01.01.31 Functional Electrical Stimulation and Neuromuscular Electrical Stimulation

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Related Policies:

- None

Summary

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 (e.g., spinal cord injury [SCI]).

Neuromuscular electrical stimulation (NMES) is a small electronic device that stimulates muscle when an individual is in resting state. The goal of NMES for an immobilized extremity following a documented injury or surgical intervention is to control edema, increase local blood circulation, maintain muscle tone or delay the development of disuse atrophy. NMES has also been proposed for conditions in which muscles atrophy, resulting in a loss of strength and mass occurs such as stroke (stroke with swallowing disorders), cerebral palsy, and congestive heart failure.

Summary of Evidence

Functional Electrical Stimulation

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 (e.g., 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.

Neuromuscular Electrical Stimulation

For individuals who receive neuromuscular electrical stimulation (NMES) for the treatment of disuse atrophy the evidence consists of systematic reviews and randomized controlled trials (RCTs) and observational studies. Relevant outcomes are symptoms, functional outcomes, and quality of life (QOL). Studies have primarily evaluated NMES as part of a comprehensive rehabilitative program and some have shown NMES to be effective. However, further RCTs with larger patient populations and longer follow up are needed to determine stimulation protocols, parameters, and therapy settings that are most beneficial for certain patient group and degree of impairment. The evidence is insufficient to determine the effects of the technology on net health outcomes. However, even though there is paucity in the peer-reviewed scientific evidence in showing consistent evidence regarding the effectiveness of neuromuscular electrical stimulation (NMES) for the treatment of disuse atrophy in individuals where the nerve supply to the muscle is intact, NMES is widely considered to be in accordance with generally accepted standards of medical practice in the United States and will be considered medically necessary when the criteria below are met, see Policy.

Additional Information

Not applicable.

OBJECTIVE

The first objective of this evidence review is to determine whether use of functional electrical stimulation (FES) (e.g., ParaStep Ambulation System) improves the net health outcome in individuals with functional disabilities related to spinal cord injury (SCI).

The second objective of this evidence review is to determine whether the use of neuromuscular electrical stimulation (NMES) improves the net health outcome in individuals with immobilized extremity following a documented injury or surgical intervention to control edema, increase local blood circulation, maintain muscle tone or delay the development of disuse atrophy; or for the treatment of conditions in which muscles atrophy, resulting in a loss of strength and mass occurs such as stroke (stroke with swallowing disorders), cerebral palsy, and congestive heart failure.

PRIOR APPROVAL

Not applicable.

POLICY

Functional Electrical Stimulation (FES)

ParaStep® Ambulation System

Functional electrical stimulation (FES) devices for exercise in individuals with spinal cord injury (e.g., Parastep® Ambulation System) is considered **investigational.** The evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

Neuromuscular Electrical Stimulation (NMES)

Neuromuscular Electrical Stimulation (NMES) may be considered **medically necessary** for the treatment of disuse atrophy (muscle atrophy/wasting) in the setting of intact nerve supply (including brain, spinal cord and peripheral nerves) to the muscle resulting from one of the following conditions:

- Previous immobilization of a joint or limb (arm or leg) by casting or splinting after a surgical intervention with failure to respond to or unable to participate in physical therapy.
- Contractures due to scarring of soft tissue (e.g., burn scarring).
- Following total hip replacement surgery prior to initiation of physical therapy (until physical therapy begins).
- Following total knee replacement surgery with failure to respond to physical therapy.

Neuromuscular Electrical Stimulation (NMES) is considered **investigational** when the above criteria is not met and for all other indications including but not limited to the following because the evidence is insufficient to determine the effects of the technology on net health outcomes:

- As a technique to increase circulation
- Cerebral palsy
- Cerebral vascular accident
- Chronic obstructive pulmonary disease (COPD)
- Dysphagia
- Following ACL/MCL repair
- For the treatment of denervated muscles
- For the treatment of hip or knee osteoarthritis except as indicated above related surgical intervention
- Prevent disuse atrophy/muscle atrophy

- Reduce post-surgical swelling
- Treatment of pain for various musculoskeletal conditions
    - Low back pain
    - Patellofemoral syndrome
    - Spinal stenosis
    - Muscle strains/sprains
    - Scoliosis

POLICY GUIDELINES

Note: *Functional Electrical Stimulation (FES) devices (E0770 functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified) are considered home exercise equipment and are generally excluded from coverage (non-covered benefit) regardless of the indication they are being prescribed.*

Coding

See the Codes table for details.

BACKGROUND

Functional Electrical Stimulation

Functional electrical stimulation (FES) is an approach to rehabilitation that applies low-level electrical current to stimulate functional movements in muscles affected by nerve damage and focus on the restoration of useful movements like standing and stepping. This evidence review will address the Parastep® Ambulation System. This system, is a transcutaneous non-invasive and micro-computerized electrical stimulation system built into a battery-powered unit, is controlled by finger-touch buttons located on a walker's hand-bars for manual selection of stimulation menus. The microcomputer shapes, controls, and distributes trains of stimulation signals that trigger action potentials in selected peripheral nerves. Walker support is used for balance. The individual can don the system in less than 10 minutes. At least 32 training sessions are required.

Neuromuscular Electrical Stimulation

When individuals are subject to insufficient use or exercise, muscles atrophy, resulting in a loss of strength and mass occurs. Muscle atrophy may also occur when the limbs are immobilized after injury or surgery. Neuromuscular electrical stimulation (NMES) is an approach to rehabilitation that stimulates the motor nerves with electrical currents, which generate muscle contractions to reverse muscle atrophy. When nerve innervation is intact, NMES promotes re-innervation and slows the development of disuse atrophy, relaxes muscle spasms, and increases voluntary muscle control.

Neuromuscular electrical stimulation devices are small electronic devices that are affixed externally to the individual's skin by way of electrodes to provide direct stimulation of affected muscles. NMES stimulates muscle to maintain its tone during temporary extremity immobilization. The goal of NMES for an immobilized extremity following a documented injury or surgical intervention is to control edema, increase local blood circulation, maintain muscle tone or delay the development of disuse atrophy. The goal for

NMES for other conditions in which muscles atrophy, resulting in a loss of strength and mass occurs is muscle strengthening and functional improvement.

Regulatory Status

Functional Electrical Stimulation (FES)

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." FDA product code: MKD.

