MEDICAL POLICY – 7.01.546
Spinal Cord and Dorsal Root Ganglion Stimulation

BCBSA Ref. Policy: 7.01.25

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>Oct. 1, 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Revised</td>
<td>Sept. 12, 2017</td>
</tr>
<tr>
<td>Replaces:</td>
<td>7.01.25</td>
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RELATED MEDICAL POLICIES:
- 1.01.507 Electrical Stimulation Devices
- 7.01.20 Vagus Nerve Stimulation
- 7.01.63 Deep Brain Stimulation
- 7.01.125 Occipital Nerve Stimulation
- 8.03.01 Functional Neuromuscular Electrical Stimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Spinal cord stimulation is used to treat certain types of pain. A small device is surgically placed beneath the skin. Small amounts of electric current are sent to the spinal cord and the current interferes with the sensation of pain. This treatment has been studied for use in several different types of pain. Medical studies prove that spinal cord stimulation is effective to treat low back pain when surgery and other treatments haven’t helped. Medical evidence also shows it can be effective for a condition known as complex regional pain syndrome. Medical studies have not shown it to be effective to treat pain in the center part of the body (the trunk) or arms/legs, cancer pain, or pain in other areas of the back. This policy discusses when spinal cord stimulation may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Spinal cord stimulation                  | Spinal cord stimulation or high-frequency spinal cord stimulation may be considered medically necessary for the treatment of severe and chronic pain due to failed lumbar back surgery syndrome or complex regional pain syndrome (also known as reflex sympathetic dystrophy) when ALL of the following conditions are met:  
  • The treatment is used as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed, or are judged to be unsuitable or contraindicated  
  AND  
  • Pain is neuropathic in nature, resulting from actual damage to the peripheral nerves  
  AND  
  • Member has obtained clearance by a licensed psychologist, psychiatrist or other licensed mental health professional  
  AND  
  • Demonstration of at least 50% pain-relief-days with a temporarily implanted electrode that was placed at least 3 days before the permanent implantation  
High-frequency spinal stimulation is considered an equally effective alternative to standard spinal cord stimulation for the medically necessary indications listed in this policy. |
| Replacement of spinal cord stimulators   | Replacement of an existing spinal cord stimulator (regular or high-frequency) may be considered medically necessary in only a small subset of patient when:  
  • The stimulator is not working or is broken  
OR  
  • Replacement is needed because the patient’s condition has changed such that the current processor is inadequate or no longer meets the functional needs and improvement is expected with a replacement device.  
Replacement of a functioning standard spinal cord stimulator
### Procedure

**Medical Necessity**

with a high-frequency spinal cord stimulator is considered not medically necessary.

### Procedure

**Medical Necessity**

### Investigational

**Spinal cord stimulation**

Spinal cord stimulation is considered investigational in all situations not outlined in the Medical Necessity section above, including but not limited to treatment of:

- Central deafferentation pain (related to CNS damage from a stroke or spinal cord injury)
- Nociceptive pain resulting from irritation to the nerves
- Axial back pain
- Peripheral neuropathy
- Critical limb ischemia as a technique to forestall amputation
- Refractory angina pectoris
- Post herpetic neuralgia
- Occipital neuralgia
- Failed cervical or thoracic surgery

**Dorsal root ganglion (DRG) stimulation**

DRG neuostimulation is considered investigational for treatment of severe and chronic pain of the trunk or limbs

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
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<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
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<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
</tr>
<tr>
<td>63661</td>
<td>Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<tr>
<td>63662</td>
<td>Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<tr>
<td>63664</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
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<tr>
<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<tr>
<td>63688</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
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**HCPCS**

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>C1822</td>
<td>Generator, neurostimulator (implantable) high frequency, with rechargeable battery and charging system</td>
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<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator</td>
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<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8684</td>
<td>Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement</td>
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<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
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<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
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<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
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<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
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<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
</tbody>
</table>

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**Related Information**

N/A
Spinal cord stimulation (SCS) delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. Spinal cord stimulation devices either have a power source (battery) that is surgically implanted or else the power source is worn externally and only the radiofrequency receiver is implanted.

