Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Neuromuscular, Functional, & Therapeutic Electrical Stimulation Therapy

Policy Number: PG0228
Last Review: 07/01/2024

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Electrical Stimulation Therapy is a method designed to restore function to damaged or destroyed nerve pathways through use of orthotic devices with microprocessor controlled electrical neuromuscular stimulation stimulating functional movement in muscle affected by nerve damage.

Neuromuscular electrical stimulation (NMES) involves the use of transcutaneous application of electrical currents to cause muscle contractions. The goal of NMES is to promote reinnervation, to prevent or retard disuse atrophy, to relax muscle spasms, and to promote voluntary control of muscles in patients who have lost muscle function due to surgery, neurological injury, or disabling condition.

Functional electrical stimulation (FES) is the direct application of electric current to intact nerve fibers in a coordinated fashion to cause involuntary but purposeful muscle contraction. FES bypasses the central nervous system and targets motor neurons innervating either skeletal muscle or other organ systems. It focuses on the restoration of useful movements, like standing, stepping, pedaling for exercise, reaching, or grasping. When used for rehabilitation of patients with spinal cord injury, FES is used to improve general health and fitness through exercise and to enable functional use of partially or completely paralyzed limbs.

Therapeutic/threshold electrical stimulation (TES) is a small battery powered unit with two electrodes that are attached to the skin over weakened muscles. Small electrical stimuli are delivered to the "weakened" muscles (usually muscles opposite the spastic muscles). It is described as the delivery of low intensity electrical stimulation to target spastic muscles during sleep. The stimulation is not intended to cause muscle contraction. Although the mechanism of action is not understood, it is thought that low intensity stimulation may increase muscle strength and joint mobility, leading to improved voluntary motor function. The technique has been used most extensively in children with spastic diplegia related to cerebral palsy, but also in those with other motor disorders, such as spina bifida.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

- **Effective August 1st, 2021, Procedures E0745, E0764, E0770, neuromuscular, functional & therapeutic electrical stimulation therapy requires prior authorization.**
- **Procedure E0744 - neuromuscular stimulator for scoliosis - is non-covered**
- **Procedures A4560, A4593, A4594 are non-covered**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Neuromuscular electrical stimulation (NMES)

Neuromuscular electrical stimulators (NMES) (E0745) and supplies (A4595) are considered medically necessary DME for disuse atrophy where the nerve supply to the muscle is intact and the member has any of the following non-neurological reasons for disuse atrophy:

- Contractures due to scarring of soft tissue (e.g., burn lesions/scarring); or
- Major knee surgery (e.g., total knee replacement) when there is failure to respond to physical therapy; or
- Atrophy secondary to prolonged casting or splinting of a limb (arm or leg); or
- Recent hip replacement surgery prior to initiation of physical therapy

In addition, ALL the following criteria is met:

- Use will be up to 2 hours per day; and
- Treatment is for disuse atrophy in muscles with an intact nerve supply; and
- Effective physical therapy cannot be performed

The following are considered experimental/investigational and not eligible for reimbursement:

- Disposable replacement neuromuscular electrical stimulator (A4560).
- NMES for all other clinical conditions, including neuromuscular tongue stimulation for management of gait impairment (A4593, A4594).
- All other use of NMES for the treatment of disuse atrophy, including use with muscles in which the nerve supply is not intact

Form-fitting conductive garments (E0731) are considered medically necessary for FDA approved garments that have been prescribed by a physician when the following criteria is met:

- The conductive area is large or requires numerous sites to be stimulated, and use conventional electrodes, adhesive tapes, and lead wires is not feasible; or
- The member has a medical condition that makes the application of conventional electrodes, adhesive tapes, and lead wires impractical; or
- The member requires electrical stimulation beneath a cast.

Form-fitting conductive garments are considered experimental/investigational and not eligible for reimbursement for all other clinical conditions because its effectiveness for indications other than the ones listed above has not been established.

Functional NMES (FNMES) as a technique to restore function following nerve damage or nerve injury (including but not limited to, upper extremity function in patients with spinal cord injury or stroke, and ambulation in patients with spinal cord injury or with foot-drop due to cerebral palsy, stroke, or multiple sclerosis) is considered experimental/investigational.

Functional electrical stimulation (FES)

Functional electrical stimulator (FES) (E0764) is considered medically necessary DME (e.g., Parastep I System) to enable members with spinal cord injury (SCI) to ambulate when ALL the following criteria are met:

- Device will be utilized for rehabilitative walking following lower extremity paralysis due to SCI; and
- Member has intact lower motor units (L1 and below) (both muscle and peripheral nerve); and
- Member has joint stability to bear weight on upper and lower extremities, and has balance and control to

maintain an upright posture independently; and
- Member demonstrated brisk muscle contraction to neuromuscular electrical stimulation and has sensory perception of electrical stimulation sufficient for muscle contraction; and
- Member has the cognitive ability to use such devices for walking and is highly motivated to use the device long term; and
- Member can transfer independently and stand for at least **≥** 3 minutes; and
- Member possesses hand and finger function to manipulate the controls; and
- Member is **≥** 6 months post recovery of spinal cord injury and restorative surgery; and
- Member does not have hip and knee degenerative disease and has no history of long bone fracture secondary to osteoporosis; and
- The member has successfully completed a training program, which consists of at least 32 physical therapy sessions with the device over a 3-month period.

Note: These criteria are adapted from the Food and Drug Administration (FDA) labeling for Parastep I System as well as information provided in published studies.

The only settings where therapists with the sufficient skills to provide these services are employed are inpatient hospitals, outpatient hospitals, comprehensive outpatient rehabilitation facilities, and outpatient rehabilitation facilities. The physical therapy necessary to perform this training must be part of a one-on-one training program.