Neuromuscular Electrical Stimulation (NMES)

A variety of NMES devices have been cleared by the U.S. Food and Drug Administration (FDA) and are available for home use:

Table 1. FDA Neuromuscular Electrical Stimulation (NMES) Devices

Device	Manufacturer	Device Type	Date
Biomove Device	Curatronic LTD.	Electromyography (EMG) triggered NMES used as a training system for rehabilitation of paralyzed muscles, mainly after stroke.	August 2005
Guardian Dysphagia Dual Chamber Unit; Guardian Aspire 2 Dysphagia; SwallowStim Dysphagia Therapy Device; and VitalStim Therapy	Medline; DJO Global	NMES Devices proposed for use of muscle re-education by application of external stimulation for pharyngeal contraction.	February 2013; June 2007
M-Wave	Zynex Medical	Next generation NMES This device has been designed for muscle re-education, prevention of disuse atrophy, increase local blood circulation, maintain, or increase range of motion, and relaxation of muscle spasms.	January 2024
RS-2m and RS-4m	RS Medical	NMES	June 2002

RS-4i	RS Medical	Sequential stimulator (also referred to as a combination unit) initially provides an interferential treatment (pain relief) followed by neuromuscular electrical stimulation (NMES) that reduces muscle spasms, increases circulation and prevents use atrophy	April 2007
The following devices are combination of NMES and transcutaneous electrical stimulation (TENS) devices			
Device	**Manufacturer**	**Device Type**	**Date**
Empi Phoenix	DJO Global	Conductive garment treats disuse atrophy by NMES and TENS can help manage pain.	May 2013
Flex-MT Plus	EMSI Inc.	NMES prevent muscle atrophy, for muscle re-education, to relax muscle spasms, to improve blood circulation, for postsurgical stimulation of calf muscles to prevent venous thrombosis, and/or to maintain or increase range of motion. TENS can help manage pain.	October 2014
Kneehab XP	Bio-Medical Research LTD.	Combines neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS) to improve knee stability during the first 90 days after surgery. Kneehab assists in regaining lost quadriceps strength.	July 2009
NexWave	Zynex Medical	Combines interferential current (IFC) therapy for the purpose of pain relief, transcutaneous	September 2011

		electrical stimulation (TENS) to provide better pain relief results and more intense therapeutic effect and neuromuscular electrical stimulation (NMES) to stimulate muscle contractions.	
QB1 System	Cymedica Orthopedics, INC.	Assists individuals to overcome quad weakness by integrating next-generation muscle activation technology in a simple compressive wrap or post-operative brace. TENS can help manage pain.	February 2015

RATIONALE

This evidence review was created in October 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through May 2025.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Ambulation in Patients with Spinal Cord Injury

Clinical Context and Therapy Purpose

Another application of FES is to provide individuals with SCI the ability to stand and walk. Using percutaneous stimulation, the device delivers trains of electrical pulses to trigger action potentials at

selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Individuals use a walker or elbow-support crutches for further support. The electric impulses are controlled by a computer microchip attached to the individual's belt, which synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits patient activation of the stepping.

Other devices include a reciprocating gait orthosis with electrical stimulation. The orthosis used is a cumbersome hip-knee-ankle-foot device linked together with a cable at the hip joint. The use of this device may be limited by the difficulties in donning and doffing the device.

The purpose of FES for ambulation in individuals who have SCI is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with SCI at segments T4 to T12.

Generally, only SCI individuals with lesions from T4 to T12 are considered candidates for ambulation systems. Lesions at T1 to T3 are associated with poor trunk stability, while lumbar lesions imply lower-extremity nerve damage.

Interventions

The therapy being considered is FES.

To date, the Parastep® Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the U.S. Food and Drug Administration (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.

Comparators

The following therapies are currently being used to make decisions about FES for ambulation: standard of care.

Outcomes

The general outcomes of interest are functional outcomes and QOL. The clinical impact of the Parastep® device rests on the identification of clinically important outcomes. The primary purpose of this device is to provide a degree of ambulation that improves the individuals ability to complete ADLs or positively affect the individual's QOL. Physiologic outcomes (i.e., conditioning, oxygen uptake) have also been reported, but they are intermediate, short-term outcomes.

Based on available literature, longer-term outcomes would require follow-up of at least 18 months.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

The evidence on FES for ambulation is shown in Table 2.

Chaplin (1996) reported on the largest study, which was on ambulation outcomes using the Parastep 1 and included 91 patients. Of these 91 patients, 84 (92%) were able to take steps, and 31 (34%) were able eventually to ambulate without assistance from another person. Duration of use was not reported. Other studies on the Parastep device include a series from the same group of investigators, which focused on different outcomes in the same group of 13 to 16 patients.

Guest et al (1997) reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury. The group's mean peak distance walked was 334 meters, but individual studies varied widely. The mean peak duration of walking was 56 minutes, again with wide variability. Anthropomorphic measurements were taken at various anatomic locations. Increases in thigh and calf girth, thigh cross-sectional area, and calculated lean tissue were all statistically significant. The authors emphasized that the device was not intended as an alternative to a wheelchair, and thus other factors such as improved physical and mental well-being should be considered when deciding whether to use the system. Graupe and Kohn (1998) noted the same point in a review article.

Brissot et al (2000) found that 13 of 15 patients evaluated in a case series achieved independent ambulation. Five of the 13 patients continued using the device for physical fitness at home, but none used it for ambulation. Sykes et al (1996) found low use of a reciprocating gait orthosis device with or without stimulation over an 18-month period, and Davis et al (2001) found mixed usability/preference scale results for ambulation, standing, and transfers with a surgically implanted neuroprosthesis in 12 patients followed for 12 months. The effects of a surgically implanted neuroprosthesis on exercise, standing, transfers, and quality of life were also reported in 2012. The device used in both studies was not commercially available at that time.

Several publications reported on physiologic responses to use of the Parastep device. Jacobs et al (1997) found a 25% increase in time to fatigue and a 15% increase in peak oxygen uptake, consistent with an exercise training effect. Needham-Shropshire et al (1997) reported no relation between use of the Parastep device and bone mineral density, although the interval between measurements (12 weeks) and the precision of the testing device might have limited the ability to detect a difference. Nash et al (1997) reported that use of the Parastep device was associated with an increase in arterial inflow volume to the common femoral artery, perhaps related to the overall conditioning response to the Parastep.

