Public Statement:

Neuromuscular Electrical Stimulation or functional electrical stimulation is used for two purposes. It is used to help maintain muscle tone and strength in an unused extremity when normal function is expected to return. It is used to enhance activity and self sufficiency in individuals with spinal cord injuries. Neuromuscular Electrical Stimulation is covered when it is medically necessary and subject to review.

Medical Policy Statement:

I. ARBenefits considers functional electrical stimulation (e.g., Parastep I System, Sigmedics, Inc., IL) medically necessary to enable members with spinal cord injury (SCI) to ambulate when all of the following criteria are met:
   • Member has intact lower motor units (L1 and below); and
   • Member can bear weight on upper and lower extremities to maintain an upright posture independently; and
   • Member demonstrated brisk muscle contraction to neuromuscular electrical stimulation and has sensory perception of electrical stimulation sufficient for muscle contraction; and
   • Member is highly motivated and has the cognitive ability to use such devices for walking; and
   • Member can transfer independently and stand for at least 3 minutes; and

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- Member possesses hand and finger function to manipulate the controls; and
- Member is at least 6 months post recovery of spinal cord injury and restorative surgery; and
- Member does not have hip and knee degenerative disease and has no history of long bone fracture secondary to osteoporosis; and
- The member has successfully completed a training program, which consists of at least 32 physical therapy sessions with the device over a three-month period.

II. ARBenefits considers neuromuscular electrical stimulators (NMES) medically necessary for disuse atrophy where the nerve supply to the muscle is intact and the member has any of the following non-neurological reasons for disuse atrophy:
- Previous casting or splinting of a limb, or
- Contractures due to burn scarring, or
- Recent hip replacement surgery (NMES is covered until physical therapy begins), or
- Previous major knee surgery (when there is failure to respond to physical therapy).

III. ARBenefits considers diaphragmatic/phrenic pacing medically necessary for the improvement of ventilatory function in stable, non-acute members with SCI when all of the following criteria are met:
- Member has high quadriplegia at or above C-3; and
- There are viable phrenic nerves; and
- Member’s diaphragm and lung function are adequate.

IV. ARBenefits considers electrical stimulation of the sacral anterior roots (by means of an implanted stimulator, the Vocare Bladder System) in conjunction with a posterior rhizotomy medically necessary for members who meet the following selection criteria:
- 3 months (female members) after or 9 months (male members) after complete supra-sacral spinal cord injury; and
- Presence of 3 of the 4 non-vesical sacral segment reflexes (i.e., ankle jerks, bulbo-cavernous reflex, anal skin reflex, and reflex erection); and
- A phasic detrusor pressure rise of 35 mm H₂O (female members) or 50 cm H₂O (male members) on cystometry.

Limits:

I. Functional electrical stimulation for walking (Parastep I System) is not considered medically necessary for members with SCI with any of the following:
- Members with cardiac pacemakers; or
- Members with severe scoliosis or severe osteoporosis; or
- Members with skin disease or cancer at area of stimulation; or
- Members with irreversible contracture; or
- Members with autonomic dysreflexia.
II. ARBenefits considers NMES experimental and investigational for improvement of muscle strength, reduction of spasticity and atrophy, and facilitation of functional motor movement due to any of the following conditions:

- Spinal cord injury; or
- Stroke (cerebrovascular accident/CVA); or
- Cerebral palsy; or
- Bell's palsy; or
- Other upper motor neuron disorders; or
- Atrophy or weakness following spinal surgery

III. ARBenefits considers NMES experimental and investigational for any of the following indications:

- For general muscle strengthening in healthy individuals; or
- For cardiac conditioning; or
- For the treatment of denervated muscles.

IV. ARBenefits considers the FES devices such as the FES Power Trainer, ERGYS, REGYS, NeuroEDUCATOR, and SpectraSTIM to be exercise equipment.

V. ARBenefits considers transurethral electrical stimulation experimental and investigational for the management of neurogenic bladder dysfunction because its effectiveness has not been established.

VI. ARBenefits considers Interferential stimulation (e.g., RS-4i Sequential Stimulator) for the control of pain experimental and investigational as there is insufficient evidence of effectiveness. (Hayes D)

VII. ARBenefits considers H-WAVE ® type stimulators experimental and investigational for any of the following indications because their effectiveness for these indications has not been established.

- To reduce pain from causes other than chronic diabetic peripheral neuropathy; or
- To reduce edema; or
- To accelerate healing; or
- To treat chronic pain due to ischemia.

