

**Subject:** Neuromuscular Stimulation in the Treatment of Muscle Atrophy**Guideline #:** CG-DME-03**Status:** Reviewed**Publish Date:** 06/28/2023**Last Review Date:** 05/11/2023

## Description

This document addresses the use of neuromuscular stimulation (also known as neuromuscular electrical stimulation or NMES), which is the application of electrical stimulation for the treatment of muscular atrophy when the nerve supply to the muscle is intact. This document does not address functional electrical stimulation (FES) or transcutaneous or percutaneous electrical nerve stimulation (TENS, PENS). NMES differs from TENS, PENS and FES, in that NMES stimulation is directed to the motor nerves, while TENS/PENS is directed to the sensory nerves and FES is for use in neurologically impaired individuals.

**Note:** Please see the following related document(s) for additional information:

- [DME.00022 Functional Electrical Stimulation \(FES\): Threshold Electrical Stimulation \(TES\)](#)
- [CG-DME-04 Electrical Nerve Stimulation, Transcutaneous, Percutaneous](#)

## Clinical Indications

### Medically Necessary:

Neuromuscular stimulator devices are considered **medically necessary** when prescribed for **any** of the following indications when muscular atrophy is present in the setting of an intact nerve supply to the muscle, including brain, spinal cord and peripheral nerves:

- As a component of post-operative rehabilitation in either of the following settings:
  - When muscular atrophy is present before an orthopedic intervention (for example, repair of anterior cruciate ligament). In this setting, neuromuscular stimulation may be initiated immediately in the post-operative phase as an adjunct to physical therapy; **or**
  - When muscular atrophy develops in the post-operative period. Individuals meeting this criterion typically are participating in a physical therapy program, but have experienced complications related to the surgery, which preclude successful physical therapy. In this setting, neuromuscular stimulation may be initiated only after the development of muscle atrophy; **or**
- As a treatment of muscular atrophy related to other medical conditions, such as disuse atrophy; **or**
- A neuromuscular stimulator garment is considered **medically necessary** when **any** of the following criteria are met:
  - There is a large area or many sites to be stimulated and use of conventional electrodes, adhesive tapes and lead wires is not feasible; **or**
  - The areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires; **or**
  - There is a documented medical condition, such as skin problems, that preclude the application of conventional electrodes, adhesive tapes and lead wires.

### Not Medically Necessary:

Neuromuscular stimulation is considered **not medically necessary** when the above criteria are not met and for all other indications, including but not limited to:

- Prevention of muscle atrophy (for example, following an orthopedic procedure);
- Treatment of pain for various musculoskeletal conditions, including, but not limited to patellofemoral syndrome, spinal stenosis, lumbago, muscle strains/sprains;
- As a technique to increase circulation;
- Devices with additional features, which are non-standard and are primarily for the comfort or convenience of the individual (for example, e-vive™).

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

### When services may be Medically Necessary when criteria are met:

#### HCPCS

- |       |  |
|-------|--|
| E0731 | Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric) [when specified as NMES garment] |
| E0745 | Neuromuscular stimulator, electronic shock unit  |

#### ICD-10 Diagnosis

All diagnoses

### When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

## Discussion/General Information

When subjected to insufficient use or exercise, muscles atrophy, resulting in a loss of strength and mass. Muscle atrophy may also occur when the limbs are immobilized after injury or surgery. NMES 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. The intensity and frequency of stimulation can vary based on the level of muscular function and treatment response. NMES can also be delivered through the use of a form-fitting conductive garment (for example, a garment with conductive fibers that are separated from the individual's skin by layers of fabric). This garment is applied when a condition exists that precludes conventional NMES electrode placement.

#### *NMES as a Component of Post-Operative Rehabilitation*

Monaghan and colleagues (2010) conducted a review of the available literature to assess the effectiveness of NMES as a means of improving quadriceps strength before and after total knee replacement. Two studies comparing NMES and exercise, and exercise alone pre- and post-operative, were identified and included in the review. These two studies reported no significant differences between the NMES and control groups for maximum voluntary isometric torque or endurance. In one study, there was significantly better quadriceps activation in the exercise and neuromuscular stimulation group compared with the exercise group alone. This difference was statistically significant at 6 weeks of follow-up, but not at 12 weeks. Raw data scores were not reported by study authors and hence, further analysis of both studies was not possible. Both studies were characterized by several weaknesses, which conferred a high degree of bias. The authors concluded that the available studies for this review preclude any conclusions for the clinical utility of NMES for quadriceps strengthening pre- and post-operative total knee replacement.