Table 2. Key Case Series

Study	Participants	Ambulation, n (%)	Distance walked	Physical Fitness	Limitations
Chaplin et al (1996)	91 adults with SCI	31 (34%) could ambulate without assistance			84 (92%) could take some steps
Guest et al (1997)	16 adults with SCI		334 meters	Improvements in the leg	
Brissot et al (2000)	15 adults with SCI	13 (87%) patients achieved independent ambulation		5 used the device for physical fitness	No patient used the device for ambulation at home

SCI: spinal cord injury.

Section Summary: Ambulation in Patients with Spinal Cord Injury

The evidence on functional FES for standing and walking in individual with SCI consists of case series. Case series are considered adequate for this condition because there is no chance for ambulation in individuals with SCI between segments T4 to T12. As stated by various authors, these systems are not designed as alternatives to a wheelchair and offer, at best, limited, short-term ambulation. Some studies have reported improvements in intermediate outcomes, but improvement in health outcomes (e.g., ability to perform ADLs) have not been demonstrated. Finally, evaluations of these devices were performed immediately after initial training or during limited study period durations. There are no data in which patients remained compliant and committed with long-term use.

Neuromuscular Electrical Stimulation

Clinical Context and Therapy Purpose

Neuromuscular electrical stimulation (NMES) stimulates muscle to maintain its tone during temporary extremity immobilization. The goal of NMES for an immobilized extremity following a documented injury or surgical intervention is to control edema, increase local blood circulation, maintain muscle tone or delay the development of disuse atrophy.

NMES may also be utilized in rehabilitative regimen for conditions in which muscles atrophy, resulting in a loss of strength and mass occurs such as with stroke to include stroke with swallowing disorders, cerebral palsy, and congestive heart failure.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with immobilized extremity following a documented injury or surgical intervention or individuals with conditions in which muscles atrophy, resulting in a loss of strength and mass occurs such as with stroke to include stroke with swallowing disorders, cerebral palsy, and congestive heart failure.

Interventions

The therapy being considered is NMES.

- Biomove Device

- Geko Neuromuscular Stimulation
- Guardian Dysphagia Dual Chamber Unit,
- Guardian Aspire 2 Dysphagia SwallowStim Dysphagia Therapy Device
- M-Wave
- VitalStim Therapy
- RS-2m Muscle Stimulator
- RS-4i Sequential Stimulator
- RS-4m Muscle Stimulator

The following devices are combination of NMES and transcutaneous electrical stimulation (TENS) devices:

- Empi Phoenix
- Flex-MT Plus
- Kneehab XP
- NexWave
- QB1 System

Comparators

The following practices are currently being used to make decisions about NMES: standard of care.

Outcomes

The general outcomes of interest are functional outcomes and QOL. Specific outcomes of interest include muscle strengthening.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Musculoskeletal Conditions

Systematic Reviews

Carvalho et al (2023) conducted a systematic review and meta-analysis on the effectiveness of neuromuscular electrical stimulation (NMES) combined with exercise in patients with knee osteoarthritis (KOA) on patient reported outcome measures (PROMS). The reviewers searched PubMed, PEDro,

LILACS, Embase, and SPORTDiscus April 2022. Six RCTs were included (n=367); four studies (Rosemffet 2004, Elboim-Gabyzon 2012, Imoto 2013, Laufer 2014) included individuals with grade II or higher OA by Kellgren and Lawrence, one study (Park 2021) included early stage OA conditions I or II by Kellgren and Lawrence, and the other recruited symptomatic individuals regardless of stage condition (Rabe 2018), however, with consideration of risk factors (BMI of 25 kg/m^2 or greater, history of knee joint injury or surgery or pain or stiffness previous 30 days) for knee OA symptoms. Age ranged 60 to 68.9 years and majority of participants were male 365/367. Outcomes were assessed utilizing VAS, NRS and WOMAC. In this meta-analysis, NMES at a specific joint angle combined with exercise was not superior to exercise alone in pain management (standardized mean difference = -0.33, 95% CI = -1.05 to 0.39, p = 0.37). There was no additional effect of NMES on exercise on self-reported functional ability, stiffness, and physical function compared with exercise alone. In only one study, symptoms, activities of daily living, sports function, and quality of life improved after whole-body electrostimulation combined with exercise. The reviewers concluded “The evidence is insufficient for the effectiveness of NMES combined with exercise in treating knee OA considering PROMs. More high-quality clinical trials are needed to support the use of NMES added to exercise in clinical practice.”

Peng et. al. (2021) performed a systematic review and meta-analysis of randomized controlled trials (RCTs) which evaluated the effect of neuromuscular electrical stimulation (NMES) regarding strength, pain and function outcomes following total knee arthroplasty (TKA). Nine RCTs (Avramidis 2003, Patterson 2009, Valdes 2010, Avramidis 2011, Stevens-Lapsley 2012, Levin 2013, Demet 2015, Yoshida 2017 and Klika 2020) involving 691 patients were included in this review, 357 patients received NMES, and 334 patients received conventional rehabilitation therapy (physical therapy and exercise). In all nine of the RCTs in the NMES group received similar NMES therapy, the frequency ranged from 30 to 100 Hz. This analysis showed that NMES improved quadriceps muscle strength after TKA within 1 months [standardized mean difference (SMD): 0.81; 95% CI: 0.51–1.11], 1–2 months (SMD: 0.55; 95% CI: 0.13–0.97), 3–4 months (SMD: 0.42; 95% CI: 0.18–0.66), and 12–13 months (SMD: 0.46; 95% CI: 0.18–0.74), pain between 1 and 2 months
[mean difference (MD): −0.62; 95% CI: −1.04 to −0.19], pain between 3 and 6 months (MD: −0.44; 95% CI: −0.74 to −0.14) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) between 3 and 4 months (MD: −0.43; 95% CI: −0.82 to −0.05), timed up and go test (TUG) within 1 month (MD: −2.23; 95% CI: −3.40 to −1.07), 3 minutes’ walk test between 3 and 6 months (MD: 28.35; 95%CI: 14.55–42.15), and SF-36 MCS between 3 and 6 months after TKA (MD: 4.20, 95% CI: 2.41–5.98). The authors noted “The most important finding of the current study was that postoperative NMES could improve short-term to long-term quadriceps muscle strength, mid-term pain, and mid-term function following TKA surgery.” The authors concluded “However, many outcomes failed to achieve statistically meaningful changes and MCID, thus the clinical benefits remained to be confirmed.”

