

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.

REFERENCES:

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

Moore SR, Sturman J, "Combined neuromuscular electrical stimulation and transcutaneous electrical stimulation for treatment of chronic back pain: a double blind, repeated measures comparison." *Archives of Physical Medicine & Rehabilitation*. 78(1):55-60, 1997 Jan.

Lake DA, "Neuromuscular electrical stimulation. An overview and its application in the treatment of sports injuries." *Sports Medicine* 13(5):320-36, 1992 May.

Paternostro-Sluga T, Fialka C, Alacamlioglu Y, Saadeh T, Fialka-Moser V, 'Neuromuscular electrical stimulation after anterior cruciate ligament surgery." *Clinical Orthopaedics & Related Research* (368):166-75, 1999 Nov.

Snyder-Mackler L, Delitto A, Bailey SL, Stralka S, "Strength of the Quadriceps Femoris Muscle and functional Recovery after Reconstruction of the Anterior Cruciate Ligament. A Prospective randomized Clinical Trial of Electrical Stimulation." *The Journal of Bone and Joint Surgery*, Vol.77-A(8):1166-1173, 1995 Aug.

St. Anthony's Complete Guide to Medicare Coverage Issues, "Neuromuscular Electrical Stimulation (NMES) in the Treatment of Disuse Atrophy", July 2000, Section 35-77, p 1-23.

Winifred S. Hayes, Hayes Inc. Online, Neuromuscular Electrical Stimulation for Muscle Rehabilitation, April 2003.

Winifred S. Hayes, Hayes Inc. Online, Functional Electrical Stimulation for Rehabilitation of Paralyzed Lower Limbs, January 2002.

Best Evidence Topic Reports, Electrical Stimulation and Bell's Palsy. *Emerg Med J* 2002; 19:428.

Adour KK, Hetzer DG, "Current medical treatment for facial palsy" *Am J Otol*. 1984 Oct;5(6):499-502.

Targan RS, Alon G, Kay SL, "Effect of long-term electrical stimulation on motor recovery and improvement of clinical residuals in patients with unresolved facial nerve palsy". *Otolaryngol Head Neck Surg*. 2000 Feb;122(2):246-252.

Diels HJ, "Facial paralysis: is there a role for a therapist?" *Facial Plast Surg*. 2000;16(4):361-364.

Schrode LW, "Treatment of facial muscles affected by Bell's palsy with high voltage electrical muscle stimulation". *J Manipulative Physiol Ther*. 1993 June;16(5):347-352.

Browning S, Hadjakoutis S, "Electrical stimulation for Bell's palsy". *Cochrane Database of Systemic Reviews*. Vol.2, 2004.

Wolf SR, idiopathic facial paralysis. HNO 1998 46:786-798.

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, CMS Coverage Issues Manual 35-72 Electrotherapy for the Treatment of Facial Nerve Paralysis (Bell's Palsy).

Saggini R, Carnial R, Coco V, Cancelli F, Ianieri M, Maccanti D. Gonarthrosis: treatment with horizontal therapy electrotherapy. Eur Med Phys 2004;40(Supp.1 to No.3):594-8.

Carroll D, Moore RA, McQuay HJ et al. Transcutaneous electrical nerve stimulation (TENS) for chronic pain (Cochrane Review). In : The Cochrane Library, Issue 3, 2002. Oxford: Update Software. The Cochrane Library

Gorodetskyi IG, Gorodnichenko AI, Tursin PS, Reshetnyak VK, Uskov ON. Non-invasive interactive neurostimulation in the post-operative recovery of patients with a trochanteric fracture of the femur. A randomised, controlled trial. J Bone and Joint Surg – Br 2007;89-B(11):1488-1494.

Monaghan B, Caulfield B, O'Mathúna DP. Surface neuromuscular electrical stimulation for quadriceps strengthening pre and post total knee replacement. Cochrane Database Syst Rev, 2010;(1):CD007177.

