- Sympathetic therapy (e.g., Dynatron) or high voltage pulsed galvanic stimulation
- Electroceutical therapy
- Percutaneous Electrical Nerve Stimulation (PENS)
- Therapeutic magnetic resonance (high frequency pulsed electromagnetic stimulation)
- Pelvic floor stimulation for pelvic pain
- Electro Acuscope Myopulse therapy
- Intramuscular electrical stimulation
- Electro-analgesia treatment (EAT) with or without peripheral nerve blocks for any indication
- Electrical stimulation for Xerostomia (dry mouth) of any etiology
- Transcranial Magnetic Stimulation (TMS) and cranial electrical stimulation
- Any combination of the above
- Treatment of chronic stable angina pectoris

Simultaneous use of SCS with programmable pump therapy is contraindicated (CMS, 2005).

Replacement/upgrade of a spinal cord stimulator may not be considered medically necessary unless the existing device malfunctions and cannot be repaired or replacement is required due to a change in the member's condition that makes the present device non-functional. Note: Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life. SCS device battery replacement is indicated for battery malfunctioning based on technical analysis of the system with formal telemetry documented. Lead replacement may not be considered medically necessary without documentation of lead malfunction by telemetry or imaging showing displacement or lead fracture.

It is not medically necessary to replace a SCS battery for a device that has not been offering pain relief to the member unless there are extenuating circumstances which can be remedied by the provider (e.g., wire revision to correct abnormal positioning or impedances). Battery replacement with a system that offers a different mode of stimulation is not medically necessary under any circumstance unless the member has had a trial of SCS with the system to be implanted.

Maximum number of trials is two per lifetime.

An Epidural Spinal Cord Stimulator is not the same as Dorsal Root Ganglion Stimulation.

This technology is considered experimental/investigational or not medically necessary if it is not utilized in accordance with nationally recognized standards of medical practice and/or identified as safe, widely used, and generally accepted as effective for the proposed use as reported in nationally recognized peer-reviewed medical literature.

Members may not be eligible under the plan for cervical spinal cord stimulators for any indication. This technology is considered experimental/ investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature.

The use of spinal cord stimulators is contraindicated for individuals with cardiac pacemakers and/or defibrillator unless otherwise medically cleared by a cardiologist (ACC, 2012).

The use of an epidural spinal cord stimulator is considered not medically necessary prior to the achievement of established goals in certain instances including but not limited to:

- The patient or family declines to continue treatment.
- The patient is unable to continue making progress toward goals secondary to medical or psychosocial complications.
- Objective clinical data demonstrates the patient is not benefiting from skilled therapeutic intervention as evidenced by minimal or no significant measurable change in a reasonable time frame. This will be related to appropriate clinical measures that are patient and diagnosis specific.
- Following a reasonable period of therapeutic intervention, it is evident a negative trend has occurred in some or all of the relevant objective functional data. Generally accepted standards of practice suggest that therapy be suspended at this time and medical re-evaluation performed.
- The member is significantly non-adherent with their specific therapeutic protocol. This includes but it not limited to:
 - Insufficient attendance at therapy sessions as outlined by the therapist's plan of care.
 - Not appropriately involved during treatment.
 - Non-compliance with therapist instructions related to:
 - Home exercise program.
 - Activity and environmental modification to prevent re-injury or re-inflammation.
 - Self-management of symptoms or acute episodes.

In addition to these general criteria, individual benefit plan contracts may vary. The member's specific contract language will govern all final determinations. Some common circumstances that are not eligible for benefit coverage under many plans include therapy to return to specific vocational and/or occupational activities.

Scope

All in and out of network programs where utilization review determinations are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum on the reporting of epidural spinal cord stimulator services.

Background

A spinal cord stimulator (SCS), also known as an Epidural (dorsal) column stimulator (DCS), is an implantable medical device used to treat chronic pain. A SCS is most commonly used for the management of failed back surgery syndrome and the treatment of reflex sympathetic dystrophy (RSD) (also known as complex regional pain syndrome), though it has also been proposed for other indications.

Spinal cord stimulation requires a surgical procedure, conducted in two phases, to place an electrode into the epidural space of the spinal column. The electrode is then connected to a pulse generator (battery) that is surgically implanted. An electrical impulse generated by the device travels to the electrodes where it creates a “tingling” sensation (paresthesia) which is thought to alter the perception of pain by the patient.