Randomized Controlled Trials

Beyond those included in the systematic reviews summarized above, we identified the following additional RCTs.

Moezy et al (2024) performed a randomized controlled trial (RCT) to assess the effectiveness of neuromuscular electrical stimulation (NMES) and exercise therapy for improving pain, muscle weakness and function in patients with knee osteoarthritis (KOA). The study group was limited to only 75 female patients diagnosed with KOA and that were randomly divided into three intervention groups whom all underwent 12 supervised treatment sessions three times per week: NMES only (specific treatment parameters Pulse Width: 600μs; Carrier Frequencies=4,000—4,050; Beat (Sweep) Frequency=50 Hz; Treatment duration: 15 min. The current intensity (mA) was adjusted to ensure muscle contractions were comfortable and effective, avoiding any pain or discomfort); exercise therapy (Exs) alone (control group:

Followed supervised protocol of 5 exercises performed in 3 sets of 10 repetitions three times per week); and combination of NMES and Exs (NMES + Exs: Specific treatment parameters followed the specific exercise protocol of the control group and NMES was applied to the patients using a frequency of 100 Hz, a pulse width ranging from 50 to 100 μs, and a quadratic biphasic symmetrical pulse shape. Treatment lasted for 20 min and involved the placement of two self-adhesive electrodes on either side of the knee. The intensity (mA) was individually adjusted to reach the threshold of a tingling sensation for each patient). All patients were instructed to discontinue the use of nonsteroidal anti-inflammatory drugs one week prior to and throughout the intervention. They were only prescribed Acetaminophen, with a maximum daily dosage of 2 g, to be used if they experienced pain. Outcome measures included: pain intensity measured by visual analog scale (VAS), knee flexion range of motion (FROM), thigh muscle girth (TG), thickness of the Vastus Medialis Oblique (VMO), timed up and go test (TUG), six-minute walk test (6MWT), and WOMAC scores and analysis was done to compare the amounts measured at baseline (BL), immediately after treatment and after 12-weeks. The NMES group exhibited a significant reduction in pain at the 12-week follow-up compared to the other groups($p=0.022$). The NMES+Exs group showed better outcomes in terms of FROM, TG, and VMO thickness post-intervention ($p < 0.0001$, $p < 0.004$, $p= 0.003$, respectively) and at the 12-week follow-up ($p < 0.0001$, $p < 0.0001$, $p = 0.038$, respectively) and during the follow-up assessments ($p < 0.0001$, $p=0.029$ respectively). The NMES+Exs group achieved better WOMAC stiffness scores at both post-intervention and follow-up evaluations ($p <0.0001$, $p <0.0001$, respectively). Furthermore, at the 12-week follow-up, NMES+Exs group outperformed the others in WOMAC pain and function subscales ($p = 0.003$, $p = 0.017$, respectively), while the NMES group demonstrated better WOMAC total scores compared to the other groups ($p=0.007$). Limitations included small sample size of only female patients mainly non-obese and short follow-up of 12-weeks. Additionally, NMES study focused solely on medium frequency and did not compare it effectiveness with other NMES frequencies. The reviewers concluded “Future research should explore the efficacy of NMES with other frequency currents and include broader patient demographics to establish more comprehensive treatment guidelines for KAO management.”

Wellauer et. al. (2022) conducted a randomized controlled trial (RCT) comparing the effectiveness of a home-based contralateral neuromuscular electrical stimulation (NMES) program against sham-NMES as a complement to standard rehabilitation on knee extensor neuromuscular function in patients following anterior cruciate ligament (ACL) reconstruction. The trial included 27 patients randomly assigned (1:1) to receive NMES (n=13) or sham-NMES (n=14). The rehabilitation program lasted 24 weeks and included a maximum of thirty-six supervised physical therapy sessions. Both intervention programs (NMES and sham-NMES) were completed from postoperative week 2 to 8 weeks, for a total duration of 6 weeks. For both programs, the first session was completed in the clinic under the supervision of a qualified physical trainer; all the other sessions were conducted at home (18 sessions in total) with the possibility to contact the trainer by phone/e-mail on each session day. The intervention programs consisted of 3 weekly sessions of 20 min of NMES or sham-NMES that were applied to the quadriceps of the nonoperative side by using of a garment-based device (Kneehab XP, Bio-Medical Research Ltd., Galway, Ireland). Patients were asked to apply by themselves NMES and sham-NMES in a comfortable seated position (e.g., on a standard chair), with the knee fixed at 90 degrees by means of a strap. In the NMES group, patients were consistently asked to increase the stimulation intensity through each session to a maximally tolerated level, which resulted in visible, sustained, tetanic quadriceps contractions with superior patellar glide. In the sham-NMES group, patients were asked to increase the stimulation intensity to a level where current could be perceived but with no resultant visible contraction of the quadriceps muscle. Patients from both groups were not blinded to the type of NMES intervention they received. The primary outcomes were knee extension strength (isometric, concentric and eccentric) with respective strength deficits (estimates of muscle weakness) that were evaluated at all time points for the nonoperative side versus at pre and week 24 for the operative side, as well as self-reported knee function at all time points using the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire. Isometric, concentric, and eccentric strength deficits (muscle weakness) increased from pre-surgery to 24 weeks post-surgery in the sham-

NMES group ($p<0.05$), while no changes were observed in the NMES group. On the stimulated (nonoperative) side, quadriceps voluntary activation and muscle thickness were respectively maintained ($p> 0.05$) and increased ($p < 0.001$) as a result of the NMES intervention, contrary to sham-NMES. Self-reported knee function improved progressively during the post operative phase ($p < 0.05$), with no difference between the two groups. Compared to sham-NMES intervention, a 6-week home based NMES program applied to quadriceps of the nonoperative side early after ACL reconstruction prevented the occurrence of knee extensor muscle weakness 6 months after surgery. Study limitations include small sample size, NMES use was not full controlled due to home-based administration of both interventions and patients were not blinded to the type of intervention they received.