Spinal cord stimulation (SCS) devices consist of several components: 1) the lead that delivers the electrical stimulation to the spinal cord; 2) an extension wire that conducts the electrical stimulation from the power source to the lead; and 3) a power source that generates the electrical stimulation. The lead may incorporate from 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk. There are two basic types of power source. In one type, the power source (battery) can be surgically implanted. In the other, a radiofrequency receiver is implanted, and the power source is worn externally with an antenna over the receiver. Totally implantable systems are most commonly used.

Spinal cord stimulation has been used in a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and complex regional pain syndrome (ie, chronic reflex sympathetic dystrophy). There has also been interest in spinal cord stimulation as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization, and in patients with refractory chest pain. The neurophysiology of pain relief after spinal cord stimulation is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits.

The patient’s pain distribution pattern dictates at what level in the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used; for example, a lead with 8 electrodes may be selected for those with complex pain patterns or bilateral pain. Implantation of the spinal cord stimulator is typically a 2-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio-receiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations.
and stimulation channels. Computer-controlled programs are often used to assist the physician in studying the many programming options that are available when complex systems are used.

Traditional SCS devices use electrical stimulation with a frequency on the order of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency (10,000 Hz) than predicate devices was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS. In addition, in 2016, FDA approved a clinician programmer “app” that allows an SCS device to provide stimulation in “bursts” rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of 1 ms.

Other neurostimulators target the dorsal root ganglion (DRG). DRGs are located between spinal nerves and the spinal cord on the posterior root and are believed to play an important role in neuropathic pain perception. Two systems have received approval or clearance from FDA.

Summary of Evidence

**Standard Spinal Cord Stimulation**

In patients with refractory trunk or limb pain, the available evidence is mixed and limited by heterogeneity. Systematic reviews have found support for the use of spinal cord stimulation (SCS) to treat failed back surgery syndrome or complex regional pain syndrome, and patients who have failed all other treatment modalities have very limited options. Therefore, SCS for failed back surgery syndrome or complex regional pain syndrome may be considered medically necessary when criteria are met. For other potential indications, eg, critical limb ischemia, refractory angina pectoris and cancer-related pain, there is insufficient evidence from controlled trials to conclude that SCS improves the net health outcome. Thus, SCS is investigational for these indications.

**SCS With Burst Stimulation**

In 2016, a supplement to an SCS device (in the form of a clinician programmer app), which allows for the provision of burst stimulation, was approved by FDA. Studies that offer direct comparisons between standard SCS and burst SCS were sought to permit evaluation of the incremental benefit of burst SCS.
SCS with burst stimulation has been evaluated in 3 crossover RCTs, each with fewer than 20 patients. Inferences drawn from these trials are limited by small sample sizes, short follow-up, and flawed statistical analyses.

**High-Frequency Spinal Cord Stimulation (HFSCS)**

In 2015, an SCS device, using a higher frequency of electrical stimulation (10 kHz) than predicate devices (which use frequencies on the order of 100-1000 Hz) was approved by the FDA. Studies that offer direct comparisons between standard SCS and high-frequency SCS (HFSCS) were sought to evaluate the incremental benefit of HFSCS.

The evidence for HFSCS compared to standard SCS consists of 1 RCT that randomized 198 patients not previously treated with SCS and reported a clinically and statistically significant benefit associated with HFSCS. The crossover RCT enrolling patients with pain despite previous treatment with SCS reported no difference between HFSCS and sham stimulation. However, interpretation on this trial is limited due to the significant period effect.

**Dorsal Root Ganglion Neurostimulators**

Studies that offer direct comparisons between standard SCS and dorsal root ganglion (DRG) neurostimulators were sought to allow an evaluation of the incremental benefit of SCS.

