Functional Neuromuscular Electrical Stimulation

Policy Number: 8.03.01  Last Review: 4/2020

Blue KC has developed medical policies that serve as one of the sets of guidelines for coverage decisions. Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the medical policies. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and/or federal law. Medical policy does not constitute plan authorization, nor is it an explanation of benefits.

When reviewing for a Medicare beneficiary, guidance from National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) supersede the Medical Policies of Blue KC. Blue KC Medical Policies are used in the absence of guidance from an NCD or LCD.

**Policy**

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for functional neuromuscular stimulation. This is considered investigational.

Neuromuscular stimulation is excluded in contracts that contain an exclusion for electrical stimulation. Verify benefits to determine whether this is a benefit exclusion or investigational.

**When Policy Topic is covered**

Not Applicable

**When Policy Topic is not covered**

Neuromuscular (electrical) stimulation is considered **investigational** as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations:

- As a technique to provide ambulation in patients with spinal cord injury; or
- To provide upper extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke); or
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).

Neuromuscular electrical stimulation (NMES) is considered investigational for all other indications, including rehabilitating leg muscles after anterior cruciate ligament surgery, strengthening leg muscles after hip fracture or hip replacement surgery, strengthening muscles of the arm after spinal cord injury, improving motor function in patients with cerebral palsy, and providing exercise for patients with severe physical limitations due to chronic osteoarthritis, obstructive pulmonary disease or chronic heart failure.

**Considerations**

Claims or prior authorization requests may come in under the product trade name of Parastep® or a device called a reciprocating gait orthosis (RGO) with electrical stimulation.

This policy does not refer to commercially available exercycles that use electrical muscle stimulation technology as a means of physical therapy and exercise for spinal cord injury patients. These exercycles are sometimes called functional neuromuscular exercisers. The goals for using these devices may be to promote cardiovascular conditioning, prevent muscle atrophy, and/or maintain bone mass. The patient’s legs are wrapped in fabric strips that contain electrodes to stimulate the muscles, thus permitting the patient to pedal. Plans may wish to review their policies on durable medical equipment and physical therapy services when reviewing electrical muscle stimulation exercycles. Some might consider this a physical therapy modality.

**Description of Procedure or Service**

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
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<tr>
<td><strong>Individuals:</strong></td>
<td><strong>Interventions of interest are:</strong></td>
<td><strong>Comparators of interest are:</strong></td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With loss of hand and</td>
<td>- Functional electrical stimulation</td>
<td>- Standard of care</td>
<td>- Functional outcomes</td>
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<tr>
<td>upper-extremity function due to</td>
<td></td>
<td></td>
<td>- Quality of life</td>
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<tr>
<td>spinal cord injury or stroke</td>
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<tr>
<td><strong>Individuals:</strong></td>
<td><strong>Interventions of interest are:</strong></td>
<td><strong>Comparators of interest are:</strong></td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With chronic footdrop</td>
<td>- Functional electrical stimulation</td>
<td>- Standard of care</td>
<td>- Functional outcomes</td>
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<tr>
<td><strong>Individuals:</strong></td>
<td><strong>Interventions of interest are:</strong></td>
<td><strong>Comparators of interest are:</strong></td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With spinal cord injury at</td>
<td>- Functional electrical stimulation</td>
<td>- Standard of care</td>
<td>- Functional outcomes</td>
</tr>
<tr>
<td>segments T4 to T12</td>
<td></td>
<td></td>
<td>- Quality of life</td>
</tr>
<tr>
<td><strong>Individuals:</strong></td>
<td><strong>Interventions of interest are:</strong></td>
<td><strong>Comparators of interest are:</strong></td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With spinal cord injury</td>
<td>- Functional electrical stimulation exercise</td>
<td>- Standard of care</td>
<td>- Symptoms</td>
</tr>
<tr>
<td>equipment</td>
<td>equipment</td>
<td></td>
<td>Functional outcomes</td>
</tr>
<tr>
<td><strong>Individuals:</strong></td>
<td><strong>Interventions of interest are:</strong></td>
<td><strong>Comparators of interest are:</strong></td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>With spinal cord injury</td>
<td>- Functional electrical stimulation exercise</td>
<td>- Standard of care</td>
<td>- Symptoms</td>
</tr>
<tr>
<td>equipment</td>
<td>equipment</td>
<td></td>
<td>Functional outcomes</td>
</tr>
</tbody>
</table>
Functional electrical stimulation (FES) involves the use of an orthotic device or exercise equipment with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in patients with damaged or destroyed nerve pathways (eg, spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy).