In 2022 Zhao et. al. in a randomized controlled trial investigated the effectiveness of neuromuscular electrical stimulation (NMES) for enhanced recovery after total hip replacement surgery. Sixty patients undergoing total hip replacement for osteoarthritis of the hip were randomized and divided into 2 groups: 1 group received postoperative treatment with the NMES device (n=30), and the other group (control group, n=30) did not receive NMES. The primary outcome measures were postoperative pain (quantified through visual analog pain score [VAS]), lower limb swelling (measurements of circumference of both the thigh and calf), and length of stay (LOS) post-surgery (number of postoperative nights in the hospital until discharge). Data was collected prior to surgery (Day 0), the first postoperative day (Day 1), the third postoperative day (Day 3), and the fifth postoperative day (Day 5). At each time point, adverse events and device deficiencies were monitored. Patients in the NMES group demonstrated a general trend of beneficial postoperative pain (day 1 and day 3 during mobilization; $P < .05$, respectively), calf swelling (mean change in calf circumference were significant postoperatively NMES group 2.5 cm; control group 1 cm), and average length of stay (LOS) from postoperative to discharge (there was significant difference between the two groups, mean LOS was 6.9 ± 1.8 for the NMES group and 8.6 ± 2.0 for the control group; $P = .002$). Study limitation is small sample size. The authors concluded that NMES is partly useful for enhanced recovery after total hip replacement.

In 2017, Talbot et. al. conducted a randomized controlled trial (RCT) that compared the effects of the traditional military amputee rehabilitation program (TMARP) plus home-based neuromuscular electrical stimulation (NMES) therapy to the effects of TMARP alone on lower extremity muscle strength, pain, and mobility in unilateral transtibial military amputees. In total, 44 participants, aged 19 to 46 years, with a unilateral transtibial amputation were randomly assigned to the TMARP plus NMES (n = 23) or to TMARP alone (n = 21). Both groups received 12 weeks of the traditional amputee rehabilitation, including pre- and post-prosthetic training. Those in the NMES group also received 12 weeks of NMES, 15 to 20 minutes/day, 5 days a week. Participants were tested at 3-week intervals during the study (baseline, 3, 6, 9, and 12 weeks) for muscle strength (Nicholas Manual Muscle Tester [NMMT]) and pain (Brief Pain Inventory [BPI]). For functional measures patients were tested after receiving their prosthesis and at study completion (weeks 6 and 12). Lower extremity muscle strength improved during the study for both treatment groups. The most marked increase in strength (measure 5 cm below the tibial tuberosity) were found in the residual limb (TMARP plus NMES: 62.1% knee extension, 53.5% knee flexion; TMARP only: 47.3% knee extension, 31.8% knee flexion) as compared to the intact limb (NMES: 7.2% knee extension, 13.4% knee flexion). There was a significant main effect of time for residual limb strength knee flexion and extension ($p = <0.01$); however, for the intact limb the change was not significant. No group differences were observed in pain reported by the two groups during the study for either BPI severity or interferences scores. Functional mobility was assessed at week 6 (when prosthesis received) which showed no difference observed between the two treatment groups and between 6 and 12 weeks both groups showed improvement in mobility, but no differences were observed between groups. Limitations include small sample size and compliance monitoring also was limited. The authors concluded “using a NMES home-based therapy with traditional in-clinic physical therapy has potential to reduce muscle atrophy and minimize strength loss in the amputated leg during the pre-prosthetic period. The addition of

home-based NMES in this population may show greater improvements and would benefit from further research."

Observational Studies

Guo et al (2018) conducted a retrospective study that investigated the safety and effectiveness of neuromuscular electrical stimulation (NMES) for patients with chronic low back pain (CLBP). Patients were age 18-75 years with a history of CLBP longer than 3 months at a single institution June 2016 and August 2017. A total of 72 patients were included and were assigned into two groups NMES (n=36) and a control group (n=36). Both groups received usual care for total of 4-weeks which consisted of pain medication nonsteroidal anti-inflammatory drugs (zaltoprofen, 80mg), 3 times daily, for 4 weeks and an educational program regarding the pathophysiology, pathology and epidemiology of CLBP. In addition to usual care the NMES group applied the device with 2 electrodes at bilateral lumbar paraspinals (L2–L5) for a total of 30 minutes each session, once daily, once weekly for a total of 4 weeks. Primary outcomes measured was pain intensity measured by numerical rating scale (NRS). The secondary outcome was disability, assessed by the Roland–Morris Disability Questionnaire (RMDQ), and the Quebec Back Pain Disability Scale (QBPDS). The outcomes were evaluated before and after 4-week treatment. After 4-week treatment, the patients in the NMES group did not show better effectiveness in pain intensity relief, as measured by NRS (P=.11); and disability improvement, as evaluated by the RMDQ (P=.14), and QBPDS (P=.33), when compared with the patients in the control group. Additionally, no adverse events related to the NMES were recorded. Limitations included small sample size, short follow up of only 4-weeks, this study did not include a comprehensive outcome measurement such as QOL for both groups and did not apply randomization which may have increased risk of patient selection. The reviewers concluded "This study found that NMES may not be effective in patients with CLBP after 4-week treatment. Future studies with larger sample size and longer treatment duration are still needed to warrant the results of this study."

Miscellaneous Conditions

Cerebral Palsy

Rocha et al (2022) conducted a systematic review of randomized controlled trials (RCTs) to evaluate the safety and efficacy of non-surgical interventions. Three RCTs assessing the effects of botulinum toxin, functional masticatory training and neuromuscular electrostimulation (NMES) were included. The evidence with very low certainty showed: no difference between botulinum toxin and placebo regarding maximum chewing strength, chewing efficiency and global oral health scale; improvement in masticatory function in favor of functional masticatory training versus conventional exercises, and in favor of strengthening exercises plus NMES versus placebo. Per this review evidence was insufficient to support the use of botulinum toxin and masticatory muscle strengthening programs alone and associated with NMES for the treatment of masticatory muscle in patients with CP. This systematic review is limited by sample size, heterogenous groups and lack of a controlled comparator group. Further randomized controlled trials (RCTs) are needed.

In 2021, Cobo-Vicente et al performed a systematic review and meta-analysis to analyze the effect of neuromuscular electrical stimulation (NMES) on skeletal muscle and biomechanics of movement, functional mobility, strength, spasticity, muscle architecture and body composition of children and adolescents with chronic neurological disorders (CNDs) and chronic diseases. There were 595 participants between 3 and 14 years of age, of which 49% were female. Most of the studies (88.9%) included in the review were about cerebral palsy. There was also one study on spinal muscular atrophy and one study about obstetric brachial plexus injury. All the studies used NMES as their main intervention with the NMES programs lasting from 4 t0 48 weeks in duration with an average application of 14 weeks. Half of the programs were home-based programs and half of the cases indicated the NMES was applied

by professionals. This analysis concluded that NMES programs for children with CNDs, specifically cerebral palsy, appears to be effective in improving strength, biomechanics of movement, and functional mobility; however, they noted that there were not enough studies to confirm that NMES produces benefits on spasticity, muscle architecture, and body composition. Limitations included little agreement in the variables analyzed in the different studies which made it hard to compare results and perform the statistical analysis of some variables, small sample size, and most of the studies focused on CP and conclusions were difficult to expand to other types of CNDs. Additional randomized controlled trials (RCTs) are needed to analyze the effect of NMES on spasticity, muscle architecture and body composition in children with CNDs and additional studies are also needed to evaluate the effectiveness of NMES in pediatric patients with other chronic diseases.

