I. Policy: Neuromuscular and Functional Electrical Stimulation (NMES)(FES)

II. Purpose/Objective:
To provide a policy of coverage regarding Neuromuscular and Functional Electrical Stimulation (NMES)(FES)

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. Coverage of NMES 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 non-neurological reasons for disuse are causing atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery. NMES can also be used in the outpatient setting as an adjunct therapy to treat muscle atrophy.

**INDICATIONS:**
- Disuse muscle atrophy, where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse are causing atrophy including but not limited to:
  - Previous casting or splinting
  - Contracture due to scarring of soft tissue as in burn lesions
  - Hip replacement surgery (until physical therapy begins)
  - Major knee surgery (when there is a failure to respond to physical therapy)

Requires pre-certification through the Plan’s Medical Management Department. Equipment must be obtained through an approved Durable Medical Equipment vendor(s). Coverage for these items is subject to the terms, conditions and limitations of the Durable Medical Equipment benefits as outlined in the applicable benefit document.

All requests for approval of neuromuscular stimulation outside the context of disuse atrophy including, but not limited to post-operative protocol, or extended use beyond one month, will require review and approval by a Plan Medical Director or designee.

**Additional indication for Medicare Business Segment:**
(See Medicare Coverage Issue Manual 160.12 for additional information).
- NMES/FES (functional electrical stimulation) to enhance the ability to walk in members with spinal cord injury (SCI).

Coverage is limited to Medicare Business Segment with SCI who have completed a training program which consists of 32 physical therapy sessions with the device over a period of 3 months. **All of the following criteria must be met:**

1. Members with intact lower motor neurons (L1 and below) (both muscle and peripheral nerve);
2. Members with muscle and joint stability for weight bearing of the upper and lower extremities that can demonstrate balance and control to maintain an upright posture independently;
3. Members that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
4. Members who possess high motivation, commitment and cognitive ability to use such devices for walking;
5. Members who can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;
6. Members who can demonstrate hand and finger function to manipulate controls;
7. Members with at least 6-month post recovery spinal cord injury and restorative surgery;
8. Members without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
9. Members who have demonstrated a willingness to use the device long-term.

NMES/FES for walking will not be considered for coverage in the Medicare business segment for members with SCI who have ANY of the following:
- Cardiac pacemakers
- Severe scoliosis or severe osteoporosis
- Skin disease or cancer at area of stimulation
- Irreversible contracture; or
• Autonomic dysreflexia

CONTRAINDICATIONS:
• Members who have a cardiac demand pacemaker
• Members with history of heart disease with arrhythmia present (These members should be evaluated by the attending physician to determine if NMES can be used)
• Skin irritations, wounds or lesions that would preclude the use of NMES electrodes at these sites
• Pregnancy

LIMITATIONS:
• Members must have documented disuse atrophy
• Members must be involved in an existing participating physical therapy program
• Members must demonstrate cognitive ability to comply with home use
• Approval by Medical Management for members meeting criteria for coverage will be limited to a maximum of four (4) weeks. Use of NMES for greater than one month will require reassessment at the completion of the first month of therapy and approval by a Health Plan Medical Director or designee.

EXCLUSIONS:
NMES is considered experimental, investigational and unproven for the following applications and is NOT COVERED:
• As a muscle strengthening regimen in healthy individuals
• For use in the treatment of scoliosis
• For reduction of spasticity or to facilitate voluntary motor control in cerebral palsy, or other upper motor neuron disorders
• Treatment of denervated muscles
• Treatment of pain

The Plan does NOT provide coverage for the use of NMES as a treatment for idiopathic facial palsy (Bell’s palsy) because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does NOT provide coverage for the use of MEDex unit (combined NMES and TENS), and RS4i (combined NMES and interferential therapy) or similar equipment as a treatment for any indication because it is considered experimental, investigational or unproven. Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does NOT provide coverage for the use of Micro-current Stimulation Devices (MENS) including, but not limited to use in the treatment of migraine headache, fibromyalgia, anxiety, depression, insomnia, cognitive dysfunction and other pain disorders because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does NOT provide coverage for the use of electromyographic impulse generated muscle stimulator (biofeedback device) as a treatment for any indication because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does NOT provide coverage for the use of horizontal therapy as a treatment for any indication because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does NOT provide coverage for the use of Functional Electrical Stimulation (e.g, NESS L300, WalkAide™, Bionicare Knee System, Odstock Dropped Foot Stimulator) to improve ambulation in members with a gait disorder such
as foot drop or hemiplegia due to multiple sclerosis, stroke or cerebral injury because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does NOT provide coverage for the use of FES (including but not limited to REGYS/ERGYS and RT300-S/RT300-SP) as in-home physical therapy and exercise equipment to prevent or reverse muscular atrophy and bone demineralization, general rehabilitation, relaxation of muscle spasms, or maintenance of range of motion because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

For Medicaid business segment: Requests for this service will be considered on a “per-case” basis through the Benefit Limit Exception process.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH:
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

HCPCS Code:
64550 Application of surface (transcutaneous) neurostimulator
64580 Incision for implantation of neurostimulator electrodes; neuromuscular
E0745 Neuromuscular stimulation, electric shock unit
E0731 Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patients skin by layers of fabric)
E0764 Functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
A4595 Electrical stimulator supplies, 2 lead per month, (e.g., TENS, NMES)
A4558 Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz

HCPCS Code: 64550 Application of surface (transcutaneous) neurostimulator
HCPCS Code: 64580 Incision for implantation of neurostimulator electrodes; neuromuscular
HCPCS Code: E0745 Neuromuscular stimulation, electric shock unit
HCPCS Code: E0731 Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patients skin by layers of fabric)
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LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
The Merck Manual, Section 21, Ch. 291, Rehabilitation


Cranial Nerve Disorders, Bell’s Palsy, Merck Manual Ch 96. http://www.merck.com/mrkshared/mmanual_home2/sec06/ch096/ch096e.jsp


Centers for Medicare and Medicaid Services, National Coverage Determination (NCD) for NMES 160.12. 1/22/2015.


Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Neuromuscular Electrical Stimulation (NMES) (160.12)


Ralston, KK, Harvey, LL, Batty, JJ, Bonsan, LL, Ben, MM, Cusmiani, RR, Bennett, JJ. Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial. J Physiother, 2013 Nov 30;59(4)


This policy will be revised as necessary and reviewed no less than annually.

Devised: 08/08/01

Revised: 08/25/03; 8/04 (add exclusion); 9/05 (description, exclusion); 10/05 (add exclusion); 10/07 (wording); 12/08 (add FES upper extremity exclusion) 6/20 (add FES exercise equipment exclusion)

Reviewed: 8/02; 10/06; 12/09, 1/11, 2/12, 2/14, 2/17, 2/18, 2/20