Neuromuscular Electrical Stimulator (NMES) Functional Electrical Stimulator (FES)

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

NMES and FES devices require precertification and physician face-to-face.

Noncovered DME item for West Virginia Medicaid members.

National Coverage Determination Policy	Medicare National Coverage Determinations Manual 100-3 Chapter 1, Part 2 (Section 160.12) Table of Contents *(Rev. 121, 05-28-10)* (Rev. 55, Issued: 05-05-06, Effective 10-01-06, Implementation: 10-02-06)
Local Coverage Determination Policy	None
Effective Date	10/01/06
Revision/Review Date	01/19, 10/18, 06/05/2018, 04/01/17, 05/01/16, 01/01/14, 09/16/14
The Health Plan	Will follow the National Coverage Guidelines above unless otherwise indicated in sections of this policy or contractual agreement.

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. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state, in order to treat

muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

COVERAGE GUIDELINES

Treatment of Muscle Atrophy

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 non-neurological reasons for disuse 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 (until orthotic training begins). *See below for an explanation of coverage of medically necessary supplies for the effective use of NMES.*

Should be part of a comprehensive rehabilitation program.

Treatment for Scoliosis in Adolescents or Juveniles in Commercial Plans

Coverage for the NMES for scoliosis is considered medically necessary for juveniles or adolescents under Commercial plans who meet coverage criteria below. All of the following criteria must be met.

1. One year or more of bone growth remaining
2. Has not been surgically treated
3. Is not currently undergoing bracing
4. Spinal curvature is between 20° and 45° per radiographic studies
5. Curvature is highly progressive. For curves between 20° - 30°, documentation should show a curvature of 5° or more within the past 12 months. Curvatures of 30° or more will be considered highly progressive for skeletally immature members
6. On the force lateral bending, there is a minimum of 50 percent correction

Use for Walking in Patients with Spinal Cord Injury (SCI)

The type of NMES that is used to enhance the ability to walk of SCI patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence. Coverage for the use of NMES/FES is limited to SCI patients for walking, who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months. The trial period of physical therapy will enable the physician treating the patient, for his or her spinal cord injury, to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program.

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.

Coverage for NMES/FES for walking will be covered in SCI patients with all of the following characteristics:

1. Persons with intact lower motor unite (L1 and below) (both muscle and peripheral nerve);

2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
3. Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;
4. Persons that possess high motivation, commitment, and cognitive ability to use such devices for walking;
5. Persons that can transfer independently and can demonstrate independent standing tolerance for at least three minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
7. Persons with at least a six month post recovery spinal cord injury and restorative surgery;
8. Persons with hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
9. Persons who have demonstrated a willingness to use the device long-term.

The covered FES system is the Parastep.

NOTE: 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.

Additional therapy after the purchase of the DME would be limited by the member's benefit plan coverage and The Health Plan policies.

See billing guidelines for Interferential Current (IFC) Therapy devices being used as a neuromuscular stimulator.

NONCOVERAGE STATEMENT

The NMES/FES for walking will not be covered in a SCI patient with any of the following:

1. Persons with cardiac pacemakers;
2. Skin disease or cancer at area of stimulation;
3. Irreversible contracture; or
4. Autonomic dysflexia.
5. **For Medicare members:** Severe scoliosis or severe osteoporosis.

The Health Plan considers all other FES/PNS systems investigational: the Walkaide, the Bioness Ness L300, Ness H200. This is not an all inclusive list.

The Health Plan does not cover FES bikes.

The Health Plan considers NMES/FES systems investigational/experimental for the following diagnoses:

1. Bell's Palsy
2. Cerebral Palsy
3. Cardiac conditioning
4. General muscle strengthening in healthy individuals
5. Treatment of denervated muscles

6. Foot drop
7. Stroke
8. Scoliosis in adults
9. Severe scoliosis or severe osteoporosis (spinal curvature > 45°) in juveniles or adolescents that do not meet the coverage guidelines above
10. Any other indications not listed as covered above

NOTE: E0744 is not covered for Medicare beneficiaries, as they are not usually adolescents or juveniles with one or more years of bone growth remaining.

Note: NMES is not covered for WV Medicaid members.

REPAIR, REPLACEMENT AND REASONABLE USEFUL LIFETIME

Replacements and repairs require precertification. See **Replacement and Repair** policy.

Repairs are not separately payable during rental period.

