BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 8.03.01 Functional Neuromuscular Electrical Stimulation

Annual Effective Policy Date: July 1, 2024

Original Policy Date: December 2012

Related Policies:

1.03.04 - Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities
1.04.04 - Myoelectric Prosthetic and Orthotic Components for the Upper Limb
1.04.05 - Microprocessor-Controlled Prostheses for the Lower Limb

Functional Neuromuscular Electrical Stimulation

Description

Description

Functional electrical stimulation (FES) involves the use of an orthotic device or exercise equipment with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in individuals with damaged or destroyed nerve pathways (eg, spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy).

OBJECTIVE

The objective of this evidence review is to determine whether use of functional neuromuscular electrical stimulation improves the net health outcome in individuals with functional disabilities related to spinal cord injury or stroke or with chronic foot drop.

POLICY STATEMENT

Neuromuscular stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations:

- To provide upper-extremity function in individuals with nerve damage (eg, spinal cord injury or poststroke); or
- To improve ambulation in individuals with foot drop caused by congenital disorders (eg, cerebral palsy) or nerve damage (eg, poststroke, or in those with multiple sclerosis); or
- As a technique to provide ambulation in individuals with spinal cord injury.

Functional electrical stimulation devices for exercise in individuals with spinal cord injury is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A variety of FES devices have been cleared by the U.S. Food and Drug Administration (FDA) and are available for home use. Table 1 provides examples of devices designed to improve hand and foot function as well as cycle ergometers for home exercise. The date of the FDA clearance is for the first 510(k) clearance identified for a marketed device. Many devices have additional FDA clearances as the technology evolved, each in turn listing the most recent device as the predicate.

Table 1. Functional Electrical Stimulation Devices Cleared by the FDA

Device	Manufacturer	Device Type	Clearance	Date	Product Code
NESS H200 (previously Handmaster)	Bioness	Hand stimulator	K022776	2001	GZI
MyndMove System	MyndTec	Hand stimulator	K170564	2017	GZI/IPF
ReGrasp	Rehabtronics	Hand stimulator	K153163	2016	GZI/IPF
WalkAide System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator	K052329	2005	GZI
ODFS (Odstock Dropped Foot Stimulator)	Odstock Medical	Foot drop stimulator	K050991	2005	GZI

ODFS Pace XL	Odstock Medical	Foot drop stimulator	K171396	2018	GZI/IPF
L300 Go	Bioness	Foot drop stimulator	K190285	2019	GZI/IPF
L100 Go	Bioness	Foot drop stimulator	K200262	2020	GZI/IPF
Foot Drop System	SHENZHEN XFT Medical	Foot drop stimulator	K162718	2017	GZI
Nerve And Muscle Stimulator	SHENZHEN XFT Medical	Foot drop stimulator	K193276	2020	GZI
MyGait Stimulation System	Otto Bock HealthCare	Foot drop stimulator	K141812	2015	GZI
MStim Drop Model LGT-233	Guangzhou Longest Science & Technology	Foot drop stimulator	K202110	2021	GZI/IPF
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer	K841112	1984	IPF
RT300	Restorative Therapies, Inc (RTI)	Cycle ergometer	K050036	2005	GZI
Myocycle Home	Myolyn	Cycle ergometer	K170132	2017	GZI
Cionic Neural Sleeve NS-100	Cionic	Foot drop stimulator	K221823	2022	GZI/IPF
EvoWalk 1.0	Evolution Devices Inc	Foot drop stimulator	K230997	2023	GZI

FDA: U.S. Food and Drug Administration.

To date, the Parastep Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep device is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6 to T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury."[1], FDA product code: MKD.

RATIONALE

Summary of Evidence

For individuals who have loss of hand and upper-extremity function due to spinal cord injury (SCI) or stroke who receive functional electrical stimulation (FES), the evidence includes a few small case series and a randomized controlled trial (RCT). Relevant outcomes are functional outcomes and quality of life. Interpretation of the evidence is limited by the low number of patients studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve the quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic foot drop who receive FES, the evidence includes RCTs, meta-analyses, and a longitudinal cohort study. Relevant outcomes are functional outcomes and quality of life. For chronic poststroke foot drop, 2 RCTs comparing FES with a standard ankle-foot orthosis (AFO) showed improved patient satisfaction with FES but no significant differences between groups in objective measures such as walking. Another RCT found no significant differences between use versus no use of FES on walking outcomes. Similarly, one meta-analysis found no difference between AFO and FES in walking speed, and another meta-analysis found no difference between FES and conventional treatments. The cohort study assessed patients' ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for foot drop in patients with multiple sclerosis showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the 2 devices was not significant. Another study found FES (combined with postural correction) and neuroproprioceptive facilitation and inhibition physiotherapy did not differ in walking speed or balance immediately or 2 months after program end. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes 3 systematic reviews of small studies with within-subject designs. All included studies only measure short-term results; it is unclear what the long-term effects of FES may be in this population. Further study is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. Relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on FES for standing and walking in patients with SCI. However, case series are considered adequate for this condition because there is no chance for unaided ambulation in this population with SCI at this level. Some studies have reported improvements in intermediate outcomes, but improvements in health outcomes (eg, ability to perform activities of daily living [ADL] , quality of life) have not been demonstrated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective comparisons. Relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on FES exercise equipment consists primarily of within-subject, pretreatment to posttreatment comparisons. Evidence was identified on 2 commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is limited evidence on the RT300 series. None of the within-subject studies showed an improvement in health benefits; however, improvement in body fat with RT300 was found in a small group of patients when FES high intensity interval cycling was added to nutrition counseling compared to nutritional counseling alone.One analysis of use for 314 individuals over 20,000 activity sessions with a Restorative Therapies device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of 6 days per week, but caloric expenditure remained low. Compliance was shown in 1 study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function; however, a small comparative study found arm cycling to improve exercise energy expenditure and cardiorespiratory fitness to a greater extent than FES leg cycling. A limitation of these studies is that they all appear to have been conducted in supervised research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2009, NICE published guidance stating that the evidence on functional electrical stimulation for foot drop of neurologic origin appeared adequate to support its use.[47,] The Institute noted that patient selection should involve a multidisciplinary team. The Institute advised that further publication on the efficacy of functional electrical stimulation would be useful, specifically including patient-reported outcomes (eg, quality of life, activities of daily living [ADL]) and these outcomes should be examined in different ethnic and socioeconomic groups.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare (2002; updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation for ambulation in spinal cord injury patients consistent with the U.S. Food and Drug Administration (FDA) labeling for the Parastep device.[1,48,] The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in its decision-making process. The decision memorandum noted that the available studies were flawed but concluded that the limited ambulation provided by the Parastep device supported its clinical effectiveness and thus its coverage eligibility. The inclusion criteria outlined by Medicare are as follows:

