Subject: Functional Electrical Stimulation for Stroke or TBI (Bioness L300 & L300 Go Foot Drop System)		Original Effective Date: 9/18/19
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DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.[1]

Contents

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The L300 Foot Drop System and the L300 Go System are external functional neuromuscular electric stimulators (NEMS or FES) that are proposed to improve mobility in individuals with drop foot due to stroke or TBI. Electrical impulses are applied to intact peripheral nerves supplying muscles in order to produce functional movement and stimulate contractions of those muscles to promote recovery of motor function. FES systems consist of a stimulator that produces electrical pulses, electrodes that deliver the electric pulses to the appropriate

sites, lead wires connecting the stimulator to the electrodes, and a control unit that provides power and commands for the system.

The NESS L300 Foot Drop System provides ankle dorsiflexion in adult and children who have foot drop following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot. The NESS 300 Foot Drop System consists of functional stimulation (FS) cuff with radiofrequency (RF) stimulation unit, a control unit, and an Intelli-Sense gait sensor.

The L300 Go System provides ankle dorsiflexion in adult and children with foot drop and/or assist knee flexion or extension in adult individuals with muscle weakness related to upper motor neuron disease/injury (e.g., stroke, spinal cord injury) or other disability. The L300 Go System electrically stimulates muscles in the affected leg to provide ankle dorsiflexion of the foot and/or knee flexion or extension; thus, it also may improve the individual's gait.

Functional neuromuscular electrical stimulation devices have received 510(k) or pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA). The FDA classified these devices as external functional neuromuscular stimulators and as Class II devices. [2 3]

RECOMMENDATION [5-17]

Functional neuromuscular electrical stimulation (FES, NMES) devices that include but are not limited to, the Bioness L300 Foot Drop System and the L300 Go System used for foot drop in children and adults as a result of stroke, TBI or any other condition are considered experimental, investigational and unproven as the safety and effectiveness of these devices has not been established based on review of the peer reviewed medical literature.

SUMMARY OF MEDICAL EVIDENCE [5-16]

Overall, the quality of the evidence is low for the use of the L300 Foot Drop System or the L300 Go System for patients with foot drop after stroke or TBI. Available studies have design limitations, lack of randomization and/or blinding, small sample size, generally short-term follow-up, and lack of and inconsistent comparators. Large randomized controlled trials comparing FES with other medical management strategies, over a long period of follow-up are needed to evaluate their indications, outcomes safety and efficacy. There is insufficient peer reviewed published evidence to assess the safety and/or impact on health outcomes or patient management regarding the use of the L300 Foot Drop System or the L300 Go System for patients with stroke or TBI.

In 2018, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a Rapid Response report that reviewed the clinical-effectiveness and cost-effectiveness nerve stimulation for foot drop. Four publications met the inclusion criteria and were reviewed. Two publications were systematic reviews and two were RCTs. No studies on cost-effectiveness were identified. No differences in functional outcomes were found between FES and ankle foot orthosis. However, FES combined with rehabilitation was more effective than rehabilitation alone for improving walking speed for patients with stroke-related foot drop in one RCT and FES was found to statistically reduce perceived exertion and several related measures in one cross-over RCT. [6]

In 2018 Prenton et al., compared the randomized controlled trial evidence for therapeutic effects on walking of functional electrical stimulation and ankle foot orthoses for foot drop caused by central nervous system conditions. 7 synthesized randomized controlled trials (n= 464) were found. Meta-analysis of walking speed at

final assessment (p = 0.46), for stroke participants (p = 0.54) and after 4-6 weeks' use (p = 0.49) showed equal improvement for both devices. The review concluded that functional electrical stimulation and ankle foot orthoses have an equally positive therapeutic effect on walking speed in non-progressive central nervous system diagnoses. The current randomized controlled trial evidence base does not show whether this improvement translates into the user's own environment or reveal the mechanisms that achieve that change. Future studies should focus on measuring activity, muscle activity and gait kinematics. They should also report specific device details, capture sustained therapeutic effects and involve a variety of central nervous system diagnoses. [15]

Prenton et al., (2016) performed a meta-analysis of seven randomized controlled trials comparing the effects of unassisted walking behaviors with assisted walking following use of functional electrical stimulation (FES) and ankle-foot orthosis (AFO) for foot drop of central neurological origin. Two of the trials reported different results from the same trial and another two trials reported results from different follow-up periods and were therefore combined, resulting in five “synthesized trials” with 815 stroke participants. Meta-analyses of data from the final assessment in each study and three overlapping time-points showed comparable improvements in walking speed over 10 meters (p=0.04-0.79), functional exercise capacity (p=0.10-0.31), timed up-and-go (p=0.812 and p=0.539) and perceived mobility (p= 0.80) for both interventions. The data suggested that an AFO has equally positive combined-orthotic effects as FES on key walking measures for foot drop caused by stroke. The review concluded that additional long-term, high-quality randomized controlled trials are required, focusing on measuring the mechanisms-of-action, whether there is translation of improvements in impairment to function, plus detailed reporting of the devices used across diagnoses. Only then can robust clinical recommendations be made. [14]

Bethoux F et al., (2016) compared changes in gait quality and function between FES and AFOs in individuals with foot drop poststroke over a 12-month period. A total of 495 subjects were randomized, and 384 completed the 12-month follow-up. Primary endpoints: 10 Meter Walk Test (10MWT) and device-related serious adverse event rate. Secondary endpoints: 6-Minute Walk Test (6MWT), GaitRite Functional Ambulation Profile, and Modified Emory Functional Ambulation Profile (mEFAP). FES proved noninferior to AFOs for all primary endpoints. Both FES and AFO groups showed statistically and clinically significant improvement for 10MWT compared with initial measurement. No statistically significant between-group differences were found for primary or secondary endpoints. The FES group demonstrated statistically significant improvements for 6MWT and mEFAP Stair-time subscore. In conclusion, at 12 months, both FES and AFOs continue to demonstrate equivalent gains in gait speed. Results suggest that long-term FES use may lead to additional improvements in walking endurance and functional ambulation; further research is needed to confirm these findings. [5]

Kluding (2013) conducted an industry-sponsored single-blind multicenter trial that randomized 197 patients to 30 weeks of a foot drop stimulator (NESS L300) or a conventional ankle-foot orthosis (AFO). The AFO group received transcutaneous electrical nerve stimulation at each physical therapy visit during the first two weeks to provide a sensory control for stimulation of the peroneal nerve in the NESS L300 group. Evaluation by physical therapists who were blinded to group assignment found that both groups improved gait speed and other secondary outcome measures over time, with similar improvement in the two groups. There were no between-group differences in the number of steps per day at home, which were measured by an activity monitor over a week. [10]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

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

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

REFERENCES

Government Agency

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Professional Society Guidelines

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Other Resources

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Review/Revision History:

9/18/19: New Policy

9/16/20: Policy reviewed, no changes. Added TOC, updated references.