OPTUM®

Utilization Management Policy

Epidural Spinal Cord Stimulator

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Related Policies

Facet Joint Block Injection
Epidural Steroid Injection
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Policy Number	**494**
Original Effective Date:	4/27/2023
Current Approval Date:	4/27/2023
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Category:	Determinations

Policy Statement

The appropriate use of epidural spinal cord stimulators can be described by the following:

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)

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

- Chronic visceral abdominal pain; **OR**
- Pain and ischemia from peripheral vascular disease (PVD); OR
- Subcutaneous placement of Electrical Stimulator Electrode arrays OR
- Peripheral Nerve Stimulation except surgical placement along Trigeminal Nerve divisions but not its branches OR
- 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 OR
- Vagus nerve stimulation for PAIN OR
- Hypoglossal nerve stimulation to treat chronic pain states caused by Obstructive sleep apnea OR
- Gastric electrical stimulation for abdominal pain OR
- P-STIM® (and its substantially equivalent FDA approved medical devices) OR
- Occipital nerve stimulation for headache and facial pain OR
- Combined occipital and supra-orbital nerve stimulation for facial pain or headaches including but not limited to migraines OR
- TENS (transcutaneous electrical nerve stimulation) for chronic low back pain OR
- Functional electrical stimulation for disuse atrophy or pain caused by gait disorders in spinal cord injured persons OR

- Neuromuscular Electrical stimulation (NMES) for the treatment of neurologic or orthopedic (e.g., scoliosis) or other abnormalities including pain OR
- Interferential therapy OR
- Pulsed electrical stimulation (PES) for pain including osteoarthritis OR
- Pudendal nerve stimulation for pudendal neuralgia or "cyclist syndrome" OR
- Microcurrent electrical nerve stimulation (MENS) OR
- H-wave stimulation OR
- Percutaneous neuromodulation therapy (PNT) or
- Scrambler therapy/ Calmare pain therapy OR
- Transdermal neuromodulation (e.g., Nometex) OR
- Transcutaneous electrical acupoint stimulation OR
- Sympathetic therapy (e.g., Dynatron) or High voltage pulsed galvanic stimulation OR
- Electroceutical therapy OR
- Percutaneous electrical nerve stimulation (PENS) OR
- Therapeutic magnetic resonance (high frequency pulsed electromagnetic stimulation) OR
- Pelvic floor stimulation for pelvic pain OR
- Electro Acuscope Myopulse therapy OR
- Intramuscular electrical stimulation OR
- Electro-analgesia treatment (EAT) with or with without peripheral nerve blocks for any indication OR
- Electrical stimulation for Xerostomia (dry mouth) of any etiology OR
- Transcranial magnetic stimulation (TMS) and cranial electrical stimulation OR
- Any combination of the above

Simultaneous use of SCS with programmable pain pump therapy (please refer to Implantable Infusion Pumps Medical Coverage Policy); **OR**

- Treatment of chronic stable angina pectoris; **OR**

- 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.

****Maximum number of trials per lifetime is TWO
for each of the 3 Indications

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 published in the English language.

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 published in the English language.

Note: The use of spinal cord stimulators is ***specifically contraindicated*** for individuals with cardiac pacemakers and/or defibrillator unless otherwise medically cleared by a Cardiologist.

The use of an epidural spinal cord stimulator may no longer be appropriate prior to the achievement of established goals in certain instances (these include but are not limited to):

- The patient or family (if relevant) declines to continue treatment.
- The patient is unable to continue to make progress towards goals secondary to medical or psychosocial complications.
- Objective clinical data demonstrates that 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 appropriate therapeutic intervention, it is evident that 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 appropriate medical re-evaluation performed.
- The member is significantly non-adherent with their specific therapeutic protocol. This includes, but is 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:
    i. Home exercise program.
    ii. Activity and environmental modification to prevent re-injury or re-inflammation.
    iii. 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.

Purpose

This process document describes Optum* by OptumHealth Care Solutions, LLC methodology and requirements for the appropriate and safe application of epidural spinal cord stimulators.

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.

Definitions

Appropriateness:

**Optum's clinical criteria incorporate measures of function, range of motion, strength, pain and other relevant factors (as described more fully below), which will be determined through utilization review that is based on the needs of the individual patient and the characteristics of the local delivery system.*

A procedure will be determined to be appropriate for authorization for a patient based on his/her particular clinical history, current clinical status (including objective and subjective data) and the established nature of their diagnosed or presumed clinical condition(s).

Discharge criteria, where appropriate, will have been met [and as such no additional authorizations will be provided] when these measurements and key clinical information, taken as a whole, indicate the member is able to reasonably perform physical tasks related to self-care, home management, and basic activities of daily living, or has reached a plateau in making progress towards these goals. In some clinical circumstances a maintenance or periodic plan of treatment is considered appropriate and may be authorized in accordance with the specifics of the criteria herein.

Unless specifically covered by the member's benefit, covered treatment goals exclude return to sport, recreational or vocational activities. As part of the treatment plan, it is the responsibility of the treating practitioners to instruct the member in the early part of the treatment program, and certainly prior to discharge, in a comprehensive home activity and exercise program, and to set the expectation for the patient's responsibility to perform their exercise or self-care regimen between treatments (when a series is performed) and to maintain an appropriate post-discharge exercise and self-care/activity regimen. These criteria are derived from recognized professional standards that may include those from the American Medical Association, the American Pain Society, American Academy of Orthopedic Surgeons, the North American Spine Society, the Centers for Medicare and Medicaid Services, the American Physical Therapy Association and other recognized clinical organizations.

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:

1. Intact globus pallidus and subthalamic nucleus (placing electrode arrays deep into the brain)

2. 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.

3. Vagus nerve (placing electrode array along the extracranial part of the vagus nerve)

4. 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.

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 parasthetic (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.

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 any 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, and 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 as well as physical evaluations); **AND**
- Pain focused face to face psychological evaluation has been obtained and indicates that 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. Successful is defined as:

- A temporary trial of at least two days duration has been undertaken with ALL of 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

Functional Outcomes

Improved functional outcomes are a key desired goal of these therapies. These outcomes will be affected by individual patient variables (age, anthropometric characteristics, and pre-morbid status) and the nature of the condition (previous history of injury or surgery to the affected region). Functional assessment will, therefore, be individually meaningful and measured, where relevant, using an appropriate, valid and reliable assessment tool.

a. Functional scales will be considered in utilization review, however, given the diverse nature of these scales, no arbitrary threshold can translate into an absolute endpoint for an episode of care. In general, regular significant measurable changes will be seen in a reasonable time frame in relation to baseline performance.

b. Given the above parameters describing pain, range of motion and function, some of the following activities may be demonstrated as applicable:

- Basic ADLs such as positioning, mobility, self-maintenance tasks, communication

- Instrumental ADLs such as home management, community living skills and occupational activities

A reasonable return, safely, efficiently, and at a maximum level of independence (with or without assistive devices) to customary basic ADL, as well as general suitability for common work activities. Some of the elements of instrumental ADLs are beyond the scope of the benefit plan. These might include, for example:

- modifications of a home environment including kitchen, bath and other modifications
- adaptations to facilitate handling money, shopping, safety preparedness, auto travel and parking, building accessibility, etc.
- occupational activities which generally span both work and leisure time pursuits and often involve significant modifications and adaptations to meet specific patient needs

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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Policy History/Revision Information

Date	Action/Description
4/27/2023	Quality Improvement Committee approved activation of the policy

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: phpolicy_inquiry@optum.com with the word "Policy" in the subject line.