Background:

Neuromuscular electrical stimulation (NMES) can be grouped into 2 categories: (i) stimulation of muscles to treat muscle atrophy, and (ii) enhancement of functional activity in neurologically impaired individuals. These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide spinal cord injury (SCI) patients with the ability to walk (e.g., The Parastep I System). Neuromuscular electrical stimulation used in this manner is commonly known as functional electrical stimulation (FES).

Spinal Cord Injury: In addition to enhancement of walking abilities in SCI patients, other clinical applications of FES include diaphragmatic/phrenic pacing, and spasticity control. Functional electrical stimulation has had some success in improving ventilatory function in adult patients with SCI (Glenn et al. 1984; Carter et al, 1987; Glenn et al, 1988).
However, it has not been consistently shown that spasticity decreases with long-term FES. Yarkony et al (1992) claimed that no definitive statement can be made regarding the type, the magnitude, or even the direction of the effect of electrical stimulation on the spasticity of patients with SCI. Current management strategy for this condition ranges from rehabilitative physical therapy, re-education therapeutic exercise, oral medications such as Dantrium, Valium, and Lioresal (baclofen), intrathecal infusion of baclofen, motor point blocks or nerve blocks, to destructive neurosurgical procedures (Merritt 1981).

**Stroke Rehabilitation:** There is insufficient evidence that FES is effective as a rehabilitative tool for patients who suffered strokes. In particular, there is little data supporting the long-term effectiveness of this modality for stroke rehabilitation.

**Rehabilitation Following Ligament/Knee Surgery:** NMES has been shown to be an effective rehabilitative regimen for patients following ligament/knee surgery. It prevents muscle atrophy associated with knee immobilization, enables patients to ambulate sooner, and reduces the use of pain medication as well as length of hospital stay (Arvidsson 1986; Lake 1992; Gotlin et al, 1994; Snyder-Mackler et al, 1995).

**Neurogenic Bladder Dysfunction:** The management of patients with neurogenic bladder dysfunction entails clean intermittent catheterization, pharmacotherapy (e.g., oxybutynin, phenoxybenzamine, and anti-cholinergic medications such as tolterodine), and surgical interventions (e.g., urinary diversion or bladder augmentation). Moreover, stimulation of sacral anterior nerve roots in association with posterior rhizotomy has been used in the treatment of patients with suprasacral SCI. The FDA approved the Vocare Bladder System as a humanitarian use device based on a study of 23 patients who received device in association with posterior rhizotomy and were followed for a minimum of 3 months. Comparisons were made with the implanted stimulator turned either on or off; thus patients served as their own controls. The primary outcome measures were improvement in bladder emptying as evidenced by the ability to void more than 200 ml on demand with post-void residual urine volumes of less than 50 ml.

**Cerebral Palsy:** Traditionally, the adverse effects of spasticity are managed by means of pharmacotherapy, physical therapy, bracing, casting, splinting, orthopedic surgeries, and more recently selective posterior rhizotomy. Various forms of electrical stimulation have also been employed for the management of patients with CP including neuromuscular electrical stimulation (NMES), which has been used to increase range of motion, decrease spasticity, and enhance muscle rehabilitation.

**Interferential Stimulation:** It has been claimed that IFS is highly effective in reducing (i) pain and use of pain medications, (ii) edema and inflammation, (iii) healing time, as well as in improving (i) range of motion, (ii) activity levels, and (iii) quality of life. However, there are very few well designed studies such as randomized, double blind, controlled clinical trials that support such claims.
H Wave Stimulation: H-wave stimulators have not been shown to be effective in reducing pain from causes other than chronic diabetic peripheral neuropathy, or in reducing edema or swelling. In particular, H-wave stimulation has not been demonstrated to be effective in treating chronic pain due to ischemia. In the study by Kumar and Marshall, patients with significant peripheral vascular disease were excluded from the trial. Furthermore, in a randomized controlled study (n = 112), McDowell et al (1995) reported that H-wave stimulation was not effective in reducing experimental ischemic pain.

References:

2. Hayes Medical Technology Directory; Interferential Therapy for Pain

Functional Electrical Stimulation for Walking:


Neuromuscular Electrical Stimulation for Disuse Atrophy:


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Neuromuscular Electrical Stimulation for Stroke:

Neuromuscular Electrical Stimulation for Spinal Cord Injury:
Diaphragmatic/Phrenic Pacing:

Sacral Nerve Stimulation:

Transurethral Electrical Bladder Stimulation:

Electrical Stimulation for Cerebral Palsy:

Electrical Stimulation for Bell's Palsy:

Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

Last modified by: Date: