



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

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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to *implantable infusion pumps, spinal cord stimulators, and neuromuscular stimulators* in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

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

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.



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• 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

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.

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

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



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• 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

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 Criterion

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



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Exclusion Criteria

- 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

- E. 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 Criterion

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



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- F. 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 Criterion

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

Exclusion Criterion

For all other indications, is considered experimental and investigational.

References:

1. U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA). Infusion pumps. Medicare Coverage Issues Manual §60-14. HCFA Pub. 6. Baltimore, MD: HCFA; 2000.
2. Ontario Ministry of Health and Long-Term Care, Medical Advisory Secretariat. Intrathecal baclofen pump for spasticity. Health Technology Review. Toronto, ON: Ontario Ministry of Health and Long-Term Care; May 2005.
3. Shilt JS, Lai LP, Cabrera MN, et al. The impact of intrathecal baclofen on the natural history of scoliosis in cerebral palsy. J Pediatr Orthop. 2008;28(6):684-687.
4. Caird MS, Palanca AA, Garton H, et al. Outcomes of posterior spinal fusion and instrumentation in patients with continuous intrathecal baclofen infusion pumps. Spine. 2008;33(4):E94-E99.



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5. Hoving MA, van Raak EP, Spincemaille GH, et al. Efficacy of intrathecal baclofen therapy in children with intractable spastic cerebral palsy: A randomised controlled trial. *Eur J Paediatr Neurol*. 2009;13(3):240-246.
6. Agency for Healthcare Policy and Research (AHCPR). Management of cancer pain. Clinical Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, MD: AHRQ; March 1994.
7. Jadad A, O'Brien MA, Wingerchuck D, et al., and the McMaster University Evidence-Based Practice Center. Management of chronic central neuropathic pain following traumatic spinal cord injury. AHRQ Evidence Report/Technology Assessment No. 45. AHRQ Pub. No. 01-E063. Rockville, MD: AHRQ; September 2001.
8. Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: A systematic review of effectiveness and complications. *Pain*. 2004;108(1-2):137-147.
9. Ontario Ministry of Health and Long Term Care, Medical Advisory Secretariat. Spinal cord stimulation for the management of neuropathic pain. *Health Technology Literature Review*. Toronto, ON: Ontario Ministry of Health and Long Term Care; March 2005.
10. National Institute for Health and Clinical Excellence (NICE). Pain (chronic neuropathic or ischaemic) - spinal cord stimulation. NICE Technology Appraisal Guidance 159. London, UK: NICE; October 2008.
11. Simpson BA, Bassett G, Davies K, et al. Cervical spinal cord stimulation for pain: A report of 41 patients. *Neuromodulation*. 2003;6(1):20-26.
12. Center for Medicare and Medicaid Services (CMS). Neuromuscular electrical stimulation (NMES) for spinal cord injury. Decision Memorandum #CAG -00153R. Baltimore, MD: CMS; July 22, 2002.
13. Center for Medicare and Medicaid Services (CMS). Neuromuscular electrical stimulation (NMES) for spinal cord injury. National Coverage Analysis (NCA). Baltimore, MD: CMS; effective April 1, 2003.
14. Bax L, Staes F, Verhagen A. Does neuromuscular electrical stimulation strengthen the quadriceps femoris: A systematic review of randomised controlled trials. *Sports Med*. 2005;35(3):191-212.
15. Monaghan B, Caulfield B, O'Mathúna DP. Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement. *Cochrane Database Syst Rev*, 2010;(1):CD007177.



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16. National Institute for Health and Clinical Excellence (NICE). Intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure due to neurological disease. Interventional Procedure Guidance 307. London, UK: NICE; July 2009.
17. Kerr C, McDowell B, McDonough S. Electrical stimulation in cerebral palsy: A review of effects on strength and motor function. *Dev Med Child Neurol.* 2004;46(3):205-213.
18. Quinn R, Cramp F. The efficacy of electrotherapy for Bell's palsy: A systematic review. *Phys Ther Rev.* 2003;8(3):151-164.
19. Kottink AI, Hermens HJ, Nene AV, et al. Therapeutic effect of an implantable peroneal nerve stimulator in subjects with chronic stroke and footdrop: A randomized controlled trial. *Phys Ther.* 2008;88(4):437-448.

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.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

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