Stevens-Lapsley and colleagues (2012) published results from a small clinical trial studying initiation of quadriceps NMES, as an adjunct to standard rehabilitation, with outcomes assessed 48 hours after total knee replacement. A total of 66 subjects were randomly assigned to the control group (standard rehabilitation) or the treatment group (standard rehabilitation plus quadriceps NMES). Muscle strength, functional performance, and self-report measures were collected pre- and post-surgery and at 3.5, 6.5, 13, 26 and 52 weeks after total knee replacement. Significant improvements in the NMES group were seen post-operative at 3.5 weeks for quadriceps and hamstring muscle strength, functional performance, knee extension, and active range of motion. At 52 weeks, the statistically significant differences between groups for most outcome measures were no longer observed, but improvements with NMES were still significant for quadriceps and hamstring muscle strength, functional performance, and some self-report measures. The authors concluded that early administration of NMES effectively reduced the loss of quadriceps strength and improved functional performance following total knee replacement. The effects were most pronounced and clinically meaningful within the first month after surgery, but persisted through 1 year after surgery. The authors acknowledged a few study limitations; treatment volume was not matched for both study arms and NMES was added to the standard of care treatment, which does not allow the evaluation of the efficacy of NMES alone. Also, testers were not blinded during testing. The authors also stated that further research evaluating early intervention after total knee replacement is warranted.

In 2017, Gatewood and colleagues conducted a systematic review of the most effective therapeutic modalities after arthroscopic knee surgery. In total, 25 studies were chosen for inclusion and included studies on the efficacy of cryotherapy, continuous passive motion, NMES, surface electromyographic biofeedback and shockwave therapy. Outcomes of interest included muscle strength, range of motion, swelling, blood loss, pain relief, narcotic use, knee function, patient satisfaction and length of hospital stay. Authors concluded that NMES improved quadriceps strength and overall knee function outcomes after surgery and should be included in rehabilitation protocols to assist with improvement in pain relief, muscle strength and knee function.

In 2020, Toth and colleagues conducted a blinded, randomized, controlled trial to examine whether early use of NMES (started soon after injury and maintained through 3 weeks post-surgery) promoted preservation of the quadricep muscle's size and contractility at the cellular level (muscle fibers) in the injured legs of individuals with anterior cruciate ligament (ACL) reconstruction (n=21). At the end of 3 weeks, NMES reduced muscle fiber atrophy ( $p<0.01$ ) through effects on fast-twitch (MHC II) fibers ( $p<0.01$  to  $p<0.001$ ). NMES preserved contractility in slow-twitch (MHC I) fibers ( $p<0.01$  to  $p<0.001$ ), increasing maximal contractile velocity ( $p<0.01$ ) and preserving power output ( $p<0.01$ ); this effect was not demonstrated in MHC II fibers. At 6 months post-surgery, there were no discernable differences in whole muscle strength. This trial provides the first data at the cellular level demonstrating the potential mechanism of action for NMES after ACL reconstruction. While the surrogate outcome of muscle fiber contractility at 3 weeks was significant, clinically significant outcomes (e.g., physical activity level or whole muscle strength) were similar during all time-points, (3 weeks and 6 months post-surgery). Further investigation is needed to correlate these cellular changes to long-term functional outcomes such as strength and return to pre-injury activity levels.

Hyer and colleagues (2021) conducted an RCT comprised of 40 study participants who had undergone repair of the Achilles tendon. An NMES device was applied at time of surgery with both participant and surgeon blinded to the device. Group 1 consisted of 20 individuals who received NMES and Group 2 was the "sham device" control group, which received a subtherapeutic dose of electrical stimulation. Calf circumference was measured, pre- and post-procedure at 2, 6, and 12 weeks. Magnetic resonance imaging (MRI) scans were conducted at 2 and 6 weeks. Self-reported functional outcome scores were also measured. Calf measurements for Group 1 were slightly higher compared to Group 2 at 6 and 12 weeks post-procedure. Functional scores were similar between Groups 1 and 2 at final follow-up. No statistically significant differences were found between the two groups.

#### *Other Uses of NMES*

Lin and colleagues (2011) investigated the long-term efficacy of NMES to enable motor recovery in the upper extremities of post-stroke individuals. A total of 46 subjects were randomized into an NMES treatment group or a control group. All subjects participated in a standard rehabilitation program. Those in the NMES group received NMES for 30 minutes, 5 days a week, for 3 weeks. Measurements were recorded before treatment, at the second and third week of treatment, and 1, 3 and 6 months after treatment ended. The Modified Ashworth Scale (MAS) for spasticity, the upper extremity section of the Fugl-Meyer motor assessment, and the Modified Barthel Index (MBI) were used to assess the results. Significant improvements were found in both groups and persisted 1 month after treatment had been discontinued. At 3 and 6 months after treatment was discontinued, the average scores in the NMES group were significantly better than those in the control group. The authors acknowledged several limitations of the study, including its small size and lack of a blinded sham group. They concluded that additional studies, using similar stimulation protocols with a larger sample, are needed to assess the value of NMES to restore functionality after stroke.