- "Persons with intact lower motor units (L1 and below)...;
- 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 who demonstrate brisk muscle contraction to NMES [neuromuscular electrical stimulation] and have sensory perception of 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 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 that have demonstrated a willingness to use the device long-term."

The exclusion criteria are as follows:

- "Persons with cardiac pacemakers;
- Severe scoliosis or severe osteoporosis;
- Skin disease or cancer at area of stimulation;
- Irreversible contracture; or
- Autonomic dysreflexia."

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-decision-memo.aspx?NCAId=55. Accessed January 22, 2024.
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. 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 handfunction in tetraplegia: clinical experiences in ten patients. Spinal Cord. Apr 2000; 38(4): 244-9. PMID 10822395
9. Anderson KD, Korupolu R, Musselman KE, et al. Multi-center, single-blind randomized controlled trial comparing functional electrical stimulation therapy to conventional therapy in incomplete tetraplegia. Front Rehabil Sci. 2022; 3: 995244. PMID 36188946
10. 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
11. Nascimento LR, da Silva LA, Arajo 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
12. 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, randomised controlled trial. Clin Rehabil. Mar 2021; 35(3): 367-377. PMID 33103916
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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

19. 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
20. 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
21. 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
22. Zhu Q, Gao G, Wang K, et al. Effect of Functional Electrical Stimulation on Gait Parameters in Children with Cerebral Palsy: A Meta-Analysis. Comput Math Methods Med. 2022; 2022: 3972958. PMID 36238472
23. Chen YH, Wang HY, Liao CD, et al. Effectiveness of neuromuscular electrical stimulation in improving mobility in children with cerebral palsy: A systematic review and meta-analysis of randomized controlled trials. Clin Rehabil. Jan 2023; 37(1): 3-16. PMID 35730135
24. 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
25. 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
26. 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
27. 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
28. 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
29. 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
30. 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
31. 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
32. 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
33. 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. 2001; 38(6): 609-17. PMID 11767968
34. 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
35. Triolo RJ, Bailey SN, Miller ME, et al. Longitudinal performance of a surgically implanted neuroprosthesis for lower-extremity exercise, standing, and transfers after spinal cord injury. Arch Phys Med Rehabil. May 2012; 93(5): 896-904. PMID 22541312
36. 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 22, 2024.
37. 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
38. 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 randomised cross-over trial. J Physiother. Dec 2013; 59(4): 237-43. PMID 24287217
39. 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
40. 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
41. 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
42. 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
43. 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
44. 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
45. 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
46. 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
47. 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 22, 2024.

48. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Neuromuscular Electrical Stimulaton (NMES) (160.12). 2006; https://www.cms.gov/medicare-coverage-database/details/ncd- details.aspx?NCDId=175&ncdver=2&DocID=160.12&SearchType=Advanced&bc=IAAAABAAAAAA&. Accessed January 22, 2024.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to read not medically necessary. Related policies added. References 25, 27 added
June 2013	Replace policy	Policy updated with literature review; references 11-12 and 29- 31 added; congenital disorders, cerebral palsy added to policy statement.
June 2014	Replace policy	Policy was updated with literature review, adding references 20 and 21. No changes were made to the policy statement. Policy Summary revised with no change to intent of policy.
June 2015	Replace policy	Policy was updated with literature review, adding references 20 and 21. Policy statement is unchanged
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; reference 1 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except "as a technique to provide ambulation in patients with spinal cord injury€š changed from investigational to not medically necessary due to FDA PMA status of the Parastep.
September 2019	Replace policy	Policy updated with literature review through March 8, 2019. Review of functional electrical stimulation exercise equipment added to policy; this is considered investigational.
September 2020	Replace policy	Policy updated with literature review through March 9, 2020; references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through January 23, 2021; references added. Policy statements unchanged.
July 2022	Replace policy	Policy updated with literature review through January 21, 2022; references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through February 6, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.
June 2024	Replace policy	Policy updated with literature review through January 22, 2024; no references added. Policy statements unchanged.