Neuromuscular Electrical Stimulation for Muscle Rehabilitation

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RETIRED 5/11/2017

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INSTRUCTIONS:

"Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations."
POLICY DESCRIPTION:

This policy describes the use of neuromuscular electrical stimulation (NMES) for rehabilitation. NMES is administered outpatient by a physical therapist or at home by patients or family members. The intensity of stimulation is barely perceptible or imperceptible with an electric current ranging from 0.001 to 10 mA. NMES is used passively to strengthen muscles with the goal of improving physical function. In functional electrical stimulation (FES), a variant of NMES, stimulation is applied while the patient is executing a physical task. FES is intended to have an orthotic effect and has the potential to have lasting effects on muscle function.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Neuromuscular electrical stimulation as a treatment for rehabilitation may be considered MEDICALLY NECESSARY for the following conditions if the peripheral nerves, spinal cord and brain are intact:

1. Upper and lower extremity weakness, secondary to spinal cord injury or acute/subacute Cerebral Vascular Accident (CVA) (acute/subacute is defined as less than 6 months after a CVA);
2. Spasticity secondary to cerebral palsy;
3. Contractures due to burn scarring;
4. Muscle atrophy due to limb casting, hip, knee or shoulder surgery or other atrophy due to orthopedic disease.

Neuromuscular electrical stimulation as a treatment for rehabilitation of the following conditions is considered EXPERIMENTAL AND/OR INVESTIGATIONAL:

1. Dysphagia secondary to CVA;
2. Foot drop secondary to multiple sclerosis;
3. Amyotrophic lateral sclerosis;
4. Muscular dystrophy;
5. Idiopathic scoliosis or spinal deformity;
6. As adjunct to physical rehabilitation for localized disuse or weakness due to pain or myofascial injury;
7. Osteoarthritis or any other degenerative disease; 8. Other conditions not listed above.

Due to inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature, comparative effectiveness studies, including randomized controlled trials, are needed to establish definitive patient selection criteria and demonstrate the safety and long-term efficacy of this technology.
Clinical Considerations:

Contraindications:

1. Patients who have cardiac pacemakers, defibrillators or with sensory deficits;
2. To improve walking in patients who have had spinal cord injury (SCI) or any of the following: severe scoliosis or severe osteoporosis, skin disease or cancer at area of stimulation, irreversible contracture or autonomic dysflexia (CMS 2006).

BACKGROUND:

Muscles can lose strength when motor control is impaired due to stroke or other neurological disorders or when activity is restricted due to severe cardiac or pulmonary diseases. To prevent atrophy in these situations, muscles can be exercised by applying electrical pulses through electrodes attached to the skin surface, a technique known as neuromuscular electrical stimulation (NMES). Specific applications of this treatment include improving motor function in patients with cerebral palsy (CP); strengthening leg muscles after hip fracture, hip replacement, or surgical repair of the anterior cruciate ligament (ACL); regaining wrist or swallowing function or strengthening abdominal and pectoral muscles after paralysis due to stroke or spinal cord injury; and treating or preventing shoulder subluxation after stroke-related paralysis.

NMES can be performed at low, medium, or high intensity to elicit mild, moderate, or strong muscle contractions. When used at very low intensity to stimulate barely perceptible contractions, this technique is referred to as threshold NMES or threshold electrical stimulation (TES). To avoid muscle strain, patients undergo high-intensity NMES for only 30 to 60 minutes per day; low-intensity and threshold NMES can be applied for much longer periods, such as all night while the patient is sleeping. Regardless of the intensity of NMES, patients are encouraged to exercise the affected muscles voluntarily to maintain and improve their strength and function.

Electrical stimulation can also be used to activate muscles of the upper or lower limbs to produce functional movement patterns, such as standing and walking in patients with paraplegia. This application of electrical stimulation is called functional electrical stimulation (FES).

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
   Neuromuscular electrical stimulators are regulated by the FDA as Class II devices, and 428 of these devices have been approved via the FDA 510(k) process. Specific information about the approval and a listing of these devices can be found by searching the 510(k) premarket notification database for product code IPF (FDA, 2007). The VitalStim® Therapy device (Chattanooga Group, a division of Encore Medical) has been approved via the 510(k) process only for stimulation of the pharyngeal muscles that are responsible for swallowing (FDA, 2002).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
Medicare has a National Coverage Determination (NCD) for neuromuscular electrical stimulation. Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other nonneurological reasons for disuse atrophy. Examples are casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). The type of NMES that is used to enhance the ability to walk in spinal cord injury (SCI) patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses in precise sequence to activate paralyzed or weak muscles. Coverage for the use of NMES/FES is limited to SCI patients for walking, who have completed a training program consisting of at least 32 physical therapy sessions with the device over a period of 3 months. The goal of physical therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy. (CMS, 2006).

Medicare does NOT have Local Coverage Determination (LCD) for Neuromuscular Electrical Stimulation. Medicare DOES have Local Coverage Determination L28524 for transcutaneous electrical joint stimulation. There is insufficient published clinical evidence to establish that treatment with transcutaneous electrical joint stimulation devices (TEJSD) meets the requirements to be considered reasonable and necessary for the treatment of osteoarthritis or any other condition. Claims for TEJSD (code E0762) will be denied as not reasonable and necessary.

