

<b>Neuromuscular, Functional, and Threshold Electrical Stimulation</b>	
<b>Type:</b> Medical Necessity and Investigational / Experimental	<b>Policy Specific Section:</b> Durable Medical Equipment
<b>Original Policy Date:</b> April 3, 2009	<b>Effective Date:</b> January 30, 2015

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Description**

Neuromuscular electrical stimulation (NMES) involves stimulation of the neuromuscular fibers over selected muscle groups with electrical current strong enough to cause muscle contractions. The NMES device consists of a battery-operated electrical stimulator that can be programmed at various frequencies, intensities, and pulse widths, and electrodes for each muscle to be

stimulated. There are three types of NMES: transcutaneous (surface), percutaneous, and subcutaneous (fully implanted) systems. Percutaneous and subcutaneous systems require surgical implantation with the patient under general anesthesia. The key difference between NMES and transcutaneous or percutaneous electrical nerve stimulation (TENS/PENS) is that NMES directs stimulation to the motor nerves, and TENS/PENS directs stimulation to the sensory nerves.

Neuromuscular electrical stimulation may be performed at low, medium, or high intensity to elicit mild, moderate, or strong muscle contractions. At medium or high intensities, NMES is used to strengthen muscles weakened by disuse, also called disuse muscle atrophy, where the nerve supply to the muscle is intact and used as part of a comprehensive rehabilitation program (e.g., after major knee surgery when physical activity is restricted). When NMES is used at low intensities that barely stimulate perceptible contractions, it is referred to as threshold NMES or threshold electrical stimulation (TES). Threshold electrical stimulation is used in a passive manner, targeting spastic muscles during sleep. This stimulation is not intended to cause muscle contraction, but thought to increase muscle strength and joint mobility, leading to improved voluntary motor function. Threshold electrical stimulation has been used in children with spastic cerebral palsy and other motor disorders, such as spina bifida.

Functional NMES, also known as functional electrical stimulation (FES), is a method of electrical stimulation used to activate muscles of the upper and lower limbs to produce functional improvement patterns in patients with damaged or destroyed nerve pathways (such as standing and walking in patients with paraplegia) or as stationary exercise for prevention or reduction of muscle atrophy by providing range of motion in patients with hemiplegia due to stroke, cerebral injury, or incomplete spinal cord injury.

The majority of FES and TES treatment approaches are still experimental in nature as there are no preferred methods or standards, and a paucity of evidence from clinical studies.

This medical policy also addresses the following implantable neurostimulator devices and their applications:

- Electrophrenic pacemaker (also known as diaphragmatic/phrenic nerve stimulation)
- Sacral anterior root stimulation stimulation as a treatment of neurogenic bladder

Note: Please refer to the following related Blue Shield Medical Policies for additional information:

- Electrical Stimulation for Pain and Other Conditions
- Sacral Nerve Neuromodulation/Stimulation
- Urinary Incontinence Outpatient Treatments

## Policy

### Neuromuscular Electrical Stimulation for Disuse Muscle Atrophy

Neuromuscular electrical stimulation (NMES) devices may be considered **medically necessary** when **both** of the following criteria are met:

- For the treatment of disuse muscle atrophy due to non-neurological reasons, such as **any** of the following:
  - Contractures due to scarring of soft tissue as in burn lesions
  - After major knee surgery (e.g., knee ligament surgery or total knee arthroplasty) when there is failure to respond to physical therapy
  - Casting or splinting of a limb
  - Following recent hip replacement surgery until physical therapy begins
- Nerve supply to the muscle is intact, including brain, spinal cord, and peripheral nerves

### **Therapeutic Neuromuscular Electrical Stimulation for Other Indications**

Neuromuscular electrical stimulation (NMES) devices are considered **not medically necessary** for **any** of the following therapeutic indications:

- Improvement of muscle strength or function in healthy individuals
- Treatment of pain for any musculoskeletal conditions
- Prevention of muscle atrophy (e.g., prior to or following an orthopedic procedure) (e.g., Kneehab XP<sup>®</sup> device)
- As a method for increasing circulation (e.g., AvivaStim XP<sup>™</sup> device)

### **Form-Fitting Conductive Garments**

Form-fitting conductive garments are considered **medically necessary** when used in conjunction with a **medically necessary** NMES device when **any** of the following criteria are met:

- Area or sites to be stimulated are inaccessible with conventional electrodes, adhesive tapes and lead wires for the patient (i.e., beneath a cast, the back)
- There is a large area or many sites to be stimulated
- A coexisting medical problem (e.g., skin problem) prevents the application of conventional electrodes, adhesive tapes, and lead wires

Form-fitting conductive garments are considered **not medically necessary** for **all** other indications not meeting the above criteria.

### **Functional NMES or Functional Electrical Stimulation**

Functional NMES, also known as functional electrical stimulation (FES), using any device, is considered **investigational** as a technique to restore function following nerve damage or injury including, but not limited to, the following:

- As a technique to provide ambulation in patients with spinal cord injury
- To restore upper extremity or lower extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke)
- To improve ambulation in patients with foot drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., post-stroke, or in those with multiple sclerosis)
- As a treatment of pain

Functional neuromuscular exercisers or FES exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise are considered exercise equipment and **not a covered benefit**.

### **Threshold Electrical Stimulation**

Threshold electrical stimulation as a treatment of motor disorders, including, but not limited to cerebral palsy or scoliosis, is considered **not medically necessary**.

### **Diaphragmatic/Phrenic Nerve Stimulation (Electrophrenic Pacemaker)**

The use of an electrophrenic pacemaker (for diaphragmatic/phrenic pacing) may be considered **medically necessary** when **all** of the following criteria are met:

- For the treatment of patients with permanent, severe ventilatory hypoventilation caused by **either** of the following:
  - Central alveolar hypoventilation syndrome either primary or secondary to a brainstem disorder
  - High quadriplegia at the upper cervical level (at or above C3)
- Patient has viable phrenic nerves

The use of an electrophrenic pacemaker is considered **not medically necessary** in patients with **any** of the following conditions:

- Patient can subsist independently of a mechanical respirator (4 continuous hours or more)
- Respiratory failure or insufficiency is anticipated to be temporary

The use of an electrophrenic pacemaker is considered **investigational** for all other indications including, but not limited to:

- Treatment of chronic obstructive pulmonary disease or restrictive lung disease
- Young children and infants
- Treatment of hiccups

**Note:** See Policy Guidelines for Contraindications to an electrophrenic pacemaker.

### **Sacral Anterior Root Stimulation for Neurogenic Bladder**

Sacral anterior root stimulation using an implantable device (e.g., VOCARE<sup>®</sup> Bladder System) to provide urination on demand and reduce post-void residual volume may be considered **medically necessary** in patients with spinal cord injury when **all** of the following criteria are met:

- Patients with a complete suprasacral spinal cord lesion
- Condition is associated with a neurogenic bladder
- When used in conjunction with posterior rhizotomy

**Note:** Electrical stimulation of sacral nerves (not nerve roots) as a treatment of urinary incontinence or retention in patients without spinal cord injury is addressed in the Blue Shield Medical Policy: Sacral Nerve Neuromodulation/Stimulation.

## Policy Guideline

Electrical stimulation used for dysphagia (VitalStim) may be billed as E0720 or E0730.

See Table for a list of CPT or HCPCS codes that describe NMES, FES or TES devices.

Note: Requesting the brand name and manufacturer of the device being requested and its intended use will aid in determining need and uses of the device.

*Any specific products referenced in this Medical Policy or the Table below are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. Some of these examples are contained in the parenthetical (e.g.) statements in the Policy Statement.*

**Table**

Type of Stimulation/ Stimulation Device	Product/Manufacturer Examples	Codes
<b>Therapeutic Neuromuscular Electrical Stimulation (NMES)</b>	<ul style="list-style-type: none"> <li>• <b>Examples of NMES devices that are considered medically necessary when used for <u>disuse muscle atrophy</u> and criteria are met:</b> <ul style="list-style-type: none"> <li>○ Besmed 550 (Multinational, Irvine, CA)</li> <li>○ Besmed 660 (Multinational, Irvine, CA)</li> <li>○ EMS 7500 (Koalaty Products, Ind., Roswell, GA)</li> <li>○ EMPI 300-PV (Empi, St. Paul, Minnesota)</li> <li>○ EMS +2 (Rehabicare, Inc., New Brighton, MN)</li> <li>○ RS-2m (RS Medical, Vancouver, WA)</li> <li>○ EMS 2000 (Koalaty Products, Ind., Roswell, GA)</li> <li>○ RS-4M (RS Medical, Vancouver, WA)</li> <li>○ Flex-MT (EMSI, Tampa Florida)</li> </ul> </li> <li>• <b>Examples of NMES devices that are considered not medically necessary when used for when <u>other therapeutic indications</u> (i.e., other than <u>disuse muscle atrophy</u>)</b> <ul style="list-style-type: none"> <li>○ Kneehab XP<sup>®</sup> device (Neurotech<sup>®</sup> USA, Minnetonka, MN)</li> <li>○ Neurotech<sup>®</sup> Recovery Back (Neurotech<sup>®</sup> USA, Minnetonka, MN)</li> <li>○ AvivaStim XP<sup>™</sup> device (Neurotech<sup>®</sup> USA, Minnetonka, MN)</li> </ul> </li> </ul>	E0745
<b>NMES Conductive Garments</b>	<ul style="list-style-type: none"> <li>• AG Garments conductive electrodes (Advanced Rehabilitation Technologies, San Diego, CA)</li> <li>• Medi-Stim, Inc., Conductive garments (Medi-Stim Inc., Wabasha, MN)</li> <li>• RS-LB<sup>™</sup> Low Back Conductive Garment (RS Medical, Camas, WA)</li> </ul>	E0731

	<ul style="list-style-type: none"> <li>• RS-FBG™ Full Back Conductive Garment (RS Medical, Camas, WA)</li> <li>• UltraStim® Kit/Electrodes (Axelgaard Manufacturing Co. Ltd., Fallbrook, CA)</li> </ul>	
<b>Functional NMES Devices</b>	<p><b>Ambulation Systems:</b></p> <ul style="list-style-type: none"> <li>• Parastep® I Ambulation System (Sigmedics, Inc., Fairborn, OH)</li> <li>• ReWalk™ (ARGO Medical Technologies, Yokneam Ilit, Israel)</li> </ul> <p><b>For Foot Drop:</b></p> <ul style="list-style-type: none"> <li>• WalkAide® System (Innovative Neurotronics, Bethesda, MD) (formerly NeuroMotion, Inc.)</li> <li>• NESS L300® Foot Drop System (Bioness, Inc, Valencia, CA)</li> <li>• Odstock® Dropped Foot Stimulator/ODFS® Pace and ODFS PACE XL (Odstock Medical Limited, Salisbury, UK; United States distributor [NDI Medical, Cleveland, OH])</li> </ul> <p><b>Upper Extremity Devices:</b></p> <ul style="list-style-type: none"> <li>• NESS H200 Hand Rehabilitation System (formerly HandMaster-NMS-1) (N.E.S.S. Ltd., Raannana, Israel; United States distributor [Bioness® Inc., Valencia, CA])</li> <li>• Handmaster NMS I (N.E.S.S. Neuromuscular Electrical Stimulation Systems Ltd., Ra'anana, Israel)</li> <li>• FREEHAND Implantable Functional Neurostimulator System (NeuroControl, Cleveland, OH)</li> </ul>	E0764 E0770
<b>Functional Neuromuscular Exercisers and FES Cycling Exercise Equipment</b>	<ul style="list-style-type: none"> <li>• FES cycling (MOTOmed®, RECK GmbH, Betzenweiler, Germany)</li> <li>• FES Power Trainer (SCIFIT Systems, Inc., Tulsa, OK)</li> <li>• ERGYS, REGYS (Therapeutic Alliances Inc., Fairborn, OH)</li> <li>• NeuroEDUCATOR (Therapeutic Alliances Inc., Fairborn, OH)</li> <li>• STimMaster Galaxy (Electrologic of America, Inc., Dayton, OH)</li> <li>• RT300 motorized FES cycle ergometer (Restorative Therapies, Inc., Baltimore, MD)</li> <li>• RT300 Leg, Leg and arm, RT300 Arm, RT300 for children (Restorative Therapies, Inc., Baltimore, MD)</li> <li>• RT600 FES stepper ergometer (Restorative Therapies, Inc., Baltimore, MD)</li> <li>• SpectraSTIM 4M (Therapeutic Alliances Inc., Fairborn, OH)</li> </ul>	E1399 (misc. DME)

