09-E0000-54

Original Effective Date: 04/15/02

Reviewed: 06/26/25

Revised: 07/15/25

Subject: Functional Neuromuscular Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Functional neuromuscular stimulation is designed to stimulate muscles and thus restore the function of the extremity. Functional neuromuscular stimulation attempts to replace stimuli from damaged or destroyed nerve pathways with sequential electrical stimulation of muscles to enable spinal cord injured patients to stand or walk independently or maintain muscle tone and strength and gait training in (e.g., post-stroke, multiple sclerosis, cerebral palsy). Electrodes are placed; implanted, transcutaneously, or percutaneously. A stimulator unit worn externally produces the pulses. The pulses are delivered via the skin surface or via implanted electrodes. Electrical impulses are delivered that stimulate the nerves to produce muscle contractions of paralyzed muscles or injured nerves.

The U.S. Food and Drug Administration (FDA) have approved several functional electrical stimulation devices (e.g., Parastep® Ambulation System, WalkAide, Bioness L300™, FES Motorized CycleErgometer).

Summary and Analysis of Evidence In a systematic review with meta-analysis by Fang et al 2021 the effect and dose-response of functional electrical stimulation cycling (FES-cycling) training on spasticity in the individuals with spinal cord injury (SCI) was investigated. Five electronic databases were searched before September 2021. The human trials and studies of English language were only included. Two authors independently reviewed and extracted the searched studies. The primary outcome measure was spasticity assessed by Modified Ashworth Scale or Ashworth Scale for lower limbs. The secondary outcome measures were walking abilities, such as 6 Min Walk Test (6MWT), Timed Up and Go (TUG), and lower limbs muscle strength (LEMS). A subgroup analysis was performed to investigate the efficacious threshold number of training sessions. A meta-regression analysis was used to examine the linear relationship between the training sessions and the effect on spasticity. A total of 764 studies were identified. After screening, 12 selected studies were used for the qualitative synthesis, in which eight of them were quantitatively analyzed. Eight studies included ninety-nine subjects in total with SCI (male: female = 83:16). The time since injury was from less than 4 weeks to 17 years. The age ranged from 20

to 67 years. American Spinal Injury Association (ASIA) impairment level of the number of participants was 59 for ASIA A, 11 for ASIA B, 18 for ASIA C, and 11 for ASIA D. There were 43 subjects with tetraplegia and 56 subjects with paraplegia. Spasticity decreased significantly (95% *CI* = - 1.538 to - 0.182, *p* = 0.013) in favor of FES-cycling training. The walking ability and LEMS also improved significantly in favor of FES-cycling training. The subgroup analysis showed that spasticity decreased significantly only in more than 20 training sessions (95% *CI* = - 1.749 to - 0.149, *p* = 0.020). The meta-regression analysis showed training sessions and spasticity were not significantly associated (coefficient = - 0.0025, SE = 0.0129, *p* = 0.849, R^2 analog = 0.37). The authors concluded that functional electrical stimulation-cycling training can improve spasticity, walking ability, and the strength of the lower limbs in the individuals with SCI. The number of training sessions is not linearly related to the decrease of spasticity. Twenty sessions of FES-cycling training are required to obtain the efficacy to decrease spasticity.

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In a review by van der Scheer et al 2021 summarized and appraised evidence on functional electrical stimulation (FES) cycling exercise after spinal cord injury (SCI), in order to inform the development of evidence-based clinical practice guidelines. Ninety-two studies met the eligibility criteria, comprising 999 adults with SCI representing all age, sex, time since injury, lesion level and lesion completeness strata. For muscle health (e.g., muscle mass, fiber type composition), significant improvements were found in 3 out of 4 Level 1-2 studies, and 27 out of 32 Level 3-4 studies (GRADE rating: 'High'). Although lacking Level 1-2 studies, significant improvements were also found in nearly all of 35 Level 3-4 studies on power output and aerobic fitness (e.g., peak power and oxygen uptake during an FES cycling test)

(GRADE ratings: 'Low'). The authors concluded that current evidence indicates that FES cycling exercise improves lower-body muscle health of adults with SCI and may increase power output and aerobic fitness.