Esnouf JE, Taylor PN, Mann GE, Barrett CL. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. Mult Scler. 2010 Sep;16(9):1141-7.

Everaert DG, Thompson AK, Chong SL, Stein RB. Does functional electrical stimulation for foot drop strengthen corticospinal connections? Neurorehabil Neural Repair. 2010 Feb;24(2):168-77.

Laufer Y, Ring H, Sprecher E, Hausdorff JM. Gait in individuals with chronic hemiparesis: one-year follow-up of the effects of a neuroprosthesis that ameliorates foot drop. J Neurol Phys Ther. 2009 Jun;33(2):104-10.

National Institute for Health and Clinical Excellence (NICE). Functional electrical stimulation for drop foot of central neurological origin. Jan 2009.

Stein RB, Everaert DG, Thompson AK, Chong SL, Whittaker M, Robertson J, Kuether G. Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders. Neurorehabil Neural Repair. 2010 Feb;24(2):152-67.

van Swigchem R, Vloothuis J, den Boer J, Weerdesteyn V, Geurts AC. Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subjects study of patients' satisfaction, walking speed and physical activity level. J Rehabil Med. 2010 Feb;42(2):117-21.

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

Barrett CL, Mann GE, Taylor PN, Strike P. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. Mult Scler. 2009; 15(4):493-504.

Paul L, Rafferty D, Young S, et al. The effect of functional electrical stimulation on the physiologic cost of gait in people with multiple sclerosis. Multiple Sclerosis. 2008; 14: 954-961

Miller L, Rafferty D, Paul L, Mattison P. A comparison of the orthotic effect of the Odstock Dropped Foot Stimulator and the Walkaide functional electrical stimulation systems on energy cost and speed of walking in multiple sclerosis. Disabil Rehabil Assist Technol. 2014 Mar 17.

Street T, Taylor P, Swain I. Effectiveness of functional electrical stimulation on walking speed, functional walking category, and clinically meaningful changes for people with multiple sclerosis. Arch Phys Med Rehabil. 2015;96(4):667-672

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

Langeard A, et al. Does muscular electrical stimulation training of the lower limb have functional effects on the elderly?: a systematic review. *Exp Gerontol* 2017 Feb 17;91:88-98.

Miller L, et al. Functional electrical stimulation for foot drop in multiple sclerosis: a systematic review and meta-analysis of the effect on gait speed. *Arch Phys Med Rehabil* 2017 Jan 11

Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: A pilot study. *Neurorehabil Neural Repair*. 2007;21(3):207-215.

Alon G, Sunnerhagen KS, Geurts AC, Ohry A. A home-based, self-administered stimulation program to improve selected hand functions of chronic stroke. *NeuroRehabilitation*. 2003;18(3):215-25.

Meijer JW, Voerman GE, Santegoets KM, Geurts AC. Short-term effects and long-term use of a hybrid orthosis for neuromuscular electrical stimulation of the upper extremity in patients after chronic stroke. *J Rehabil Med*. 2009;41(3):157-161

Weber, DJ, Skidmore, ER, Niyonkuru, C, Chang, CL, Huber, LM, Munin, MC. Cyclic functional electrical stimulation does not enhance gains in hand grasp function when used as an adjunct to onabotulinumtoxinA and task practice therapy: a single-blind, randomized controlled pilot study. *Arch Phys Med Rehabil*. 2010 May;91(5):679-86.

Knutson, JS, Gunzler, DD, Wilson, RD, Chae, J. Contralaterally Controlled Functional Electrical Stimulation Improves Hand Dexterity in Chronic Hemiparesis: A Randomized Trial. *Stroke; a journal of cerebral circulation*. 2016 Oct;47(10):2596-602.