For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive FES, the evidence includes case series. The relevant outcomes are functional outcomes and quality of life (QOL). Evidence on FES for the upper limb in patients with SCI or stroke includes a few small case series. Interpretation of the evidence is limited by the low number of patients studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve the QOL. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic footdrop who receive FES, the evidence includes randomized controlled trials and a systematic review. The relevant outcomes are functional outcomes and QOL. For chronic poststroke footdrop, two randomized controlled trials comparing FES with a standard ankle-foot orthosis showed improved patient satisfaction with FES but no significant differences between groups in objective measures like walking. A randomized controlled trial with 53 subjects examining neuromuscular stimulation for footdrop in patients with multiple sclerosis showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes a systematic review of small studies with within-subject designs. Further study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. No controlled trials were identified on FES for standing and walking in patients with SCI. However, case series are considered adequate for this condition, because there is no chance for unaided ambulation in this population with SCI at this level. Some studies have reported improvements in intermediate outcomes, but improvements in health outcomes (eg, ability to perform activities of daily living, QOL) have not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective within-subject comparisons. The relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on FES exercise
equipment consists primarily of within-subject, pre- to post-treatment comparisons. Evidence was identified on 2 commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is a limited amount of evidence on the RT300 series. None of the studies showed an improvement in health benefits and 1 analysis of use for 314 individuals over 20000 activity sessions with a Restorative Therapeutics device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of six days per week, but caloric expenditure remained low. Compliance was shown in one study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function. A limitation of these studies is that they all appear to have been conducted in supervised in research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

Background
Functional electrical stimulation
FES is an approach to rehabilitation that applies low-level electrical current to stimulate functional movements in muscles affected by nerve damage. It focuses on the restoration of useful movements, like standing, stepping, pedaling for exercise, reaching, or grasping.

FES 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, cycle, or grasp. Functional neuromuscular stimulators are closed-loop systems that provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities (eg, walking). These systems are contrasted with open-loop systems, which are used for simple tasks (eg, muscle strengthening alone); healthy individuals with intact neural control benefit the most from this technology.

Applications, described in more detail in the Rationale section, include upper-extremity grasping function after spinal cord injury and stroke, lifting the front of the foot during ambulation in individuals with footdrop, ambulation and exercise for patients with spinal cord injury. Some devices are used primarily for rehabilitation rather than home use. This evidence review focuses on devices intended for home use.

Regulatory Status
A variety of FES devices have been cleared by the U.S. Food and Drug Administration (FDA) and are available for home use. Table 1 provides examples
of devices designed to improve hand and foot function as well as cycle ergometers for home exercise. The date of the FDA clearance is for the first 510(k) clearance identified for a marketed device. Many devices have additional FDA clearances as the technology evolved, each in turn listing the most recent device as the predicate.

Table 1. Functional Electrical Stimulation Devices Cleared by the FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Device Type</th>
<th>Clearance</th>
<th>Date</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freehand®</td>
<td>No longer manufactured</td>
<td>Hand stimulator</td>
<td></td>
<td>1997</td>
<td></td>
</tr>
<tr>
<td>NESS H200® (previously Handmaster)</td>
<td>Bioness</td>
<td>Hand stimulator</td>
<td>K022776</td>
<td>2001</td>
<td>GZC</td>
</tr>
<tr>
<td>MyndMove System</td>
<td>MyndTec</td>
<td>Hand stimulator</td>
<td>K170564</td>
<td>2017</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>ReGrasp</td>
<td>Rehabtronics</td>
<td>Hand stimulator</td>
<td>K153163</td>
<td>2016</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>WalkAide® System</td>
<td>Innovative Neurotronics (formerly NeuroMotion)</td>
<td>Foot drop stimulator</td>
<td>K052329</td>
<td>2005</td>
<td>GZI</td>
</tr>
<tr>
<td>ODFS® (Odstock Dropped Foot Stimulator)</td>
<td>Odstock Medical</td>
<td>Foot drop stimulator</td>
<td>K050991</td>
<td>2005</td>
<td>GZI</td>
</tr>
<tr>
<td>ODFS® Pace XL</td>
<td>Odstock Medical</td>
<td>Foot drop stimulator</td>
<td>K171396</td>
<td>2018</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>L300 Go</td>
<td>Bioness</td>
<td>Foot drop stimulator</td>
<td>K190285</td>
<td>2019</td>
<td>GZI/IPF</td>
</tr>
<tr>
<td>Foot Drop System</td>
<td>SHENZHEN XFT Medical</td>
<td>Foot drop stimulator</td>
<td>K162718</td>
<td>2017</td>
<td>GZI</td>
</tr>
<tr>
<td>MyGait® Stimulation System</td>
<td>Otto Bock HealthCare Medical</td>
<td>Foot drop stimulator</td>
<td>K141812</td>
<td>2015</td>
<td>GZI</td>
</tr>
<tr>
<td>ERGYS (TTI Rehabilitation Gym)</td>
<td>Therapeutic Alliances</td>
<td>Leg cycle ergometer</td>
<td>K841112</td>
<td>1984</td>
<td>IPF</td>
</tr>
<tr>
<td>RT300</td>
<td>Restorative Therapies, Inc (RTI)</td>
<td>Cycle ergometer</td>
<td>K050036</td>
<td>2005</td>
<td>GZI</td>
</tr>
<tr>
<td>Myocycle Home</td>
<td>Myolyn</td>
<td>Cycle ergometer</td>
<td>K170132</td>
<td>2017</td>
<td>GZI</td>
</tr>
<tr>
<td>StimMaster Orion</td>
<td>Electrologic (no longer in business)</td>
<td>Cycle ergometer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration.

