Electrical muscle stimulation

Clinical Policy ID: CCP.1377

Recent review date: **4/2024**

Next review date: **8/2025**

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:

- **Correcting foot drop of central neurological origin when an ankle-foot orthosis is not tolerated (Moll, 2017; National Institute for Health and Care Excellence, 2009; Prenton, 2018).**
- **Attenuating muscle disuse atrophy in immobilized lower limbs following a non-neurological injury or surgery with intact nerve supply (Conley, 2021; Hauger, 2018; Wylde, 2018).**
- **Correcting or preventing glenohumeral subluxation after an acute or subacute stroke (Lee, 2017; Winstein, 2016).**
- **Restoring upper limb function after an acute or subacute stroke or spinal cord injury with minimal volitional movement, combined with task-specific training (de Freitas, 2018; Fehlings, 2017; Mirkowski, 2019; Monte-Silva, 2019; National Institute for Health and Care Excellence, 2023).**
- **To enable independent ambulation using Parastep 1® for those with spinal cord injury who meet criteria including:**
    - **Intact lower motor units from L1 down.**

- **Stability for weight bearing with balance/trunk control.**
- **Responsive muscles and sensation to stimulation**
- **Independent transfers and standing three plus minutes.**
- **Motivation/ability to use device long term.**
- **Finger function to operate controls.**
- **Six plus months post-injury/surgery.**
- **No hip/knee degeneration or osteoporotic fractures.**

- ~~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

Electrical stimulation is one of many interventions employed to restore body movement critical for daily function and quality of life. Available in many forms, electrical stimulation facilitates changes in either bioelectrical or biochemical communication among cellular components to effect muscle action, pain modulation, and performance. Electrodes may be positioned transcutaneously, percutaneously, or subcutaneously. Small portable units with modifiable capabilities are the most popular, because they allow providers to set parameters and design custom programs that patients can use in the clinic or at home (Doucet, 2012).

Transcutaneous methods such as transcutaneous electrical nerve stimulation and interferential current work at lower frequencies (0.5 to 100 Hz) in the bioelectric range to alter pain signals that travel to the brain, thereby decreasing acute and chronic pain without any discernable muscle contraction. Other benefits may be improved circulation, lymphatic flow, swelling, and muscle function. Similarly, higher-frequency electrical stimulation is used to decrease pain, improve circulation, and speed wound healing (Doucet, 2012).

Electrical muscle stimulation, also referred to as neuromuscular electrical stimulation or e-stim, typically delivers higher frequencies (20 – 50 Hz) to produce muscle tetany and contraction. It has two main purposes: 1) to treat muscle atrophy during temporary extremity immobilization; and 2) to pair the stimulation simultaneously or intermittently with a functional task in neurologically impaired individuals (commonly referred to as functional electrical stimulation). Electrical muscle stimulation was first applied clinically to correct foot drop in paraplegics and has become an integral part of modern rehabilitation programs (Doucet, 2012).

Electroceutical therapy, also referred to as bioelectric nerve block, uses even higher electrical frequencies (ranging from 1 to 20,000 Hz) to mimic the human bioelectric system. An example of this is the Hako-Med PRO ElecDT 2000. This device employs a proprietary concept called Horizontal® Therapy into its product, which the manufacturer claims can treat both bioelectrical and biochemical cellular communication components in one treatment session by holding the bioelectric intensity constant while changing the frequency. Due to safety concerns, it may only be prescribed and administered under the supervision of a health care provider experienced in this method of treatment.

