Medical Coverage Policy | Functional Neuromuscular Electrical Stimulation

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OVERVIEW

Neuromuscular electrical stimulation (NMES) involves the use of a device that transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of these devices, NMES and functional electrical stimulation (FES). NMES stimulates the muscle when the patient is in a resting state to treat muscle atrophy. FES is used to enhance functional activity of neurologically impaired patients. FES is used to enhance the ability in spinal cord injury (SCI) patients to walk. These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence.

MEDICAL CRITERIA

Medicare Advantage Plans

Spinal Cord Injury

FES for walking is covered in SCI patients when all of the criteria listed below is met:

- Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);
- 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;
- Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;
- Persons that possess high motivation, commitment, and cognitive ability to use such devices for walking;
- Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;
- Persons that can demonstrate hand and finger function to manipulate controls;
- Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
- Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
- Persons who have demonstrated a willingness to use the device long-term.

Muscle Atrophy

NMES for the treatment of muscle atrophy is covered when one of the criteria below is met:

- 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.)

Commercial Products

Not applicable

PRIOR AUTHORIZATION

Medicare Advantage Plans

Prior authorization is required and obtained via the online tool for participating providers. See the Related Policies section.

Commercial Products
Not applicable

POLICY STATEMENT

Medicare Advantage Plans
Neuromuscular electrical stimulation may be considered medically necessary for the treatment of muscle atrophy when the medical criteria above is met.

Functional electrical stimulation may be considered medically necessary for the treatment of spinal cord injury when the medical criteria above is met.

NMES/FES is not covered for all other indications as there is insufficient peer reviewed scientific literature that demonstrates that the procedure/service is effective.

Commercial Products
Neuromuscular stimulation (NMES/FES) is considered not medically necessary as a technique to restore function following nerve damage or nerve injury, as a technique to provide ambulation in patients with spinal cord injury; or to provide ambulation in patients with footdrop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., poststroke, or in those with multiple sclerosis), as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable durable medical equipment or not medically necessary/not covered benefits/coverage.

BACKGROUND

NMES involves the use of a device that transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of neuromuscular stimulation. NMES is one type of device that stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type, FES, is used to enhance functional activity of neurologically impaired patients to treat spinal cord injuries.

Neural prosthetic devices consist of an orthotic and a microprocessor-based electronic stimulator with one or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce functionally useful movements that allow patients to sit, stand, walk, and grasp. Functional neuromuscular stimulators are closed-loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities such as walking. These are contrasted with open-loop systems, which are used for simple tasks such as muscle strengthening alone, and typically in healthy individuals with intact neural control.

One application of functional NMES is to restore upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadriplegia). The Neurocontrol Freehand System is an implantable upper extremity neuroprosthesis intended to improve a patient's ability to grasp, hold, and release objects and is indicated for use in patients who are tetraplegic due

to C5 or C6 spinal cord injury. The implantable Freehand System is no longer marketed in the U.S., though the company provides maintenance for devices already implanted. The Handmaster NMS I (neuromuscular stimulator) is another device that uses surface electrodes and is purported to provide hand active range of motion and function for patients with stroke or C5 tetraplegia.

Other neural prosthetic devices have been developed for functional NMES in patients with footdrop. Footdrop is weakness of the foot and ankle that causes reduced dorsiflexion and difficulty with ambulation. It can have various causes such as cerebral palsy, stroke, or multiple sclerosis (MS). Functional electrical stimulation of the peroneal nerve has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation. In these devices, a pressure sensor detects heel off and initial contact during walking. A signal is then sent to the stimulation cuff, initiating or pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of such devices used for treatment of footdrop are the Innovative Neurotronics's (formerly NeuroMotion Inc.) WalkAide®, Bioness' radiofrequency controlled NESS L300™, and the Odstock Foot Drop Stimulator. An implantable peroneal nerve stimulator system (ActiGait) is being developed in Europe.

Another application of functional electrical stimulation is to provide spinal cord-injured patients with the ability to stand and walk. Generally, only spinal cord injury patients with lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1 to T3 are associated with poor trunk stability, while lumbar lesions imply lower-extremity nerve damage. Using percutaneous stimulation, the device delivers trains of electrical pulses to trigger action potentials at selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Patients use a walker or elbow-support crutches for further support. The electrical impulses are controlled by a computer microchip attached to the patient's belt that synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices include a reciprocating gait orthosis with electrical stimulation. The orthosis used is a cumbersome hip-knee-ankle-foot device linked together with a cable at the hip joint. The use of this device may be limited by the difficulties in putting the device on and taking it off.