To date, the Parastep® Ambulation System (Sigmedics, Northfield, IL) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep® device is approved to “enable appropriately selected skeletally mature spinal cord injured patients (level C6-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.”\(^4\) FDA product code: MKD.

**Rationale**

This evidence review was created in March 1996 and has been updated regularly using searches of the MEDLINE database. The most recent literature update was performed through March 8, 2019.
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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

**Upper-Extremity Function After Spinal Cord Injury and Stroke**

**Clinical Context and Therapy Purpose**

One application of functional electrical stimulation (FES) 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 question addressed in this evidence review is: Does FES for the upper-extremity improve health outcomes?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population(s) of interest are patients with SCI or stroke with chronic upper-extremity paresis.

**Interventions**

The therapy being considered is FES. NeuroControl Corp. developed the Freehand System, an implantable upper-extremity neuroprosthesis, to improve the ability to grasp, hold, and release objects for patients with tetraplegia due to C5 or C6 SCI. NeuroControl is no longer in business, but FES centers in the U. S. and United Kingdom provide maintenance for implanted devices.
The NESS H200 (previously known as the Handmaster NMS I system) is an upper-extremity device that uses a forearm splint and surface electrodes. The device, controlled by a user-activated button, is intended to provide hand function (fine finger grasping, larger palmar grasping) for patients with C5 tetraplegia or stroke.

Other hand stimulators that have been cleared for marketing in the U.S. are:

- ReGrasp by Rehabtronics
- MyndMove by MyndTec. This device is currently being studied in a clinical trial for rehabilitation.

Comparators
The following practices are currently being used to make decisions about FES for upper-extremity paresis: function without FES.

Outcomes
The general outcomes of interest include the ability to grasp, hold, and lift objects, along with other selected activities of daily living (ADL).

Study Selection Criteria
RCTs are reviewed when available. In the absence of RCTs, the evidence reviewed might include non-randomized comparative studies and prospective within-subject baseline to post-treatment study designs.

Review of Evidence

FreeHand System
Much of the early published evidence assessing upper-extremity devices to restore function in patients with SCIs reported on experience with the Freehand System, an implantable device no longer marketed in the U. S.\(^2\,^3\,^4\,^5\).

Handmaster
Studies with the first version of the NESS H200 (Handmaster), were reported in patients with upper-extremity paresis following stroke and SCI (see Tables 2 and 3).

Alon et al (2003) evaluated the Handmaster device in 7 subjects with C5 or C6 SCI who practiced using the device daily in an effort to regain the ability to grasp, hold, and release objects.\(^6\) All patients were observed two to three times during the week for three weeks, and they were evaluated on their ability to perform the following tasks: pick up a telephone, eat food with a fork, perform an individually selected ADL task, and perform two tasks relating to grasping, holding, and releasing certain items. At the end of the study, all seven subjects successfully used the device for each required task. Improvements occurred in secondary measures of grip strength, finger linear motion, and Fugl-Meyer Assessment scores (the instrument assesses sensorimotor recovery after stroke).
Alon et al (2002), reporting on a case series of 29 patients, investigated whether the Handmaster system could improve select hand function in persons with chronic upper-extremity paresis following stroke. The main outcome measures were three ADL tasks: lifting a two-handled pot, holding a bag while standing with a cane, and another ADL chosen by the patient. At the end of the 3-week study period, the percentage of successful trials compared with baseline were: lifting pot, 93% vs 0%, lifting 600-gram weight, 100% vs 14%; and lifting bag, 93% vs 17%. All subjects performed their selected ADLs successfully and improved their Fugl-Meyer Assessment scores using the neuroprosthesis.

Use of the Handmaster NMS I, another upper-extremity device, was reported by Snoek et al (2000) for a series of 10 patients with cervical SCIs. After two 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 with but not without the Handmaster.

**Table 2. Key Case Series Characteristics**

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Treatment</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alon et al (2003)</td>
<td>7 patients with C5 or C6 SCI</td>
<td>Handmaster NMS</td>
<td>3 weeks of training</td>
</tr>
<tr>
<td>Alon et al (2002)</td>
<td>29 patients with chronic upper-extremity paresis following stroke</td>
<td>Handmaster NMS</td>
<td>3 weeks of training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 months of training</td>
</tr>
</tbody>
</table>

SCI: spinal cord injury

**Table 3. Key Case Series Results**

<table>
<thead>
<tr>
<th>Study</th>
<th>ADL</th>
<th>Pre-Training</th>
<th>Post-Training</th>
<th>Post-Training</th>
</tr>
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<tbody>
<tr>
<td>Alon et al (2003)</td>
<td>Pick up a telephone</td>
<td>0%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Eat with a fork</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Individually selected ADL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alon et al (2002)</td>
<td>Lifting Pot</td>
<td>0%</td>
<td>93%</td>
<td>93%</td>
</tr>
<tr>
<td></td>
<td>Lifting 600-gram weight</td>
<td></td>
<td>14%</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td>Lifting bag</td>
<td></td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Snoek et al (2000)</td>
<td>Grasp and Release</td>
<td>20%</td>
<td>60%</td>
<td></td>
</tr>
</tbody>
</table>

ADL: activities of daily living.