Regulation

The U.S. Food and Drug Administration regulates neuromuscular electrical stimulators for clinical use either through the 510(k) process or the premarket approval process. Devices required to go through the more rigorous premarket approval process have additional issues of safety and efficacy. Several devices have been approved for a range of indications that often overlap with other transcutaneous methods (U.S. Food and Drug Administration, 2023a, 2023b):

- **Stroke rehabilitation by muscle re-education.**
- **Relaxation of muscle spasm.**
- **Attenuation of disuse atrophy.**
- **Increasing local blood circulation.**
- **Muscle re-education for other conditions.**
- **Maintaining or increasing range of motion.**
- **Prevention of deep vein thrombosis following surgery.**

Unlike neuromuscular electrical stimulators (product codes IPF, GZI, and MKD), approved uses for transcutaneous methods, such as interferential current therapy, typically include control of pain. As such, these devices are regulated as transcutaneous electrical nerve stimulators (product code LIH).

~~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). **The strongest evidence for neuromuscular electrical stimulation based on systematic reviews and meta-analyses supports its use for improving swallowing function and limb strength in stroke patients, as well as strengthening muscles in patients with knee surgery, chronic kidney disease, and advanced diseases like respiratory failure, heart failure, and cancer. Potential benefits are also seen for enhancing rehabilitation and gross motor function in cerebral palsy, postural control in spastic diplegia, and respiratory function in spinal cord injury.**

Professional Clinical Guidelines

Neuromuscular electrical stimulation is reasonably recommended in several circumstances for stroke rehabilitation based on generally strong levels of evidence, according to joint guidelines issued by the American Heart Association/American Stroke Association (Winstein, 2016). It can be considered as an alternative to an ankle foot orthosis for treating foot drop, supported by strong Level B evidence. Neuromuscular electrical stimulation is also reasonably recommended for individuals in the first few months post-stroke who have minimal voluntary movement, in order to facilitate improvement, backed by strong Level A evidence. Managing increased muscle tone temporarily with neuromuscular electrical stimulation as an adjunct to rehabilitation therapy is a reasonable option with moderate Level A

evidence. Finally, neuromuscular electrical stimulation is reasonably recommended for treating shoulder instability, with the strongest Level A evidence (Winstein, 2016).

The National Institute for Health and Care Excellence has issued two guidelines related to electrical muscle stimulation. The first issued in 2009 noted that evidence supports the safety and efficacy of the treatment for improving gait in patients with drop foot caused by upper motor neuron lesions from conditions like stroke, cerebral palsy, multiple sclerosis or spinal cord injury (National Institute for Health and Care Excellence, 2009). A supplemental guideline issued in 2023 notes that electrical stimulation is not recommended for routine use in the rehabilitation of the hand or arm after stroke. However, a trial of electrical stimulation therapy is suggested as part of a comprehensive rehabilitation program for individuals who exhibit evidence of muscle contraction post-stroke but cannot move their arm against resistance. The continuation of this therapy is advised if it leads to improvements in the person's strength and their ability to practice functional tasks, such as maintaining range of motion or enhancing grasp and release (National Institute for Health and Care Excellence, 2023).

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.

Post-Stroke Dysphagia and Motor Impairment

Several systematic reviews have found that neuromuscular electrical stimulation improves swallowing function and limb strength in stroke patients. Alamer (2020) analyzed 11 randomized controlled trials with 784 patients and found moderate to high quality evidence that neuromuscular electrical stimulation combined with swallowing therapy was more effective than swallowing therapy alone for improving dysphagia post-stroke. Chiang (2019) compared different stimulation techniques in 19 randomized controlled trials with 691 stroke patients and found neuromuscular electrical stimulation significantly improved swallowing function versus placebo. Wang (2021) meta-analyzed 20 studies totaling 914 stroke patients and found neuromuscular electrical stimulation groups had significantly better dysphagia outcomes than control groups. For limb function, Yang (2019) reviewed 48 randomized controlled trials with 1712 stroke patients and found neuromuscular electrical stimulation significantly improved arm function and strength compared to placebo. Monte (2019) meta-analyzed 26 randomized controlled trials with 782 patients and found a robust short-term effect of electromyography-triggered neuromuscular electrical stimulation on upper limb motor impairment, especially in chronic stroke.