There are 4 neural structures that can be targeted for direct electrical neurostimulation and have been documented as safe and effective:

- Intact globus pallidus and subthalamic nucleus (placing electrode arrays deep into the brain)
- Intact posterior funiculus (gracilis) or the dorsal columns of the thoraco-lumbar spinal cord (placing electrode arrays into the epidural dorsal space) for intractable pain caused by neuropathic lesion of either axonotmesis or neurotmesis type nerve injury under Seddon classification or 2nd through 5th degrees under Sunderland classification.
- Vagus nerve (placing electrode array along the extracranial part of the vagus nerve)
- Ventral sacral nerve roots (placing electrode array through neuroforamen of S2, S3 or S4 sacral nerve roots)

The only electrical stimulation relevant for chronic intractable pain is the funiculus gracilis or epidural dorsal column stimulation.

Description

Indications for coverage

Temporary Percutaneous Electrode Placement

In the first phase, a local anesthetic is given, and an electrode is inserted with the assistance of fluoroscopy to guide the electrodes to the desired level in the spinal epidural space. Over the next two to three days extensive 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 the second phase of permanent implanted electrodes and generator device (Garcia et al., 2024).

Permanent Electrode Placement and Implantation of a Pulse Generator

In the second phase, the patient is kept awake, though sedated, during the procedure to help guide epidural electrode placement and ensure that the SCS provides adequate paresthesia (tingling) sensation over the affected area. Permanent electrodes are placed; a connector wire is tunneled under the skin and connected to an

implantable pulse generator which is inserted into a surgically prepared pocket in the abdomen (Garcia et al., 2024).

Documentation requirement

Pre-op

- Presence of an indication. For failed back surgery indication- presence of intractable pain caused by a neuropathic lesion of either axonotmesis or neurotmesis type nerve injury under Seddon classification or 2nd through 5th degrees under Sunderland classification. In its absence, a letter of medical necessity from a spine surgeon stating no further spine surgery is indicated for pain.
- For CRPS diagnosis-independent evaluation from a neurologist in addition to a comprehensive pain evaluation by the pain specialist, anesthesiologist, physiatrist, neurosurgeon, podiatrist, or orthopedist.
- Physical exam clearly showing the presence of an intact and normally functioning dorsal column.
- Choice of SCS battery and electrode based on needs of the medical condition being treated and the ability of the member to properly maintain the device.

Intra-op

- Performed either under fluoroscopic guidance or CT guidance in prone posture.
- Patient is fully awake during the key portion (stimulation mapping of pain location) of the procedure whether it is trial or permanent implantation.

Post-op

- Reprogramming in supine, sitting, and standing postures confirm that SCS induced paresthesia continue to be concordant to the pain pattern and is able to satisfactorily manage or control the chronic intractable pain symptoms.

Temporary Trial

A temporary trial of lumbar/thoracic epidural spinal cord stimulation may be covered for any of the conditions listed above when all of the following criteria are met:

- Implantation of the stimulator is used only as a late (if not last) resort for patients with chronic intractable pain

AND

- Other treatment modalities (pharmacological, surgical, physical, psychological, and injection therapies) have been tried and did not provide satisfactory pain control.

AND

- Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to stimulator trial (screening must include psychological and physical evaluations).

AND

- Pain focused face to face psychological evaluation has been obtained and indicates the member is a favorable candidate for permanent spinal cord stimulation.

Permanent Implantation

Permanent implantation of a lumbar/thoracic spinal cord stimulator may be covered when a temporary trial has been successful as defined by:

- A temporary trial of at least three days duration has been undertaken with all the criteria listed above met

AND

- Demonstration of at least a 50% reduction in pain and improved function with the temporarily implanted electrode prior to the permanent implantation.

Coding Information

Note: The Current Procedural Terminology (CPT) codes listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member's benefit document.

Code	Description
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
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	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
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

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Review and Approval History

Date	Description
4/27/2023	Quality Improvement Committee approved activation of the policy.
06/12/2024	Annual review. Content transferred to new template. Approval by Optum Clinical Advisory Committee.
06/13/2024	Approved by OrthoNet Quality Improvement Committee (QIC).