Electrical muscle stimulation

Clinical Policy ID: CCP.1377

Recent review date: 5/2022

Next review date: 9/2023

Policy contains: Functional electrical stimulation; neuromuscular electrical stimulation; physical rehabilitation

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Coverage policy

Electrical muscle stimulation (also referred to as neuromuscular electrical stimulation) is clinically proven and, therefore, medically necessary when used in accordance with U.S. Food and Drug Administration labeling instructions for each device for the following indications:

- **To correct lack of ankle dorsiflexion (foot drop) of central neurological origin when an ankle-foot orthosis is not tolerated (Healthcare Common Procedure Coding System code E0770) (Moll, 2017; National Institute for Health and Care Excellence, 2009; Prenton, 2018).**
- **To attenuate muscle disuse atrophy in immobilized lower limbs (Healthcare Common Procedure Coding System code E0745) following a non-neurological injury or surgery where the nerve supply to the muscle is intact (e.g., post orthopedic surgery, casting, splinting, or soft-tissue scarring) (Bistolfi, 2018; (Conley, 2021; Hauger, 2018; Wylde, 2018).**
- **To correct or prevent glenohumeral subluxation following an acute or subacute stroke (Lee, 2017; Winstein, 2016).**

- **To restore upper limb function (Healthcare Common Procedure Coding System code E0770) following an acute or subacute stroke or spinal cord injury in the presence of minimal volitional movement, when combined with task-specific training (e.g., grasp function), after a trial showing evidence of muscle contraction but an inability to move the arm against resistance (de Freitas, 2018; Fehlings, 2017; Mirkowski, 2019; Monte-Silva, 2019; National Institute for Health and Care Excellence, 2013).**
- **To enable independent, unbraced ambulation using the Parastep 1® system (Sigmedics Inc., Fairborn, Ohio) (Healthcare Common Procedure Coding System code E0764) for skeletally mature members with spinal cord injury, who meet all of the following criteria (Sigmedics, 2019):**
    - **Intact lower motor units (both muscle and peripheral nerve of L1 and below).**
    - **Muscle and joint stability of the upper and lower extremities for weight bearing, with demonstration of balance and trunk control to independently maintain an upright posture.**
    - **Demonstration of brisk muscle contraction to neuromuscular stimulation and have sensory perception of electrical stimulation sufficient for muscle contraction.**
    - **Ability to transfer independently and demonstrate independent standing tolerance for at least three minutes.**
    - **Possession of high motivation, commitment, and cognitive ability to use the device for walking.**
    - **Demonstration of hand and finger function to manipulate the device controls.**
    - **At least six-month post-recovery from spinal cord injury and restorative surgery.**
    - **Absence of degenerative disease of the hip and knee, and no history of long bone fracture secondary to osteoporosis.**
    - **Demonstration of a willingness to use the device for a long term.**

A U.S. Food and Drug Administration-approved conductive garment (Healthcare Common Procedure Coding System code E0731) used in conjunction with neuromuscular electrical stimulation is medically necessary for members with a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation), where the nerve supply to the muscle is intact, for any of the following indications:

- **There is a large area or many sites to be stimulated, and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes, and lead wires.**
- **There is a medical condition (e.g., skin condition) that precludes the application of conventional electrodes, adhesive tapes, and lead wires.**
- **Area to be treated for disuse atrophy or chronic intractable pain is inaccessible to conventional electrodes, adhesive tapes, and lead wires (e.g., underneath a cast).**

Limitations

All other uses of electrical muscle stimulation are not medically necessary, as the safety and effectiveness has not been established. These include, but are not limited to:

- **Muscle disuse atrophy in members with spinal cord injury.**
- **Pain control.**
- **Non-medical uses (e.g., exercise).**
- **Oropharyngeal dysphagia (Almeida, 2020; Alamer, 2020; Diéguez-Pérez, 2020; López-Liria, 2020).**
- **Edema reduction (Burgess, 2019).**
- **Knee osteoarthritis in a non-surgical member (Novak, 2020).**

