Clinical Policy Title: Spinal cord stimulators for chronic pain

Clinical Policy Number: CCP.1098

Effective Date:	**October 1, 2014**
Initial Review Date:	March 19, 2014
Most Recent Review Date:	April 2, 2019
Next Review Date:	April 1, 2020

Policy contains:

- Refractory angina pectoris.
- Complex regional pain syndrome.
- Failed back surgery syndrome.
- Neuropathic pain.
- Spinal cord stimulator.

Related policies:

CCP.1003	Spine pain — epidural steroid injections
CCP.1010	Radiofrequency ablation treatment for spine pain
CCP.1030	Spine pain — facet joint injections
CCP.1043	Chiropractic care
CCP.1063	Spinal surgeries
CCP.1072	Spine pain — trigger point injections
CCP.1101	Hierarchy of chronic pain
CCP.1151	Biofeedback for chronic pain
CCP.1299	Cryoneurolysis

Coverage policy

AmeriHealth Caritas considers the use of spinal cord stimulators to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

- Diagnosed with (InterQual®, 2018b; Mekhail, 2018):
  - Chronic and severe, intractable pain associated with failed back surgery syndrome, complex regional pain syndrome, or diabetic peripheral neuropathy.
  - Canadian Cardiovascular Society functional class III or IV chronic, stable refractory angina pectoris, receiving optimal medical management, and not a candidate for

percutaneous coronary intervention or surgical revascularization (requires secondary review).

- Documentation of (InterQual, 2018a, 2018b):
  - Ineffective results with more conservative approaches such as medications, physical therapy, surgery, psychological therapy, and other modalities.
  - Careful screening, evaluation (including behavioral health), and diagnosis by a multidisciplinary team prior to implantation.
  - Patient education, discussion, and disclosure of the risks and benefits of this therapy.
  - A temporary trial (three to seven days) with a percutaneously implanted neurostimulator electrode that resulted in at least a 50 percent pain reduction.
- Implantation was performed in an outpatient setting.
- No contraindications to the procedure.

For Medicare members only:

AmeriHealth Caritas considers the use of spinal cord stimulators to be clinically proven and, therefore, medically necessary when provided in accordance with Medicare National Coverage Determination 160.7 and Medicare Local Coverage Determinations L35450 and L36035 for the following indications:

- Lumbosacral arachnoiditis.
- Post-surgical or traumatic nerve root injury.
- Failed back syndrome (post-laminectomy syndrome).
- Complex regional pain syndrome I and II.
- Phantom limb syndrome.
- End-stage peripheral vascular disease.
- Post-herpetic neuralgia.
- Cauda equina injury.
- Incomplete spinal cord injury.
- Plexopathy.
- Intercostal neuralgia.

Limitations:

All other uses of spinal cord stimulation are not medically necessary, including treatment of cancer-related pain.

AmeriHealth Caritas will reimburse for placement of a maximum of two leads or 16 “contacts,” and for two spinal cord stimulator trials per anatomic spinal region per patient per lifetime.

If a trial fails, a repeat trial is not medically necessary unless there are extenuating circumstances that lead to trial failure. Appropriate medical documentation to support a repeat trial is required on appeal.

Contraindications to spinal cord stimulation include:

- No partial sparing of the dorsal column fibers (e.g., total paraplegia) of the treated area (Medicare Local Coverage Determination L36035).
- Severe diseases likely to interfere with neuromodulation procedures (e.g., coagulopathies and immunodeficiency diseases) (Medicare Local Coverage Determination L36035).
- Local or systemic sepsis (Manchikanti, 2013).
- Pregnancy (Fedoroff, 2012).
- Active or untreated abuse of alcohol, drugs, or medication (Medicare Local Coverage Determination L36035).
- Major psychiatric disorders, including somatization (Medicare Local Coverage Determination L36035).
- Severe cognitive impairment rendering a patient incapable of giving informed consent for the procedure or operating the device (Medicare Local Coverage Determination L36035).
- Presence of a demand pacemaker or implanted defibrillator (Medicare Local Coverage Determination L36035).
- Therapeutic diathermy (Medicare Local Coverage Determination L36035).

Alternative covered services:

These include, but are not limited to, the following:

- Pharmaceuticals (e.g., analgesics, nonsteroidal anti-inflammatories, and antidepressants).
- Chiropractic care.
- Surgery.
- Psychological/behavioral treatment.
- Physical therapy.
- Interventional procedures (e.g., nerve blocks, spinal injections) for administering local anesthesia.
- Trigger point injections.
- Transcutaneous electrical stimulation.

Background

Chronic pain affects an estimated 100 million Americans, and approximately 25 million people experience moderate to severe chronic pain sufficient to cause significant activity limitations and diminished quality of life (Chou, 2014). Although numerous treatments are available, there has been a dramatic increase in prescription opioids for long-term management of chronic pain and a parallel increase in opioid-related overdoses and hospitalizations. There is a need to balance the benefits and harms of opioid use and consider non-opioid treatment modalities that can provide safe and effective chronic pain relief.