<p><b>Threshold Stimulation</b></p>	<ul style="list-style-type: none"> <li>• NT200-TES (Bio-Medical Research LTD, Laurel, MD)</li> <li>• Scoliosis Treatment Recovery System (Authur L. Copes, Baton Rouge, LA)</li> <li>• Copes Scoliosis Dynamic Brace (Authur L. Copes, Baton Rouge, LA)</li> </ul>	<p>E0744 (Scoliosis)  E0745 (may be used)  E1399 (misc. DME)</p>
<p><b>Diaphragmatic/Phrenic Nerve Stimulation</b></p> <p><b>Electrophrenic Pacemaker</b></p> <p>Note: CPT/HCPCS codes represented in 3<sup>rd</sup> column reflect codes that may be used for certain devices and procedures pertaining to phrenic nerve stimulation, however, other electrode, receiver and transmitter codes may also be used.</p>	<ul style="list-style-type: none"> <li>• NeuRx DPS™ RA/4 Respiratory Stimulation System (Synapse Biomedical, Inc., Oberlin, OH) (FDA/<u>Humanitarian Device Exemption</u>-Amyotrophic Lateral Sclerosis (ALS) and Spinal Cord Injury)</li> <li>• Mark IV™ Breathing Pacemaker System (Avery Biomedical Devices Inc., Commack, NY)</li> </ul>	<p><b>CPT Codes:</b>  64575 (NeuRx DPS)  64580 (NeuRx DPS)  64585  (revision/removal)  64590 (Mark IV)  <b>HCPCS Codes:</b>  C1767 (Mark IV)  C1778 (NeuRx DPS)  C1816  C1820 (Mark IV)  C1883-incidental  C1897 (NeuRx DPS)  L8680 (NeuRx DPS)  L8682  L8683  L8685 (Mark IV)  L8686 (Mark IV)  L8687 (Mark IV)  L8688 (Mark IV)  L8696 (Mark IV)  (Replacement antenna [external])  A9999 (NeuRX DPS)  (Stimulator/cables/connecters)  E1399 (Replacement kit)  A4601 (battery)  <b>ICD9-PROC</b>  34.85</p>
<p><b>Sacral Anterior Root Stimulation (VOCARE® System)</b></p> <p><i>See contraindications to this procedure and further pre- and post-operative testing codes below under VOCARE Bladder System.</i></p>	<ul style="list-style-type: none"> <li>• VOCARE® Bladder System (also known as the FineTech-Brindley Bladder Control System) (FineTech Medical Ltd., England)</li> </ul>	<p><b>Rhizotomy Proc:</b>  63185  63190  63655  <b>Device HCPCS:</b>  L8680  L8682  L8684  <b>ICD9 Proc:</b>  03.1  03.93</p>

**Neuromuscular Electrical Stimulation Supplies**



The following supplies are used in conjunction with a NMES (E0745) and are included in the rental allowance:

- Electrodes, any type (A4556)
- Lead wires (A4557, A4595)
- Conductive paste or gel, if needed (A4558)
- Tape or other adhesive, if needed (A4364, A4450, A4452)
- Adhesive removal, skin preparation materials (A4455, A4456)
- Batteries, any (A4630)
- Battery charger, if rechargeable batteries are used

The following supplies are included in the first months allowance for a NMES purchase:

- Lead wires (A4557)
- Conductive paste or gel, if needed, (A4558)
- Batteries (A4630)
- One month's supply of electrodes, any type (A4556)

No separate or additional reimbursement is made for the following devices as they are considered items of convenience and are **not covered benefits**:

- Adapters (i.e., snap, Banana, alligator, tab, button, clip)
- Belt clips
- Carrying pouches
- Covers

### **VOCARE Bladder System**

The VOCARE Bladder System is contraindicated for patients with the following characteristics:

- Poor or inadequate bladder reflexes
- Active or recurrent pressure ulcers
- Active sepsis
- Implanted cardiac pacemaker

All of the following are separately reimbursable for pre-and post-operative testing for the implantation of a sacral anterior root stimulator combined with rhizotomy:

- 51600: Injection procedure for cystography or voiding urethrocytography
- 51726: Complex cystometrogram
- 51741: Complex uroflometry
- 51797: Voiding studies, intra-abdominal voiding pressure
- 74430: Cystography
- 74420: Urography, retrograde
- 72148-72149: MRI of the lumbar spinal canal, with or without contrast, respectively



## Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:  
[http://myworkpath.com/healthcareservices/MedicalOperations/PSR\\_Determination\\_Pages.htm](http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm)

### Documentation Required for Clinical Review

- History and physical including: previous treatment plan and response, type of stimulation requested, treatment plan
- Make and model of device being requested (if applicable)
- Multidisciplinary evaluation notes

#### Post Service

- Operative report(s) (if applicable)

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

# APPENDIX to Neuromuscular, Functional, and Threshold Electrical Stimulation Policy

## Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider **MUST** confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

## Evidence Basis for the Policy

### Rationale

#### Neuromuscular Electrical Stimulation

Neuromuscular electrical stimulation (NMES), also referred to as neuromuscular stimulation, involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. In comparison to transcutaneous electrical neurostimulation (TENS), NMES delivers a stronger current with a wider pulse width. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy, referred to as therapeutic NMES. The second type is used to activate muscles of the upper or lower limbs to produce functional movement patterns, such as standing and walking, in neurologically impaired patients (e.g., paraplegics) and is referred to as functional NMES or functional electrical stimulation (FES).

In order to avoid muscle strain, patients generally undergo high-intensity NMES for 30 to 60 minutes a day; more than 2 hours in a 24 hour period is not recommended. In most cases, high-intensity NMES therapy is performed for 20 to 40 sessions provided over 4 to 8 weeks. Low-intensity and threshold NMES (or threshold electrical stimulation [TES]) can be applied for much longer periods, such as all night while the patient is sleeping for typically 6 months to a year (Hayes Inc., 2008). Regardless of the intensity of NMES, patients are encouraged to voluntarily exercise the affected muscles in order to maintain and improve their strength and function. Typically, NMES is used as component of a comprehensive rehabilitation program. Neuromuscular electrical stimulation can be administered on an outpatient basis by a physical therapist, and in some cases, by the patient or family member at home (Hayes Inc., 2008).

Neuromuscular electrical stimulators are regulated by the U.S. Food and Drug Administration (FDA) as Class II devices and many of these have been FDA approved. Examples include, but not limited to, EMS 7500 (Koalaty Products, Ind., Roswell, GA), Empi 300PV™ (Empi, St. Paul, Minnesota) and EMS+2 (Rehabicare, Inc., New Brighton, MN), RS-2m 2-channel Muscle Stimulator (RS Medical, Vancouver, WA), EMS 2000 (Koalaty Products, Ind., Roswell, GA), BioStim NMS Digital (BioMedical Life Systems, Vista, CA), Besmed 550 and Besmed 660 (Multinational, Irvine, CA) and the RS-LB™ Low Back Conductive Garment/RS-FBG™ Full Back Conductive Garment (RS Medical, Camas, WA).

The 510(k) FDA approval of a NMES device, such as the EMS 7500 (Koalaty Products, Ind., Roswell, GA), states the device is approved for the following:

- Relaxing muscle spasms
- Increasing local blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Muscle re-education
- Maintaining and increasing range of motion
- Preventing or retarding disuse atrophy

### **Therapeutic Neuromuscular Electrical Stimulation for Disuse Atrophy**

Neuromuscular electrical stimulation is proposed to promote muscle restoration and to prevent or diminish muscle atrophy and spasms and is an established treatment modality for disuse atrophy when the nerve supply is intact. While the evidence is limited, NMES for the treatment of disuse muscle atrophy appears to be the standard of care.

In 1983, the Centers for Medicare and Medicaid Services (CMS) requested a technology assessment from the Office of Health Technology Assessment (OHTA) on the use of NMES in the treatment of muscle disuse atrophy in clinical cases where neural supply (including brain, spinal cord and peripheral nerves) to the muscle is intact or where other non-neurological reasons for disuse are causing atrophy. The technology assessment concluded “the use of NMES for the treatment disuse atrophy is considered effective therapy where the cause of the muscle disuse is not permanent and there is no nervous system involvement.” Upon these recommendations, CMS (1984) issued a positive national coverage determination (NCD) for NMES specific to the OHTA conclusions. Some examples of covered conditions referenced included casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins) (CMS, 2002).

The issue was re-examined by the CMS Technology Advisory Committee (TAC) in November 1990 and the Committee requested OHTA conduct a report examining the use of NMES in the treatment of disuse atrophy for patients with permanent nervous system involvement. In this brief report, OHTA (1991) concluded there was “insufficient objective evidence of clinical effectiveness of NMES to conclude that the technology has identifiable, demonstrated medical benefits in patients with non-intact innervation of the muscle.” Additionally, the report found “no published objective data supporting the benefit of NMES in improving circulation, preventing thromboembolic disease, reducing edema or preventing osteoporosis in patients with disuse atrophy and nervous system involvement.”

Lake (1992) reported that in sports medicine, NMES has been used for muscle strengthening, maintenance of muscle mass and strength during prolonged periods of immobilization, selective muscle retraining, and the control of edema. It appeared that when NMES and voluntary exercise are combined there is no significant difference in muscle strength after training when compared to either NMES or voluntary exercise alone. The use of NMES to prevent muscle atrophy associated with prolonged knee immobilization following ligament reconstruction surgery or injury has been extensively studied. NMES has been shown to be effective in preventing the decreases in muscle strength, muscle mass and the oxidative capacity of thigh muscles following

knee immobilization. In all but one of the studies, NMES was shown to be superior in preventing the atrophic changes of knee immobilization when compared to no exercise, isometric exercise of the quadriceps femoris muscle group, isometric co-contraction of both the hamstrings and quadriceps femoris muscle groups, and combined NMES-isometric exercise. It has also been reported that NMES applied to the thigh musculature during knee immobilization improves the performance on functional tasks.

Lieber et al. (1996) compared NMES to voluntary muscle contraction in a RCT of 40 men and women, ages 15 to 44, following reconstruction surgery of the anterior cruciate ligament (ACL). None of the subjects had a previous history of neuromuscular injury. Each subject was randomly assigned to either an electrical stimulation group or a voluntary contraction group. The subjects received treatment for 30 minutes a day for five weeks. The authors found no significant difference between the groups in terms of maximum voluntary knee extension torque throughout the study period. In addition, one year after surgery, there was still no significant difference between groups with regard to knee extension torque ( $p>0.4$ ). These data suggest that NMES and voluntary muscle contraction treatments, when performed at the same intensity, are equally effective in strengthening skeletal muscle that has been weakened by surgical repair of the ACL.

Bax and colleagues (2005) designed a systematic review of randomized controlled trials to determine whether NMES is an effective modality for strength augmentation of the quadriceps femoris. Thirty-five trials were included and evaluated. The limited evidence suggest that, both for the unimpaired and impaired quadriceps, MNES can improve strength in comparison with no exercise and that exercises appear to be more effective in most situations.

## **Therapeutic Neuromuscular Electrical Stimulation Following Orthopedic Procedures**

### *Quadriceps Strengthening*

A 2010 Cochrane review evaluated the evidence on use of NMES for quadriceps strengthening pre and post total knee arthroplasty/replacement (TKA) ((**Monaghan et al., 2010**). The literature search, performed through December 2008, identified only two RCTs with a total of 69 patients. Both studies had a high risk of bias. One study (after TKA) found significantly better quadriceps muscle activation with NMES compared to the control group at 6 weeks, but not 12 weeks post training. The other study (before TKA) reported no significant differences for endurance, function or quality of life after surgery. Pain outcomes, patient satisfaction or adverse effects were not reported in either study. The authors concluded that these studies did not permit any conclusions to be made about NMES for quadriceps strengthening before or after TKA.