Malhotra and colleagues (2013) conducted a single-blind, randomized controlled trial (RCT) to assess the treatment effects of surface NMES on wrist pain, spasticity, and contractures in individuals with no functional use of their arms following stroke. A total of 90 subjects were randomized to either the treatment group (30 minutes of surface NMES to the wrist and finger extensors and 45 minutes of physiotherapy) or the control group (45 minutes of physiotherapy alone). Treatment duration was 6 weeks. Although the treatment appeared to prevent pain and deterioration of contractures, there were no statistically significant improvements in stiffness and spasticity. Statistical analyses of the differences between the treatment and control groups suggest that the prevention of pain and contractures may not have been clinically meaningful. Other limitations include lack of patient-relevant outcome measures to assess the degree of change in functional use of participant's arms and lack of follow-up.

In 2016, the American Heart Association (AHA) in conjunction with the American Stroke Association (ASA) published guideline

recommendations for adult stroke rehabilitation and recovery. In the guidelines, all recommendations for NMES are based on a Level of Evidence Grade-A, meaning the data is derived from “multiple randomized, clinical trials or meta-analyses.” A Class IIb recommendation was given for the treatment of hemiplegic shoulder, thus the usefulness or efficacy is considered less well established by evidence or opinion. A Class IIa recommendation (the weight of evidence or opinion is in favor of the procedure or treatment) was given for NMES as therapy to treat dysarthria or apraxia of speech, as an alternative to an ankle-foot orthosis for foot drop and treatment for restoring activity of upper extremities. A Class III recommendation was given for dysphagia, therefore NMES is not recommended by the AHA/ASA at this time as an efficacious treatment in individuals as a component of stroke rehabilitation and recovery for dysphagia secondary to stroke.

Maddocks and colleagues (2013) reported on 11 studies involving a total of 218 participants with chronic obstructive pulmonary disease (COPD), chronic heart failure, and thoracic cancer. The primary outcome measure was evaluating the effectiveness of NMES for improving muscle strength, and secondary measures included the safety of NMES, muscle mass, exercise capacity, breathlessness, and health-related quality of life (HR-QOL). The authors concluded that NMES appears to improve leg muscle strength and the ability to exercise; however, these results need to be confirmed in larger clinical trials. A meta-analysis conducted by Pan and colleagues (2014) analyzed results of eight randomized clinical trials including 156 individuals with COPD who underwent NMES to improve quadriceps strength. Study investigators found that NMES was not associated with an improvement in muscle strength, walking distance, or muscle fiber characteristics. Authors concluded that evidence to support the use of NMES as an intervention to improve muscle strength in individuals is inadequate.

In 2014, McAlindon and colleagues published guidelines by the Osteoarthritis Research Society International (OARSI) on the non-surgical management of knee osteoarthritis. The guideline recommendations were based on meta-analyses, systematic reviews and RCTs published through 2013. Interventions were ranked according to the RAND/UCLA Appropriateness Method. Recommendations were provided from evidence-based consensus, which categorized 29 interventions into one of four categories; (1) appropriate, (2) appropriate for specific subpopulations; (3) uncertain appropriateness, or (4) not appropriate. NMES was considered by expert consensus to be an inappropriate treatment modality for osteoarthritis of the knee.

In 2017, Patsaki and colleagues enrolled 128 individuals following discharge from the intensive care unit (ICU). Individuals enrolled were randomly assigned to daily NMES sessions and individualized rehabilitation or to a control group. At hospital discharge muscle strength was assessed by the Medical Research Council (MRC) score along with hand grip. Secondary outcomes included functional ability and hospital length of stay. MRC, handgrip, functional status and hospital length of stay did not differ at hospital discharge between groups ( $p>0.05$ ). Change in MRC 1 and 2 weeks after ICU discharge trended higher in the NMES group but was not significant, while it was marginally significantly higher in the NMES group with ICU-acquired weakness at 2 weeks ( $p=0.05$ ). Authors conclude that NMES and personalized physiotherapy in ICU survivors did not result in improvement of muscle strength and functional status at hospital discharge, potentially with the exception of those with ICU-acquired weakness. Further investigation may be warranted.