**Section Summary: FES of the Upper Limb**

The evidence on FES for the upper limb in patients with SCI or stroke includes a limited number of small case series. Interpretation of the evidence for upper-extremity neuroprostheses for these populations is limited by the small number of patients studied and lack of data demonstrating its utility outside the investigational (study) setting.
FES for Chronic Footdrop

Clinical Context and Therapy Purpose
Other FES devices have been developed to provide FES for patients with footdrop. Footdrop is weakness of the foot and ankle that causes reduced dorsiflexion and difficulty with ambulation. It can have various causes such as cerebral palsy, stroke, or multiple sclerosis (MS). FES of the peroneal nerve has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation.

The question addressed in this evidence review is: Does FES improve the net health outcome in patients with footdrop.

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are patients with footdrop due to stroke, MS, or cerebral palsy.

Interventions
The therapy being considered is FES.

With these devices, a pressure sensor detects heel-off and initial contact during walking. A signal is then sent to the stimulation cuff, initiating or pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of such devices used for treatment of footdrop are:

- WalkAide by Innovative Neurotronics (formerly NeuroMotion),
- L300 Go by Bioness
- MyGait by Otto Bock
- OFDS (Odstock Foot Drop Stimulator) and ODFS Pace XL by Odstock.

An implantable peroneal nerve stimulator system (ActiGait®) is being developed by Otto Bock in Europe.

Comparators
The following therapies are currently being used to make decisions about foot drop: foot/ankle orthoses.

Outcomes
Ability to walk is the primary outcome of interest. There are established measures of walking, mobility and QOL. These include:

- 10-meter walk test (10MWT)- Assesses the time it takes to walk 10 meters
- 6-minute walk test (6MWT)- assesses the distance walked in 6 minutes
- Timed up-and-go - assesses the time required to get up from a chair and take a step
• Stroke Impact Scale

**Study Selection Criteria**
RCTs are reviewed when available. In the absence of RCTs, the evidence reviewed includes non-randomized comparative studies and prospective within-subject pre-to post-treatment study designs.

**Review of Evidence**

**Stroke**

Two multicenter RCTs were identified on FES for dropped foot (see Tables 4 and 5).

FES with a dropped foot stimulator (WalkAide) was compared with an ankle-foot orthosis (AFO) in a 2014 industry-sponsored multicenter non-inferiority trial (NCT01087957) that included 495 Medicare-eligible individuals who were at least 6 months poststroke. A total of 399 individuals completed the 6-month study. Primary outcome measures were the 10MWT, a composite measure of daily function, and device-related serious adverse events. Seven secondary outcome measures assessed function and QOL. The intention-to-treat analysis found that both groups improved walking performance over the six months, and the FES device was found noninferior to the AFO for the primary outcome measures. Only the WalkAide group showed significant improvements from baseline to six months on several secondary outcome measures, but there were no statistically significant between-group differences for any outcome.

The Functional Ambulation: Standard Treatment vs Electronic Stimulation Therapy Trial (FASTEST; NCT01138995) was a 2013 industry-sponsored, single-blinded, multicenter trial that randomized 197 stroke patients to 30 weeks of a dropped foot stimulator (NESS L300) or a conventional AFO. The AFO group received transcutaneous electrical nerve stimulation at each physical therapy visit during the first 2 weeks to provide a sensory control for stimulation of the peroneal nerve received by the NESS L300 group. Evaluation by physical therapists blinded to group assignment found that both groups improved gait speed and other secondary outcome measures over time, with a similar improvement in the two groups. There were no between-group differences in the number of steps per day at home, which was measured by an activity monitor over a week. User satisfaction was higher with the footdrop stimulator.

Secondary analysis of data from this study was reported by O’Dell et al (2014). Comfortable gait speed was assessed in the 99 individuals from the NESS L300 group at 6, 12, 30, 36, and 42 weeks, with and without the use of the footdrop stimulator. A responder was defined as one achieving a minimal clinically important difference of 0.1 m/s on the 10MWT or advancing by at least one Perry Ambulation Category (which measures functional walking ability in the home or community). Noncompleters were classified as nonresponders. Seventy percent of participants completed the assessments at 42 weeks, and 67% of participants were classified as responders. Of the 32 participants classified as
nonresponders, 2 were nonresponders, and 30 were noncompleters. The percentage of patients in the conventional AFO group classified as responders at 30 weeks was not reported. There were 160 adverse events, of which 92% were classified as mild. Fifty percent of the adverse events were related to reversible skin issues, and 27% were falls.