In **2009**, **Petterson** et al. randomized 200 patients to progressive volitional strength training with or without conventional NMES. Both groups received outpatient physical therapy 2 or 3 times a week for 6 weeks with a minimum of 12 therapy visits. The novel volitional strength training program specifically targeted the quadriceps femoris muscle, with the intensity and type of strengthening based on the individual's assessments. The NMES component consisted of 10 electrically elicited contractions of the quadriceps femoris muscle at the patient's maximum tolerance. Nineteen patients (9.5%) did not complete treatment; 16 of the 19 (84%) were in the NMES group. At 3 and 12 months after surgery, patients were evaluated by investigators who were blinded to the treatment group. There were no significant differences between the NMES and progressive strength training control groups for any of the outcome measures, which

included the Short Form (SF)-36, Knee Outcome Survey, knee range of motion, Timed Up and Go, Stair-Climbing Test, and 6-Minute Walk.

An additional 41 patients who did not participate in the intervention were tested 12 months after surgery as the standard of care group. Although the standard of care group had more physical therapy, patients in this group were weaker and exhibited worse function at 12 months compared with both treatment groups. Progressive strength training had a moderate effect size for quadriceps strength ( $d=0.63$ ), Timed Up and Go ( $d=0.69$ ), and 6 Minute Walk ( $d=0.70$ ), and a large effect size for the Stair-Climbing Test ( $d=0.86$ ). Quadriceps strength was the single strongest predictor of Stair-Climbing Test performance.

In 2011, Stevens-Lapsley et al. reported a trial of 66 patients randomized (stratified for sex and decade of age) to standard rehabilitation or standard rehabilitation plus NMES. Another 365 patients who were scheduled for TKA at this institution did not meet eligibility criteria due to age not between 50 to 85 years (11%), BMI > 35 (13%), moderate to severe contralateral pain (31%), other orthopedic conditions that limited their function (7%), smokers (8%), uncontrolled diabetes or neuropathy (7%), or other health conditions (23%). The control group had a higher weight and body mass index than the NMES group, and showed significant differences at baseline for the SF-36 physical component score.

Standard outpatient rehabilitation consisted of six treatments at home over 2 weeks followed by 10 to 12 sessions over 6 weeks with a defined set of core exercises. Weights for the resistive exercises were increased to maintain a 10-repetition maximum intensity level. All participants were also given a home exercise program. The NMES was initiated 48 hours after surgery and applied twice per day (maximum tolerable intensity for 15 contractions) for 6 weeks. Evaluation for muscle strength, functional performance, and self-report measures were obtained before surgery and at 3.5, 6.5, 13, 26, and 52 weeks after TKA. Evaluations were not blinded, but standardized scripts and methods were used to minimize potential bias with testing.

At 3.5 weeks after TKA, the NMES group had less of a reduction from baseline than the control group for quadriceps and hamstring muscle strength, the Timed Up and Go Test, the Stair-Climbing Test, 6-Minute Walk Test, the global rating scale, and knee extension active range of motion. The objective 6-Minute Walk Test showed the largest difference, with the NMES group walking 390 meters compared to 295 meters for the control group. At 52 weeks the differences between groups were attenuated, but improvements with NMES were still statistically significant for quadriceps and hamstring muscle strength, functional performance, and some self-report measures. For example, the NMES group walked an average of 525 meters in 6 minutes compared to 478 meters for the control group. The effects of NMES were found to be most clinically meaningful within the first month after surgery. This study is limited by the strict selection criteria, small number of subjects included in the study, unequal measures at baseline, lack of an active (e.g., volitional isometric muscle contraction) control group, and lack of investigator blinding. Funding for this investigator-initiated study included grants from several public sources and a peer-reviewed grant from the manufacturer. It was noted that none of the sponsors had any influence on the study design, implementation, or data analysis and interpretation.

*Quadriceps Strengthening Following Anterior Cruciate Ligament (ACL) Reconstruction*



Kim et al. (2010) included eight RCTs in their 2010 systematic review of the effects of NMES after ACL reconstruction on quadriceps strength, function and patient-oriented outcomes. The number of subjects in each study ranged from 20 to 30 and the quality of the studies, assessed using the Physiotherapy Evidence Database (PEDro) scale, was a mean of 4.3 out of 10. Most of the studies evaluated quadriceps strength outcomes; only one study reported functional performance and one study assessed self-reported outcomes. Due to heterogeneity in the studies, meta-analysis was not performed. Effect sizes for quadriceps strength outcomes ranged from an equal effect to a moderate effect of NMES over exercise alone. Effect sizes for functional test outcomes were calculated from one small RCT (20 patients) and ranged from 0.07 to 0.64, indicating inconclusive effects for the outcomes tested. Self-reported outcomes from one RCT showed moderate effect sizes for a 4-week NMES treatment regimen.

In 2011, Feil et al. reported an industry-sponsored single blind RCT that evaluated the addition of a garment-integrated NMES device (Kneehab) or conventional NMES to standard postoperative rehabilitation. This device provides a larger surface area of stimulation than conventional NMES and has the potential for increased stimulation intensity, greater ease of use, and improved compliance. One-hundred and thirty-one patients between the ages of 18 and 55 years with isolated rupture of the ACL and no additional injury in the knee joint were enrolled. Thirty-five patients (26.7%) were excluded from analysis due to deviation from the course of rehabilitation or additional surgery on the knee. The two NMES groups underwent 20-minute sessions of NMES three times a day, 5 days a week, for 12 weeks with the stimulation superimposed on isometric volitional contractions. The control group performed volitional isometric muscle contractions without NMES. Outcome measures included isokinetic strength of the knee extensors along with functional tests (single-legged hop and shuttle-run).

Six, 12 and 24 week follow-up was available for 96 patients (73%). There were no significant differences between standard NMES and the isometric volitional contraction control group for any measures. The Kneehab group showed statistically significant improvements over both conventional NMES and standard controls for quadriceps strength, shuttle run, and single-legged hop, although it is not clear whether the differences were clinically significant. For example, there was a 2 second difference between the Kneehab and control group in the shuttle run and a 24 cm difference between groups for the single-legged hop. Improvements were seen at the 6 week test and persisted at 12 and 24 weeks. There was no significant difference between the groups with respect to the Tegner score and the International Knee Documentation Committee (IKDC) knee examination score. Improvement over the baseline corrected Lysholm score was better in the Kneehab group compared with the control group, but there was no significant difference in mean scores at follow-up. There was a trend for the Kneehab group to return to work (2.70 weeks) sooner than both the control group (3.67,  $p=0.79$ ) and the standard NMES group (3.88 weeks,  $p=0.061$ ). Compliance with the three daily sessions over 12 weeks (60 hours) was reported from patient diaries at 80% for controls, 65% for standard NMES, and 75% for the Kneehab group. This study is limited by the high drop-out rate and the unclear clinical significance of the results.

### *Summary*

Evidence from two of three recent RCTs indicates that conventional NMES (two pairs of electrodes) is no better than progressive strength training or isometric volitional contractions for

improving quadriceps function after orthopedic procedures. A third trial suggests that NMES may result in short-term improvements in objective measures of knee function when added to standard physical therapy, but this study is limited by strict selection criteria, the small number of subjects included in the study, unequal measures at baseline, and lack of investigator blinding. Thus, evidence for an improvement in quadriceps function with conventional NMES applied after orthopedic surgery is mixed and inconclusive.

One of the three recent RCTs compared the efficacy of a novel garment-integrated NMES device (Kneehab) to either conventional NMES or isometric volitional contractions. This study showed statistically significant improvements in quadriceps strength and performance on some functional tests over the two control groups, although the clinical significance of the results is unclear. Additional studies are needed to evaluate this device.

Overall, current evidence does not permit conclusions concerning the effect of this technology on health outcomes.

### **Functional Neuromuscular Electrical Stimulation**

Functional NMES or functional electrical stimulation (FES) is a method being developed to restore function to patients with damaged or destroyed nerve pathways through use of an orthotic device with microprocessor controlled electrical neuromuscular stimulation (neuroprosthesis).

Neural prosthetic devices consist of an orthotic and a microprocessor-based electronic stimulator with one or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce functionally useful movements that allow patients to sit, stand, walk, and grasp. Functional neuromuscular stimulators are closed-loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters which are required for complex activities such as walking. These are contrasted with open-loop systems, which are used for simple tasks such as muscle strengthening alone, and typically in healthy individuals with intact neural control.

One application of functional NMES is to restore upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadriplegia). The Neurocontrol Freehand System (NeuroControl, Cleveland, OH) is an implantable upper extremity neuroprosthesis intended to improve a patient's ability to grasp, hold, and release objects and is indicated for use in patients who are tetraplegic due to C5 or C6 spinal cord injury. The implantable Freehand System is no longer marketed in the United States, though the company provides maintenance for devices already implanted. The NESS H200 (NESS Ltd., Raanana, Israel), formerly HandMaster NMS I® [neuromuscular stimulator], is another device that uses surface electrodes and is purported to provide hand active range of motion and function for patients with stroke or C5 tetraplegia. Bioness® Inc., (Valencia, CA) partnered with NESS Ltd., to launch the H200® Wireless Hand Rehabilitation System in the United States.

Other neural prosthetic devices have been developed for functional NMES in patients with foot drop. Foot drop is weakness of the foot and ankle that causes reduced dorsiflexion and difficulty



with ambulation. It can have various causes such as cerebral palsy (CP), stroke or multiple sclerosis (MS). Functional electrical stimulation of the peroneal nerve has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation. Examples of such devices used for treatment of foot drop are the Innovative Neurotronics' WalkAide® (Austin, Texas), (formerly NeuroMotion, Inc., Edmonton, Alberta, Canada), the NESS L300™ radiofrequency-controlled foot drop system (Bioness Inc., Valencia, CA), and the Odstock Foot Drop Stimulator (Odstock Medical Ltd., Salisbury, UK).

Another application of FES is to provide spinal cord-injured patients with the ability to stand and walk. Generally, only spinal cord injury patients with lesions from T4-T12 are considered candidates for ambulation systems. Lesions at T1–T3 are associated with poor trunk stability, while lumbar lesions imply lower extremity nerve damage. 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). Patients use a walker or elbow-support crutches for further support. The electrical impulses are controlled by a computer microchip attached to the patient's belt that 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 (RGO) (Fillauer, Inc., Chattanooga, TN) 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 putting the device on and taking it off.

Neuromuscular stimulation is also proposed for motor restoration in hemiplegia and treatment of secondary dysfunction (e.g., muscle atrophy and alterations in cardiovascular function and bone density) associated with damage to motor nerve pathways.

### *Regulatory Status*

The Neurocontrol Freehand system received approval from the U.S. Food and Drug Administration (FDA) in 1997 through the pre-market approval (PMA) process. The Handmaster NMS I system was originally cleared for use in maintaining or improving range of motion, reducing muscle spasm, preventing or retarding muscle atrophy, providing muscle re-education, and improving circulation; in 2001, its 510(k) marketing clearance was expanded to include provision of hand active range of motion and function for patients with C5 tetraplegia.

The WalkAide device first received 510(k) marketing clearance from the FDA in the 1990s; the current version of the WalkAide device received 510(k) marketing clearance in September 2005. The Odstock Foot Drop Stimulator received 510(k) marketing clearance in 2005. The Bioness NESS L300 received 510(k) marketing clearance in July 2006. The FDA summaries for the devices state that they are intended to be used in patients with drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

To date, the Parastep® I Ambulation System (Sigmedics, Inc., Fairborn, OH) is the only non-invasive functional walking neuromuscular stimulation device to receive PMA from the FDA. The Parastep device is approved to:

...enable appropriately selected skeletally mature spinal cord injured patients (level C6-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.

### **Ambulation in Patients with Spinal Cord Injury**

The clinical impact of the Parastep device rests on identification of clinically important outcomes. The primary outcome of the Parastep device, and the main purpose of its design, is to provide a degree of ambulation that improves the patient's ability to complete the activities of daily living, or positively affect the patient's quality of life. Physiologic outcomes (i.e., conditioning, oxygen uptake, etc.) have also been reported, but these are intermediate, short-term outcomes and it is not known whether similar or improved results could be attained with other training methods. In addition, the results are reported for mean peak values, which may or may not be a consistent result over time. The effect of the Parastep on physical self-concept and depression are secondary outcomes and similar to the physiologic outcomes; interpretation is limited due to lack of comparison with other forms of training.