Absolute contraindications to electrical muscle stimulation include (Sigmedics, 2019):

- **Autonomic dysreflexia.**
- **Cardiac pacemakers.**
- **Presence of irreversible contracture.**
- **Presence of skin disease or cancer at the area of stimulation.**
- **Severe osteoporosis.**
- **Severe scoliosis.**

Requirements for functional electrical stimulation of the upper or lower extremities include attended physical therapy training with the device. The physical therapist performing this training must have sufficient skills to provide these services that are part of a one-on-one training program in inpatient hospitals, outpatient hospitals, comprehensive outpatient rehabilitation facilities, and outpatient rehabilitation facilities.

A conductive garment used with neuromuscular electrical stimulation (Healthcare Common Procedure Coding System code E0731) is not medically necessary when the service can be delivered effectively through the use of conventional electrodes, adhesive tapes, and lead wires.

The use of the Hako-Med PRO ElecDT® 2000 (Hako Med Holdings Inc., Las Vegas, Nevada, distributed in the United States by Alive Inc., 2021) for electrical muscle stimulation is not medically necessary, as its safety and effectiveness has not been established.

Replacement supplies are considered medically necessary when used with medically necessary neuromuscular electrical stimulation up to plan limits.

For Medicare members only

Electrical muscle stimulation is reasonable and necessary in accordance with Medicare National Coverage Determinations 160.12 and 160.13 and Decision Memo for Neuromuscular Electrical Stimulation for Spinal Cord Injury (CAG-00153R). The approved indications are:

- **To treat 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. Treatment involves stimulating the muscle when the patient is in a resting state.**
- **To enhance the ability to walk in members with spinal cord injury.**

All other uses are not medically necessary.

For members with spinal cord injury, coverage is limited to enhancing ambulation and completing a training program, which consists of at least 32 physical therapy sessions with the device over three months. The trial period of physical therapy will enable the physician treating the member for spinal cord injury to properly evaluate the member's ability to use these devices frequently and for the long term. 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 only settings where therapists with sufficient skills to provide these services are employed in inpatient hospitals, outpatient hospitals, comprehensive outpatient rehabilitation facilities, and outpatient rehabilitation facilities (Centers for Medicare & Medicaid Services, 1988, 2006, 2019a, 2019b).

Alternative covered services

- **Occupational therapy.**
- **Physical therapy.**
- **Speech therapy.**
- **Specialist consultation.**

- **Hip-knee-ankle-foot orthoses.**

Background

The evidence from several systematic reviews, meta-analyses, and guidelines suggests electrical muscle stimulation is safe and efficacious when used in accordance with established rehabilitation protocols requiring supervision or in unattended settings (Fehlings, 2017; Gatewood, 2017; Ho, 2014; Lee, 2017; Moll, 2017; National Institute for Health and Care Excellence, 2009, 2013; Prenton, 2016; Winstein, 2016). Overall, the evidence is of low quality with few randomized controlled trials, and heterogeneous with respect to devices and treatment protocols, making it difficult to identify the optimal treatment regimen for any one indication. Most of the literature consists of studies of adults with spinal cord injury or stroke or after orthopedic knee surgery, and, to a lesser extent, in children with cerebral palsy.

Neuromuscular fatigue is the main limitation of electrical muscle stimulation. Its delivery can be customized to reduce fatigue and optimize force output by adjusting the associated stimulation parameters (e.g., frequency, amplitude, intensity, electrode placement, and pulse patterns). Conductive garments may be used to provide pathways for electrodes and lead wires for large or hard-to-reach areas (Doucet, 2012).