Abd Elmonem et al (2024) in a randomized comparative trial compared the effects of neuromuscular electrical stimulation (NMES) with interrupted serial casting (SC) versus SC alone on various aspects of lower limb function in children with diplegic cerebral palsy (CP). The trial included 33 children, 3-7 years of age, with more male patients than female. The study participants had level two or three classifications according to the Gross Motor Function Classification System (GMFCS), and grade two or three spasticity according to the Modified Ashworth Scale (MAS) with jump gait or equinus patterns. They were divided into two groups in a random manner: Group A received interrupted progressive SC with Tomato fiberglass cast for 5 days/week for eight consecutive week; and Group B received the same interventions as group A along with NMES administered 30 minutes three times weekly for eight consecutive weeks. Measurements were taken at baseline and after the 8th week intervention to compare the two groups, measuring ankle dorsiflexion range of motion (ROM) with GemRed digital angle ruler, the maximum voluntary isometric contraction of ankle dorsiflexors and knee extensors were assessed with Lafayette Manual Muscle Tester, dynamic spasticity of the hamstring and gastrocnemius muscles was evaluated with Modified Tardieu Scale and the Observation Gail Scale (OGS) was utilized to evaluate the children's gait. Both groups exhibited significant improvement in dorsiflexion ROM, popliteal angle, gastrocnemius dynamic spasticity, and hamstring dynamic spasticity after the intervention ($p = 0.0001$ for all). However, significant differences ($p < 0.05$) in dorsiflexor strength, knee extensor strength, and observational gait scale score were observed between groups after the intervention favoring group B. Limitations of this study included the generalizability of the inclusion criteria related to baseline spasticity grade, GMFCS level and specific gait patters and did not include a post-treatment follow-up assessment.

Oropharyngeal Dysphagia

Wang et. al. (2023) conducted a systematic review and meta-analysis on the clinical efficacy of transcutaneous neuromuscular electrical stimulation (NMES) in the treatment of individuals with post-stroke dysphagia. The reviewers searched CNKI, Wanfang, VIP, SinoMed, PubMed, Embase, Cochrane Library, and Web of Science databases from the establishment of the databases to June 2022 for RCTs in which 46 studies with 3,346 patients. The inclusion criteria included individuals with ischemic or hemorrhagic stroke on imaging; dysphagia after stroke diagnosed by clinical examination with no other neurological diseases or other dysphagia; and received the same swallow therapy (ST). Outcome measures included: (1) Functional Oral Intake Scale (FOIS); (2) Penetration-Aspiration Scale (PAS–Fluid); (3) Functional Dysphagia Scale (FDS); (4) the Swallowing Quality of Life questionnaire (SWAL-QOL); (5) the forward movement distance of the hyoid bone (FMHB); (6) the upward movement distance of the hyoid bone (UMHB); (7) the complication rate (CR); (8) the Standardized Swallowing Assessment (SSA); (9) the water swallow test (WST); and (10) the videofluoroscopic swallow study (VFSS). The analyses indicated showed that NMES combined with routine swallowing therapy (ST) could effectively improve swallowing function Penetration-Aspiration Scale (MD = −0.63, 95% CI [−1.15, −0.12], P = 0.01), Functional Oral Intake Scale (MD = 1.32, 95% CI [0.81, 1.83], P < 0.00001), Functional Dysphagia Scale (MD = − 8.81, 95% CI [−16.48, −1.15], P = 0.02), the Standardized Swallowing Assessment (MD = −6.39, 95% CI [−6.56, −6.22], P < 0.00001), the Videofluoroscopic Swallow Study (MD = 1.42, 95% CI [1.28,

1.57], P < 0.00001) and the Water swallow test t (MD = −0.78, 95% CI [−0.84, −0.73], P < 0.00001). Limitations included the following: the majority of these studies were from China which may have led to regional bias, most trials did not report the blinding method utilized
(may be placebo effect and observer bias) which may have reduced the quality of the study, only 6 studies had follow-up visits and adverse events were only reported in some of the studies which resulted insufficient evidence to support safety. The reviewers concluded “There is insufficient evidence on the safety of NMES + ST. Moreover, due to the small number of included literature and low quality of evidence, more large sample, high-quality, multi-center RCT studies are needed to prove the clinical efficacy of NMES in addition to ST in the treatment of post-stroke dysphagia.”

Miller et al (2022) conducted a systematic review to evaluate the most recent studies regarding the potential effectiveness of neuromuscular electrical stimulation (NMES) as a treatment for oropharyngeal dysphagia. Eighteen studies were identified with varying patient groups, stimulation protocols, electrode placement and therapy settings. However, 16 studies reported beneficial outcomes in relation with NMES. The authors concluded that there is a considerable amount of level 2 studies which suggest that NMES is an effective treatment option, especially when combined with traditional dysphagia therapy (TDT) for patients with dysphagia after stroke and patients with Parkinson's disease, or with different kinds of brain injuries. However, further research is still needed to clarify which stimulation protocols, parameters and therapy settings are most beneficial for certain patient groups and degrees of impairment.