POSITION STATEMENT:

NOTE: For neuromuscular electrical stimulation, refer to Neuromuscular Electrical Stimulation, 09-E0000-25. For diaphragmatic-phrenic nerve stimulation, refer to Diaphragmatic-Phrenic Nerve Stimulation (i.e., Electrophrenic Pacemaker), 02-61000-33.

Functional neuromuscular stimulation for walking **meets the definition of medical necessity** in individuals with spinal cord injury when **ALL** of the following criteria are met:

- Intact lower motor units (L1 and below) (both muscle and peripheral nerve); **AND**
- 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; **AND**
- Demonstration of brisk muscle contraction; **AND**
- Demonstration of high motivation, commitment, and cognitive ability for device use; **AND**
- Able to transfer independently; **AND**
- Demonstration of standing independently for at least three minutes; **AND**
- Demonstration of hand and finger function to manipulate controls; **AND**
- Post-recovery from spinal cord injury and restorative surgery of at least 6 months; **AND**
- Absence of hip and knee degenerative disease; **AND**
- Absence of history of long bone fracture secondary to osteoporosis; **AND**
- Individual demonstrates a willingness to use the device long-term; **AND**
- No contraindications* to functional neuromuscular stimulation for walking.

Functional neuromuscular stimulation is considered **experimental or investigational** for all other indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

*Contraindications for functional neuromuscular stimulation for walking:

- Cardiac pacemakers
- Severe scoliosis
- Severe osteoporosis
- Skin disease at area of stimulation
- Cancer at area of stimulation
- Irreversible contractures
- Autonomic dysreflexia.

BILLING/CODING INFORMATION:

HCPCS Coding:

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
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT** and **PROGRAM EXCEPTIONS**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Local Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Neuromuscular Electrical Stimulator (NMES) (160.12), located at cms.gov.

No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Diaphragmatic-Phrenic Nerve Stimulation (i.e., Electrophrenic Pacemaker), 02-61000-33

Neuromuscular Electrical Stimulator (NMES), 09-E0000-25

OTHER:

Other names used to report functional neuromuscular stimulation:

Electrical Stimulation
Functional Electrical Stimulation
Neuromuscular Stimulation

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy and Coverage Committee on 06/26/25

GUIDELINE UPDATE INFORMATION:

04/15/02	New Medical Coverage Guideline.
04/15/03	Reviewed; Program Exception added for Medicare & More.

04/15/04	Review and revision of guideline; consisting of updated references and no change in coverage statement.
01/15/05	Review and revision of guideline; consisting of updated references.
01/01/06	Review and revision of guideline; consisting of updated references. Annual HCPCS coding update: consisting of the deletion of K0600 and the addition of E0764.
11/15/06	Review and revision of guideline consisting of updated references.
07/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
11/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: revised descriptor for code E0764.
01/15/10	Annual review; updated position statement (added restore muscular function and other conditions and indications). Updated Medicare Advantage products program exception. Updated references.
12/15/10	Annual review: Revised descriptor. Revised position statement to include upper extremity function in patients with nerve damage (e.g., spinal cord injury, post stroke) and to improve ambulation in patients with foot drop caused by nerve damage (e.g., post-stroke, multiple sclerosis). Reformatted Medicare Advantage program exception. Updated references.
01/15/13	Annual review; no change to position statement. Added Medical Coverage Guideline reference and link for Diaphragmatic-Phrenic Nerve Stimulation (i.e., Electrophrenic Pacemaker), 02-61000-33 and updated references.
03/15/13	Code update; added E0770.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
09/15/18	Review; no change in position statement. Updated references.
0715/19	Revision; added for exercise in members with spinal cord injury. Updated references.
09/15/21	Review; revised position statement. Updated program exceptions and references.
11/15/22	Review; no change in position statement. Updated references.
05/15/24	Position statements maintained.
07/15/24	Review; no change in position statement. Updated references.
07/15/25	Review; add position statement for functional electrical stimulation (FES) and spinal cord injury. Updated references.