Neuromuscular electrical stimulation of any type is contraindicated in persons with cardiac pacemakers. Other contraindications are specific to the device, although few have been described either in product labeling or the literature. In the case of functional electrical stimulation, the manufacturer of the Parastep 1 system lists autonomic dysreflexia, irreversible contracture, skin disease or cancer at area of stimulation, severe osteoporosis, and severe scoliosis as additional contraindications (Sigmedics, 2019). It is reasonable to extrapolate these to other functional electrical stimulation devices.

There is insufficient evidence to recommend the Hako-Med PRO ElecDT 2000 for electrical muscle stimulation. The evidence consists of three randomized controlled trials that addressed treatment of pain related to knee osteoarthritis or spinal fractures or degeneration (Di Sante, 2012; Zambito, 2006, 2007). While these studies found favorable results for horizontal therapy compared to interferential modalities or placebo, evidence-based guidelines found inconclusive evidence to support transcutaneous electrical nerve stimulation or other electrotherapy for these indications and made no mention of horizontal/electroceutical therapy (American Association of Orthopaedic Surgeons, 2013; Qaseem, 2017).

Neuromuscular electrical stimulation

In an immobilized extremity, neuromuscular electrical stimulation can control edema, increase local blood circulation, maintain muscle tone, or delay the development of disuse atrophy (Doucet, 2012). It has been proposed as treatment for muscle atrophy in conditions such as cerebral palsy, congestive heart failure, progressive neuromuscular diseases, chronic obstructive pulmonary disease, and upper extremity hemiplegia. In these populations, the rationale for use is to enhance the effects of rehabilitation or provide an alternative for patients with muscle weakness who have difficulty engaging with traditional rehabilitation services.

There is sufficient evidence to recommend neuromuscular electrical stimulation as part of a comprehensive rehabilitation program to attenuate muscle atrophy in immobilized limbs following a non-neurological injury or surgery where the nerve supply to the muscle is intact (e.g., post orthopedic surgery, casting or splinting, soft-tissue scarring) (Gatewood, 2017). For all other indications, there lacks sufficient evidence of comparative effectiveness to recommend neuromuscular electrical stimulation as

an adjunct to, or replacement for, standard rehabilitation interventions (Dewar, 2015; Hajibandeh, 2015; Jones, 2016; Maltais, 2014; Martimbianco, 2017; McAlindon, 2014; McCaughey, 2016; Mills, 2015; Newberry, 2017).

Functional electrical stimulation

In the lower extremities, functional electrical (muscle) stimulation has been used to perform stationary exercise and assist with standing and walking. For persons with upper extremity paralysis caused by injury or disease of the central nervous system, it has been used to improve hand function and range of motion, and correct or prevent glenohumeral subluxation in stroke. Devices used to augment stationary exercise are considered exercise equipment and not necessarily for medical use.

There is sufficient evidence to support functional electrical stimulation for the following indications as part of a comprehensive rehabilitation program:

- **To correct foot drop in persons with stroke or spinal cord injury when an ankle-foot orthosis is not tolerated (Moll, 2017; National Institute for Health and Care Excellence, 2009; Prenton, 2016).**
- **To improve hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis, and minimal volitional movement, after a trial showing evidence of muscle contraction but inability to move the arm against resistance (Fehlings, 2017; National Institute for Health and Care Excellence, 2013; Winstein, 2016).**
- **To correct or prevent glenohumeral subluxation in patients after stroke (Lee, 2017; Winstein, 2016).**
- **In spinal cord injury care, to assist in ambulation using the Parastep I system (Ho, 2014; Sigmedics, 2019).**

In 2019, we added seven systematic reviews and meta-analyses that confirm previous findings for the following indications: to attenuate muscle disuse atrophy in immobilized lower limbs after orthopedic surgery to the lower limbs (Bistolfi, 2018; Hauger, 2018; Wylde, 2018); to restore upper limb hand and wrist function in post-stroke hemiplegia (de Freitas, 2018; Mirkowski, 2019; Monte-Silva, 2019); to correct foot drop (Prenton, 2018).