### Table 4. Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bethoux et al (2014)</td>
<td>US</td>
<td>29</td>
<td>2010-2013</td>
<td>495 Medicare-eligible individuals who were at least 6 months poststroke</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 months with WalkAide</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6 months with conventional AFO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30 weeks of NESS L300</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30 weeks with conventional AFO</td>
<td></td>
</tr>
</tbody>
</table>

AFO: Ankle-Foot orthosis; RCT: randomized controlled trial.

### Table 5. Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Improvement in 10MWT (m/s)</th>
<th>Daily Function</th>
<th>Improvement in 6MWT (m)</th>
<th>Functional Mobility</th>
<th>Device safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bethoux et al (2014)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=399</td>
<td>0.186</td>
<td>5.0</td>
<td>33.1</td>
<td>2.2</td>
<td>0</td>
</tr>
<tr>
<td>WalkAide</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFO</td>
<td>0.195</td>
<td>3.9</td>
<td>18.0</td>
<td>1.5</td>
<td>2</td>
</tr>
<tr>
<td>p-Value Non-inferiority</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>0.17</td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Kluding et al (2013)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in SIS mobility score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>L300</td>
<td>0.14±0.16</td>
<td>7.06±13.79</td>
<td>40.9±62.1</td>
<td>−5.93 (13.06)</td>
<td></td>
</tr>
<tr>
<td>AFO</td>
<td>0.15±0.14</td>
<td>5.83±13.26</td>
<td>48.6±51.1</td>
<td>−4.38 (21.37)</td>
<td></td>
</tr>
<tr>
<td>p-Value</td>
<td>0.75</td>
<td>0.52</td>
<td>0.34</td>
<td>0.54</td>
<td></td>
</tr>
</tbody>
</table>

6MWT: 6-minute walk test; 10MWT: 10-meter walk test; AFO: Ankle-foot orthosis; RCT: randomized controlled trial; SIS: stroke impact scale; TUG: timed up-an-go.

Limitations in study design and conduct are shown in Table 6. The primary limitation for both studies was unequal loss to follow-up, with higher loss to follow-up in the FES group. Inability to tolerate the electrical stimulation has been noted in some studies.

### Table 6. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bethoux et al (2014)</td>
<td></td>
<td></td>
<td></td>
<td>1. 19% loss to follow-up with a higher loss to follow-up in the Walk-Aide</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Kluding et al (2013) [11] discontinued the study due to 18% loss to follow-up with a higher loss to follow-up in the L300 group.

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- **Allocation key:** 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
- **Blinding key:** 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
- **Selective Reporting key:** 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- **Data Completeness key:** 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
- **Power key:** 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
- **Statistical key:** 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**Multiple Sclerosis**

Two publications from one RCT were identified on use of a dropped foot stimulator in patients with MS (see Tables 7 and 8). Barrett et al (2009) assessed FES to improve walking performance in patients with MS [12]. Fifty-three patients with secondary progressive MS and unilateral dropped foot were randomized to an 18-week program of an Odstock Dropped Foot Stimulator device or a home exercise program. 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 two 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. Six patients in the FES group and 3 in the exercise group dropped out, leaving 20 in the FES group and 24 in the exercise group. The primary outcome measure was the 10MWT. At 18 weeks, the exercise group walked significantly faster than the FES group (p=0.028). A 2010 publication by the same investigators reported on the impact of the treatment on ADL [13]. Results of 53 patients from the trial previously described were reported, using the Canadian Occupational Performance Measure. The Canadian Occupational Performance Measure is a validated semi-structured interview (higher scores indicate improvement) originally designed to assist 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 FES group (35% of the identified problems increased by a score of ³2) than in the exercise group (17% of problems increased by a score of ³2). The median satisfaction rating improved from 2.2 to 4.0 in the FES group and remained stable (2.6 to 2.4) in the exercise group. The median number of falls recorded per patient over the 18-week study was 5 in the FES group and 18 in the exercise group. About 70% of the falls occurred while not using the FES device or an AFO.
Table 7. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study; Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrett et al (2009)</td>
<td>EU</td>
<td>1</td>
<td>53 patients with unilateral dropped foot</td>
<td>18 weeks of ODFS Twice daily exercises that were tailored to the patient</td>
</tr>
<tr>
<td>Esnouf et al (2010)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ODFS; Odstock dropped foot stimulator; RCT: randomized controlled trial.