Replacements are not covered due to neglect or misuse.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS CODES COVERED IF COVERAGE GUIDELINES ARE MET

A4556	ELECTRODES (E.G., APNEA MONITOR), PER PAIR
A4557	LEAD WIRES (E.G., APNEA MONITOR), PER PAIR
A4558	CONDUCTIVE GEL OR PASTE, FOR USE WITH ELECTRICAL DEVICE (E.G., TENS, NMES), PER OZ
A4595	ELECTRICAL STIMULATOR SUPPLIES, 2 LEAD, PER MONTH, (E.G. TENS, NMES)
E0744	NEUROMUSCULAR STIMULATOR FOR TREATMENT OF SCOLIOSIS
E0745	NEUROMUSCULAR STIMULATOR, ELECTRONIC SHOCK UNIT
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
E0770	FUNCTIONAL ELECTRONIC STIMULATOR, TRANSCUTANEOUS STIMULATION OF NERVE AND OR MUSCLE GROUPS, ANY TYPE, COMPLETE SYSTEM, NOT OTHERWISE SPECIFIED

ICD-10 CODE COVERED FOR MEDICARE BENEFICIARIES FOR FES: E0764/E0770

G82.20	PARAPLEGIA-PARALYSIS OF BOTH LOWER LIMBS

ICD-10 CODES IF CRITERIA MET FOR E0745

M62.50	MUSCULAR WASTING AND DISUSE ATROPHY, NOT ELSEWHERE CLASSIFIED [SEE CRITERIA] FOR NMES
S12-S12.9XXA, S14.109A, S22-S22.009B, S24-S24.109A, S32.0-S3210XB, S34-S34.139A	FRACTURE OF CERVICAL VERTEBRA AND OTHER PARTS OF THE NECK. FRACURE OF THE OTHER PARTS OF NECK. FRACTURE OF NECK, UNSPECIFIED. INJURY OF NERVES AND SPINAL CORD AT THE NECK. FRACTURE OF RIB(S), STERNUM, AND THORACIC SPINE. INJURY OF NERVES AND SPINAL CORD AT THORAX LEVEL. FRACTURE OF LUMBAR SPINE AND PELVIS. INJURY OF LUMBAR AND SACRAL SPINAL CORD AND NERVES AT ABDOMEN,LOWER BACK AND PELVIS LEVEL. [NOT COVERED FOR FES OF UPPER EXTREMITIES].
S14.1095, S24.1095, S34.1095, S34.1395	LATE EFFECTS OF SPINAL CORD INJURY [NOT COVERED FOR FES OF UPPER EXTREMITIES]
S14.101A, S14.102A, S14.103A, S14.104A-S34.109A	SPINAL CORD INJURY WITHOUT EVIDENCE OF SPINAL BONE INJURY (CERVICAL, THORACIC, LUMBAR) [NOT COVERED FOR FES OF UPPER EXTREMITIES]

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
    a. Member's name
    b. Date
    c. Description of item. Order must include any specific feature of the base code and every addition requested. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
    d. Order must include diagnosis code
    e. Physician signature with date. Date stamps are not appropriate

f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.

3. Proof of delivery to be kept on file by the provider of the item.

4. Functional level and prosthetist/orthotist assessment.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

ELECTRICAL STIMULATOR PROVIDED WHILE MEMBER IN PART A FACILITY

Reimbursement for electrical stimulation provided to a member while the member is covered in a Part A facility (hospital or inpatient acute rehabilitation or long term acute care facility) will be included in the facility reimbursement if the device is intended for use while the member is in the facility for inpatient treatment or rehabilitation. In order for it to be billed separately, it must be given two days or less before discharge from the Part A covered stay and it must meet the above guidelines and be medically necessary for home use.

Reimbursement for an electrical stimulator provided while a member is in a SNF receiving Part A services, will be reimbursed according to individual facility contracts.

EQUIPMENT RETAINED FROM A PRIOR PAYOR:

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

BILLING GUIDELINES

Accessories/supplies are not separately billable during rental period or with initial purchase of device.

HCPCS code E0764 includes the entire system for FES devices. Therefore, individual components such as walkers, crutches, or other supplies must not be billed separately.

Utilization above the current allowable quantities will not be reimbursed unless corroborated by medical record of the medical necessity of the quantity of supplies being used.

A precertification is required for requests above the allowable amounts.

No more than one month's equipment or supplies are allowed for one month's prospective billing. Claims submitted retroactively, however, may include multiple months. Providers are reminded that timely filing will apply.

E0770 is only covered if the device has been verified by the PDAC. Currently, the only products that are coded E0770 are the Walkaide by Innovative Neurotronics, Odstock ODFS Pace FES System by Odstock Medical/ Boston Brace, Ness L300 and H200 devices by Bioness.

Currently the Parastep I by Sigmedics is the only product allowed to be billed with code E0764.