The largest study was conducted by Chaplin (1996), who reported on the ambulation outcomes using the Parastep I in 91 patients. Of these 91 patients, 84 (92%) were able to take steps and 31 (34%) were able to eventually ambulate without assistance from another person. Duration of use was not reported. Other studies on the Parastep device include a series of five studies from the same group of investigators, which focused on different outcomes in the same group of 13 to 16 patients (Klose et al., 1997; Jacobs et al., 1997; Needham-Shropshire et al., 1997; Guest et al., 1997; Nash et al., 1997). In a 1997 study, Guest and colleagues reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury. All patients underwent 32 training sessions prior to measuring ambulation. The group's mean peak distance walked was 334 meters, but there was wide variability, as evidenced by a standard deviation (SD) of 402 meters. The mean peak duration of walking was 56 minutes, again with wide variability, evidenced by a SD of 46 minutes. It should be noted that peak measures reflect the best outcome over the period evaluated; peak measures may be an inconsistent, one-time occurrence for the individual patient. The participants also underwent anthropomorphic measurements of various anatomic locations. Increases in thigh and calf girth, thigh cross-sectional area, and calculated lean tissue were all statistically significant. The authors emphasize that the device is not intended to be an alternative to a wheelchair, and thus other factors such as improved physical and mental well-being should be considered when deciding whether or not to use the system. The same limitations were noted in a review article by Graupe and Kohn (1998), who state that the goal for ambulation is for patients to get out of the wheelchair at will, stretch, and take a few steps every day.

Jacobs and colleagues (1997) reported on physiologic responses related to use of the Parastep device. There was a 25% increase in time to fatigue and a 15% increase in peak values of oxygen uptake, consistent with an exercise training effect. There were no significant effects on arm strength. Needham-Shropshire and colleagues (1997) reported no relationship between use of the Parastep device and bone mineral density, although the time interval between measurements (12 weeks) and the precision of the testing device may have limited the ability to detect a difference. Nash and colleagues (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. Also, Guest and colleagues (1997) reported significant improvements in physical self-concept and decreases in depression scores. Finally, it should be noted that evaluations of the Parastep device were performed immediately following initial training or during limited study period durations (Brissot et al., 2000; Chaplin, 1996; Davis et al., 2001; Sykes et al., 1996). There are no data regarding whether patients remained compliant and committed with long-term use.

Brissot and colleagues (2000) reported independent ambulation was achieved in 13 of 15 patients, with 2 patients withdrawing from the study. In the home setting, 5 of the 13 patients continued using the device for physical fitness, but none used it for ambulation. Sykes and colleagues (1996) found low use of a reciprocating gait orthosis device (RGOs) with or without stimulation over an 18-month period. In addition, the more recent Davis et al. (2001) study of a surgically implanted neuroprosthesis for standing and transfers after spinal cord injury showed mixed usability/preference scale results for ambulation with device assistance versus conventional transfers in 12 patients followed up for a 12-month period post-discharge. Therefore, the advantage of using device assistance could not be evaluated.

A Hayes Inc. (2011) review pertaining to the effect of FES on the general physical fitness and health of patients spinal cord injury found that FES is promising, however, the evidence was sparse and conflicting. While evidence was positive regarding FES improving various physical function and overall functional status, the studies reviewed were of insufficient quality to allow confident conclusions. The evidence for particular types of outcomes in specific populations was very sparse, with some studies having severe methodological weaknesses. The authors advised that FES as a means of assisting walking or enhancing gait training in patients with incomplete spinal cord injury, was promising, however the evidence did not include RCTs powered to detect differences with known clinical or practical importance. Further, there was little objective assessment of the long-term health outcomes and functional benefits of FES. A Hayes annual review in 2012 reflected no changes to the conclusions discussed above.

The effect of a surgically implanted neuroprosthesis on exercise, standing, transfers, and quality of life was reported in 2012 (Rohde et al., 2012; Triolo et al., 2012). This study was supported by the U.S. Department of Veterans Affairs, the Office of Orphan Product Development of the FDA, the New York State Department of Health, and the National Center for Research Resources of the National Institutes of Health. The device is not commercially available at this time.

In conclusion, as stated by various authors, the Parastep system is not designed to be an alternative to a wheelchair and offers, at best, limited, short-term ambulation. Final health outcomes, such as ability to perform activities of daily living or quality of life, have not been reported.

## **Functional Neuromuscular Electrical Stimulation of the Upper Extremity**

### *Spinal Cord Injury*

Most of the early published evidence for upper extremity devices to restore function in patients with spinal cord injuries report experience with the Freehand System, an implantable device that

is no longer marketed in the United States (Mulcahey et al., 1997; Mulcahey et al., 2004; Taylor et al., 2002). The device is controlled through a joystick on the shoulder or wrist. A disadvantage of this system is that additional surgery is required to repair hardware failures. The published studies, all case series with fewer than 10 subjects, suggest that the device may give patients the ability to grasp and release objects and independence or greater independence in such activities of daily living as using a fork or the telephone in the study setting. User satisfaction was generally high, and most subjects reported continued use of the device at home, although details of specific activities or frequency of use at home are not provided. In a review of the role of electrical stimulation for rehabilitation and regeneration after spinal cord injury, Hamid and Hayek (2008) report that the company which marketed the Freehand System in the United States, no longer manufactures new devices.

Use of the Handmaster NMS I was reported in a series of 10 patients with cervical spinal cord injuries (Snoek et al., 2000). After 2 months of training, performance on a defined set of tasks and one or more tasks chosen by the patient was evaluated. In six patients, a stimulated grasp and release with either one or both grasp modes (key- and palmar pinch) of the Handmaster was possible. Four patients could perform the set of tasks using the Handmaster, while they were not able to do so without the Handmaster. Eventually, one patient continued using the Handmaster during activities of daily living (ADLs) at home. In another study using the Handmaster device, seven subjects with C5 or C6 spinal cord injury practiced using the device daily on one of their paralyzed hands to regain the ability to grasp, hold, and release objects (Alon & McBride, 2003). They were observed two to three times weekly for 3 weeks, and their ability to pick up a telephone, eat food with a fork, and perform an individually selected ADL task plus 2 grasp, hold, and release tasks was evaluated. At the end of the study, all seven subjects were successful at using the device in the studied ADLs and grasp, hold, and release tasks. Improvements occurred in secondary measures of grip strength, finger linear motion, and Fugl-Meyer (developed to assess sensory-motor recovery after stroke) scores.

Hamid & Hyek (2008) noted that, with either device, there is a time delay of 1 to 2 seconds between command generation and execution of grasp function that interferes with the speed with which the patient can grasp and release objects.

### *Stroke*

Alon and colleagues (2002), reporting on a case series of 29 patients, investigated whether the Handmaster system could improve selected hand function in persons with chronic upper extremity paresis following stroke. The main outcome measures were three ADL tasks: lifting a 2-handled pot, holding a bag while standing with a cane, and another ADL chosen by the patient. Secondary measures included lifting a 600-gram weight, grip strength, electrically induced finger motion, Fugl-Meyer spherical grasp, and perceived pain scale. At the end of the 3-week study period, the percent of successful trials compared to baseline were: lifting pot, 93% versus 0%, lifting 600-gram weight, 100% versus 14%, and lifting bag, 93% versus 17% - all respectively. All subjects performed their selected ADL successfully and improved their Fugl-Meyer scores using the neuroprosthesis.

Hayes Inc. (2008) performed a systematic review of six randomized trials evaluating NMES of the extensor muscles as an adjunct to physical therapy for the rehabilitation of wrist and finger

muscles in patients who developed hemiparesis due to a stroke. The authors reported that while these trials reported that NMES provided statistically significant improvements in measures of wrist and finger function and strength, the evidence was insufficient as the interpretation of results were hampered by small study populations and limited short-term follow up (0 to 24 weeks). There were no changes to the Hayes conclusions, in a 2012 review of the peer-reviewed literature.

Another systematic review was performed by Hayes in 2009, and again in 2012, of RCTs and non-RCTs regarding FES with surface electrodes for upper extremity rehabilitation post stroke. The authors advised that some of the available data indicated that FES with surface electrodes was safe and associated with minor and infrequent complications. Further, some of the data indicated that the combination of FES and conventional occupational therapy/physical therapy (COPT) may be at least as beneficial but may not improve outcome, compared with COPT alone. In other study comparisons, no definitive conclusions could be drawn due to the small population of patients' evaluated, methodological flaws, and the variation in protocols and outcome measures.

### *Summary*

In conclusion, interpretation of the evidence for upper extremity neuroprostheses for patients with spinal cord injuries or post-stroke is limited by the small number of subjects and lack of data demonstrating its utility outside the study setting. The available evidence is insufficient to conclude that NMES improves outcomes by providing some upper extremity function.

## **Functional Neuromuscular Electrical Stimulation for Chronic Foot Drop**

### *Stroke and Spinal Cord Injury*

In 1999, Taylor et al. reported a retrospective study on the clinical use of the Odstock dropped foot stimulator in 151 patients with chronic foot drop resulting from an upper motor lesion. This retrospective study included 27 age-matched able-bodied controls and 140 patients (93%) who used the device for at least 4 1/2 months (111 patients with chronic foot drop due to stroke, 21 patients with multiple sclerosis [MS, described below], and 8 patients with incomplete spinal cord injury). The average time since stroke was 5.4 years. Walking speed was assessed on a 10-meter course. The physiologic cost index (PCI), which is an indication of the amount of effort in walking, was assessed by the difference between resting heart rate and heart rate during walking, divided by the average walking speed over the 4-minute walking period and reported as beats per meter. In stroke patients, the immediate (orthotic) effect of the stimulation was an increase in walking speed of 12% and a decrease in PCI of 18%. An improvement over time was also observed, with an increase in walking speed of 14% and a reduction of PCI of 19%, suggesting a therapeutic, as well as orthotic effect for this group. Over 50% of patients with stroke or spinal cord injury achieved a therapeutic effect of greater than 10% increase in walking speed or 10% decrease in PCI.

Three reports from Israel described the effects of the NESS L300™ for post-stroke foot drop. Hausdorff and Ring (2008) reported on gait symmetry and rhythmicity in 24 patients with chronic hemiparesis whose walking was impaired by foot drop. Subjects increased time wearing the prosthesis from 1 hour per day to all day over a 4-week period, then wore it all day for 4



weeks. All 24 patients reported, in response to a yes/no question, that they increased their physical activities (not quantified) and had greater confidence in walking on inclines and/or uneven ground while wearing the prosthesis. Fourteen subjects recalled one or more falls occurring in the 2 months before the study, and no subject reported falling while wearing the prosthesis. Laufer et al. (2009) reported a repeated measures follow-up of 16 patients with chronic hemiparesis who used the prosthesis for 1 year and were available for follow-up. Outcome measures included the Short Version and the Participation domain of the Stroke Impact Scale. Gains of 18% in physical functioning and 25% in participation in community life were attained 2 months after application of the device and maintained at 1 year. In a study by Ring et al. (2009), 15 patients with chronic hemiparesis from stroke or traumatic brain injury who regularly used an ankle-foot orthosis (AFO) that was adapted to the neuroprosthesis increased their daily use while using their AFO the remainder of the day (van Swigchem et al., 2010). Outcomes related to ADL, safety, or quality of life were not reported.

Van Swigchem et al. published a within-subject comparison of a functional NMES device (NESS L300) and an AFO in 26 patients with chronic (>6 months) post-stroke foot drop in 2010. Baseline walking speed on a 10-meter walkway was assessed with the patient's custom-made AFO; physical activity at home was measured with a pedometer and averaged over 7 days, and satisfaction with the device was assessed with a "purpose-designed" 5-point questionnaire. After a 2-week period of adaptation to the NESS L300, walking speed was assessed with both the AFO and the NMES devices. For the next 6 weeks, patients increased use of the NMES device to the whole day, using the AFO 1 hour a day in order to maintain familiarity of walking with this device. At the end of the study, walking speed was assessed with both the AFO and the NMES devices, while activity at home and satisfaction were assessed for the NMES device. Two patients dropped out of the study due to discomfort from the electrical stimulation (n=1) and skin reaction to the electrodes (n=1). The remaining 24 patients provided an average satisfaction rating of 3.0 (neutral) for the AFO and 4.0 (satisfied) for the NMES device regarding comfort to wear, appearance, quality of gait, walking distance, effort of walking, and stability during gait. The objective measures of walking speed (1.02 for the AFO and 1.03 for NMES) and steps per day (5,541 for the AFO and 5,733 for NMES) were not significantly different for the two devices.