One unblinded RCT and several case series evaluated DRG neurostimulators in patients with chronic trunk and/or limb pain. The RCT (N=152) found that patients receiving DRG neurostimulation had significantly higher rates of treatment success at 3 and 12 months than those receiving standard SCS devices. Both groups experienced paresthesias, so blinding would have been possible. Several case series have also been published. The largest series (N=32) with the longest follow-up found that 60% of patients had 50% or greater reduction in overall pain at 12 months. Additional RCTs, especially blinded and with a sham-control group as well as an SCS control, are needed.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
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<tr>
<td>NCT01697358a</td>
<td>Prospective, Randomized Study of Multicolumn Implantable Lead Stimulation for Predominant Low Back Pain</td>
<td>300</td>
<td>Apr 2016 (ongoing)</td>
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<td>NCT02112474</td>
<td>The Pain Suppressive Effect of Alternative Spinal Cord Stimulation Frequencies</td>
<td>30</td>
<td>Nov 2016 (ongoing)</td>
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<tr>
<td>NCT02514590a</td>
<td>Wireless High Frequency Spinal Cord Stimulation for Chronic Pain</td>
<td>80</td>
<td>Aug 2017</td>
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<tr>
<td>NCT02902796</td>
<td>Comparison of 1000 Hertz (Hz), Burst, and Standard Spinal Cord Stimulation in Chronic Pain Relief</td>
<td>22</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02093793a</td>
<td>A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation</td>
<td>406</td>
<td>Apr 2019</td>
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<tr>
<td>NCT03014583</td>
<td>Study Comparing Conventional, Burst and High Frequency (HF) Spinal Cord Stimulation (SCS) in Refractory Failed Back Surgery Syndrome (FBSS) Patients After a 32-contact Surgical Lead Implantation (MULTIWAVE)</td>
<td>28</td>
<td>Jul 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

*a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

In 2016, the European Academy of Neurology (EAN) published guidelines on neuromodulation in management of chronic pain. These guidelines updated the 2007 the European Federation of Neurological Societies (EFNS) recommendations. For neuropathic pain and complex regional pain syndrome (CRPS), the quality of evidence and effect size were rated as “low” and tolerability/safety was rated as “moderate”. EAN issued a “weak” recommendation for use of spinal cord stimulation (SCS) added to conventional medical management in CRPS, chronic back and leg pain, and painful diabetic neuropathy, and as an alternative to reoperation in postsurgical chronic back and leg pain.

In 2013, International Association for the Study of Pain (IASP) published recommendations on management of neuropathic pain. IASP issued 2 recommendations on SCS; both were
considered weak due to the amount and consistency of the evidence. The recommendations supported the use of SCS for failed back surgery syndrome (FBSS) and for CRPS.

In 2012, the Special Interest Group of the Canadian Pain Society published a guideline on interventions for neuropathic pain. The guideline stated that clinicians should consider offering a trial of SCS to patients with failed back syndrome and complex regional pain syndrome who are not surgical candidates and who have failed conservative evidence-based treatments. (Recommendation based on good evidence with moderate certainty, Grade B strength of recommendation). The guideline also stated that clinicians should consider offering a trial of SCS to patients with traumatic neuropathy and brachial plexopathy who are not surgical candidates and have failed conservative evidence-based treatments. (Recommendation based on fair evidence with moderate certainty, Grade C strength of recommendation).

In 2013, the American Society of Interventional Pain Physicians updated their evidence-based guidelines for interventional techniques in the management of chronic spinal pain. The guidelines included the statement that there is fair evidence in support of SCS in managing patients with failed back surgery syndrome.

In 2008, the National Institute for Health and Care Excellence (NICE) issued guidance on SCS for chronic pain of neuropathic or ischemic origin. NICE recommended SCS as a treatment option for adults with chronic pain of neuropathic origin (measuring at least 50 mm on a 0-100 mm visual analog scale) that continues for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of an assessment by a specialist team.