Newer, relatively invasive procedures may benefit patients with chronic pain when applied judiciously. These include image-guided interventions (epidural injections of glucocorticoids for radicular pain), radiofrequency treatment of facet joints, and implanted intra-spinal electrodes.

Spinal cord stimulation:

Spinal cord stimulation, also known as epidural electrical stimulation of the dorsal columns of the spinal cord, was introduced in the 1960s as a surgical alternative for the treatment of chronic pain (Slavin, 2014). Its mechanism of action directs mild electrical pulses to interfere with pain messages reaching the brain. The device consists of a receiver with thin wire electrodes placed in the epidural space and a generator that transmits pulses across the patient's skin to the receiver (21CFR882.5880). A short trial with an externally placed pulse generator is placed to determine efficacy and patient acceptability, followed by subcutaneously implanting the generator. It is a reversible procedure. Multiple technological advancements, such as rechargeability, multiple leads and configurations, miniaturization, and magnetic resonance imaging compatibility, have expanded potential clinical applications (Slavin, 2014).

There are two types of spinal cord stimulators — an implantable pulse generator or radio frequency (American Association of Neurological Surgeons, 2019). The implantable pulse generator contains either a chargeable or rechargeable battery. A chargeable battery requires a minor surgical procedure when the battery needs replacement, whereas a rechargeable battery uses an external wireless power charger. Radio frequency spinal cord stimulators consist of a transmitter worn outside the body that delivers radio waves through the skin to an implanted receiver. The transmitter contains an antenna, electronics, and a replaceable or rechargeable battery. Both types may use remote programming devices to adjust the intensity of the stimulation.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane Library.

We conducted searches on February 26, 2019. Search terms were: “spinal cord stimulation” (MeSH) and “chronic pain” (MeSH).

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic

reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Spinal cord stimulator implantation is an invasive procedure best reserved for cases of severe intractable and chronic pain (failed back surgery syndrome, complex regional pain syndrome, or noncardiac ischemic pain) that have failed to respond to standard medical or less invasive approaches. The evidence base is sparse: While some small randomized or controlled clinical trials with short-term follow-up have been published for some chronic pain indications, the literature remains incomplete and systematic reviews often need to include sub-optimal study designs in addressing their questions.

For example, Taylor (2014) included 74 studies of all designs (n = 3,025 total patients) in their systematic review, of which 63 studies reported data to allow inclusion in a quantitative analysis. Spinal cord stimulation was effective in reducing pain irrespective of the location of chronic back and leg pain or prior back surgery (mean level of pain relief across studies 58 percent, 95 percent confidence interval 53 percent to 64 percent) at an average follow-up of 24 months. However, substantial statistical heterogeneity ($P < .0001$) existed with respect to the level of pain relief reported, and multivariable meta-regression analysis showed no predictive patient or technology factors. The authors recommended randomized controlled trials to confirm results in this population.

A randomized controlled trial compared pain, functioning, and psychological measures of patients referred for spinal cord stimulators (n = 73) or behavioral pain management (n = 29) for treatment of chronic low back pain (Davis, 2015). Patients referred for behavioral pain management and spinal cord stimulation reported similar pain, functioning, and coping, but spinal cord stimulators were associated with fewer psychological symptoms. This could indicate patient reporting bias or clinical referral bias. Patients should be carefully selected after multidisciplinary pain team evaluation that includes behavioral health specialists.

Policy update:

We added one new systematic review of chronic spine pain (Grider, 2016) that found sufficient evidence from randomized controlled trials to support spinal cord stimulation for treatment of lumbar failed back surgery syndrome after an inadequate response to standard nonsurgical therapies. These findings do not change this policy's previous conclusions. However, we clarified the policy to specifically exclude malignant and cardio-ischemic causes of chronic pain, and include important contraindications to the procedure.

In 2018, we added one guideline that provides recommendations on the safe anesthetic and perioperative management of patients with implanted spinal cord stimulators (Harned, 2017). No policy changes are warranted.

In 2019, we added one narrative review (Fedoroff, 2012), one comprehensive systematic review and meta-analysis (Mekhail, 2018), and InterQual criteria (2018a, 2018b) to the policy. There is limited evidence from low-quality randomized controlled trials and observational studies supporting the efficacy of spinal cord stimulation for treatment of individuals with refractory Canadian Class III or IV angina pectoris who are receiving optimal medical management and are not candidates for percutaneous coronary intervention or surgical revascularization. In this population, spinal cord stimulation provided superior analgesia, improved functional outcomes, and lowered analgesia medication use compared to medical management. This indication was added to the list of medically necessary indications with the caveat that approval is based on secondary review. The policy ID was changed from CP# 03.03.01 to CCP.1098.

References

Professional society guidelines/other:

21CFR882.5880.

American Association of Neurological Surgeons. Spinal cord stimulation. https://www.aans.org/Patients/Neurosurgical-Conditions-and-Treatments/Spinal-Cord-Stimulation. Accessed February 26, 2019.