In 2010, Stein et al. reported improvements in both the orthotic and therapeutic effects of NMES in 41 patients with chronic non-progressive foot drop (26 stroke, 9 spinal cord injury, 3 surgical complication, 2 head injury, and 1 cerebral palsy) and 32 patients with progressive foot drop (described in more detail following) after 1, 2, 3, 6, 9, and 11 months of use. The orthotic effect of the device was considered to be the immediate effect of NMES measured at any of the time points with the stimulator on compared to off. The therapeutic effect was the improvement over time (improvement in neuromuscular function) measured under the same conditions (i.e., stimulator on versus on or stimulator off versus off) at different time points. With the stimulator on compared to off (orthotic effect), walking speed improved by 5% for a figure 8 (0.59 versus 0.56 milliseconds [m/s]) and 6% for a 10-meter test (0.80 versus 0.76 m/s). With the stimulator off, walking speed at 3 months had improved by 17% for a figure 8 (0.56 versus 0.48 m/s) and 12% for a 10-meter test (0.76 versus 0.68 m/s, all respectively) compared to baseline. The combined (orthotic and therapeutic) improvement in walking speed over the 3 months was 23% for the figure 8 (0.59 versus 0.48 m/s) and 18% for the 10-meter test (0.80 versus 0.68 m/s, both

respectively). Only 14 subjects (35%) returned for testing after 11 months due to external factors (e.g., cost of the device, distance from the test site). Analysis indicated no differences between subjects who were in the study for 3 months and those who returned at 11 months. Continued use resulted in total improvement of 39% on the figure 8 (0.74 versus 0.54 m/s) and 32% on the 10-meter test (1.02 versus 0.77 m/s, both respectively). The PCI improved by 18% (0.70 versus 0.86 beats/minute, respectively) at 11 months. Subjects with non-progressive foot drop used the device for an average 73% of days, 7.3 hours per day, and walked nearly 2 km/day.

Rosewilliam et al. (2012) evaluated whether surface NMES of the wrist and hand combined with routine therapy could facilitate recovery of arm function in patients with stroke. Participants were randomized to surface NMES using surface electrical stimulators for 30 minutes, twice in a working day for 6 weeks in addition to standardized upper limb therapy or just standardized upper limb therapy. The authors reported that there were statistically significant improvements in measures of wrist extensor (mean difference 0.5; 95% confidence interval [CI], 0.0-1.0) and grip strength (mean difference 0.9; 95% CI, 0.1-1.7) over the treatment period. Arm function (ARAT score) was not significantly different between the groups over the treatment period at 6 weeks (mean difference 1.9; 95% CI, -2.9 to 6.8) or over the study period at 36 weeks (mean difference 6.4; 95% CI, -1.8 to 14.7), and the rate of recovery was not significantly different (mean difference 0.7; 95% CI, -0.2 to 1.6). The authors concluded that in patients with severe stroke, with no functional arm movement, electrical stimulation of wrist extensors improves muscle strength for wrist extension and grip; however, larger studies are required to study its influence on arm function.

### *Multiple Sclerosis*

The 1999 study by Taylor et al. described earlier included 21 patients with MS. This group showed a 7% decrease in walking speed and a 16% increase in PCI over the course of the study when not using the Odstock dropped foot stimulator (absence of a therapeutic effect), while use of the stimulator (orthotic effect) resulted in an increase in walking speed of 16% and a decrease in PCI of 24%.

In 2009, an RCT of functional NMES to improve walking performance in patients with MS was published by Barrett and colleagues. Fifty-three patients with secondary progressive MS and unilateral dropped foot were randomized to an 18-week program of either NMES of the common peroneal nerve using a single channel Odstock Dropped Foot Stimulator or a home exercise program, and assessed at 6, 12, and 18 weeks. Patients in the stimulator group were encouraged to wear the device most of the day, switching it on initially for short walks and increasing daily for 2 weeks, after which they could use the device without restriction. Subjects in the control group were taught a series of exercises tailored to the individual to be done twice daily. The primary outcome measure was walking speed over a 10-meter distance. Two secondary outcome measures were energy efficiency based on increase in heart rate during walking and walking distance in 3 minutes. Six subjects in the NMES group and 3 subjects in the exercise group dropped out very early in the study leaving 20 subjects in the NMES group and 24 in the exercise group. In the NMES group, mean changes between baseline and 18-week measures were non-significant for all three outcome measures, both with and without stimulation. However, within the NMES group, when mean values for walking speed and distance walked were compared with and without stimulation, outcomes were significantly better with stimulation. In the exercise



group, increases in walking speed over 10 meters and distance walked in 3 minutes were highly significant,  $p=0.001$  and  $p=0.005$  respectively. At 18 weeks, the exercise group walked significantly faster than the NMES group ( $p=0.028$ ). The authors noted a number of limitations of their study: power calculations were based on the 10-meter walking speed measure only and indicated that 25 subjects would be required in each group, patients were highly selected, clinical assessors also provided treatment (issues with blinding), and the validity and reliability of the 3-minute walk test have not been confirmed (fatigue prevented use of the validated 6-minute test). In addition, subjects in the exercise group were told they would receive a stimulator at the end of the trial, which may have impacted adherence to the exercise regimen, as well as retention in the trial. The authors concluded that:

While a simple program of home exercise therapy appears to significantly increase walking speed and endurance over an 18-week intervention period, single channel common peroneal stimulation does not. However, it does appear to have a significant orthotic benefit, resulting in significantly increased walking speed and endurance when performance without stimulation is compared to performance with stimulation.

A 2010 publication by the same group of investigators reported the impact of 18 weeks of physiotherapy exercises or the Odstock Dropped Foot Stimulator on activities of daily living (ADL) (Esnouf et al., 2010). Results of 53 patients from the trial described above were reported, using the Canadian Occupational Performance Measure (COPM). The COPM is a validated semi-structured interview that was originally designed to assist the design of occupational therapy interventions. The interviews at baseline identified 265 problems of which 260 activities were related to walking and mobility. Subjective evaluation at 18 weeks showed greater improvements in performance and satisfaction scores in the NMES group (35% of problems had an increased score of 2 or more) than the exercise group (17% of problems had an increased score of 2 or more). The median satisfaction rating improved from 2.2 to 4.0 in the NMES group and remained stable (from 2.6 to 2.4) in the exercise group. The median number of falls recorded per patient over the 18-week study period was 5 in the NMES group and 18 in the exercise group. About 70% of the falls occurred while not using the NMES device or an ankle-foot orthotic device.

In a preliminary study, Sheffler et al. (2009) compared functional ambulation tasks under conditions of no device or peroneal nerve stimulator. Eleven subjects with MS, dorsiflexion weakness, and prior usage of an AFO were evaluated on the timed 25-foot walk component of the MS Functional Composite and the Floor, Carpet, Up and Go, Obstacle, and Stair components of the Modified Emory Function Ambulation Profile. Performance on Stair and Obstacle components was enhanced in the stimulator condition versus no device ( $p=0.05$  and  $p=0.09$ , respectively), and there were no significant differences between no device and stimulator conditions on other measures. The authors concluded that “the neuroprosthetic effect of the peroneal nerve stimulator is modest relative to no device in the performance of specific functional tasks of ambulation in MS gait. A longitudinal, controlled trial is needed to show effectiveness.”

The study by Stein et al. (2010) described above also assessed the orthotic and therapeutic effects of NMES in 32 patients with progressive foot drop (31 MS and 1 familial spastic paresis). With

the stimulator on compared to off (orthotic effect), walking speed improved by 2% for a figure-8 test and 4% for a 10-meter test. With the stimulator off (therapeutic effect), walking speed at 3 months had improved by 9% for a figure-8 test and 5% for a 10-meter test when compared to baseline. The combined improvement in walking speed over the 3 months was 13% for the figure 8 (0.61 versus 0.53 m/s) and 13% for the 10-meter test (0.88 versus 0.78 m/s), both respectively. The 20 subjects (63%) who returned for testing at 11 months did not show continued improvement when compared to 3-month test results, with a combined (orthotic and therapeutic) improvement of 13% on the figure 8 (0.62 versus 0.55 m/s) and 10% on the 10-meter test (0.86 versus 0.78 m/s), (both respectively) compared to baseline. The PCI was not significantly improved (0.73 versus 0.78 **b/m**), both respectively. Subjects with non-progressive foot drop used the device for an average 85% of days, 9.2 hours per day, and walked about 2 km/day.

In a Hayes Inc. (2011) review of six clinical studies that evaluated the effect of surface FES for the treatment of foot drop in patients with MS, there was suggestion that use of the WalkAide System or the ODFS Pace may improve walking speed. However, the results were conflicting (i.e., some studies reported significant increases in walking speed [7% to 14%] compared to baseline, while others reported no differences in walking speed). Overall, there was very limited evidence on the effect of FES on other patient-relevant, functional measures. Most of the evidence evaluated surrogate outcome measures, including gait and walking parameters, measured in highly-controlled experimental settings, to predict functional status in everyday environments. The authors stated that these types of results may not have immediate clinical relevance to the patient, or may not translate directly to functional improvement in ADL or quality of life improvement. Additionally, the studies were of case series and poorly controlled RCTs, so the validity of the studies is unclear, and the quality of evidence is low (i.e., insufficient power of small clinical studies to detect statistical differences in treatment groups, and lack of blinding). The authors concluded that well-designed studies were necessary to sufficiently examine the effects of FES on functional status with emphasis on the practical dimensions of everyday life. Studies with subgroup analyses were also requested in order to determine the patient characteristics and conditions that were associated with clinically meaningful and successful outcomes. A Hayes update review of the literature in 2012 reflected there were no anticipated impacts on the prior conclusions.

### *Cerebral Palsy*

Cauraugh et al. conducted a 2010 meta-analysis of 17 studies on NMES and gait in children with cerebral palsy. Fourteen of the studies used a pretest-post-test, within-subjects design. A total of 238 participants had NMES. Included were studies on acute NMES, functional NMES and therapeutic NMES (continuous subthreshold stimulation). Five of the studies examined functional NMES, and one of these studies examined percutaneous NMES. There were three outcome measures for impairment; range of motion, torque/movement, and strength/force. There were six different outcome measures for activity limitations; gross motor functions, gait parameters, hopping on one foot, 6-minute walk, Leg Ability Index, and Gillette gait index. Moderate effect sizes were found for impairment (0.616) and activity limitations (0.635). The systematic review is limited by a lack of blinding in the included studies and the heterogeneity of outcome measures. The review did not describe if any of the included studies used a commercially available device.

A 2012 report by Prosser and colleagues examined the acceptability and effectiveness of a commercially available foot drop stimulator in 21 children who had mild gait impairments and unilateral foot drop. Three children did not experience an improvement in walking and did not complete the study. Gait analysis in the remaining 18 showed improved dorsiflexion when compared to baseline. There was no significant change in other gait parameters, including walking speed. The average daily use was 5.6 hours (range, 1.5 to 9.4) over the 3 months of the study, although the participants had been instructed to use the device for at least 6 hours per day. Eighteen children (86%) chose to keep using the device after the 3-month trial period. Data from this period were collected but not reported.

In 2013, Meilahn assessed the tolerability and efficacy of a commercially available neuroprosthesis in 10 children (age, 7 to 12 years) with hemiparetic cerebral palsy who typically wore an AFO for correction of foot drop. All of the children tolerated the fitting and wore the device for the first 6 weeks. The mean wear time was 8.4 hours per day in the first 3 weeks and 5.8 hours per day in the next 3 weeks. Seven children (70%) wore the device for the 3-month study period, with average use of 2.3 hours daily (range, 1.0 to 6.3 hours/day). Six children (60%) continued to use the neuroprosthesis after study completion. Gait analysis was performed, but quantitative results were not included in the report. Although it was reported that half of the subjects improved gait velocity, mean velocity was relatively unchanged with the neuroprosthesis.