Table 8. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Improvement in 10MWT (m/s) (sd)</th>
<th>Daily Function</th>
<th>Improvement in 6MWT (m/SD)</th>
<th>Functional Mobility</th>
<th>Device safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrett et al (2009)</td>
<td>N=44</td>
<td>Physiologic Cost Index</td>
<td>124 (8.5)</td>
<td>35%</td>
<td>Falls</td>
</tr>
<tr>
<td>Esnouf et al (2010)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FES</td>
<td>0.74 (0.026)</td>
<td>0.69 (0.041)</td>
<td>124 (8.5)</td>
<td>35%</td>
<td>Falls</td>
</tr>
<tr>
<td>Exercise</td>
<td>0.82 (0.024)</td>
<td>0.70 (0.037)</td>
<td>112 (7.9)</td>
<td>17%</td>
<td>18</td>
</tr>
<tr>
<td>p-Value</td>
<td>0.028</td>
<td>0.81</td>
<td>0.334</td>
<td>&lt;0.05</td>
<td>0.036</td>
</tr>
</tbody>
</table>

3MWT: 3-minute walk test; 6MWT: 6-minute walk test; 10MWT: 10-meter walk test; FES: functional electrical stimulation; sd: standard deviation; RCT: randomized controlled trial.

Limitations in relevance and design and conduct are denoted in Tables 9 and 10. In Barrett et al (2009), power calculations were based on the 10MWT measure only and indicated that 25 subjects would be required in each group, patients were highly selected, clinical assessors also provided treatment (compromising blinding), and the validity and reliability of the 3-minute walk test have not been confirmed (fatigue prevented use of the validated 6MWT). In addition, subjects in the exercise group were told they would receive a stimulator at the end of the trial, which may have biased exercise adherence and retention in the trial.

Table 9. Limitations in Relevance

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrett et al (2009)</td>
<td>4. Patients were highly selected</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esnouf et al (2010)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
Table 10. Limitations in Study Design and Conduct

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Data Completeness</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrett et al (2009)12,</td>
<td>1-3</td>
<td>2,3</td>
<td>was</td>
<td>6. Not intent to treat analysis</td>
<td>2. Loss to follow-up resulted in insufficient power</td>
<td></td>
</tr>
<tr>
<td>Esnouf et al (2010)13</td>
<td></td>
<td></td>
<td>assessed by the treating physician</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Cerebral Palsy

A systematic review was identified on use of a dropped foot stimulator for children with cerebral palsy (see Table 11).

Cauraugh et al (2010) conducted a systematic review and meta-analysis of 17 studies on FES and gait in children with cerebral palsy (see Table 11).14. Fourteen studies used a pretest-posttest that included a within-subjects design. A total of 238 participants had FES. Included were studies on acute FES, FES, and therapeutic FES (continuous subthreshold stimulation). Five studies examined FES, one of which examined percutaneous FES. Impairment was assessed by three outcome measures: range of motion, torque/movement, and strength/force. Activity limitations was assessed by six outcome measures: gross motor functions, gait parameters, hopping on one foot, 6MWT, Leg Ability Index, and Gillette Gait Index. Moderate effect sizes were found for impairment (0.616) and activity limitations (0.635). Studies selected for the review lacked blinding and were heterogeneous for outcome measures. Reviewers did not report whether any study used a commercially available device.

Table 11. Systematic Review Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cauraugh et al (2010)14</td>
<td></td>
<td>17</td>
<td>Children with cerebral palsy</td>
<td>238 treated with FES 224 no stimulation controls</td>
<td>Within subject pretest-posttest</td>
</tr>
</tbody>
</table>

FES: functional electrical stimulation
Section Summary: FES for Chronic Foot drop
For chronic post stroke footdrop, two RCTs comparing FES with a standard AFO showed improved patient satisfaction with FES but no significant differences between groups in objective measures like walking. An RCT with 53 subjects examining neuromuscular stimulation for footdrop in patients with MS showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be confirmed in a larger number of patients. The literature on FES in children with cerebral palsy includes a systematic review of small studies with within-subject designs. Further study in a larger number of subjects is needed to permit conclusions on the effect of the technology on health outcomes.

Ambulation in Patients With SCI
Clinical Context and Therapy Purpose
Another application of FES is to provide patients with SCI the ability to stand and walk. Using percutaneous stimulation, the device delivers trains of electrical pulses to trigger action potentials at selected nerves at the quadriceps (for knee extension), the common peroneal nerve (for hip flexion), and the paraspinals and gluteals (for trunk stability). Patients use a walker or elbow-support crutches for further support. The electric impulses are controlled by a computer microchip attached to the patient’s belt, which synchronizes and distributes the signals. In addition, there is a finger-controlled switch that permits patient activation of the stepping.

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

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

The question addressed in this evidence review is: Does FES improve the net health outcome?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are patients with SCI.

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

Interventions
The therapy being considered is FES for ambulation.

To date, the Parastep® Ambulation System (Sigmedics, Northfield, IL) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep® device is approved to “enable appropriately selected skeletally mature spinal cord injured patients (level C6-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.”1

Comparators
The following therapies are currently being used to make decisions about FES for ambulation: no walking.