Cerebral Vascular Accident

Oh et al (2023) conducted a systematic review and meta-analysis that evaluated the effectiveness of combined mirror therapy with neuromuscular electrical stimulation (NMES) in post stroke individuals regarding improvement of their lower extremity motor function recovery related to walking speed, spasticity, balance and other gait parameters (cadence, step length, stride length). The reviewers searched PubMed, Cochrane Library, Embase, Scopus databases and Google Scholar from the date of the inception until October 2022. Six RCTs were selected (published between 2014 and 2021) which included 181 stroke survivors who had experienced hemiplegia at any stage of stroke and exhibited various impairment of motor function of lower extremities related to ambulation, balance, muscle tone and spasticity. Primary outcome measure was walking speed with secondary outcomes assessed Berg Balance Scale (BBS) score, modified Ashworth scale (MAS) score, and several gait parameters (i.e., cadence, step length and stride length). Analyses indicated that MT combined with NMES provided greater improvement relative to control group in the following: walking speed (SMD= 0.67, 95% [CI] 0.26–1.07, P= 0.001), Berg Balance Scale (SMD= 0.72; 95% CI 0.31–1.13; P= 0.0007), cadence (SMD= 0.59, 95% CI 0.02–1.16, P= 0.04), step length (SMD= 0.94, 95% CI 0.35–1.53, P= 0.002), and stride length (SMD= 0.95, 95% CI 0.36–1.54, P= 0.002), but not with Ashworth scale (SMD= − 0.40, 95% CI − 1.05 to 0.26, P= 0.23). Limitations included small sample size, outcomes were assessed immediately after treatment and blinding of therapists and participants was not implemented in any of the studies which potentially resulted in performance bias. The reviewers concluded, “While MT and NMES may be a promising intervention for improvement of post-stroke lower extremity lower extremity motor function, because of the small sample size of this meta-analysis and reduced overall evidence level, additional larger scale studies with higher methodological quality to include comparing the effectiveness of the combination of MT and NMES therapy versus NMES or MT alone in improving lower extremity motor function and impairment of stroke survivors should be conducted.”

Ohnishi et al (2022) conducted a randomized controlled trial (RCT) to investigate the effect of combined therapy with repetitive facilitative exercise (RFE) and neuromuscular electrical stimulation (NMES) on stroke patients with severe upper paresis. This study included a total of 99 stroke patients with very severe paresis and with scores of zero or 1a in the Finger-Function test of the Stroke Impairment Assessment Set (SIAS). Participants were randomly divided into four groups, namely, NMES, RFE, RFE

under NMES, and conventional training (CT) groups. A total of 20 minutes of group-specific training in addition to 40 minutes of conventional exercise per day, seven times a week for 4 weeks after admission, was performed. The upper extremity items of the Fugl-Meyer Assessment (FMA) were evaluated before and after the training period. The total score gains of the FMA, FMA wrist item, and FMA finger item were larger in the RFE under NMES group than those in the CT group ($p < 0.05$). A limitation of this study was that the number of joint movement repetitions was arbitrary, although the training period of each group was defined. The authors concluded that additional studies are warranted to verify the effects of treatments with a fixed number of movements.

Xie et al (2022) conducted a two-arm randomized controlled trial (RCT) to investigate the effects of simultaneous use of neuromuscular electrical stimulation on median nerve (m-NMES) and language training (m-NMES-LT) on cerebral oscillations and brain connection, as well as the effect on clinical efficacy following cerebrovascular accident (CVA). A total of 21 right-handed adult patients with aphasia after stroke were randomly assigned to language training (LT) group (n = 10) and m-NMES-LT group (n = 11), and tissue concentration of oxyhemoglobin and deoxyhemoglobin oscillations were measured by functional near-infrared spectroscopy in resting and treatment state during three consecutive weeks. Five characteristic frequency signals (I, 0.6-2 Hz; II, 0.145-0.6 Hz; III, 0.052-0.145 Hz; IV, 0.021-0.052 Hz; and V, 0.0095-0.021 Hz) were identified using the wavelet method. The wavelet amplitude (WA) and wavelet phase coherence (WPCO) were calculated to describe the frequency-specific cortical activities. The m-NMES-LT induced higher WA values in contralesional prefrontal cortex (PFC) in intervals I, II, and V, and ipsilesional motor cortex (MC) in intervals I-V than the resting state. The wavelet phase coherence (WPCO) values between ipsilesional PFC-MC in interval III-IV, and between bilateral MC in interval III-IV were higher than resting state. In addition, there was a positive correlation between WPCO and Western Aphasia Battery in m-NMES-LT group. Limitation of this study was small sample size which made it difficult to determine whether these conclusions can be generalized to a larger population. Further studies are needed to determine the clinical usefulness of NMES related to language training.

Pulmonary Indications

Donadio et al. (2022) conducted a randomized controlled trial (RCT) to evaluate the effects of a supervised resistance-training program, associated or not with neuromuscular electrical stimulation (NMES), on muscle strength, aerobic fitness, lung function and quality of life in children with cystic fibrosis (CF) presenting with mild-to-moderate pulmonary impairment. A total of 27 patients, aged between 6 and 17 years, were enrolled in this study. Subjects were randomly allocated to control (CON); exercise (EX); or exercise and NMES (EX + NMES) groups and evaluated at baseline and at the end of an 8-week individualized exercise-program (3 days/week, 60min/session). NMES was applied in the quadriceps and the interscapular region, simultaneously to the exercises. CON group followed the CF team recommendations. The main outcome measures were lung function, cardiorespiratory fitness, functional capacity, quality of life and muscle strength. No interactions were found for cardiorespiratory fitness. Functional capacity presented differences, indicating a better performance in both EX and EX + NMES. No changes between groups were seen for quality of life and lung function. As for muscle strength, EX and EX + NMES presented large effect sizes and differences, compared to CON, for quadriceps ($p = 0.004$, $\eta 2p = 0.401$), pectoral ($p = 0.001$, $\eta 2p = 0.487$), dorsal ($p = 0.009$, $\eta 2p = 0.333$) and handgrip ($p = 0.028$, $\eta 2p = 0.278$). This study concluded resistance exercise-training program led to improvements in muscle strength and functional capacity in CF patients with mild-to-moderate pulmonary impairment. The addition of NMES to the training program resulted in no extra favorable effects.

Wu et al. (2020) conducted a systematic review and meta-analysis to determine the effects of NMES on exercise capacity, functional performance, symptoms and health-related quality of life (HRQoL) in patients with chronic obstructive pulmonary disease (COPD). Studies explored the effect of NMES versus usual care and compared NMES plus conventional exercise versus exercise training alone with or without

sham training for NMES. Study participants totaled 447 adults with confirmed diagnosis of severe or very severe stable COPD. The study outcome showed no statistical increase in HRQoL among participants allocated with NMES and that NMES had no benefit for the peak rate of oxygen uptake and peak power. There was insufficient evidence to support the positive effects exerted by NMES in COPD patients.