A Hayes Inc. review (2010) of five prospective, controlled studies, including four RCTs, reported generally positive but non-significant benefits to lower limb physical function in pediatric cerebral palsy patients. A single RCT demonstrated a modest effect of NMES on trunk muscles, as measured by sitting posture. A single comparator study suggested NMES might enhance the use of dynamic bracing for upper limbs. Five controlled trials, including one RCT, reported negative results with respect to the orthotic effect of FES on the lower limbs and/or mixed results regarding the ability of FES to provide improvements lasting beyond the use of FES. Hayes reported that none of the studies provided sufficient evidence to assess the impact of NMES/FES on important patient outcomes (e.g., complications of cerebral palsy, ADL functioning, or quality of life). While there were no safety issues associated with either NMES or FES, the authors concluded that the quality of evidence for NMES and FES was limited due to sparse data, methodological weaknesses within each study, heterogeneity in study protocols, intermediate versus patient-important outcome measures, and/or lack of follow-up. Annual Hayes Inc. reviews of the peer-reviewed literature, including 2012, did not change the conclusions drawn in 2010.

### *Practice Guidelines and Position Statements*

In January 2009, the National Institute for Health and Clinical Excellence (NICE) published guidance stating that the current evidence on FES for drop foot of neurologic origin appears adequate to support its use, provided that normal arrangements are in place for clinical governance, consent, and audit. They noted that patient selection should involve a multidisciplinary team. The NICE guidance advises that further publication on efficacy of FES would be useful; specifically including patient-reported outcomes, such as quality of life and ADLs, and these outcomes should be examined in different ethnic and socioeconomic groups.

### *Summary*

In conclusion, two recent within-subject studies have evaluated tolerability and efficacy of a commercially available neuroprosthesis in children with cerebral palsy. Both of the studies, which should be considered preliminary, show no improvement in walking speed with the device. In addition, daily use decreased over the course of one trial. Study in a larger number of subjects over a longer duration is needed to permit conclusions concerning the effect of the technology on health outcomes.

## **Functional Neuromuscular Electrical Stimulation for Other Conditions and Uses**

### *Advanced Diseases*

A Cochrane review by Maddocks et al. (2013) evaluated the effectiveness of NMES for improving muscle strength in adults with advanced disease. This review considered 11 small clinical trials comparing NMES to no exercise or 'placebo NMES' in patients with advanced chronic obstructive pulmonary disease (COPD), chronic heart failure or thoracic cancer. The authors found that NMES appears to be effective and results in improvements in leg muscle strength and ability to exercise. However, "these benefits needed to be confirmed in larger trials and further research is required to help determine effects on other outcomes such as quality of life and use of healthcare services."

Hayes Inc. (2008) performed a review of a number of small, randomized controlled or comparative studies evaluating NMES as a means to rehabilitate muscles after stroke-related paralysis or orthopedic surgery, or in patients with activity restrictions due to severe cardiac or pulmonary disease, or in patients with cerebral palsy. Some studies reported that use of NMES as an adjunct to physical therapy may improve patient outcomes, particularly for rehabilitation of wrist and finger function after stroke-related partial paralysis, prevention or correction of shoulder subluxation after partial paralysis due to stroke, and treatment of swallowing disorders after stroke. However, the authors concluded that these findings were conflicting, and other studies found little evidence of long-term benefit. In general, sample sizes were too small and there were insufficient follow-up times to support definitive conclusions regarding the benefit of NMES for any specific indication. A subsequent Hayes review of the peer-reviewed literature (2012) did not change the conclusions.

### *Heart Failure*

In a systematic review of 13 studies (10 were RCTs), Arena and others (2010) evaluated the evidence supporting NMES and inspiratory muscle training (IMT) for the treatment of systolic heart failure. The authors advised that the studies reported improvement in aerobic capacity, peak oxygen uptake and strength and endurance of muscle groups. However, study limitations included patient population (mostly males), differing NMES training protocols, variance in the type of muscle contraction elicited (i.e., titanic versus twitch), the use of different muscle groups and different comparators. The percent improvement in peak oxygen uptake was consistently greater with conventional therapy, such as with a bicycle or treadmill.

In another review of RCTs analyzing the role of NMES in patients with congestive heart failure (9 studies) and COPD (5 studies), Sillen and colleagues (2009) reported that some of the studies reviewed showed significant improvements with NMES compared to not exercising or usual

care. However, the clinical outcomes were conflicting. The authors concluded that additional studies were required to provide sufficient evidence to establish that NMES was clinically useful in this patient population.

### *Dysphagia*

Electrical stimulation has been proposed as a treatment for dysphagia. This treatment provides direct electrical stimulation of the oral structure or transcutaneous stimulation of the throat musculature. Dysphagia can be caused by any condition that weakens or damages the muscles and nerves used for swallowing. These conditions include, but are not limited to, cerebral palsy, Parkinson's disease, traumatic brain injury, and stroke.

VitalStim™ is an electrical stimulation device that is classified by the FDA as a Class II device.

Kiger et al. (2006) in a comparative study examined the outcomes using VitalStim therapy to outcomes using traditional swallowing therapy for deglutition disorders. The study included 22 patients who had an initial and a follow-up videofluoroscopic swallowing study or fiberoptic endoscopic evaluation of swallowing and were divided into the two groups. Outcomes measurements included changes in oral and pharyngeal phase dysphagia severity, dietary consistency restrictions, and progress from nonoral to oral intake. The authors concluded that the results did not show a statistically significant difference in outcomes between the experimental and control group.

Carnaby-Mann and Crary (2007) performed a meta-analysis to evaluate the effect of transcutaneous NMES on swallowing rehabilitation. A random-effects model was used to pool study results. A total of 81 studies were reviewed and seven were accepted for analysis. These seven studies included 255 patients with dysphagia due to multiple diagnoses. Outcomes included swallowing scale, weight gain, laryngeal elevation, and functional eating. The authors concluded that this preliminary meta-analysis revealed a small but significant summary effect for transcutaneous NMES for swallowing. However, because of the small number of studies and low methodological grading for these studies, caution should be taken when interpreting the findings. There is need for further studies.

Shaw and associates (2007) conducted a retrospective analysis of 18 patients with dysphagia for the effectiveness of VitalStim therapy. All patients underwent pre-therapy evaluation by speech-language pathologists, including modified barium swallow and/or functional endoscopic evaluation of swallowing and clinical evaluation of swallowing that included assessment of laryngeal elevation, diet tolerance, and swallowing delay. All subjects were assigned an overall dysphagia severity score and after therapy underwent the same assessments. Their results showed that 11 of the 18 patients demonstrated some improvements with their swallowing and 6 of the 18 were improved enough to no longer require a feeding tube. However, only two of the five with "severe dysphagia" showed any improvement and these patients continued to require tube feedings. The authors concluded that VitalStim therapy seems to help those with mild to moderate dysphagia, but the patients with the most severe dysphagia did not gain independence from tube feedings.

In summary, there is insufficient evidence in peer-reviewed scientific literature to conclude that electrical stimulation is effective in the treatment of dysphagia.



### *Facial Palsy*

Facial palsy is a type of paralysis resulting when facial nerve function is affected due to infection, trauma, toxic exposures, or neuromas. Facial palsy that occurs suddenly without apparent cause is referred to as idiopathic or Bell's palsy. Electrical stimulation has been investigated as a treatment option for facial palsy. Electrical stimulation is applied to the affected facial muscles to provide muscle innervation with the proposed intention of preventing muscle degeneration.

Buttress et al. (2002) reviewed the published literature to establish whether electrical stimulation had any advantages over facial exercises in promoting recovery after Bell's palsy. Only one study was found in review of 270 papers. The authors concluded that there is no evidence to suggest that either facial exercises or electrical stimulation is beneficial to patients with Bell's palsy.

Electrotherapy for the treatment of facial nerve paralysis is not covered under Medicare because its clinical effectiveness has not been established in peer reviewed literature.

### *Ongoing Clinical Trials*

There are a number of clinical trials examining neuroprostheses (NCT00890916; NCT00583804; NCT01237860); however, there are no published study results according to the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website, as of June 2013.

### *Summary*

In conclusion, there is insufficient evidence to support the effectiveness of NMES in the prevention and/or management various conditions and indications, as overall studies in the form of RCTs and case series included small, heterogeneous patient populations and short-term follow-ups. Evidence for NMES to provide functional movement is limited by the small number of subjects studied to date. A cross-over study of NMES and AFO in patients with chronic post-stroke foot drop showed improved satisfaction with NMES but no change in walking speed. A small randomized trial examining neuromuscular stimulation for foot drop in patients with MS showed a reduction in falls and improvement in satisfaction when compared to a program of exercise, but did not demonstrate a clinically significant benefit in walking speed. The literature on NMES in children with cerebral palsy includes a systematic review of small studies with within-subject designs.

For other conditions and indications (e.g., heart failure, COPD, dysphagia), studies reported various outcomes including no improvement with NMES, conflicting outcomes, and in some cases, effects that did not last. Due to different outcome measures and treatment regimens, it was difficult to establish whether NMES produced meaningful patient clinical outcomes for other conditions or uses.

Additional study in a larger number of subjects is needed to permit conclusions regarding the effect of this technology on health outcomes. Therefore, functional NMES remains investigational.

## **Threshold Electrical Stimulation as a Treatment of Motor Disorders**

Threshold electrical stimulation is provided by a small electrical generator, lead wires, and surface electrodes that are placed over the targeted muscles. The intensity of the stimulation is set at the sensory threshold and does not cause a muscle contraction.

Threshold electrical stimulation is described as the delivery of low-intensity electrical stimulation to target spastic muscles during sleep at home. The stimulation is not intended to cause muscle contraction. Although the mechanism of action is not understood, it is thought that low-intensity stimulation may increase muscle strength and joint mobility, leading to improved voluntary motor function. The technique has been used most extensively in children with spastic diplegia related to cerebral palsy but also in those with other motor disorders, such as spina bifida.

Devices used for threshold electrical stimulation are classified as “powered muscle stimulators.” As a class, the FDA describes these devices as “an electronically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.”

Validation of therapeutic electrical stimulation requires randomized, controlled studies that can isolate the contribution of the electrical stimulation from other components of therapy. Physical therapy is an important component of the treatment of cerebral palsy and other motor disorders. Therefore, trials of threshold electrical stimulation ideally should include standardized regimens of physical therapy. Randomized studies using sham devices are preferred to control for any possible placebo effect.

A randomized study published by Steinbok and colleagues in 1997 included 44 patients with spastic cerebral palsy who had undergone a selective posterior lumbosacral rhizotomy at least 1 year previously. All patients had impaired motor function, but some form of upright ambulation. Patients were randomly assigned to receive either a 12-month period of 8 to 12 hours of nightly electrical stimulation or no therapy. The principal outcome measure was the change from baseline to 12 months in the Gross Motor Function Measure (GMFM), as assessed by therapists blinded to the treatment. The patients and their parents were not blinded; the authors stated that the active device produced a tingling sensation that precluded a double-blind design. Patients were encouraged to maintain whatever ongoing therapy they were participating in. The type of physical therapy in either the control or treatment group was not described.

After 1 year, the mean change in the GMFM was 5.5% in the treated group, compared to 1.9% in the control group, a statistically significant difference. The authors state that this 3.6% absolute difference is clinically significant. For example, a child who was previously only able to rise and stand while pushing on the floor, could now do so without using hands. While these results point to a modest benefit, the lack of control for associated physical therapy limits the interpretation.

Five additional studies were identified in the literature over the next 10 years, none of them demonstrating effectiveness. Dali and colleagues (2002) published the results of a trial that randomly assigned 57 children with cerebral palsy to receive either threshold electrical stimulation or a dummy device for a 12-month period. Visual and subjective assessments showed



a trend in favor of the treatment group, while there was no significant effect of therapeutic electrical stimulation in terms of motor function, range of motion, or muscle size. The authors concluded that therapeutic electrical stimulation was not shown to be effective in this study.

Two smaller randomized controlled studies found no improvement in muscle strength with electrical stimulation. In the van der Linden et al. (2003) study, 22 children with cerebral palsy were randomly assigned to receive 1 hour of electrical stimulation to the gluteus maximus daily over a period of 8 weeks to improve gait. No clinical or statistically significant between-group differences were found in measurements of hip extensor strength, gait analysis, passive limits of hip rotation, and section E of the GMFM. Fehlings and colleagues (2002) also found no evidence of improved strength in 13 children with types II/III spinal muscular atrophy who were randomly assigned to either receive electrical stimulation or a placebo stimulator during a 12-month period. A study of 24 patients with cerebral palsy demonstrated positive results for the subset that received stimulation combined with dynamic bracing; however, the effect did not last after discontinuing treatment (Ozer et al., 2006).

