CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN

- Spinal Cord Stimulation
- Motor Cortex Stimulation

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Spinal Cord Stimulation:
Spinal cord stimulation delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. 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 chronic reflex sympathetic dystrophy.

Spinal cord stimulation 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.
CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

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**Description:** (cont.)

**Spinal Cord Stimulation:** (cont.)
The individual'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 a spinal cord stimulator is typically a two-step process:

- Temporary Spinal Cord Stimulation: An electrode is temporarily implanted in the epidural space allowing a trial period of stimulation to determine if stimulator will be effective.
- Permanent Spinal Cord Stimulation: After stimulator effectiveness is confirmed, the electrodes and power source or radiofrequency receiver are permanently implanted

Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

**Motor Cortex Stimulation:**
Motor cortex stimulation, which utilizes the same electrodes as spinal cord stimulation but delivers the electrical stimulation to the motor cortex, has been investigated for the management of chronic, intractable pain of various origins, such as facial, phantom limb and central (post-stroke) pain.

**Criteria:**

For peripheral subcutaneous field stimulation, see BCBSAZ Medical Coverage Guideline, “Peripheral Subcutaneous Field Stimulation”.

**Temporary Spinal Cord Stimulation:**

- Temporary spinal cord stimulation for the treatment of severe and/or chronic neurologically-based intractable pain of the trunk or limbs is considered medically necessary with documentation that pain is refractory to all other pain therapies, e.g., pharmacological, surgical, psychological and physical.
CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

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Criteria: (cont.)

Permanent Spinal Cord Stimulation:

- Permanent spinal cord stimulation for the treatment of severe and/or chronic neurologically-based intractable pain of the trunk or limbs is considered **medically necessary** with documentation of ALL of the following:
  
  1. Pain is refractory to all other pain therapies, e.g., pharmacological, surgical, psychological and physical
  2. Temporarily implanted electrode demonstrates pain relief prior to permanent implantation

- Spinal cord stimulation for all other indications not previously listed is considered **experimental or investigational** based upon:
  
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

  These indications include, **but are not limited to**:
  
  - Critical limb ischemia as a technique to forestall amputation
  - Nerve stimulation for headaches
  - Refractory angina pectoris

Motor Cortex Stimulation:

- Motor cortex stimulation for all indications is considered **experimental or investigational** based upon:
  
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome.

  These indications include, **but are not limited to**:
  
  - Trigeminal neuralgia
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Resources:


CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

- Spinal Cord Stimulation
- Motor Cortex Stimulation

**Resources:** (cont.)


CORTICOSPINAL STIMULATION FOR TREATMENT OF PAIN (cont.)

▪ Spinal Cord Stimulation
▪ Motor Cortex Stimulation

Resources: (cont.)


FDA Summary Statements for spinal cord stimulator implantable. Device names include, *but are not limited to:*

- Genesis and Eon Family Neurostimulation (IPG) Systems
- Itrel® 3
- Precision Spinal Cord Stimulator (SCS) System
- PrimeAdvanced™
- Restore®
- RestoreAdvanced™
- Synergy™
- SynergyCompact+™ and SynergyPlus+™ Neurostimulators (Medtronic)

- FDA-approved indication: As an aid in the management of chronic, intractable, unilateral or bilateral pain associated with the following: 1) failed back syndrome or low back syndrome or failed back; 2) radicular pain syndrome or radiculopathies resulting in pain secondary to failed back syndrome; 3) post laminectomy pain; 4) unsuccessful disk surgery; 5) degenerative disk disease/herniated disk pain refractory to conservative and surgical interventions; 6) peripheral causalgia; 7) epidural fibrosis; 8) arachnoiditis or lumbar adhesive arachnoiditis; 9) complex regional pain syndrome or reflex sympathetic dystrophy or causalgia; and 10) multiple back surgeries.