Neuromuscular stimulation is also proposed for motor restoration in hemiplegia and treatment of secondary dysfunction (e.g., muscle atrophy and alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways.

Functional NMES is a method being developed to restore function to patients with damaged or destroyed nerve pathways (e.g., stroke, spinal cord injury, multiple sclerosis, cerebral palsy) through use of an orthotic device with microprocessor-controlled electrical stimulation. Evidence for neuromuscular stimulation to provide functional movement in patients with spinal cord injury is limited by the small number of subjects studied to date. For chronic poststroke footdrop, a large randomized controlled trial and crossover study of NMES versus ankle-foot orthosis (AFO) show improved satisfaction with NMES but no change in objective measures of walking. A small randomized trial examining neuromuscular stimulation for footdrop in patients with MS showed a reduction in falls and improvement in satisfaction when compared with a program of exercise, but did not demonstrate a clinically significant benefit in walking speed. The literature on NMES in children with cerebral palsy includes a systematic review of small studies with within-subject designs; additional study in a larger number of subjects is needed. Due to insufficient evidence for some indications, and a lack of improvement for others, functional NMES remains not medically necessary.

The Centers for Medicare and Medicaid Services (CMS) states that 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. It is also used for 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).

FES is limited to SCI patients for walking, who have completed a training program consisting of at least 32 physical therapy sessions with the device over a period of three months. The physical therapy trial period is necessary for the treating physician to accurately assess the patient's ability to use the devices frequently and over a long period of time. 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 FES devices to achieve walking, not to reverse or retard muscle atrophy.

Therapists with sufficient support skills are only allowed to provide these services in the following settings: inpatient hospitals, outpatient hospitals, comprehensive outpatient rehabilitation facilities, and outpatient rehabilitation facilities.

CODING

The following HCPCS Codes are covered for Medicare Advantage Plans only when medical criteria above is met and not medically necessary for Commercial Products:

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

RELATED POLICIES

Prior Authorization via Web-Based Tool for Durable Medical Equipment (DME)

PUBLISHED

Provider Update, July 2022
Provider Update, July 2021
Provider Update, July 2020
Provider Update, August 2019
Provider Update, November 2018

REFERENCES

1. Centers for Medicare & Medicaid Services. Decision Memo for Neuromuscular Electrical Stimulation (NMES) for Spinal Cord Injury (CAG-00153R). 2002; https://www.cms.gov/medicare-coverage-database/details/nca-decisionmemo.aspx?NCAId=55. Accessed January 19, 2022.
2. Mulcahey MJ, Betz RR, Kozin SH, et al. Implantation of the Freehand System during initial rehabilitation using minimally invasive techniques. Spinal Cord. Mar 2004; 42(3): 146-55. PMID 15001979
3. Mulcahey MJ, Betz RR, Smith BT, et al. Implanted functional electrical stimulation hand system in adolescents with spinal injuries: an evaluation. Arch Phys Med Rehabil. Jun 1997; 78(6): 597-607. PMID 9196467
4. Taylor P, Esnouf J, Hobby J. The functional impact of the Freehand System on tetraplegic hand function. Clinical Results. Spinal Cord. Nov 2002; 40(11): 560-6. PMID 12411963
5. Venugopalan L, Taylor PN, Cobb JE, et al. Upper limb functional electrical stimulation devices and their man-machine interfaces. J Med Eng Technol. 2015; 39(8): 471-9. PMID 26508077
6. Alon G, McBride K. Persons with C5 or C6 tetraplegia achieve selected functional gains using a neuroprosthesis. Arch Phys Med Rehabil. Jan 2003; 84(1): 119-24. PMID 12589632
7. Alon G, McBride K, Ring H. Improving selected hand functions using a noninvasive neuroprosthesis in persons with chronic stroke. J Stroke Cerebrovasc Dis. Mar-Apr 2002; 11(2): 99-106. PMID 17903863
8. Snoek GJ, IJzerman MJ, in 't Groen FA, et al. Use of the NESS handmaster to restore hand function in tetraplegia: clinical experiences in ten patients. Spinal Cord. Apr 2000; 38(4): 244-9. PMID 10822395
9. Jaqueline da Cunha M, Rech KD, Salazar AP, et al. Functional electrical stimulation of the peroneal nerve improves post-stroke gait speed when combined with physiotherapy. A systematic review and meta-analysis. Ann Phys Rehabil Med. Jan 2021; 64(1): 101388. PMID 32376404