Kerr and colleagues (2006) randomly assigned 60 children with cerebral palsy to 1 hour daily neuromuscular stimulation (n=18), overnight threshold electrical stimulation (n=20), or overnight sham stimulation (n=22). Blinded assessment following 16 weeks of treatment showed no difference among the groups, as measured by peak torque or by a therapist-scored gross motor function. A parental questionnaire on the impact of disability on the child and family showed improvement for the two active groups but not the sham control. Compliance in the threshold electrical stimulation group was 38%; compliance in the placebo group was not reported. Retrospective analysis indicated that the study would require 110 to 190 subjects to achieve 80% power for measures of strength and function.

A 2006 systematic review of electrical stimulation or other therapies given after botulinum toxin injection, conducted by the American Academy for Cerebral Palsy and Developmental Medicine, concluded that the available evidence is poor (Lannin et al, 2006).

### *Scoliosis*

In 1995 Nachemson and Peterson published the results of a retrospective study comparing the outcomes of bracing and electrical stimulation. One intervention group received underarm braces (p=111), a second group received nighttime surface electrical stimulation (p=46), and a third group was followed for observation only (p=129). Treatment was considered successful if it prevented six degrees of increase or more in the scoliotic curve until the patients were 16 years of age. The results showed that treatment with a brace was associated with a success rate of 74%; observation only, with a success rate of 34%; and electrical stimulation, with a success rate of 33%. Since that time, many scoliosis experts have abandoned the use of ES.

A systematic review performed by Rowe and colleagues (1997) of six studies (including RCTs and non-RCTs) evaluating non-operative treatments for idiopathic scoliosis in 322 patients. While lateral electrical surface stimulation was associated with a lower weighted mean proportion of success than observation only, the difference was not significant. Further, bracing was significantly more successful than lateral electrical surface stimulation. Of note, the authors also noted that electrical stimulation was no longer a treatment used for scoliosis.

### *Practice Guidelines and Position Statements*

The National Institute of Neurological Disorders and Stroke (2013) states that threshold electrical stimulation is a controversial therapy and that studies have not been able to demonstrate its effectiveness or any significant improvement with its use.

#### *Summary*

The studies published to date demonstrate that threshold electrical stimulation is not effective for treatment of spasticity, muscle weakness, reduced joint mobility, or motor function; therefore the treatment is considered not medically necessary.

### **Diaphragmatic/Phrenic Nerve Stimulation (Electrophrenic Pacemaker)**

The electrophrenic pacemaker, also referred to as phrenic pacing, diaphragm pacing or electrophrenic respiration, or diaphragmatic/phrenic nerve (D/P) pacing, electrically stimulates the diaphragm via the phrenic nerve, the major nerve supply to the diaphragm that controls breathing. Electrophrenic pacing is an alternative to invasive mechanical ventilation. The procedure is performed laparoscopically, and the device implanted cervically or thoracically. The pacer system consists of an implanted generator, electrodes, leads, and an external antenna and transmitter. The generator is secured in a subcutaneous pocket in the chest wall and is controlled by an external transmitter. The battery is contained within the external transmitter. The transmitter controls the intensity, duration and rate of impulse (i.e., the respiratory rate). Depending upon the patient's condition, pacing may be either unilateral or bilateral and intermittent or continuous. The repetitive electrical stimulus of the phrenic nerve by the pacer produces a rhythmic contraction of the diaphragm and a normal breathing pattern (i.e., inhalation upon electrical stimulation and exhalation on cessation of stimulation), and effectively lowers the floor of the chest cavity, creating negative pressure within the chest and drawing air into the lungs (Creasey et al., 1996). For phrenic pacing to be effective, patients must have intact phrenic nerves, a functional diaphragm, and uncompromised lung function. The timing and strength of the pacing signal is programmed when the patient begins training to use the device. Both the patient and caregiver are able to turn the device on and off (Adler et al., 2009; Onders et al., 2011).

Diaphragmatic/phrenic nerve stimulation allows patients to speak since it does not interfere with sound production in the larynx (Esclarin et al., 1994). Other benefits include an improved sense of well-being and overall health, and reduced anxiety and fear of ventilator disconnection. Since it also allows for breathing through the nose, D/P pacing restores use of the sense of smell to patients whose ventilation had been previously supported via a tracheotomy (DiMarco, 2001; Hirschfeld et al., 2008; Adler et al., 2009). Patients should demonstrate sufficient cognitive function and motivation to undertake a lengthy rehabilitation and training program required after implantation of the D/P device (Hayes Inc., 2011). Some patients are successful only after lengthy training and rehabilitation; and some who are successful choose not to use the device (Hayes Inc., 2011).

The reported complication rate for D/P pacing varies widely, with some studies reporting complications in approximately 10% of patients, while others reported complication rates up to

50% (Hayes Inc., 2011). Complications include infection rates of 3% to 7%, dehiscence or cellulitis at the site, and capnothorax (a carbon dioxide pneumothorax due to tracking during laparoscopy) (Onders et al., 2009). Mechanical failures have also been reported including breakage or disconnection of the electrode wires from the impulse generator, as well as, dislodged electrodes in pediatric patients due to their active growth and lifestyle.

Diaphragmatic/Phrenic pacing devices that have received FDA approval include the:

- Mark IV™ Breathing Pacemaker System (Avery Biomedical Devices Inc., )
- NeuRx DPS™ RA/4 Respiratory Stimulation System (Synapse Biomedical Inc., )

The Mark IV Breathing Pacemaker System was approved by the FDA PMA process as a Class III neurologic therapeutic device. The original premarket approval on the Mark IV System was prior to 1987; modifications to the device were approved in March 2003. The Mark IV is indicated for persons who require chronic ventilatory support because of upper motor neuron respiratory muscle paralysis or central alveolar hypoventilation and whose remaining phrenic nerve, lung, and diaphragm function are sufficient to accommodate electrical stimulation (CDRH, 2011). Non-randomized comparative, prospective case series, and retrospective reviews have reported that the Mark IV System is a safe and effective alternative to invasive mechanical ventilation in carefully selected patients (Shaul et al., 2002; Hirschfield et al., 2008; Ali et al., 2008).

The NeuRx DPS RA/4 System accomplishes respiratory pacing using intramuscular electrodes inserted via laparoscopy. Under the Humanitarian Device Exemption (HDE), the FDA approved the device to be used by patients aged 18 years or older. The device is intended for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours per day (CDRH, 2008). In order to receive HDE approval, a manufacturer must first be granted Humanitarian Use Device (HUD) exemption by demonstrating the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States per year. Studies demonstrating safety and probable benefit from the device are required for this approval; however, clinical trials evaluating its effectiveness are not required. Additionally, a hospital or health care facility institutional review board must approve use of the device at that facility before the device is used in a patient. The FDA HDE approval of the NeuRx device was based on a prospective, non-randomized, multicenter clinical trial (FDA, 2008; Onders et al., 2009).

Shaul and colleagues (2002) reviewed nine children ranging in age from 5 to 15 years and who suffered from congenital central hypoventilation syndrome (CCHS) or cervical spinal cord injury. These children underwent thoracoscopic placement of bilateral phrenic nerve electrodes. Four patients experienced postoperative complications (pneumonia, atelectasis, bradycardia, and pneumothorax). Average follow-up had been 30 months (range, 15 to 49 months). Eight patients reached their long-term pacing goals. The authors concluded that phrenic nerve electrodes can be implanted thoracoscopically and allow the successful use of diaphragmatic pacing therapy.

A long-term study of 12 patients with tetraplegia (Elefteriades et al., 2002) found that after a mean of 14.8 years, 6 of 12 patients implanted at the study institution were using the device full time and living at home.

Heirshfield et al. (2008) in a prospective data collection compared mechanical ventilation to phrenic nerve stimulation (PNS). Thirty-two of the patients with functioning phrenic nerves and diaphragm muscles were treated with PNS and 32 patients with destroyed phrenic nerves were mechanically ventilated. They found that respiratory treatment with PNS significantly reduces frequency of respiratory infections and improves patients' quality of life.

Ali et al (2008) reviewed their 20-year experience with diaphragmatic pacing as a treatment modality for CCHS. The group was small, consisting of four females and two males with their age from between 4 to 23 years. The results showed all patients as ventilator free during the day and active and productive, either attending school or working full time. They concluded that diaphragmatic pacing is an effective treatment of congenital central alveolar hypoventilation syndrome (CCAHS). As equipment has improved, there is much less need for replacement of components. Patients can lead a much more normal existence by being ventilator free at least during the day, enabling them to participate in normal daily activities.

A retrospective review of phrenic nerve stimulation for ventilatory support (Khong et al., 2010) summarized the experience of 19 patients in Australia. Although the information available to these authors was incomplete, they confirmed that 11 of the pacers remained implanted and in active use. A retrospective study of 20 patients in France who received D/P pacers reported that only 1 patient was unable to adapt to D/P pacing, and established the feasibility of video-assisted thoracoscopic implantation of phrenic nerve stimulators (Le Pimpec-Barthes et al., 2011).

Two prospective studies (Alsheklee et al., 2008; Onders et al., 2009) reported the results of D/P pacemaker implantation in patients with cervical spinal cord injuries or amyotrophic lateral sclerosis (ALS), prospectively enrolling 26 and 88 patients, respectively. Pacemakers were implanted in patients who had intact phrenic nerve and diaphragm function.

Diaphragmatic/phrenic pacing was successful in more than 95% of these patients, with spinal cord injury patients able to use this method of ventilation in lieu of a mechanical ventilator. Patients with ALS achieved a reduction in the rate of decline of ventilatory function, delaying the need for a mechanical ventilator.

Onders et al. (2010) retrospectively analyzed the experience of patients who had cardiac pacemakers at the time of implantation of diaphragmatic pacing electrodes in order to prove that these devices would not interact. All but 1 of 20 patients were successfully implanted with D/P pacers, and a single instance of device-device interaction was managed without difficulty; 71% used D/P pacing full time.

In general, all published studies demonstrated a very high success rate in terms of the percentage of patients who receive implanted D/P pacers and use them successfully for all or part of the time. Success rates ranged from 50% to 100%, with success defined as use of D/P pacing to provide ventilatory support on a full- or part-time basis. Some patients were able to avoid mechanical ventilation completely and no longer required a tracheotomy, while other patients continued to prefer or require mechanical ventilation for part of the time (Hayes Inc., 2011).

Limitations to the studies discussed above included that none of the studies were blinded or randomized and patients were self-selected which assured a highly motivated patient population.

Hayes Inc. (2011) performed a systematic review of prospective and retrospective studies regarding D/P pacing and advised that while there is a high incidence of complications among patients using this type of device, none were life-threatening and approximately 80% of those studied achieved permanent D/P pacing. The evidence was sufficient for D/P pacing for the treatment of chronic ventilatory insufficiency in patients whose remaining phrenic nerve, lung, and diaphragm function were intact and sufficient to accommodate electrical stimulation. In an annual review by Hayes (2012) of the more recent literature, the authors reported no anticipated changes to the conclusions of the 2011 assessment.

A new application for use of D/P stimulation has been reported in the literature in heart failure patients with central sleep apnea (Augostini, 2012; Ponikowski et al., 2012) however, these studies are preliminary and the authors have reported that further study is needed.

#### *Professional Societies and Organizations*

The American Thoracic Society published an Official Clinical Policy Statement in 1999 that included their recommendation that D/P stimulation is an appropriate mode of ventilatory support for older infants and toddlers with congenital central hypoventilation syndrome, since it allows them to overcome some of the social isolation associated with mechanical ventilation (Weese-Mayer et al., 2009).

A technology assessment from the Canadian Agency for Drugs and Technology and Health (CADTH) stated that a laparoscopically implanted diaphragm pacing system provides an alternative to mechanical ventilation and allows patients to increase day-to-day freedom and minimize the risk of respiratory infection (Dibidino & Morrison, 2009).