### 3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Neuromuscular stimulators are covered with authorization for treatment of disuse muscle atrophy where nerve supply to the muscle is intact and where there is a non-neurological reason for the disuse atrophy.

<table>
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<th>CLINICAL EVIDENCE:</th>
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<tr>
<td>NMES has been used to treat disuse atrophy, muscle weakness, and spasticity. These conditions can result from spinal cord injury, stroke, cancer, knee and hip surgery, multiple sclerosis, cerebral palsy, the casting of limbs and peripheral neuropathy.</td>
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<th>SUMMARY:</th>
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<tr>
<td>Six randomized trials evaluated NMES of the extensor muscles as an adjunct to physical therapy for the rehabilitation of wrist and finger muscles in patients who developed hemiparesis due to a stroke. These trials reported that NMES enabled statistically significant improvements in measures of wrist and finger function and strength.</td>
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Five RCTs evaluated NMES as an adjunct to physical therapy for rehabilitation of leg muscles after ACL surgery. The magnitude of improvements ranged from slight to moderate and, none of these studies involved any follow-up after the post-treatment assessment. The other two RCTs that evaluated NMES for...
post-ACL surgery rehabilitation provided over 10 months of follow-up, and both found that NMES does not improve patient outcomes. Further studies are needed to determine if NMES provides durable, clinically significant benefits to patients after ACL surgery. The results of the reviewed RCTs do not provide sufficient evidence to conclude that NMES provides a benefit in patients with spasticity related to cerebral palsy.

Evidence pertaining to the effect of functional electrical stimulation (FES) on the general physical fitness and health of patients with spinal cord injury (SCI) is promising but sparse and conflicting. In general, the evidence regarding the effectiveness of FES in improving various measures of physical function and overall functional status is positive but not of sufficient quality to allow confident conclusions. For particular types of outcome in specific patient populations, the volume of evidence is very sparse, and some studies have serious methodological weaknesses. To date, the most promising application of FES appears to be as a means of assisting walking or enhancing gait training in patients with incomplete SCI, but the evidence base for this indication does not include randomized controlled trials powered to detect differences with known clinical or practical importance. There has been little objective assessment of the long-term duration of the health and functional benefits of FES. Surface FES is a safe technology, although caution is required when
the technology is used to restore ambulation in previously nonambulatory patients. Implantable FES poses the risks associated with invasive procedures.

There is some evidence from six clinical studies that evaluated the effect of surface FES for treatment of foot drop in patients with MS, which suggests that use of the WalkAide System or the ODFS Pace may improve walking speed; however, the results were conflicting.

Overall, there was very limited evidence on the effect of FES on other patient-relevant, functional measures. For example, none of the studies evaluated whether FES enabled patients to walk up and down stairs, walk on uneven ground, perform side steps, or whether its use improved confidence while performing these various activities. Since the studies were case series and poor-quality randomized controlled trials (RCTs) the validity of the evidence is unclear.

Data from one randomized controlled trial and one small, uncontrolled study of ES of the thyrohyoid and digastric muscles demonstrated improvement of oropharyngeal dysphagia secondary to stroke and prevention of aspiration. In some patients, the beneficial effect was maintained for over 2 years and recurrences were successfully retreated. However, additional studies with larger numbers of patients are needed to confirm this initial success and to determine patient selection criteria based on etiology of dysphagia.

### APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<th>HCPCS Codes</th>
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<tr>
<td>E0744</td>
<td>Neuromuscular stimulator for scoliosis</td>
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<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
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<tr>
<td>E0762</td>
<td>Transcutaneous electrical joint stimulation device system, includes all accessories</td>
</tr>
<tr>
<td>E0764</td>
<td>Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program</td>
</tr>
<tr>
<td>E0770</td>
<td>Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified</td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<th>ICD-9 Codes</th>
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<tr>
<td>342.x*</td>
<td>Hemiplegia and hemiparesis</td>
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<tr>
<td>343.x*</td>
<td>Infantile cerebral palsy</td>
</tr>
<tr>
<td>344.0x*</td>
<td>Quadriplegia and quadriparesis</td>
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<tr>
<td>ICD-10 Codes</td>
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<tr>
<td>E82.x*</td>
<td>Paraplegia and tetraplegia</td>
</tr>
<tr>
<td>G80</td>
<td>Cerebral palsy</td>
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<tr>
<td>G82.x*</td>
<td>Paraplegia and tetraplegia</td>
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**CPT® Codes**

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<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
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<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<tr>
<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator</td>
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<td>64555</td>
<td>Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
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<tr>
<td>64575</td>
<td>Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)</td>
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<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
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<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
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**REFERENCES:**


20. de Kroon JR, IJzerman MJ, Lankhorst GJ, Zilvold G. Electrical stimulation of the upper limb in stroke: stimulation of


41. Hesse S, Werner C, Pohl M, et al. Computerized arm training improves the motor control of the severely affected


65. Paul L, Rafferty D, Young S, Miller L, Mattison P, McFadyen A. The effect of functional electrical stimulation on the
### POLICY HISTORY:

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<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
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