Guidelines for Implantable Infusion Pumps, Spinal Cord Stimulators, and Neuromuscular Stimulators

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Purpose:

To provide implantable infusion pump, spinal cord stimulator, and neuromuscular stimulator guidelines for Population Health and Provider Alliances associates to reference when making benefit determinations.

Exclusion Criteria *(individually cited in sections within this Procedure)*

Some benefit plans may specifically exclude or limit coverage for certain devices.

• Implantable Infusion Pumps

Coverage Guidelines

Implanted infusion pumps can be considered medically necessary durable medical equipment (DME) under the following circumstances:

A. An implantable infusion pump used to intrathecally administer anti-spasmodic drugs would be considered necessary when Member has BOTH:
   1. Failed a six-week trial of non-invasive methods of spasticity control, such as oral antispasmodic drugs, *and*
   2. Member has a favorable response to a trial intrathecal dosage of the anti-spasmodic drug prior to pump implantation;

B. An implantable infusion pump used to administer opioid drugs and/or clonidine intrathecally or epidurally would be considered necessary when Member has BOTH:
   1. Not responded adequately to non-invasive methods of pain control, such as systemic opioids; *and*
   2. Member has substantial pain relief to a preliminary trial of intraspinal opioid drug administration with a temporary intrathecal/epidural catheter.

Exclusion Criteria

A. Implantable infusion pumps are considered experimental and investigational for infusion of either: heparin for recurrent thromboembolic disease; insulin to treat diabetes; or baclofen for chronic neuropathic pain.

- **Dorsal Column Stimulation**

Coverage Guidelines

Dorsal column stimulators can be considered medically necessary durable medical equipment (DME) under the following circumstances:

A. Failed back surgery syndrome with low back pain and significant radicular pain; Complex regional pain syndrome (aka reflex sympathetic dystrophy); or (iii) Inoperable chronic ischemic limb pain secondary to peripheral vascular disease; *Plus,* the Member meets ALL of the following criteria:
   1. Member does not have any untreated existing drug addiction problems, *and*
   2. Member experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation, *and*
   3. Member has obtained psychiatric clearance, *and*
   4. Other more conservative methods of pain management have been tried & failed, *and*
   5. There is documented pathology (i.e., an objective basis for the pain complaint).

Exclusion Criteria

B. Dorsal Column Stimulation is considered experimental and investigational for the management of Members with chronic malignant pain; other chronic non-malignant pain such as cephalgia, diabetic neuropathy, headache, inguinal pain, intercostal neuralgia, occipital neuralgia, phantom limb syndrome, post-herpetic neuralgia, and trigeminal neuralgia; or spasticity.

C. Cervical spinal cord stimulation is considered experimental and investigational for cervical trauma; disc herniation; or failed cervical spine surgery syndrome that presents with arm pain, neck pain, or cervicogenic headache.

Coverage Guidelines

B. Dorsal Column Stimulation can be considered medically necessary DME for the management of intractable angina when the Member meets ALL of the following criteria:
   1. Member experienced significant pain reduction (50% or more) with a 3- to 7-day trial of percutaneous spinal stimulation, *and*
   2. Member has documented significant coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting or percutaneous transluminal coronary angioplasty, *and*
   3. Member has had maximal optimal pharmacotherapy for at least one (1) month; *and*
   4. Member's angina pectoris is New York Heart Association (NYHA) Functional Class III or Class IV; *and*
   5. Reversible ischemia is documented by symptom-limited treadmill exercise test.

Exclusion Criterion

D. Dorsal column stimulation is considered experimental and investigational for all other indications.

- **Neuromuscular Stimulation**

Coverage Guidelines

A. Functional Electrical stimulation [FES] (e.g., including by not limited to Parastep I System) for Members with spinal cord injury can be considered medically necessary durable medical equipment (DME) when ALL of the following criteria are met:
   1. Member has intact lower motor units (L1 and below); *and*
   2. Member can bear weight on upper and lower extremities to maintain an upright posture independently; *and*
   3. Member demonstrated brisk muscle contraction to neuromuscular electrical stimulation and has sensory perception of electrical stimulation sufficient for muscle contraction; *and*
   4. Member is highly motivated and has the cognitive ability to use such devices for walking; *and*
   5. Member can transfer independently and stand for at least three (3) minutes; *and*
   6. Member possesses hand and finger function to manipulate the controls; *and*
   7. Member is at least six (6) months post recovery of spinal cord injury and restorative surgery; *and*
   8. Member does not have hip and knee degenerative disease and has no history of long bone fracture secondary to osteoporosis; *and*
   9. The Member has successfully completed a training program, which consists of at least 32 physical therapy sessions with the device over a 3-month period.