10. Nascimento LR, da Silva LA, Araujo Barcellos JVM, et al. Ankle-foot orthoses and continuous functional electrical stimulation improve walking speed after stroke: a systematic review and meta-analyses of randomized controlled trials. Physiotherapy. Dec 2020; 109: 43-53. PMID 33120054
11. Hachisuka K, Ochi M, Kikuchi T, et al. Clinical effectiveness of peroneal nerve functional electrical stimulation in chronic stroke patients with hemiplegia (PLEASURE): A multicentre, prospective, randomized controlled trial. Clin Rehabil. Mar 2021; 35(3): 367-377. PMID 33103916
12. Bethoux F, Rogers HL, Nolan KJ, et al. The effects of peroneal nerve functional electrical stimulation versus ankle foot orthosis in patients with chronic stroke: a randomized controlled trial. Neurorehabil Neural Repair. Sep 2014; 28(7): 688-97. PMID 24526708
13. Kluding PM, Dunning K, O'Dell MW, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. Stroke. Jun 2013; 44(6): 1660-9. PMID 23640829
14. O'Dell MW, Dunning K, Kluding P, et al. Response and prediction of improvement in gait speed from functional electrical stimulation in persons with poststroke drop foot. PM R. Jul 2014; 6(7): 587-601; quiz 601. PMID 24412265
15. Berenpas F, Geurts AC, den Boer J, et al. Surplus value of implanted peroneal functional electrical stimulation over ankle-foot orthosis for gait adaptability in people with foot drop after stroke. Gait Posture. Jun 2019; 71: 157-162. PMID 31071538
16. Prokopiusova 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. PMID 32383574
17. 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. PMID 30974955
18. Barrett CL, Mann GE, Taylor PN, et al. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. Mult Scler. Apr 2009; 15(4): 493-504. PMID 19282417
19. Esnouf JE, Taylor PN, Mann GE, et al. 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. Sep 2010; 16(9): 1141-7. PMID 20601398
20. Cauraugh JH, Naik SK, Hsu WH, et al. Children with cerebral palsy: a systematic review and meta-analysis on gait and electrical stimulation. Clin Rehabil. Nov 2010; 24(11): 963-78. PMID 20685722
21. Chaplin E. Functional neuromuscular stimulation for mobility in people with spinal cord injuries. The Parastep I System. J Spinal Cord Med. Apr 1996; 19(2): 99-105. PMID 8732878
22. Klose KJ, Jacobs PL, Broton JG, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 1. Ambulation performance and anthropometric measures. Arch Phys Med Rehabil. Aug 1997; 78(8): 789-93. PMID 9344294
23. Jacobs PL, Nash MS, Klose KJ, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 2. Effects on physiological responses to peak arm ergometry. Arch Phys Med Rehabil. Aug 1997; 78(8): 794-8. PMID 9344295
24. Needham-Shropshire BM, Broton JG, Klose KJ, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 3. Lack of effect on bone mineral density. Arch Phys Med Rehabil. Aug 1997; 78(8): 799-803. PMID 9344296
25. Guest RS, Klose KJ, Needham-Shropshire BM, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 4. Effect on physical self-concept and depression. Arch Phys Med Rehabil. Aug 1997; 78(8): 804-7. PMID 9344297
26. Nash MS, Jacobs PL, Montalvo BM, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 5. Lower extremity blood flow and hyperemic responses to occlusion are augmented by ambulation training. Arch Phys Med Rehabil. Aug 1997; 78(8): 808-14. PMID 9344298
27. Graupe D, Kohn KH. Functional neuromuscular stimulator for short-distance ambulation by certain thoracic-level spinal-cord-injured paraplegics. Surg Neurol. Sep 1998; 50(3): 202-7. PMID 9736079