#### **Stimulation of the Sacral Anterior Root Combined with Posterior Sacral Rhizotomy with Spinal Cord Injury**

Suprasacral spinal cord injury may result in neurogenic bladders, characterized in part by frequent urinary tract infections from inadequate bladder emptying. The high bladder pressures related to large post-void residuals can lead to autonomic dysreflexia, vesicoureteral reflux, upper urinary tract dilations, hydronephrosis, and eventual renal failure. (Autonomic dysreflexia is a clinical phenomenon affecting patients with a spinal cord injury above the sympathetic outflow at T5-T6. Any noxious stimulus arising below this level may irritate reflex sympathetic activity, which may result in life-threatening hypertension.) Bladder management after spinal cord injury typically attempts to increase bladder capacity, maintain low pressure storage of urine, minimize risk of urinary tract infection by limiting post-void residual urine, and prevent incontinence. Conservative treatment of neurogenic bladder includes use of anticholinergic drugs to control reflex incontinence and autonomic hyperreflexia, and intermittent or permanent catheterization for bladder emptying. External sphincterotomy or urinary diversion is a surgical option.

Sacral anterior root electrical stimulation is intended to provide bladder evacuation by delivering stimulation to intact spinal nerve roots to elicit functional contraction of the innervated muscles.



Note: Stimulation of the sacral anterior motor nerve roots must be distinguished from stimulation of the sacral sensory nerve. Stimulation of the sacral sensory nerve, indicated as a treatment of incontinence and urinary retention in patients without spinal cord injury, is considered separately in Blue Shield Medical Policy: Sacral Nerve Neuromodulation/Stimulation.

Implantation of a sacral anterior root stimulator is typically performed in conjunction with a simultaneous posterior rhizotomy. The rhizotomy results in an areflexive bladder with low intravesicular pressure and high compliance. When the patient activates the implanted stimulator, the urethral sphincter and bladder contract and relax, allowing the bladder to empty on demand with low residual urine volumes.

While sacral anterior root stimulation has been widely used in Europe for many years, only one implantable device, the Vocare® Bladder System/FineTech Brindley Bladder Control System (FineTech Medical Ltd., England), has received approval by the FDA for stimulation of the sacral anterior nerve root. The FDA-labeled indication, approved in 1999, is as follows:

The Neurocontrol VOCARE Bladder System is indicated for the treatment of patients who have clinically complete spinal cord lesions with intact parasympathetic innervation of the bladder and are skeletally mature and neurologically stable, to provide urination on demand and to reduce post-void residual volumes of urine.

The VOCARE Bladder System is contraindicated for patients with the following characteristics:

- Poor or inadequate bladder reflexes
- Active or recurrent pressure ulcers
- Active sepsis
- Implanted cardiac pacemaker

The use of the VOCARE Bladder System consists of the following implantable external and surgical components:

- Implanted components consist of the implantable receiver-stimulator, which is implanted subcutaneously. The receiver-stimulator is attached to extradural electrodes that are attached to the sacral anterior nerve roots.
- External components consist principally of an external, battery-powered controller and transmitter. The external controller generates and delivers a sequence of electrical pulses that are emitted as electromagnetic fields from the transmitter. The transmitter is placed on the skin over the subcutaneously implanted receiver-stimulator.
- The surgical components include a variety of surgical tools to assist in the identification of the appropriate nerve roots for posterior rhizotomy and the optimal placement of the implanted extradural electrodes.
- Posterior rhizotomy requires an S1-S3 laminectomy. The extradural electrodes are implanted during the same procedure.

Extensive pre- and postoperative urodynamic testing is an associated part of the overall procedure.

The Vocare Bladder System received FDA approval under a Humanitarian Device Exemption (HDE). This category of FDA approval is applicable to those devices intended to treat a population of less than 4,000 individuals. An HDE does not require clinical data validating the effectiveness of the device, but rather only data validating its safety and an assessment that the probable benefit exceeds the risks.

There are varying degrees of neurological impairment in spinal cord injury depending on the location and severity of the injury. The American Spinal Injury Association (ASIA) Impairment Scale is a system used to classify or describe the extent of spinal cord injuries:

- Complete: No motor or sensory function is preserved in the sacral segments S4-S5.
- Incomplete: Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.
- Incomplete: Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.
- Incomplete: Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.
- Normal: Motor and sensory function are normal.

Supra-sacral spinal cord injury may result in neurogenic bladder, characterized in part by frequent urinary tract infections from inadequate bladder emptying. The high bladder pressures related to large post-void residuals can lead to autonomic dysreflexia, vesicoureteral reflux, upper urinary tract dilations, hydronephrosis, and eventual renal failure.

Implantable stimulation of sacral anterior nerve roots in association with posterior rhizotomy has been widely used in Europe for several decades. Case series of over 500 patients have been reported (Brindley, 1994). The FDA approval of the Vocare Bladder System was based on a trial of 23 patients who underwent implantation of the device in association with posterior rhizotomy and were followed up for a minimum of 3 months (Creasey, 2001). Comparisons were made with the device turned either on or off; thus patients served as their own controls. The principal outcome measures were improvement in bladder emptying as evidenced by the ability to urinate more than 200 mL on demand with post-void residuals less than 50 mL. Secondary endpoints include reduction in the use of urinary catheters, number and severity of episodes of urinary incontinence, reduction in incidence of urinary tract infections, and results of a user satisfaction survey. After three months, 90% of the patients were able to void greater than 200 mL on demand and 81% had a post-void residual less than 50 mL. A total of 73% of patients reported fewer urinary tract infections, and at 6 months, about one half of the patients were using the stimulator exclusively for micturition; no external devices, such as catheters, were needed.

A study by Creasey et al. (2001) suggested that use of a neuroprosthesis greatly reduced the cost of managing a neurogenic bladder. Their results showed that at one year follow-up, 18 of 21 patients could urinate more than 200mL with the neuroprosthesis, and 15 of 21 had post-void volumes less than 50mL (median, 15mL). Urinary tract infection, catheter use, reflex incontinence, anticholinergic drug use, and autonomic dysreflexia were substantially reduced.

The results reported in this small clinical trial are consistent with those reported in larger case series (Creasey et al., 2001). For example, Van Kerrebroeck and colleagues (1996) reported on



the outcomes of 47 patients who were followed up for a minimum of 6 months. Complete continence was reported in 43 of the 47 patients, and 41 of the 47 patients used only the stimulator for bladder emptying. The residual urine volume also decreased to less than 50 mL in 41 patients. The incidence of urinary tract infections also decreased. Egon and colleagues (1998) reported on a case series of 93 patients. A total of 83 of the 93 patients used their implants for micturition with residual volumes less than 50 mL.

A small study of 12 patients has also suggested that use of a neuroprosthesis greatly reduces the cost of managing a neurogenic bladder (Creasey & Dahlberg, 2001).

In another study by Vignes et al. (2007) showed that 90 percent of their patients gained satisfactory continence and no longer required an incontinence appliance. Bladder capacity and compliance increased dramatically. As a consequence, urinary infection rate decreased. The majority of patients remained dry, and more than 80% had a complete voiding or a post-void residue of less than 50ml and did not require any catheterization. Anterior sacral root stimulation combined with sacral posterior rhizotomy is a valuable method to restore bladder function in spinal cord-injured patients suffering from hyperactive bladder.

In a Cochrane Review (Herbison & Arnold, 2009) anterior sacral root stimulation was briefly described and the authors stated: "These devices have demonstrated efficacy so that it is unlikely that randomized trials will be undertaken (Brindley, 1994; Creasey, 1993; Van Kerrebroeck, 1993)."

## Benefit Application

Exercise equipment is not a covered benefit as listed under General Exclusions and Limitations. Please refer to the member's Evidence of Coverage.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

*This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.*

Type	Number	Description
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Type	Number	Description
CPT	63650	Percutaneous implantation of neurostimulator electrode array, epidural
	63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
	63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
	63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
	63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
	63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64565	Percutaneous implantation of neurostimulator electrode array; neuromuscular
	64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64580	Incision for implantation of neurostimulator electrode array; neuromuscular
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
	64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

Type	Number	Description
	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
	95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
	95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (Li
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
<b>HCPC</b>	<b>C1767</b>	Generator, neurostimulator (implantable), non-rechargeable

Type	Number	Description
	C1778	Lead, neurostimulator (implantable)
	C1787	Patient programmer, neurostimulator
	C1816	Receiver and/or transmitter, neurostimulator (implantable)
	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1897	Lead, neurostimulator test kit (implantable)
	E0720	Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation
	E0730	Transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation
	E0731	Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)
	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
	E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

Type	Number	Description
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
	L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only
	L8696	Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each
<b>ICD9 Procedure</b>	03.93	Implantation or replacement of spinal neurostimulator lead(s)
	04.92	Implantation or replacement of peripheral neurostimulator lead(s)
	34.85	Implantation of diaphragmatic pacemaker
	86.94	Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable
	86.95	Insertion or replacement of multiple array neurostimulator pulse generator, not specified as rechargeable
	86.96	Insertion or replacement of other neurostimulator pulse generator
	86.97	Insertion or replacement of single array rechargeable neurostimulator pulse generator
	86.98	Insertion or replacement of multiple array (two or more) rechargeable neurostimulator pulse generator
<b>ICD9 Diagnosis</b>	All Diagnoses	
<b>Place of Service</b>	All Places of Service	

## Tables

N/A

## Definitions

**Atrophy:** A continuous decline of a body part or tissue, usually a muscle, following a period of disuse or immobility.

**Cerebral palsy:** A group of conditions, caused by brain damage before birth or during infancy, characterized by impairment of muscular coordination with symptoms such as spasticity, paralysis, or seizures.

**Congenital Central Hypoventilation Syndrome (CCHS):** Congenital central hypoventilation syndrome (CCHS) is a rare neurological disorder present at birth that is characterized by inadequate breathing during sleep and, in more severely affected individuals, also during waking periods. This disorder is associated with a malfunction of the nerves that control involuntary body functions, such as breathing.

**Hemiplegia:** An impairment in motor and/or sensory function affecting one-half of the body, an arm and a leg. People with hemiplegia are the most likely to walk.

**Nerve root:** The start of the nerve as it leaves the spinal cord.

**Neurogenic bladder:** A loss of normal bladder function caused by nervous system impairments (spinal cord injury or cerebral palsy). The bladder may be underactive (unable to empty well) or overactive and spastic (emptying by uncontrolled reflexes).

**Paraplegia:** An impairment in motor and/or sensory function of the lower limbs. It is usually the result of spinal cord injury or a congenital condition such as spina bifida which affects the neural elements of the spinal canal.

**Percutaneous:** Through the skin.

**Quadriplegia:** A permanent paralysis of the trunk, lower and upper limbs. It is caused by injury or disease affecting the spinal cord at the neck.

**Rhizotomy:** A surgical procedure in which spinal nerve roots are cut; done to relieve intractable pain (anterior roots) or to stop severe spasms (posterior roots).

**Spasticity:** An increase in muscle tone (tension) that occurs following injury to the brain or spinal cord, causing the muscles to be continuously contracted. This contraction causes stiffness or tightness of the muscles and may interfere with gait, movement, and speech, and swallowing.

**Transcutaneous:** Across the skin.

## Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

- Urinary Incontinence Outpatient Treatment
- Sacral Nerve Neuromodulation/Stimulation
- Electrical Stimulation for Pain and Other Conditions



- Spinal Cord Stimulation
- Gastric Electrical Stimulation
- Deep Brain Stimulation

## Key / Related Searchable Words

N/A

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## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
4/3/2009	<p>New Policy Adoption Developed new policy: NMES for disuse atrophy</p> <p>Revised: Electrical/Electromagnetic Stimulation for the Treatment of Arthritis</p> <p>Adopted BCBSA:</p> <ul style="list-style-type: none"> <li>• Threshold Electrical Stimulation as a Treatment of Motor Disorders</li> <li>• Stimulation of the Sacral Anterior Root Combined with posterior</li> <li>• Sacral Rhizotomy in Patients with Spinal Cord Injury</li> </ul> <p>Functional Neuromuscular Stimulation to Provide Ambulation</p>	Medical Policy Committee
11/4/2009	Coding Update	Administrative Review
2/8/2010	Coding Update	Administrative Review
10/29/2010	Coding Update	Administrative Review
7/8/2013	Policy revision with position change	Medical Policy Committee
1/30/2015	Coding update	Administrative Review

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on

individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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