Bistolfi A, et al. Evaluation of the effectiveness of neuromuscular electrical stimulation after total knee arthroplasty: a meta-analysis. *Am J Phys Med Rehabil* 2018 Feb;97(2):123-130

Kressler, JJ, Ghersin, HH, Nash, MM. Use of functional electrical stimulation cycle ergometers by individuals with spinal cord injury. *Top Spinal Cord Inj Rehabil*, 2014 Dec 6;20(2).

Hooker, SS, Figoni, SS, Rodgers, MM, Glaser, RR, Mathews, TT, Suryaprasad, AA, Gupta, SS. Physiologic effects of electrical stimulation leg cycle exercise training in spinal cord injured persons. *Arch Phys Med Rehabil*, 1992 May 1;73(5).

BeDell, KK, Scremin, AA, Perell, KK, Kunkel, CC. Effects of functional electrical stimulation-induced lower extremity cycling on bone density of spinal cord-injured patients. *Am J Phys Med Rehabil*, 1996 Jan 1;75(1).

Griffin, LL, Decker, MM, Hwang, JJ, Wang, BB, Kitchen, KK, Ding, ZZ, Ivy, JJ. Functional electrical stimulation cycling improves body composition, metabolic and neural factors in persons with spinal cord injury. *J Electromyogr Kinesiol*, 2008 Apr 29;19(4).

Dolbow, DD, Gorgey, AA, Ketchum, JJ, Gater, DD. Home-based functional electrical stimulation cycling enhances quality of life in individuals with spinal cord injury. *Top Spinal Cord Inj Rehabil*, 2013 Nov 19;19(4). PMID 24244097.

Dolbow, DD, Gorgey, AA, Ketchum, JJ, Moore, JJ, Hackett, LL, Gater, DD. Exercise adherence during home-based functional electrical stimulation cycling by individuals with spinal cord injury. *Am J Phys Med Rehabil*, 2012 Oct 23;91(11). PMID 23085704

Johnston, TT, Smith, BB, Mulcahey, MM, Betz, RR, Lauer, RR. A randomized controlled trial on the effects of cycling with and without electrical stimulation on cardiorespiratory and vascular health in children with spinal cord injury. *Arch Phys Med Rehabil*, 2009 Aug 5;90(8). PMID 19651272

Sadowsky, CC, Hammond, EE, Strohl, AA, Commean, PP, Eby, SS, Damiano, DD, Wingert, JJ, Bae, KK, McDonald, JJ. Lower extremity functional electrical stimulation cycling promotes physical and functional recovery in chronic spinal cord injury. *J Spinal Cord Med*, 2013 Oct 8;36(6)

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;93(4)

Hunt, KK, Fang, JJ, Saengsuwan, JJ, Grob, MM, Laubacher, MM. On the efficiency of FES cycling: a framework and systematic review. *Technol Health Care*, 2012 Oct 20;20(5)

Janssen TW, Beltman JM, Elich P, et al. Effects of electric stimulation-assisted cycling training in people with chronic stroke. *Arch Phys Med Rehabil*. 2008; 89(3):463-469

Ambrosini E, Ferrante S, Pedrocchi A, et al. Cycling induced by electrical stimulation improves motor recovery in postacute hemiparetic patients: a randomized controlled trial. *Stroke*. 2011; 42(4):1068-1073

Esquenazi A, Talaty M, Packel A, Saulino M. The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury. *Am J Phys Med Rehabil*. 2012;91(11):911-921

Raab K, Krakow K, Tripp F, Jung M. Effects of training with the ReWalk exoskeleton on quality of life in incomplete spinal cord injury: A single case study. *Spinal Cord Series Cases*. 2016;15025

Talaty M, Esquenazi A, Briceno JE. Differentiating ability in users of the ReWalk Powered Exoskeleton: An analysis of walking kinematics. 2013 IEEE International Conference on Rehabilitation Robotics, Seattle, Washington, June 24 -26, 2013.