We consolidated CCP.1027 Electrical stimulation for oropharyngeal dysphagia into this policy and updated the findings. The initial policy found insufficient evidence to support electrical muscle stimulation for treating dysphagia based on systematic review findings (Chen, 2016; Scutt, 2015). A new Cochrane review (Bath, 2018) of six low-quality randomized controlled trials (n = 312 participants) found neuromuscular electrical stimulation was probably effective for reducing pharyngeal transit time (mean difference -0.23, 95% confidence interval -0.39 to -0.08, *P* = .003) but did not reduce the proportion of participants with dysphagia at end of trial (*P* = .22) or penetration aspiration score (*P* = .24), and did not improve swallowing ability (*P* = .20). No policy changes are warranted. The Policy ID was changed from CP# 09.02.09 to CCP.1377.

In 2020, we added four new systematic reviews to the policy (Burgess, 2019; Chiang, 2019; Thomaz, 2019; Yang, 2019). We addressed a specific request to consider the medical necessity of the Bioness, Inc. (Valencia, California) product line of functional electrical stimulators. Bioness products represent one of several manufacturers of electrical muscle stimulators that have received regulatory approval and are marketed in the United States. The clinically proven uses listed in the coverage section define the medical necessity of these and other products. The results of the new information is consistent with the current the current policy, and no changes to the policy are warranted.

In 2021, we added several systematic reviews and meta-analyses to the policy. One systematic review (Conley, 2021) confirmed the clinical efficacy of, and defined parameters for, neuromuscular electrical stimulation following knee surgery. Another systematic review (Novak, 2020) of nine randomized controlled trials examined the efficacy of neuromuscular electrical stimulation in improving quadriceps femoris muscle strength and in decreasing pain in patients with knee osteoarthritis. While neuromuscular electrical stimulation was an effective treatment for knee osteoarthritis, it was not possible to isolate its effects on strength and knee pain from those of other interventions with which it was combined. The investigators identified frequency of at least 50 Hz and no more than 75 Hz with a pulse duration between 200 and 400 µs and a treatment duration of 20 mins as necessary for successful treatment, which future research could apply to determine its clinical efficacy relative to other interventions.

Other systematic reviews found insufficient evidence to support electrical muscle stimulation for a range of indications. These indications are: to improve muscle strength and activity participation among patients with cystic fibrosis (Poncin, 2020), chronic obstructive pulmonary disease (Burge, 2020), and peripheral artery disease (Jéhannin, 2020), and patients on hemodialysis (Schardong, 2020; Valenzuela, 2020); to prevent myopathy in a critical care population (Zayed, 2020); and to treat dysphagia of various etiologies (Almeida, 2020; Alamer, 2020; Diéguez-Pérez, 2020; López-Liria, 2020). The new results warrant no policy changes.

Findings

The evidence from several systematic reviews, meta-analyses, and guidelines suggests electrical muscle stimulation is safe and efficacious when used in accordance with established rehabilitation protocols requiring supervision or in unattended settings (Fehlings, 2017; Gatewood, 2017; Ho, 2014; Lee, 2017; Moll, 2017; National Institute for Health and Care Excellence, 2009, 2013; Prenton, 2016; Winstein, 2016). Overall, the evidence is of low quality with few randomized controlled trials, and heterogeneous with respect to devices and treatment protocols, making it difficult to identify the optimal treatment regimen for any one indication. Most of the literature consists of studies of adults with spinal cord injury or stroke or after orthopedic knee surgery, and, to a lesser extent, in children with cerebral palsy.

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On March 9, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Electric Stimulation Therapy/therapeutic use" (MeSH), "Electric Stimulation Therapy/therapy" (MeSH), and "electrical stimulation." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

4/2018: initial review date and clinical policy effective date: 5/2018

5/2019: Policy references updated. Consolidated CCP.1027 into this policy. Policy ID changed.

5/2020: Policy references updated.

5/2021: Policy references updated.

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