Muscle Strengthening in Other Populations

Quadriceps strength after knee surgery: Gatewood (2017) reviewed 7 studies with over 300 patients and found neuromuscular electrical stimulation improved post-operative quadriceps strength and function. Conley (2021) identified optimal neuromuscular electrical stimulation parameters from 8 randomized controlled trials with 559 patients.

Chronic kidney disease: Schardong (2020) meta-analyzed 10 studies with 242 hemodialysis patients and found neuromuscular electrical stimulation significantly improved quadriceps strength, upper limb strength, and functional capacity. Valenzuela (2020) reviewed 8 trials with 221 patients and found neuromuscular electrical stimulation during dialysis improved walk distance, cycling workload, and limb strength.

Advanced disease: A Cochrane review by Jones (2016) of 18 randomized controlled trials with 933 participants found neuromuscular electrical stimulation improved quadriceps strength and muscle mass in patients with respiratory disease, heart failure, and cancer.

Spinal cord injury: de Freitas (2018) analyzed 5 studies with 170 patients but found insufficient evidence that neuromuscular electrical stimulation was superior to other treatments for improving strength.

Rehabilitation and Functional Outcomes

Beyond strength, neuromuscular electrical stimulation may enhance rehabilitation and physical function in certain populations. Chen (2023) meta-analyzed 14 randomized controlled trials with 421 children with cerebral palsy and found neuromuscular electrical stimulation significantly improved walking speed and gross motor scores compared to conventional therapy alone. McCaughey (2016) reviewed 14 studies in 129 spinal cord injury patients and found abdominal functional electrical stimulation acutely improved cough and chronically increased vital capacity and peak expiratory flow. Dewar (2015) concluded level II evidence from 2 studies supported functional stimulation combined with rehabilitation for improving postural alignment in children with spastic diplegia, but called for more research.

Edema and Pain Management

A few reviews suggest potential benefits of neuromuscular electrical stimulation for managing edema and pain, though the evidence is limited. Burgess (2019) found 6 of 7 studies totaling over 200 patients showed neuromuscular electrical stimulation effectively reduced edema in various conditions. Novak (2020) reviewed 9 randomized controlled trials and recommended neuromuscular electrical stimulation combined with strengthening exercises for reducing pain in knee osteoarthritis. However, Zayed (2020) meta-analyzed 6 randomized controlled trials with 718 critically ill patients and found no significant effect of neuromuscular electrical stimulation on ICU outcomes. Martimbianco (2017) found very low quality evidence from up to 4 trials with 118 participants that neuromuscular electrical stimulation plus exercise slightly reduced patellofemoral pain compared to exercise alone.

Specialty Populations

A few systematic reviews examined neuromuscular electrical stimulation in specialty populations with mixed findings:

Dysphonia: Almeida (2020) reviewed 11 studies with 382 patients and found while neuromuscular electrical stimulation showed some improvements in laryngeal function and vocal quality, heterogeneity in designs prevented determinations of overall effectiveness for treating dysphonia.

Parkinson's dysphagia: López-Liria (2020) found 2 studies with 199 Parkinson's patients where neuromuscular electrical stimulation did not significantly improve dysphagia compared to traditional therapy alone.

Chronic Obstructive Pulmonary Disease: An statement by Maltais noted neuromuscular electrical stimulation is emerging as a useful modality for muscle dysfunction in severe chronic obstructive

pulmonary disease and exacerbations but did not quantify the evidence or make a formal recommendation. Orthopedic Applications Regarding orthopedic uses, evidence is lacking to support neuromuscular electrical stimulation, especially long-term. McAlindon's guidelines reviewed one systematic review and two randomized controlled trials with 107 patients and determined neuromuscular electrical stimulation was "not appropriate" for treating knee osteoarthritis. Wylde (2018) reviewed 17 randomized controlled trials with 2485 participants and found no interventions, including 1 neuromuscular electrical stimulation trial, reduced chronic pain beyond 3 months after total knee replacement.