Outcomes
The clinical impact of the Parastep device rests on the identification of clinically important outcomes. The primary purpose of this device is to provide a degree of ambulation that improves patient ability to complete the ADLs or positively affect the patient’s QOL. Physiologic outcomes (ie, conditioning, oxygen uptake) have also been reported, but they are intermediate, short-term outcomes.

Study Selection Criteria
RCTs are reviewed when available. In the absence of RCTs, the evidence reviewed includes non-randomized comparative studies and prospective within-subject baseline to post-treatment study designs

Review of Evidence
The evidence on FES for ambulation is shown in Table 12.

The largest study (Chaplin, 1996) reported on ambulation outcomes using the Parastep 1 and included 91 patients.15, Of these 91 patients, 84 (92%) were able to take steps, and 31 (34%) were able eventually to ambulate without assistance from another person. Duration of use was not reported. Other studies on the Parastep device include a series from the same group of investigators, which focused on different outcomes in the same group of 13 to 16 patients.16,17,18,19,20,21

Guest et al (1997) reported on the ambulation performance of 13 men and 3 women with thoracic motor complete spinal injury.19 The group’s mean peak distance walked was 334 meters, but individual studies varied widely. The mean peak duration of walking was 56 minutes, again with wide variability. Anthropomorphic measurements were taken at various anatomic locations. Increases in thigh and calf girth, thigh cross-sectional area, and calculated lean tissue were all statistically significant. The authors emphasized that the device was not intended as an alternative to a wheelchair, and thus other factors such as improved physical and mental well-being should be considered when deciding whether to use the system. The same point was noted in a review article by Graupe and Kohn (1998).21
Brissot et al (2000) found that 13 of 15 patients evaluated in a case series achieved independent ambulation.²² Five of the 13 patients continued using the device for physical fitness at home, but none used it for ambulation. Sykes et al (1996) found low use of a reciprocating gait orthosis device with or without stimulation over an 18-month period,²⁶ and Davis et al (2001) found mixed usability/preference scale results for ambulation, standing, and transfers with a surgically implanted neuroprosthesis in 12 patients followed for 12 months.²⁷ The effects of a surgically implanted neuroprosthesis on exercise, standing, transfers, and QOL were also reported in 2012.²⁸,²⁹ The device used in both studies was not commercially available at that time.

Several publications reported on physiologic responses to use of the Parastep device. Jacobs et al (1997) found a 25% increase in time to fatigue and a 15% increase in peak oxygen uptake, consistent with an exercise training effect.¹⁷ Needham-Shropshire et al (1997) reported no relation between use of the Parastep device and bone mineral density, although the interval between measurements (12 weeks) and the precision of the testing device might have limited the ability to detect a difference.¹⁸ Nash et al (1997) reported that use of the Parastep device was associated with an increase in arterial inflow volume to the common femoral artery, perhaps related to the overall conditioning response to the Parastep.²⁰

Table 12. Key Case Series

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Participants</th>
<th>Ambulation (%)</th>
<th>Distance walked</th>
<th>Physical Fitness</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaplin et al (1996)¹⁵</td>
<td>15 adults with SCI</td>
<td>31 (34%) could ambulate without assistance</td>
<td>84 (92%) could take some steps</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guest et al (1997)¹⁹</td>
<td>16 adults with SCI</td>
<td>334 meters</td>
<td>Improvements in the leg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brissot et al (2000)²²</td>
<td>15 adults with SCI</td>
<td>13 (87%) patients achieved independent ambulation</td>
<td>5 used the device for physical fitness</td>
<td>no patient used the device for ambulation at home</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SCI: spinal cord injury.

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

**FES Exercise Equipment**

**Clinical Context and Therapy Purpose**

The U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion recommend 2 days per week of muscle-strengthening for both healthy adults and adults with disabilities and at least 150 minutes to 300 minutes (5 hours) of moderate-intensity aerobic activity per week or 75 minutes to 150 minutes of vigorous aerobic activity. In patients with SCI, inactivity due to injury or barriers to exercise can lead to multiple degenerative changes that include muscle atrophy, bone mass loss and osteoporosis, and reduction in cardiopulmonary function. Other adverse effects of inactivity that are common with SCI include muscle spasms and weight gain, which may predispose individuals to metabolic syndrome, type 2 diabetes, and their associated health problems.

FES cycle ergometers are available in rehabilitation facilities. An ergometer is a device that measures work performed by exercising. When the term ergometer is used in the context of FES, it refers to exercise equipment that measures both position and speed, and stimulates muscles in a prescribed sequence to provide co-ordinated movement (e.g., cycling) of the paralyzed limb. The devices can provide increasing resistance as work capacity increases, and reduce stimulation when fatigue is detected (e.g., a speed of cycling below 35 rpm). Some models of FES cycle ergometers have been designed for home exercise in individuals with SCI, and are the focus of this evidence review.