A small, randomized clinical trial investigated the effect of 7 to 14 days of NMES therapy on individuals with severe traumatic brain injury (TBI) in the ICU. Outcomes included the impact of NMES on muscle architecture, neuromuscular electrophysiological disorders (NED), peak force and length of stay. A total of 60 individuals were included in the intent to treat analysis, but only 40 completed the study ( $n=20$  in the control group;  $n=20$  in the NMES group). After 14 days, the control group presented a significant reduction in muscle thickness of tibialis anterior and rectus femoris, while muscle thickness was preserved in the NMES group. The control group experienced a higher incidence of NED (47% in the control group vs. 0% in the NMES group;  $p<0.0001$ ), and the NMES group demonstrated an increase in the evoked peak force in contrast to the control group. The time needed for the NMES protocol to prevent muscle architecture disorders and treat weakness was at least 7 days, and 14 days to treat NED. Differences in length of stay were not significant. Authors conclude that NMES applied daily for 14 consecutive days may reduce muscle atrophy, the incidence of NED, and muscle weakness in individuals with severe TBI. The small sample size, lack of blinding, high dropout rate and lack of clinically meaningful outcomes were some of the weaknesses of this trial design (Silva, 2019).

In 2022, Zhao and colleagues conducted a randomized feasibility study of a novel NMES device (i.e., geko™) to assess its efficacy and safety up to 5 days following total hip replacement surgery. A total of 60 individuals undergoing total hip replacement for osteoarthritis of the hip were randomized to 2 groups: 1 group received postoperative treatment with the NMES device ( $n=30$ ), and the control group ( $n=30$ ) did not receive NMES or a sham treatment. Primary outcome measures were postoperative pain, lower limb swelling, and length of stay (LOS) post procedure. While the NMES group demonstrated a trend of beneficial postoperative pain control, calf swelling, and reduced average LOS, differences did not reach significance at day 5 post procedure. Study authors conclude, “larger study is required with this device in the future to determine its effectiveness...”

Although there has been an advent of NMES devices with non-standard features, including mobile device capabilities (e-vive™), they are primarily for convenience and comfort, evidence regarding any clinical benefit beyond standard NMES is lacking (Delanois, 2019).

Ongoing clinical trials for NMES identified in the ClinicalTrials.gov database are currently in progress for other indications including muscle strengthening for cerebral palsy, muscular sclerosis, rheumatoid arthritis, and post-operative total hip replacement.

## References

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#### Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: Neuromuscular electrical stimulation (NMES). NCD #160.12. Effective October 1, 2006. Available at: <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Accessed on April 05, 2023.
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## Index

Disuse Atrophy  
 geko™  
 Muscle Atrophy  
 Neuromuscular Stimulation  
 OnPulse™

## History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information and References sections.
Reviewed	05/12/2022	MPTAC review. Updated Discussion/General Information and References sections.
Revised	05/13/2021	MPTAC review. Clarified MN statement by removing 'FDA approved' language. Updated Discussion/General Information and References sections. Reformatted Coding section.
Revised	05/14/2020	MPTAC review. Added devices primarily for convenience or comfort to the NMN statement. Updated Discussion/General Information and References sections.
Revised	06/06/2019	MPTAC review. Clarification to Clinical Indications. Updated Description, Discussion/General Information and References section.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Discussion/General Information and References section.
Reviewed	08/03/2017	MPTAC review. Updated Discussion/General Information and References section.
Reviewed	08/04/2016	MPTAC review. Updated References section. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. Clarified criteria, updated Description, Discussion/General Information and Reference sections.
Reviewed	08/14/2014	MPTAC review. Updated Description, Discussion/General Information, and Reference sections.
Reviewed	08/08/2013	MPTAC review. Updated Discussion/General Information and References.
Reviewed	08/09/2012	MPTAC review. Discussion/General Information and References updated.
Reviewed	08/18/2011	MPTAC review. Coding, Discussion/General Information and References updated.

Reviewed	08/19/2010	MPTAC review. Place of Service deleted. Background and References updated.
Reviewed	08/27/2009	MPTAC review. References updated.
Reviewed	08/28/2008	MPTAC review. References updated.
Reviewed	08/23/2007	MPTAC review. References updated.
Revised	09/14/2006	MPTAC review. Revision addressed use of neuromuscular stimulation garment. References updated.
Reviewed	06/08/2006 11/22/2005	MPTAC review. References and coding updated. Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Document Number</b>	<b>Title</b>
Anthem, Inc.	N/A		
Anthem BCBS	N/A		
WellPoint Health Networks, Inc.	06/24/2004	None	Neuromuscular Stimulation in the Treatment of Muscle Atrophy

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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