Functional electrical stimulation (FES) is considered experimental/investigational and not medically necessary for all indications, including but not limited to:
- When used to prevent or reverse muscular atrophy (wasting) and bone demineralization (loss), by stimulating paralyzed limbs for the performance of stationary exercise, or to correct gait disorders. This includes, but is not limited to, functional electrical stimulation ergometer devices (for example, ERGYS® and ERGYS® 2); **or**
- When used to promote ambulation when member does not have intact lower motor units (L1 and below) (both muscle and peripheral nerve) (for example, Parastep® I System); **or**
- When used to activate muscles of the upper limb or lower limb to produce functional movement patterns. This includes, but is not limited to, the NESS H200® Handmaster Rehabilitation System, NESS L300™ Foot Drop System, ODFS Dropped Foot Stimulator, and the WalkAide® System. Functional neuromuscular electrical stimulation used to enhance functional activity of neurologically impaired members is non-covered as there is no scientific evidence of effectiveness in improving health outcomes.

The use of functional electrical stimulation (FES) devices for exercise in patients with spinal cord injury is considered experimental/investigational.

Therapeutic/threshold electrical stimulation (TES)
Threshold electrical stimulation (TES) is considered experimental/investigational and not medically necessary for all indications including, but not limited to, treatment of motor disorders such as cerebral palsy or scoliosis. TES as a treatment of scoliosis was widely investigated in the 1980s. However, retrospective studies suggested that the outcomes associated with electrical stimulation were not significantly different from the natural history of scoliosis.

Non-Coverage:
Neuromuscular stimulation is considered experimental/investigational as a technique to restore function following nerve damage or nerve injury, not an all-inclusive listing:
- As a technique to provide ambulation in members with a spinal cord injury (when member does not have intact lower motor units (L1 and below) (both muscle and peripheral nerve)
- To provider upper extremity function (E0770) in members with nerve damage (e.g., spinal cord injury or post-stroke)
- To improve ambulation in members with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., post-stroke or in those with multiple sclerosis)

NMES/FES for walking will not be covered in spinal cord injury patients with ANY of the following:

- Persons with cardiac pacemakers
- Severe scoliosis or severe osteoporosis
- Skin disease or cancer at area of stimulation
- Irreversible contracture
- Autonomic dysflexia

The use of functional electrical stimulation (FES) devices for exercise in patients with spinal cord injury is considered experimental/investigational.

Exercise devices such as the FES Power Trainer, ERGYS, REGYS, NeuroEDUCATOR, STimMaster Galaxy, RT200 Elliptical, RT300 FES Cycle Ergometer (also referred to as a FES bicycle), RT600 Step and Stand Rehabilitation Therapy System, and SpectraSTIM are considered exercise equipment, and excluded coverage.

CODING/BILLING INFORMATION:
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

HCPCS CODES	
A4560	Neuromuscular electrical stimulator (NMES), disposable, replacement only (new 04/01/2023) Not Covered
A4593	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, controller (new 04/01/2024) Not Covered
A4594	Neuromodulation stimulator system, adjunct to rehabilitation therapy regime, mouthpiece, each (new 04/01/2024) Not Covered
A4595	Electrical stimulator supplies, 2 leads, per month, (e.g., TENS, NMES)
E0731	Form-fitting conductive garment for delivery of TENS or NMES with conductive fibers separated from the patient's skin by layers of fabric
E0744	Neuromuscular stimulator for scoliosis Not Covered
E0745	Neuromuscular stimulator, electronic shock unit (FES, NMES, TES)
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories (FES)
E0764	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 (FES)
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (FES)
L8680	Implantable neurostimulator electrode, each (FES, NMES)
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator (FES, NMES)
L8682	Implantable neurostimulator radiofrequency receiver (FES, NMES)
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver (FES, NMES)
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension (FES, NMES)
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension (FES, NMES)
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension (FES, NMES)
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension (FES, NMES)
L8689	External recharging system for battery (internal) for use with implantable neurostimulator (FES, NMES)

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/15/2009

Date	Explanation & Changes
07/01/11	• No changes
08/22/14	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/22/15	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/28/16	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
10/27/17	• Changed title from “Electrical Stimulation Therapy” to “Neuromuscular, Functional, & Therapeutic Electrical Stimulation Therapy.” • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/25/18	• Effective 7/16/18 code E0770 is now covered without prior authorization for Advantage per ODM guidelines • Limits may apply • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/17/2020	• Medical policy placed on the new Paramount Medical Policy Format
05/17/2021	• Policy reviewed and updated to reflect most current clinical evidence • Procedure 64565 documented as deleted code: Deleted Code (for percutaneous electrical neuromuscular stimulation or neuromodulation using needle(s) or needle electrode(s) [e.g., PENS, PNT], use 64999) • Added the following procedure codes for reference: 63655, 63685, 64550, 64555, 64575, 64585, 64590, 64595, 64999, A4495, E0762, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 • Coverage criteria indicated for Neuromuscular electrical stimulation (NMES) • Coverage criteria indicated for Functional electrical stimulation (FES) • Effective August 1st, 2021, Prior Authorization now required for procedure E0770 (Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified) for all product lines • Effective August 1st, 2021, Prior Authorization now required for procedures E0745 (Neuromuscular stimulator, electronic shock unit) and E0764 (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) for HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan
02/15/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/29/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/05/2024	• Medical Policy placed on the new Paramount Medical Policy format
07/01/2024	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Removed all the referenced surgical procedure codes as not indicated for the policy • Added noncovered codes A4560, A4593, A4594

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review