Zeilig G, Weingarden H, Zwecker M. Safety and tolerance of the ReWalk™ exoskeleton suit for ambulation by people with complete spinal cord injury: A pilot study. *J Spinal Cord Med*. 2012;35(2):96-101.

Manns PJ, Hurd C, Yang JF. Perspectives of people with spinal cord injury learning to walk using a powered exoskeleton. *J Neuroeng Rehabil*. 2019;16(1):94.

Guanziroli E, Cazzaniga M, Colombo L, et al. Assistive powered exoskeleton for complete spinal cord injury: Correlations between walking ability and exoskeleton control. *Eur J Phys Rehabil Med*. 2019;55(2):209-216.

Benson I, Hart K, Tussler D, van Middendorp JJ. Lower-limb exoskeletons for individuals with chronic spinal cord injury: Findings from a feasibility study. *Clin Rehabil*. 2016;30(1):73-84.

Muijzer-Witteveen H, Sibum N, van Dijsseldonk R, et al. Questionnaire results of user experiences with wearable exoskeletons and their preferences for sensory feedback. *J Neuroeng Rehabil*. 2018;15(1):112.

Khan AS, Livingstone DC, Hurd CL, et al. Retraining walking over ground in a powered exoskeleton after spinal cord injury: A prospective cohort study to examine functional gains and neuroplasticity. *J Neuroeng Rehabil*. 2019;16(1):145

Prokopiousova T, Pavlikova M, Markova M, et al. Randomized comparison of functional electric stimulation in posturally corrected position and motor program activating therapy: treating foot drop in people with multiple sclerosis. *Eur J Phys Rehabil Med*. Aug 2020; 56(4): 394-402.

Renfrew LM, Paul L, McFadyen A, et al. The clinical- and cost-effectiveness of functional electrical stimulation and ankle-foot orthoses for foot drop in Multiple Sclerosis: a multicentre randomized trial. *Clin Rehabil*. Jul 2019; 33(7): 1150-1162.

Yu JY, Rajagopal A, Syrkin-Nikolau J, et al. Transcutaneous afferent patterned stimulation therapy reduces hand tremor for one hour in essential tremor patients. *Front Neurosci*. 2020;14:530300.

Cala Health, Inc. Prospective study for symptomatic relief of ET with Cala therapy (PROSPECT). *ClinicalTrials.gov*. Identifier: NCT03597100

Isaacson SH, Peckham E, Tse W, et al. Prospective home-use study on non-invasive neuromodulation therapy for essential tremor. *Tremor Other Hyperkinet Mov* 2020;10:29

Pascual-Valdunciel A, Hoo GW, Avrillon S, et al. Peripheral electrical stimulation to reduce pathological tremor: A review. *J Neuroeng Rehabil*. 2021;18(1):33

Anderson KD, Korupolu R, Musselman KE, et al. Multi-center, single-blind randomized controlled trial comparing functional electrical stimulation therapy to conventional therapy in incomplete tetraplegia. *Front Rehabil Sci*. 2022;3:995244

Loh MS, Kuan YC, Wu CW, et al. Upper Extremity Contralaterally Controlled Functional Electrical Stimulation Versus Neuromuscular Electrical Stimulation in Post-Stroke Individuals: A Meta-Analysis of Randomized Controlled Trials. *Neurorehabil Neural Repair*. 2022;36(7):472-82.

Glattko KE, Tummala SV, Chhabra A. Anterior Cruciate Ligament Reconstruction Recovery and Rehabilitation: A Systematic Review. J Bone Joint Surg Am.2022;104(8):739-54

Ou CH, Shiue CC, Kuan YC, et al. Neuromuscular Electrical Stimulation of Upper Limbs in Patients With Cerebral Palsy: A Systematic Review and Meta-analysis of Randomized Controlled Trials. Am J Phys Med Rehabil. 2023;102(2):151-58

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, 6/24

CMS UM Oversight Committee Approval: 12/23

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>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.