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Developed By: Medical Criteria Committee	

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Description:

Electrical stimulators are small electronic devices that are worn externally by a patient and affixed to the skin by way of electrodes. Electrical stimulators may be used for a variety of purposes including reducing acute post-operative pain and swelling, treating chronic intractable pain, maintaining muscle tone during temporary extremity immobilization, reducing spasticity, and assisting spinal cord injured patients to grasp, stand, and walk independently. Electrical stimulators for use by patients in the home setting can be further broken down into the following categories:

Transcutaneous Electrical Nerve Stimulation (TENS): Electrical impulses are sent from a portable, battery-powered pulse generator using skin electrodes placed over the affected tissue. TENS is characterized by biphasic current and selectable parameters. It stimulates sensory nerves to block pain signals and generate endorphins. TENS is commonly used for the treatment of acute post-operative pain and chronic intractable pain.

Neuromuscular Electrical Stimulation (NMES): Also known as therapeutic electrical stimulation, NMES strengthens muscles weakened by disuse. Through multiple channels, NMES attempts to stimulate motor nerves and alternately causes contraction and relaxation of muscles. These devices are used to prevent or stop disuse atrophy, relax muscle spasm, increase blood circulation, maintain or increase range-of-motion, and re-educate muscles.

Functional Neuromuscular Stimulation (FNS or ENS-Electrical Neuromuscular Stimulation): FNS attempts to replace destroyed nerve pathways through electrical stimulation of muscles. This is performed in an attempt to enable spinal cord injured patients to grasp, stand or walk independently or at least maintain healthy muscle tone and strength.

H-wave Stimulation: H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation in terms of its waveform. H-wave stimulation is intended to emulate the H waveform found in nerve signals and therefore enables greater and deeper penetration of a low frequency current while using less power than other machines. *H-wave stimulation must be distinguished from the H-waves that are a component of electromyography.*

Interferential Stimulation: Interferential stimulation is a type of electrical stimulation that uses paired electrodes of two independent circuits carrying medium-frequency alternating currents. Interferential stimulators have been investigated as a technique to reduce pain, restore muscle function and improve range of motion. An example of an interferential stimulation device is the RS-4i.

Microcurrent Stimulation (MENS): Microcurrent stimulation machines have been used for the symptomatic relief of chronic intractable pain and as an adjunctive treatment in the management of post-surgical pain problems. MENS utilizes a unique waveform that acts on the body's naturally occurring electrical impulses to decrease pain and facilitate healing. MENS units have also been used in the treatment of migraines, anxiety, depression, insomnia, and cognitive dysfunction. An example of a MENS device is the Alpha-Stim.

Galvanic Stimulation: Galvanic stimulation applies high voltage, direct current to reduce edema in acute injuries associated with major tissue trauma. Direct current creates an electrical field over the treated area that, theoretically, changes blood flow. The positive pad behaves like ice, causing reduced circulation to the area and a reduction in swelling. The negative pad behaves like heat, causing increased circulation and faster healing. An example of a galvanic stimulator is the SporTX.

Sympathetic Therapy: Sympathetic therapy is used for the symptomatic relief of chronic pain. Electrical stimulation is delivered via peripheral nerves in order to create a form of stimulation of the sympathetic nervous system. Sympathetic therapy is initiated in a clinical setting followed by home therapy.

BioniCare® Knee Device: BioniCare® utilizes low-level pulsed electrical stimulation for relieving pain and symptoms associated with osteoarthritis of the knee.

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Criteria:

1. ODS will allow coverage for TENS units up to the plan limitations when used for the treatment of post-operative musculoskeletal pain or chronic intractable musculoskeletal pain.

*ODS considers TENS experimental and investigation for the following uses:

- Headaches
- Abdominal or pelvic pain
- Temporomandibular joint (TMJ) pain

2. ODS will allow coverage for NMES up to the plan limitations for the prevention and/or treatment of disuse atrophy when **all** of the following criteria are met:

- a. The nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves; and
- b. The patient had previous casting or splinting of a limb, contractures due to burn scarring, prolonged immobilization due to injury, or major hip or knee surgery (until physical therapy begins); and
- c. The patient is at least 2 years of age

*If the above criteria are met, approval for NMES will be limited to a 2 month rental. Further authorization will require review of the patient's current condition and response to NMES.

*ODS considers NMES experimental and investigational for the following uses:

- General muscle strengthening in healthy individuals
- Treatment of scoliosis
- Treatment of denervated muscles
- Cardiac conditioning
- Reducing spasticity or facilitating voluntary motor control

3. ODS considers form-fitting conductive garments medically necessary for use with an approved TENS unit or NMES when **all** of the following conditions are met:

- a. The conductive garment is approved for marketing by the FDA; and
- b. A physician has prescribed the conductive garment for use in delivering covered TENS or NMES; and
- c. The patient cannot manage without the conductive garment due to a large number of sites to be stimulated at frequent intervals or the patient has skin problems that preclude the application of electrodes, adhesive tapes and lead wires.

4. ODS considers functional neuromuscular stimulations (FNS) experimental and investigational for all indications including but not limited to assisting spinal cord injured patients to stand, grasp and walk independently.

5. ODS considers the following electrical stimulation devices experimental and investigational for home use for any indication because their effectiveness has not been established:

- a. Interferential stimulators (see separate criteria for interferential stimulation devices)
- b. H-wave stimulators
- c. Microcurrent stimulators (i.e. Alpha-Stim)
- d. Galvanic stimulators (i.e. SportTX)
- e. Sympathetic stimulators
- f. BioniCare® Knee Device

Information to be Submitted with Pre-Authorization Request:

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- Ordering physician's chart notes
- Appropriate imaging studies or other diagnostic test results
- Conservative treatment tried

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