Interferential Current (IFC) Therapy is a form of electrotherapy in which two currents are applied and "crossed" resulting in a different frequency at the interference (crossing) point. This approach allows a higher frequency current to be applied to the skin to overcome skin resistance with a lower frequency current created in the underlying tissue. Lower frequency currents are thought to produce stronger effects with less discomfort.

IFC devices can be configured to mimic the effects of neuromuscular stimulators (NMES) used for the treatment of disuse atrophy. The following HCPCS codes must be used when billing for IFC devices used as a NMES device:

E0745 (NEUROMUSCULAR STIMULATOR, ELECTRONIC SHOCK UNIT)

Supplies (leads, electrodes, batteries, etc.) used with IFC devices are billed using the existing NMES supply codes.

Not otherwise classified (NOC) or miscellaneous codes must not be used to bill Medicare for IFC devices or for supplies used with an IFC device.

Accessories allowance for covered FES system is as follows:

A4595 is an allowance for all necessary supplies used during the month regardless of the number of lead/electrode changes made. All necessary supplies such as electrodes, coupling gel, adhesive, adhesive remover, etc. are considered as included in the monthly allowance. If two leads are required, then a maximum of one unit/month is allowed. If four leads/electrodes are required, then two units a month would be allowed. No units over the allowable will be authorized.

DISPENSING SUPPLIES

The Health Plan is following Medicare's guidelines for supplies provided on a reoccurring basis.

Suppliers are not to automatically dispense supplies according to allowable limits. Suppliers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member or caregiver prior to dispensing the supplies. Supplies should not be shipped/delivered sooner than 10 days prior to end of usage. *Please refer to CMS Program Integrity Manual for more information.* (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

The DME supplier is responsible to monitor utilization of rented and covered frequently purchased supplies for member owned equipment, that they would request reimbursement from The Health Plan.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid (ABN).

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. dmepdac.com/

AMA CPT/ADA CDT COPYRIGHT STATEMENT

INTERNET LINKS AND SOURCES

Medicare National Coverage Determinations Manual. Chapter 1, Part 2 (Sections 90 – 160.26) Coverage Determinations. Last accessed 10/30/18. Retrieved from: cms.gov/manuals/downloads/ncd103c1_Part2.pdf

Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Neuromuscular Electrical Stimulaton (NMES) (160.12) Last accessed 10/30/18. Retrieved from: cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=175&ncdver=2&bc=BAABAAAAAAAA&

West Virginia Medicaid Internet Provider Manual. Chapter 506. Covered Services, Limitations, and Exclusions for DME Medical Supplies. Last accessed 10/30/18. Retrieved from: dhhr.wv.gov/bms/Pages/default.aspx

Department Health and Human Services. Centers for Medicare and Medicaid Services. Medicare Learning Network® website. Detailed Written Orders and Face-to-Face Encounters. MM8304 Revised May 31, 2013. Effective Date: July 1, 2013

Related CR Transmittal #: R468PI. Implementation Date: July 1, 2013. Last accessed 10/30/18. Retrieved from: cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8304.pdf

National Scoliosis Foundation: scoliosis.org/forum/archive/index.php/t-2958.html

Scoliosis Research Society (SRS) website. Last accessed 10/30/18. Retrieved from: http://www.srs.org/

Anciaux M, Lenaert A, Van Beneden ML, et al. Transcutaneous Electrical Stimulation (TCES) for the Treatment of Adolescent Idiopathic Scoliosis: Preliminary Results. Acta Orthopaedica Belgica. 1991; 57(4):399-405

Brown JC, Axelgaard J, Howson DC. Multicenter Trial of a Noninvasive Stimulation Method for Idiopathic Scoliosis: A Summary of Early Treatment Results. Spine. 1984; 9(4):382-387

Dutro CL, Keene KJ. Electrical Muscle Stimulation in the Treatment of Progressive Adolescent Idiopathic Scoliosis: A Literature Review. J Manipulative Physical Ther. 1985; 8(4):257-260

Durham JW, Moskowitz A, Whitney J. Surface Electrical Stimulation versus Brace in Treatment of Idiopathic Scoliosis. Spine 1990 Sep; 15 (9):888-92

CGS Medicare: A Celerian Group Company website. Correct Coding-Interferential Current (IFC) Therapy Devices. March 16, 2017. Last accessed 10/30/18. Retrieved from: http://www.cgsmedicare.com/articles/cope2493.html

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11

Jurisdiction B DME MAC: Joint DME MAC Publication. Functional Electrical Stimulation (FES) - Coverage and HCPCS Coding - revised. July 10, 2014 5:01 pm