Spinal Cord Stimulation for the Treatment of Pain

DESCRIPTION

Standard spinal cord stimulation (SCS; also known as dorsal column stimulation) delivers low-frequency electrical stimulation percutaneously into the epidural space of the spinal cord to block the sensation of pain for individuals with chronic neuropathic pain in the trunk or limbs. SCS has been proposed for a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and complex regional pain syndrome. An additional SCS modality is high-frequency spinal cord stimulation, which uses electrical stimulation at 10-kHz, and is sometimes referred to as HF-10 therapy.

Spinal cord stimulation devices consist of implantable electrodes, a receiver/transducer, and a programmable transmitter that may be worn externally or may be fully implanted. An initial trial period of approximately 5-10 days is usually required, and if considered successful would be followed by implantation of the permanent spinal cord stimulator. Clinical trials typically define ‘success’ as a 45-50% or greater reduction in pain scores at the end of the 5-10 day trial period, even if that reduction was not sustained.

Dorsal root ganglion (DRG) are located between spinal nerves and the spinal cord on the posterior root and play an important role in neuropathic pain perception. Two examples of systems targeting the dorsal root ganglion have received approval or clearance from FDA. The Freedom® Spinal Cord Stimulator is a wireless injectable stimulator for treating chronic, intractable pain of the trunk and/or lower limbs. The device can be placed to target the spinal cord or dorsal root ganglion. The Axium® is an implanted system that delivers electrical stimulation to the dorsal root ganglion.

The proposal is to add words or statements in red and delete words or statements with a strikethrough.

POLICY

- Spinal cord stimulation is considered **medically necessary** if the medical appropriateness criteria are met. *(See Medical Appropriateness below.)*

- Dorsal root ganglion stimulation is considered **investigational medically necessary** if the medical appropriateness criteria are met.

- Spinal cord stimulation, either standard or high frequency, for the treatment of pain associated with conditions/diseases including, but not limited to, the following is considered **investigational**:
  - Intractable angina
  - Plexus lesions caused by trauma or malignancy
  - Multiple sclerosis and spasticity disorders
  - Paraplegia and other spinal cord lesions
  - Nociceptive pain resulting from irritation to the nerves
  - Acute peripheral nerve injuries or deafferentation pain (related to central nervous system damage from stroke, spinal cord injury, surgery, entrapment, or scars)
  - Postherpetic neuralgia
  - Critical limb ischemia to forestall amputation
  - Cancer-related pain
  - Heart failure

- Any spinal cord stimulator utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered **investigational**.

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MEDICAL APPROPRIATENESS

- Spinal cord stimulation (SCS) is considered medically appropriate if ALL of the following are met:
  - Indicated for ANY ONE of the following:
    - A trial treatment with temporarily implanted epidural spinal cord stimulator or dorsal root ganglion stimulator when ALL of the following are met:
      - Standard or high frequency spinal cord stimulation
      - Used for dorsal column stimulation
    - Neuropathic pain, including but not limited to, failed back surgery syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy.
    - Chronic intractable pain of the trunk or limbs
    - Other treatment modalities (e.g., pharmacologic, surgical, physical, or psychologic therapies) have been tried for at least 6 months and failed, or were judged unsuitable, or contraindicated
    - Revision surgery is not an option or would have low chance of success
    - No serious, untreated drug habituation exists
    - Individual has undergone careful screening, evaluation, and diagnosis by a multi-disciplinary team. Psychological evaluation obtained
  - A permanently implanted epidural spinal cord stimulator or dorsal root ganglion stimulator when ALL of the following are met:
    - Demonstration of pain relief for a duration of 5 – 10 days with temporarily implanted electrode
    - Standard or high frequency spinal cord stimulation

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For individuals with treatment-refractory chronic pain of the trunk and limbs who have received spinal cord stimulation (SCS), high-frequency SCS or dorsal root ganglion (DRG) stimulation the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SOURCES


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**EFFECTIVE DATE**

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