Exclusion Criteria

A. Functional Electrical Stimulation is considered experimental and investigational for Members with any of the following:
   1. Cardiac pacemakers;
   2. Severe scoliosis or severe osteoporosis; *or*
   3. Skin disease or cancer at area of stimulation; *or*
   4. Irreversible contracture; *or*
   5. Autonomic dysreflexia.

Coverage Guidelines

B. Neuromuscular electrical stimulators (NMES) for disuse atrophy where the nerve supply to the muscle is intact can be considered medically necessary for any of the following:
   1. Contractures due to burn scarring, *or*
   2. Major knee surgery with documented failure to respond to physical therapy; *or*
   3. Previous casting or splinting of a limb, *or*
   4. Recent hip replacement surgery prior to beginning physical therapy.

Exclusion Criteria

B. More than two (2) hours of NMES per day is considered not medically necessary.

C. Functional Electrical Stimulation (FES) of the upper extremities (e.g., including by not limited to NESS H200) to improve muscle strength, reduce spasticity and atrophy, and facilitate functional motor movement is considered experimental and investigational for the following:
   1. Spinal cord injury; *or*
   2. Stroke; *or*
   3. Traumatic brain injury; *or*
   4. Upper motor neuron disorders (e.g., Parkinson's disease).

D. Both FES and NMES are considered experimental and investigational for all other indications including, but not limited to, the following:
   1. Bell's palsy; *or*
   2. Cerebral palsy; *or*
   3. Cardiac conditioning; or general muscle strengthening in healthy individuals; *or*
   4. Treatment of denervated muscles.

The following devices including, but not limited to, are considered to be exercise equipment and as such are considered not a covered benefit:

FES Power Trainer	SpectraSTIM	REGYS	RT300 motorized FES ergometer
STimMaster Galaxy	NeuroEDUCATOR	ERGYS	Any similar devices

Coverage Guidelines

C. Diaphragmatic/phrenic pacing (e.g., including, but not limited to, the NeuRx DPS RA/4 Respiratory Stimulation System) for improvement of ventilatory function in stable, non-acute Members with spinal cord injury can be considered medically necessary when ALL of the following criteria are met:
   1. Member has high quadriplegia at or above C-3; *and*
   2. There are viable phrenic nerves; *and*
   3. Diaphragm and lung function are adequate.

   Can also be considered medically necessary for:
   1. The treatment of central alveolar hypoventilation; and
   2. For individuals with amyotrophic lateral sclerosis.

Exclusion Criteria

E. Diaphragmatic/phrenic pacing is considered experimental and investigational for all other indications.

Coverage Guidelines

C. Electrical stimulation of the sacral anterior roots by means of an implanted stimulator in order to provide urination on demand and to reduce post-void residual volumes of urine,(e.g. including but not limited to the Vocare Bladder System) in conjunction with a posterior rhizotomy in Members who have clinically complete spinal cord lesions with intact parasympathetic innervation of the bladder and who are skeletally mature and neurologically stable, can be considered medically necessary when ALL of the following criteria are met:
   1. Three (3) months (female Members) after or nine (9) months (male Members) after complete supra-sacral spinal cord injury; *and*
   2. There is phasic detrusor pressure rise of 35 mm H2O (female Members) or 50 cm H2O (male Members) on cystometry; *and*
   3. Presence of three (3) of the four (4) non-vesical sacral segment reflexes (i.e., ankle jerks, bulbo-cavernous reflex, anal skin reflex, and reflex erection).

Exclusion Criteria

F. Electrical stimulation of the sacral anterior roots in conjunction with posterior rhizotomy is considered experimental and investigational for all other indications

G. Transurethral electrical stimulation for the management of neurogenic bladder dysfunction and all other indications is considered experimental and investigational.

H. Peroneal nerve stimulator (e.g., including, but not limited to the WalkAide device, the Bioness, or NESS L300 Foot Drop System) for Members with foot drop.

I. For all other indications, is considered experimental and investigational.

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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

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