**Medicare National Coverage**

According to Medicare policy, the implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
- 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;
Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);

All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient must be available; and

Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

Regulatory Status

A large number of neurostimulator devices, some used for spinal cord stimulation (SCS), have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process. Examples of fully implantable SCS devices approved through the PMA process include the Cordis programmable neurostimulator (Cordis Corp., Downers Grove, IL), approved in 1981; the Itrel® (Medtronic, Minneapolis, MN), approved in 1984; the Genesis and Eon devices (St. Jude Medical) approved in 2001; and the Precision Spinal Cord Stimulator (Advanced Bionics, Switzerland), approved in 2004. FDA product code: LGW.

In May 2015, the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp., Menlo Park, CA), a totally implantable neurostimulator device, was approved by FDA for the following indications: “chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome (FBSS), intractable low back pain, and leg pain.”1 This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Spinal Modulation, Menlo Park, CA) was approved by FDA through the PMA process. This is an implanted device that stimulates the dorsal root ganglion. It is indicated as an aid in the management of moderate-to-severe intractable pain of the lower limbs in adults with complex regional pain syndrome types I and II.

In August 2016, the Freedom Spinal Cord Stimulator (Stimwave Technologies, Fort Lauderdale, FL), a wireless injectable stimulator, was cleared for marketing by FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs. The Freedom device has implanted/injected microstimulators that contain electrode(s). The microstimulators with electrodes are powered through a wireless pack worn externally (external battery pack). The device can be placed to target the spinal cord (ie, levels T7 to L5) or to target the dorsal root ganglion.
In October 2016, FDA approved BurstDR™ stimulation (St. Jude Medical, Plano, TX), a clinician programmer application that provides intermittent “burst” stimulation for patients with certain St. Jude SCS devices.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>04/10/12</td>
<td>New policy replacing 7.01.25.</td>
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<tr>
<td>07/20/12</td>
<td>Clarification made to first policy statement; pain is defined in single nerve-root distribution change to lumbosacral nerve root distribution, as approved by MPC on April 10, 2012.</td>
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<tr>
<td>08/27/12</td>
<td>Update Related Policies – Add 7.01.20. Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>04/16/13</td>
<td>Replace policy. No change to policy statements. References 14, 18, 21, 22 added.</td>
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<td>12/19/13</td>
<td>Update Related Policies. Remove 1.01.19 as it was archived.</td>
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<tr>
<td>07/14/14</td>
<td>Annual Review. Policy statement revised. Spinal cord stimulation may now be considered medically necessary for pain due to complex regional pain syndrome when criteria are met. “Lumbar” added as clarification to failed back surgery syndrome and criteria revised. Rationale extensively updated. References added.</td>
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<td>03/31/15</td>
<td>Annual Review. Policy statements unchanged. Policy updated with literature review through December 2014. References 5, 6, 16 added. Remove ICD-9 codes 03.93, 03.94, 86.05, 86.09 and 86.94, along with associated ICD-10 codes; these do not suspend and are informational only.</td>
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<td>05/27/15</td>
<td>Coding update; ICD-9 procedure code 86.96 added to policy; ICD-10 PCS codes adding per cross walk remediation.</td>
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<td>01/29/16</td>
<td>Coding update. Added HCPCS code L8679.</td>
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<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Clarified policy statement adding, licensed mental health provider. No new references added.</td>
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<td>Coding Update. Removed CPT code 95973 as it was deleted as of 01/01/2016.</td>
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<td>04/14/17</td>
<td>Policy moved into new format; no change to policy statements. Evidence Review section reformatted.</td>
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<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Minor update to Medically Necessary policy statement to include Demonstration of at least 50% pain relief with a temporarily implanted electrode that was placed at least 3 days before the permanent implantation. Added HCPCS code L8683.</td>
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<td>08/25/17</td>
<td>Coding update, removed CPT codes 95970, 95971, and 95972.</td>
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<td>10/01/17</td>
<td>Annual Review, approved September 12, 2017. Policy section updated with the inclusion of high-frequency stimulation, high frequency with burst, and dorsal root ganglion stimulators. Title changed to include dorsal root ganglion stimulators. New HCPCS codes added. Removed CPT codes 95970, 95971, and 95972. Replacement and upgrade device criteria added. References 13, 17, 19-25, 30 and 40 added.</td>
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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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