Molina Clinical Policy
Bioness L300 Foot Drop System & L300 Go System (Functional Electrical Stimulation for Stroke or TBI): Policy No. 346

Last Approval: 10/13/2021
Next Review Due By: October 2022

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

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. [2,3]

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. [2,3]

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]

COVERAGE POLICY [4-13]

Functional neuromuscular electrical stimulation (FES, NMES) devices **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. This includes (but is not limited to) the Bioness L300 Foot Drop System and the L300 Go System used for foot drop in children/adults as a result of stroke, TBI or other conditions.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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.

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.[7]

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.[8]

Prenton, et al. 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.[9]

Bethoux, et al. compared changes in gait quality and function between FES and AFOs in individuals with foot drop poststroke over a 12-month period (n=495). Subjects were randomized; 384 completed the 12-month follow-up. Primary endpoints included a 10 Meter Walk Test (10MWT) and device-related serious adverse event rate. Secondary endpoints included a 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 differences were found between-group for primary or secondary endpoints. The FES group demonstrated statistically significant improvements for 6MWT and mEFAP Stair-time subscore. 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 improvements in walking endurance and functional ambulation; further research is needed.[10]

Kluding 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.[11]

SUPPLEMENTAL INFORMATION

None.

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CODING & BILLING INFORMATION

CPT Codes - N/A

HCPCS Code

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/13/2021	Policy reviewed, no changes, updated references.
9/16/2020	Policy reviewed, no changes, updated references.
9/18/2019	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. http://www.cms.gov/mcd/search.asp.
2. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 510(k) summary: NESS L300 system kit (K122784). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Accessed August 15, 2021.
3. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). 510(k) summary: L300 Go System (K162407). Published January 27, 2017. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. Accessed August 15, 2021.

Peer Reviewed Publications

4. Hayes. Health technology assessment: Functional electrical stimulation for rehabilitation following spinal cord injury. https://evidence.hayesinc.com. Published Nov. 16, 2017. Updated April 5, 2021. Accessed Aug. 23, 2021. Registration and login required.
5. AMR Peer Review. Policy reviewed on June 25, 2019 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Pain Management and Physical Medicine and Rehabilitation.
6. National Institute for Health Care and Excellence (NICE). Guidance IPG278: Functional electrical stimulation for drop foot of central neurological origin. Published January 2009. https://www.nice.org.uk/guidance/ipg278/. Accessed August 15, 2021.

Other Peer Reviewed and Professional Organization Publications (used in the development of this policy)

7. Chuong H, Adcock L. Foot drop stimulators for foot drop: A review of clinical, cost-effectiveness and guidelines (CADTH rapid response report – summary with critical appraisal). https://cadth.ca/sites/default/files/pdf/htis/2018/RC1032%20Drop%20Foot%20Stimulator%20Final.pdf. Published November 2018. Accessed August 15, 2021.
8. Prenton S, Hollands KL, et al. Functional electrical stimulation and ankle foot orthoses provide equivalent therapeutic effects on foot drop: A meta-analysis providing direction for future research. J Rehabil Med. 2018 Feb 13;50(2):129-139. doi: 10.2340/16501977-2289. Accessed August 15, 2021.
9. Prenton, S, Hollands, KL, et al. Functional electrical stimulation versus ankle foot orthoses for foot-drop: A meta-analysis of orthotic effects. J Rehabil Med. 2016 Oct 5;48(8):646-656. doi: 10.2340/16501977-2136. Accessed August 15, 2021.
10. 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. 2014 Sep;28(7):688-97. doi: 10.1177/1545968314521007. Accessed August 15, 2021.
11. Kluding PM, Dunning K, O'Dell MW, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. Stroke. 2013 Jun;44(6):1660-9. doi: 10.1161/STROKEAHA.111.000334. Accessed August 15, 2021.
12. Dunning, K, O'Dell, MW, Kluding, P, McBride, K. Peroneal stimulation for foot drop after stroke: A systematic review. Am J Phys Med Rehabil. 2015 Aug;94(8):649-64. doi: 10.1097/PHM.0000000000000308. Accessed August 15, 2021.
13. Lee, D, Lee, G, Jeong, J. Mirror therapy with neuromuscular electrical stimulation for improving motor function of stroke survivors: A pilot randomized clinical study. Technol Health Care. 2016 Jul 27;24(4):503-11. doi: 10.3233/THC-161144. Accessed August 15, 2021.

APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*