American Society of Anesthesiologists Task Force on Chronic Pain Management, American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology.* 2010;112(4):810-833. Doi: 10.1097/ALN.0b013e3181c43103.

Chou R, Deyo R, Devine B, et al. The effectiveness and risks of long-term opioid treatment of chronic pain. Evidence Report/Technology Assessment No. 218. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 14-E005-EF. Rockville, MD. Agency for Healthcare Research and Quality website. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/chronic-pain-opioid-treatment_research.pdf. Published September 2014. Accessed February 26, 2019.

InterQual 2018 Medicare: Procedures Criteria. Spinal Cord Stimulator. Dorsal Column (Spinal Cord) Neurostimulator – NCD. Change HealthCare LLC. Philadelphia, Pennsylvania.(a)

InterQual 2018.1 Procedures Criteria. Spinal Cord Stimulator (SCS) Insertion and Spinal Cord Stimulator

Temporary Electrode Trial. Change HealthCare LLC. Philadelphia, Pennsylvania.(b)

Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician.* 2013;16(2 Suppl):S49-283. Pain Physician Journal website: http://www.painphysicianjournal.com/current/pdf?article=MTg3Mg%3D%3D&journal=74. Accessed February 26, 2019.

Peer-reviewed references:

Davis C, Kyle B, Thorp J, Wu Q, Firnhaber J. Comparison of pain, functioning, coping, and psychological distress in patients with chronic low back pain evaluated for spinal cord stimulator implant or behavioral pain management. *Pain Medicine*. 2015;16(4);753-760. Doi: .1111/pme.12526.

Fedoroff IC, Blackwell E, Malysh L, McDonald WN, Boyd M. Spinal cord stimulation in pregnancy: A literature review. *Neuromodulation.* 2012;15(6):537-541; discussion 541. Doi: 10.1111/j.1525-1403.2012.00448.x.

Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: A systematic review. *Pain Physician.* 2016;19(1):E33-54. Pain Physician Journal website. https://www.painphysicianjournal.com/current/pdf?article=MjQ4Mw%3D%3D&journal=93. Accessed February 26, 2019.

Harned ME, Gish B, Zuelzer A, Grider JS. Anesthetic considerations and perioperative management of spinal cord stimulators: Literature review and initial recommendations. *Pain Physician.* 2017;20(4):319-329. Pain Physician Journal website. http://www.painphysicianjournal.com/current/pdf?article=NDQwOA%3D%3D&journal=105. Accessed February 26, 2019.

Slavin KV. Spinal stimulation for pain: future applications. *Neurotherapeutics*. 2014;11(3):535-542. Doi: 10.1007/s13311-014-0273-2.

Taylor RS, Desai MJ, Rigoard P, Taylor RJ. Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis. *Pain Practice.* 2014;14(6):489-505. Doi: 10.1111/papr.12095.

Centers for Medicare & Medicaid Services National Coverage Determination:

160.7 Electrical Nerve Stimulators.

Local Coverage Determinations:

A54817 Spinal Cord Stimulation for Chronic Pain - code guide.
A56309 Spinal Cord Stimulation for Chronic Pain Revision to the Part A and Part B LCD.
L35450 Spinal Cord Stimulation (Dorsal Column Stimulation).
L36035 Spinal Cord Stimulation for Chronic Pain.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT code	Description	Comments
63650	Single catheter electrode array inserted percutaneously into epidural space	
63655	Laminectomy for implantation of electrodes or plate/paddle, epidural	
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed	
63662	Removal of spinal neurostimulator electrode plate/paddles(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/paddles(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	

ICD-10 Code	Description	Comments
G56.40	Complex regional pain syndrome type II unspecified upper limb	
G56.41	Complex regional pain syndrome type II of right upper limb	
G56.42	Complex regional pain syndrome type II of left upper limb	
G57.70	Complex regional pain syndrome type II of unspecified lower limb	
G57.71	Complex regional pain syndrome type II of right lower limb	
G57.72	Complex regional pain syndrome type II of left lower limb	
G89.21	Chronic pain due to trauma	
G89.22	Chronic post-thoracotomy pain	
G89.28	Other chronic postoperative pain	
G89.29	Other chronic pain	
G89.4	Chronic pain syndrome	
G90.50	Complex regional pain syndrome I, unspecified	

ICD-10 Code	Description	Comments
G90.511	Complex regional pain syndrome I of right upper limb	
G90.59	Complex regional pain syndrome I of unspecified lower limb	
G90.512	Complex regional pain syndrome I of left upper limb	
G90.513	Complex regional pain syndrome I of upper limb, bilateral	
G90.519	Complex regional pain syndrome I of unspecified upper limb	
G90.521	Complex regional pain syndrome I of right lower limb	
G90.522	Complex regional pain syndrome I of left lower limb	
G90.523	Complex regional pain syndrome I of lower limb, bilateral	

HCPCS Level II	Description	Comment
C1767	Generator, neurostimulator (implantable), nonrechargeable	
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	
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	
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, nonrechargeable, includes extension	
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	