Adverse Events and Limitations

Across the reviewed studies, no serious adverse events related to neuromuscular electrical stimulation were reported. However, several reviews noted limitations in the current evidence base, including small sample sizes, heterogeneous designs and outcome measures, lack of long-term follow-up, and overall low quality of many included studies. Newberry (2017) concluded evidence was insufficient to evaluate neuromuscular electrical stimulation effectiveness, largely due to poor quality and heterogeneous study design.

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.

Functional Electrical Stimulation for Stroke

Several studies have investigated the impact of functional electrical stimulation on walking and upper extremity function in stroke patients. A systematic review and meta-analysis by Prenton (2016) synthesized 7 randomized controlled trials with a total of 815 stroke participants. The analysis found that functional electrical stimulation and ankle foot orthoses produced comparable improvements in walking speed, functional exercise capacity, timed up-and-go, and perceived mobility. The authors concluded that ankle foot orthoses have equally positive combined-orthotic effects as functional electrical stimulation on key walking measures for foot-drop caused by stroke.

In a systematic review and meta-analysis, Lee JH (2017) examined 11 randomized controlled trials with a total of 432 participants (216 receiving functional electrical stimulation plus conventional therapy, 216 receiving conventional therapy alone) to assess the effectiveness of functional electrical stimulation for managing shoulder subluxation post-stroke. The studies included participants with acute stroke who were 2.0±2.2 months (intervention) and 1.6±1.7 months (control) post-stroke, and those with chronic stroke who were 9.4±4.1 months (intervention) and 9.1±3.9 months (control) post-stroke.

Functional Electrical Stimulation for Spinal Cord Injury

The use of functional electrical stimulation for restoring functions in individuals with spinal cord injury has been reviewed in several studies. Fehlings (2017) reviewed two randomized controlled trials involving a total of 89 patients with acute and subacute cervical spinal cord injury. One study found that compared to occupational therapy alone, functional electrical stimulation combined with occupational therapy resulted in significantly greater improvements on the Functional Independence Measure Motor subscore (15.0 vs 4.1 points), Functional Independence Measure Self-Care subscore (20.1 vs 10 points), and Spinal Cord Independence Measure Self-Care subscore (10.2 vs 3.1 points). The other study found no significant differences between functional electrical stimulation, biofeedback, combined functional

electrical stimulation/biofeedback, and conventional strengthening for recovering tenodesis grasp. Based on this low-quality evidence, the guideline suggests offering functional electrical stimulation to improve hand and upper extremity function in individuals with acute and subacute cervical spinal cord injury.

Ho (2014) systematically reviewed functional electrical stimulation applications for various functions in spinal cord injury patients. The largest clinical trial of an upper extremity functional electrical stimulation neuroprosthesis (the Freehand trial) included 28 participants, all of whom improved independence in at least one task. A second generation implanted functional electrical stimulation system (IST-12) has been implanted in 12 spinal cord injury subjects, with each demonstrating improvement in at least 2 activities. For lower extremity function, functional electrical stimulation neuroprosthesis recipients exhibited mean and median standing times of 10 and 3 minutes respectively, with some recipients in a Phase II trial standing over 20 minutes.

Functional Electrical Stimulation for Cerebral Palsy

Moll (2017) conducted a systematic review assessing the effect of functional electrical stimulation on ankle dorsiflexors in children and adolescents with spastic cerebral palsy during walking. The review included 14 articles (11 studies) with a total of 127 patients aged 5 to 19 years with Gross Motor Function Classification System levels I to III receiving functional electrical stimulation. Only five articles (three studies) were of level I to III evidence. Ankle dorsiflexion angle was the most frequently investigated outcome. Adverse events included skin irritation, poor tolerance, and acceptation issues. The review found some evidence supporting functional electrical stimulation use in children with spastic cerebral palsy for improving ankle and gait biomechanics, but more high-quality research is needed.In 2024, condensed and reorganized findings section clearly noting affirmative guidelines, and synthesizing commonalties across studies reviewed. No new studied were added and no policy changes are warranted.

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~~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.~~

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On **April 3, 2024**, 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

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