

Policy Name:	Functional Electrical Stimulation (FES), Upper and Lower Limb
Effective Date:	6/21/2021

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Function Electrical Stimulation in a Rehabilitation Facility:

Functional electrical stimulation (FES) therapy / functional neuromuscular electrical simulation (NMES) therapy is **COVERED** when used in a rehabilitation facility and supervised by a skilled provider (e.g., occupational therapist, physical therapist).

Note: FES used in exercise programs (e.g., programs not led by a skilled provider; activity-based locomotor exercise [ABLE] programs) are usually excluded services in the member’s plan document.

FES Devices Used in the Home Setting:

Upper and lower limb FES devices used in the home setting are considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policies; *Powered Robotic Lower-Limb Exoskeleton Devices* (e.g., *ReWalk™*, *Indego®*) and *Transcutaneous Electrical Joint Stimulation Devices*.

Description

Functional electrical stimulation (FES), a form of neuromuscular electrical stimulation, is purported to enhance movement or function of organs, muscles, and extremities. FES systems use microprocessor-based technology that determines what level of stimulation is provided. Delivery channels for individual pulses are provided by a set of electrodes applied to the neuromuscular system. Current is applied percutaneously by placing the electrodes on the individual’s skin over the muscle(s) to be activated. In individuals with weak or paralyzed muscles, FES is intended to allow muscles to function and perform activities by facilitating muscle contractions and activity. FES is differentiated from NMES in that FES uses electrical impulses to activate paralyzed or weak muscles in precise sequences with the intent of restoring functional abilities (e.g. walking, grasping).

FES devices were first developed as neuroprostheses intended to permanently substitute impaired function in individuals with spinal cord injury (SCI), stroke, head injury, and other neurologic disorders. FES lower limb neuroprostheses intended for community and home use for extended ambulation and/or assistance with foot drop are available and are of various designs. Two examples include Parastep (Sigmedics) and NESS L300 (Bioness). FES devices used for upper extremity function are available as arm splints with a built in man-machine interface (MMI) and are purported to induce neural plasticity to improve reach-to-grasp movement following stroke or SCI. Two

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examples include the NESS H200 (Bioness) and WalkAide (AxioBionics). Both lower and upper limb neuroprostheses can be applied in a facility or home/community setting.

Therapeutic rehabilitative FES devices used for lower extremity mobility are available as upright units, supine units, or as ergometric bicycles. FES ergometric cycling incorporates stationary cycling with stimulation to promote exercise, with the intent of strengthening muscle contractions through repetitive pedaling. FES ergometric bicycles are also purported for use in the home setting. Therapeutic FES is applied while the individual is executing a physical task, with the intent of having an orthotic effect with the potential of lasting improvement in muscle function. FES is suggested for use during the active rehabilitation phase for adults and children with neurologic dysfunction caused by impaired motor neuron function when peripheral nerve function is preserved (e.g., SCI, brain injury, stroke, cerebral palsy). Lower limb FES devices are largely used for exercise, although it is suggested as therapy to assist with breathing, cardiovascular function, grasping, transferring, standing and/or walking.

Activity-based locomotor exercise programs are an approach to rehabilitative therapy that involves exercise for individuals with paralysis or other neurological conditions. It uses activity-based exercises incorporating locomotor training, functional electrical stimulation (FES)/neuromuscular electrical stimulation (NMES), and exercises using other devices to guide locomotor activities. These programs often employ principles espoused by the Christopher and Dana Reeve Foundation's NeuroRecovery Network program. One regional program is the Courage Kenny Rehabilitation Institute's activity-based locomotor exercise (ABLE) program.

FDA Approval

FES devices require some level of FDA approval. Certain devices are classified as Class III devices requiring complete PMA approval, while others are classified as Class II devices requiring 510(k) approval.

Examples of FDA approved FES /NMES devices include, but are not limited to:

1. RT300-S (adult version) and RT300-SP (Pediatric version) FES bicycle (Restorative Therapies, Inc.)
2. RT600 Upright FES Device System (Restorative Therapies, Inc.)
3. ERGYS (Therapeutic Alliances, Inc.) Leg Cycle Ergometer
4. Sage 10 FES Controller (Restorative Therapies)
5. Parastep (Sigmedics Inc.)
6. Freehand Upper Extremity Neuroprosthesis (NeuroControl Corp.)
7. WalkAide (Innovative Neurotronics Inc.)
8. NESS L300 (Bioness Inc.) Leg Rehabilitation System
9. NESS H200 (Bioness Inc.) Hand Rehabilitation System
10. MyndMove Upper Extremity System (MyndTec Inc.)
11. Lokomat Robotic-Assisted Gait Training System (Hocoma AG Medical Engineering)

An example of a lower-limb robotic-assisted treadmill is the Lokomat (Nocoma AG). This device is classified by the FDA as an isokinetic testing and evaluation system and is considered a Class II device.

The Giger MD device (COMBO Ltd.) is an example of a supine dynamic spinal unloading device. Although the company's website indicates that this device has received FDA approval, no information is posted on the FDA website.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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HCPC Codes

- **E0770** - Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
- **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
- **S9451** – Exercise classes, non-physician provider, per session

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Re-Review Date(s): 5/16/2018
2/17/2020 – administrative update; format
4/21/2021

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