28. Brissot R, Gallien P, Le Bot MP, et al. Clinical experience with functional electrical stimulation-assisted gait with Parastep in spinal cord-injured patients. Spine (Phila Pa 1976). Feb 15 2000; 25(4): 501-8. PMID 10707398
29. Sykes L, Ross ER, Powell ES, et al. Objective measurement of use of the reciprocating gait orthosis (RGO) and the electrically augmented RGO in adult patients with spinal cord lesions. Prosthet Orthot Int. Dec 1996; 20(3): 182-90. PMID 8985998
30. Davis JA, Triolo RJ, Uhlir J, et al. Preliminary performance of a surgically implanted neuroprosthesis for standing and transfers--where do we stand?. J Rehabil Res Dev. Nov-Dec 2001; 38(6): 609-17. PMID 11767968
31. Rohde LM, Bonder BR, Triolo RJ. Exploratory study of perceived quality of life with implanted standing neuroprostheses. J Rehabil Res Dev. 2012; 49(2): 265-78. PMID 22773528
32. Triolo RJ, Bailey SN, Miller ME, et al. Longitudinal performance of a surgically implanted neuroprosthesis for lowerextremity exercise, standing, and transfers after spinal cord injury. Arch Phys Med Rehabil. May 2012; 93(5): 896-904. PMID 22541312
33. U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion. Physical activity guidelines, second edition. https://health.gov/paguidelines/second-edition/. Accessed January 19, 2022.
34. Hunt KJ, Fang J, Saengsuwan J, et al. On the efficiency of FES cycling: a framework and systematic review. Technol Health Care. 2012; 20(5): 395-422. PMID 23079945
35. Ralston KE, Harvey L, Batty J, et al. Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomized cross-over trial. J Physiother. Dec 2013; 59(4): 237-43. PMID 24287217
36. Dolbow DR, Gorgey AS, Ketchum JM, et al. Home-based functional electrical stimulation cycling enhances quality of life in individuals with spinal cord injury. Top Spinal Cord Inj Rehabil. 2013; 19(4): 324-9. PMID 24244097
37. Dolbow DR, Gorgey AS, Ketchum JM, et al. Exercise adherence during home-based functional electrical stimulation cycling by individuals with spinal cord injury. Am J Phys Med Rehabil. Nov 2012; 91(11): 922-30. PMID 23085704
38. Johnston TE, Smith BT, Mulcahey MJ, et al. 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. Aug 2009; 90(8): 1379-88. PMID 19651272
39. Dolbow DR, Credeur DP, Lemacks JL, et al. Electrically induced cycling and nutritional counseling for counteracting obesity after spinal cord injury: A pilot study. J Spinal Cord Med. Jul 2021; 44(4): 533-540. PMID 31971487
40. Sadowsky CL, Hammond ER, Strohl AB, et al. Lower extremity functional electrical stimulation cycling promotes physical and functional recovery in chronic spinal cord injury. J Spinal Cord Med. Nov 2013; 36(6): 623-31. PMID 24094120
41. Griffin L, Decker MJ, Hwang JY, et al. Functional electrical stimulation cycling improves body composition, metabolic and neural factors in persons with spinal cord injury. J Electromyogr Kinesiol. Aug 2009; 19(4): 614-22. PMID 18440241
42. Farkas GJ, Gorgey AS, Dolbow DR, et al. Energy Expenditure, Cardiorespiratory Fitness, and Body Composition Following Arm Cycling or Functional Electrical Stimulation Exercises in Spinal Cord Injury: A 16-Week Randomized Controlled Trial. Top Spinal Cord Inj Rehabil. 2021; 27(1): 121-134. PMID 33814890
43. Kressler J, Ghersin H, Nash MS. Use of functional electrical stimulation cycle ergometers by individuals with spinal cord injury. Top Spinal Cord Inj Rehabil. 2014; 20(2): 123-6. PMID 25477734
44. National Institute for Health and Care Excellence (NICE). Functional electrical stimulation for drop foot of central neurological origin [IPG278]. 2009; http://www.nice.org.uk/nicemedia/pdf/IPG278Guidance.pdf. Accessed January 19, 2022.
45. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Neuromuscular Electrical Stimulaton (NMES) (160.12). 2006; NCDId=175&ncdver=2&DocID=160.12&SearchType=Advanced&bc=IAAAABAAAAAA&.

Accessed January 19, 2022.