

Policy: MP001

Section: Medical Benefit Policy

Subject: Neuromuscular and Functional Electrical Stimulation NMES/FES

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

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.

For other related policies please see:

- **MP 113 – Electrical and Electromagnetic Stimulation to Promote Wound Healing**
- **MP 146 – Sympathetic Therapy**
- **MP 244 – Pelvic Floor Stimulation**

INDICATIONS:

Commercial and Non-Medicare Business Segments

Neuromuscular electrical stimulation (NMES)

- 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.

Functional Electrical Stimulation (FES):

Functional neuromuscular stimulation (FNS)/functional electrical stimulation (FES) (e.g. Parastep® Ambulation System) may be considered medically necessary to enable members with spinal cord injury to ambulate when all of the following criteria are met:

- Intact lower (both muscle and peripheral nerve) motor units at L1 and below; and
- Sufficient muscle/joint stability and control to maintain an independent upright posture and weight bearing for a minimum of 3 minutes; and
- Documentation of sensory perception of electrical stimulation sufficient for muscle contraction and a brisk muscle contraction to FES; and
- There is a minimum of 6 months post recovery of spinal cord injury and restorative surgery; and
- The member can transfer independently and has sufficient hand and finger function to manipulate controls; and
- The member demonstrates the motivation, commitment and cognitive ability to use such device for walking.

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/FES 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 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 FES of the upper extremities (e.g., NESS H200 Handmaster NMS1 System) to improve muscle strength, treat atrophy or reduce spasticity due to traumatic brain injury, stroke, spinal cord injury or upper motor neuron 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 Functional Electrical Stimulation (eg, 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.

The Plan does **NOT** provide coverage for the use of FES including but not limited to RT300 FES cycle ergometer used for upper limb paralysis or hemiplegia 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 robotic lower body exoskeleton suits (e.g., the ReWalk, Ekso system, etc) 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 NMES to the tongue base as a treatment for obstructive sleep apnea 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. **(see also MP201)**

The Plan does **NOT** provide coverage for the use of the Cala Trio nerve stimulating device for the treatment of essential tremors 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.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

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 Open implantation of neurostimulator electrode array, 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
- A4560 Neuromuscular electrical stimulator (nmes), disposable, replacement only
- 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
- K1007 Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors (ReWalk Personal Prosthetic Exoskeleton System)
- K1018 External upper limb tremor stimulator of the peripheral nerves of the wrist [*Cala Trio*]
- K1028 Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
- K1029 Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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.

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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'l exclusion), 2/13 (added exclusion/references), 2/15 (added exclusion), 2/16 (added exclusion); 2/19 (add FES upper extremity exclusion) 6/20 (add FES exercise equipment exclusion); 6/21 (add FES indication, add exclusions); 6/22 (add exclusions for essential tremor and OSA)

Reviewed: 8/02; 10/06; 12/09, 1/11, 2/12, 2/14, 2/17, 2/18, 2/20, 6/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

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