Post-Surgical Muscle Weakness

Takino et al (2023) in a multicenter, parallel, two-arm, sham-controlled RCT examined the effectiveness of neuromuscular electrical stimulation (NMES) on post-surgical muscle weakness in individuals aged ≥65 years of age who underwent cardiovascular surgery whom had diabetes mellitus (n=180). The participants were assigned to NMES (n=90) median duration 60 minutes for 5 sessions or sham group (n=90). The primary outcome was the percent change in isometric knee extension strength (%ΔIKES) from preoperative to postoperative day 7. Secondary outcomes were the percent change in usual walking speed (%ΔUWS), maximum walking speed (%ΔMWS), and grip strength (%ΔGS). %ΔIKES was significantly lower in the NMES than sham group (NMES: mean -2%, 95% confidence interval [CI] -6 to 1; sham: -13%, 95% CI -17 to -9, $p < 0.001$). For the secondary outcomes in particular the percent change in MWS from preoperative time point to POD7 MWS was significantly lower in the NMES (-2.4 [5.9 to1.1]) than sham group (-13.0 [16.7 to -9.3]) treatment difference (10.5 [5.4 to 15.7]) p = 0.04 and percent change in UWS was lower in the NMES (-12.9 [-5.9 to1.1]) than sham group (-13.0 [-16.7 to-9.3]) treatment difference (10.5 [5.4 to 15.7]) p = 0.18. Limitation included trial physiotherapists could not be blinded due to visibility of NMES induced muscle contractions. While this study may have shown some promise in a short course of NMES < 1 week of mitigated postsurgical muscle weakness and functional decline, further studies are needed to determine treatment protocols of NMES to include amplitudes for muscle contractions to improve muscle weakness and functional decline.

Section Summary: Neuromuscular Electrical Stimulation

The evidence on neuromuscular electrical stimulation (NMES) consists of systematic reviews, RCTs and observational studies. Some studies may have shown NMES to be effective, however, further RCTs with larger patient populations and longer follow up are needed to determine stimulation protocols, parameters and therapy settings that are most beneficial for certain patient groups and degrees of impairment.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

American Heart Association and American Stroke Association

In 2016, the American Heart Association (AHA) and American Stroke Association (ASA) (*Endorsed by the American Academy of Physical Medicine and Rehabilitation and the American Society of*

Neurorehabilitation) issued a guideline for adult stroke rehabilitation and recovery that included the following recommendation regarding neuromuscular electrical stimulation (NMES):

- **Recommendations: Assessment, Prevention, and Treatment of Hemiplegic Shoulder Pain**
  - NMES may be considered (surface or intramuscular) for shoulder pain. (Class IIa: The weight of the evidence or opinion is in favor of the procedure or treatment; Level of Evidence A: Data derived from multiple randomized, clinical trials or meta-analyses).
- **Recommendations: Dysphagia Screening, Management and Nutritional Support**
  - Drug therapy, NMES, pharyngeal electrical stimulation, physical stimulation, tDCS and transcranial magnetic stimulation are of uncertain benefit and not currently recommended. (Class III: Conditions for which there is evidence and/or general agreement that the procedure or treatment is not useful/effective and in some cases may be harmful; Evidence A: Data derived from multiple randomized, clinical trials or meta-analyses).
- **Recommendations: Spasticity**
  - Physical modalities such as NMES or vibration applied to spastic muscles may be reasonable to improve spasticity temporarily as an adjunct to rehabilitation therapy. (Class IIb: Usefulness/efficacy is less well established by evidence or opinion; Evidence A: Data derived from multiple randomized, clinical trials or meta-analyses).
- **Recommendations: Mobility**
  - NMES is reasonable to consider as an alternative to an AFO for foot drop. (Class IIa: The weight of the evidence or opinion is in favor of the procedure or treatment; Level of Evidence A: Data derived from multiple randomized, clinical trials or meta-analyses).
- **Recommendations: Upper Extremity Activity, Including ADLs, IADLs, Touch and Proprioception**:
  - NMES is reasonable to consider for individuals with minimal volitional movement within the first few months after stroke for individuals with shoulder subluxation. (Class: IIa The weight of the evidence or opinion is in favor of the procedure or treatment; Level of Evidence A: Data derived from multiple randomized, clinical trials or meta-analyses).

National Institute of Health and Care Excellence

In 2023, National Institute of Health and Care Excellence (NICE) this guideline on stroke rehabilitation in adults recommended further research be conducted on the use of neuromuscular electrical stimulation (NMES) for treatment of dysphagia before it can be recommended due to the size of the trials and the low quality of evidence.

In 2022, NICE published a guideline for the management of knee osteoarthritis (OA) in which they concluded that NMES should not be offered to individuals with OA because there is insufficient evidence of benefit. The guideline stated that, “although there were many studies on electrotherapy, the findings were inconsistent and mostly showed little benefit.” The committee found that most studies were small with less than 100 participants and that the evidence from direct comparisons of electrotherapy with other interventions was uncertain.

In 2018, NICE guidance on transcutaneous NMES for oropharyngeal dysphagia in adults found current evidence on efficacy for adults with dysphagia after a stroke to be limited in quality and quantity although it may have potential benefit. They also noted that, for adults with dysphagia not caused by a stroke, there is insufficient evidence on efficacy to support the use of this procedure. NICE states that “this technology should only be used with special arrangements for clinical governance, consent and audit or research;

and encourages further research into transcutaneous NMES for this condition, which clearly documents indications for treatment and details of patient selection."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	None	
HCPCS		
	A4560	Neuromuscular electrical stimulator (nmes), disposable, replacement only
	E0744	Neuromuscular stimulator for scoliosis
	E0745	Neuromuscular stimulator, electronic shock unit
	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 (ParaStep®)
	E1399	Miscellaneous durable medical equipment
Type of Service	Durable Medical Equipment	
Place of Service	Outpatient, Home-based	

POLICY HISTORY

Date	Action	Action
May 2025	Annual Review	Policy Renewed
May 2024	Annual Review	Policy Renewed
October 2023	Annual Review	Policy Revised – content moved from retired policy “Electrical Stimulation for Treatment of Muscle Rehabilitation, Pain and Miscellaneous Conditions”
August 2022	Annual Review	Policy Revised
December 2021	Interim Review	Policy Revised
August 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
July 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
September 2015	Annual Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	Policy Revised and New Policy Created
January 2013	Annual Review	Policy Renewed
January 2012	Annual Review	Policy Renewed
February 2011	Interim Review	Policy Revised
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst

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