The proposed benefit of FES exercise equipment is to counteract the health consequences of paralyzed limbs and include:

- Prevention of muscle atrophy
- Reduction of muscle spasms
- Improvement of circulation
- Improvement in range of motion
- Improvement in cardiopulmonary function
- Reduction in pressure sore frequency
- Improvements in bowel and bladder function
- Decreased incidence of urinary tract infections

Hunt et al (2012) conducted a systematic review of the efficiency of FES cycling. They recommended that future work address factors that limited cycling performance including the crude recruitment of muscle groups, non-optimal timing of muscle activation, lack of synergistic and antagonistic joint control, and non-physiologic recruitment of muscle fibers.

The question addressed in this evidence review is: Does FES improve the net health outcome? Three specific issues will be addressed:

- Are there demonstrated health benefits of FES cycle ergometers in patients with SCI?
- Do the different devices provide similar health benefits?
- What levels of compliance are needed to obtain a health benefit?
- The following PICOTS were used to select literature to inform this review.
  - Patients
  - The relevant population of interest are patients with lower extremity paresis.

**Interventions**
The therapy being considered is FES for home exercise.

The majority of home FES devices are cycle ergometers for the lower limbs of patients with lower extremity paresis, although some devices may also include upper arm exercise. All of the devices have evolved over the past three decades. Some have internet capability and can be programmed remotely.

- The REGYS and ERGYS series ergometers are manufactured by Therapeutic Alliances. These devices are the largest, include a computer console, and require transfer to an integrated seat. The ERGYS3 is a 4th generation device; earlier models continue to be utilized.
- There are several models of the RT300 by Restorative Therapies, Inc (RTI). The RT300-S includes both leg and arm cycles. This device is used with the patient's own wheelchair and does not require a transfer.
- The Myocycle Home by Myolyn is designed for home use and is the simplest of the cycle ergometers.
- The StimMaster Orion was manufactured by Electrologic. Electrologic ceased business operations in 2005

**Comparators**
The following therapy is currently being used to make decisions about cycle ergometers: standard care without home exercise equipment.

**Outcomes**
The general outcomes of interest are reduction in muscle atrophy and muscle spasms, reversal of bone mass loss, improvement in circulation and cardiopulmonary function, and QOL. These should be measured after at least three months of exercise in a home environment with self-directed activity, although supervised training protocols may provide useful information regarding the potential health benefits of cycle ergometers.

**Study Selection Criteria**
RCTs are reviewed when available. In the absence of RCTs, the evidence reviewed includes non-randomized comparative studies and prospective within-subject pre-to post-treatment study designs. Within-subject studies of at least ten individuals were considered for this review.

**Review of Evidence**
Three within-subject comparisons of health benefits of the RT300 are described in Table 13. Ralson et al (2013) reported on the acute effects (2 weeks) of the cycle ergometer and found no significant benefit on urine output, lower limb swelling,
and spasticity compared to standard rehabilitation.\textsuperscript{25} Dolbow et al (2013) reported an improvement in QOL on 2 of 4 domains.\textsuperscript{26} However, only 11 of the original 17 participants who remained in the study after the first 8 weeks were included in this report, and this detail was not reported in the second publication.\textsuperscript{27,26} It is notable that the incentive to remain in the study in the first eight weeks was strong, because the Veterans Affairs Medical Center purchased the devices for participants who met exercise requirements over the first eight weeks of device rental. In the third study, Johnston et al (2009) conducted an RCT to evaluate the health benefits of home FES cycling in children with a pediatric RT300.\textsuperscript{28} The three groups in this study were FES cycling, passive cycling, and electrical stimulation controls. There was no significant difference in health measures across the groups, although the FES group had a greater within subject improvement in one of four health measures. Compliance was supervised by parents, who filled out activity logs and had regular contact with study personnel. Because this study was conducted over a decade ago, it is uncertain if newer models of the RT300 would show greater health benefits.

Table 13. Summary of Studies on the RT300

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Participants</th>
<th>Treatment</th>
<th>Assessment</th>
<th>Training Duration</th>
<th>Outcome</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ralston et al (2013)\textsuperscript{25}</td>
<td>Prospective within subject comparison</td>
<td>14 individuals with recent SCI</td>
<td>2 week crossover of FES cycling 4 times per week with the RT300 or standard rehab</td>
<td>Urine output, lower limb swelling, spasticity</td>
<td>2 weeks</td>
<td>No benefit compared to standard rehab</td>
<td>Only 2 weeks of FES may not have been sufficient</td>
</tr>
<tr>
<td>Dolbow et al (2013)\textsuperscript{26}</td>
<td>Prospective within subject comparison</td>
<td>11 male veterans with SCI (73% with tetraplegia)</td>
<td>Home FES that increased in speed, resistance, and duration over 8 weeks</td>
<td>Quality of Life</td>
<td>8 weeks</td>
<td>Improvement in physical and environmental domains but not psychological and social</td>
<td>Selective reporting of the 11 participants who completed the initial study (Dolbow et al 2012)\textsuperscript{27}</td>
</tr>
<tr>
<td>Johnston et al (2009)\textsuperscript{28}</td>
<td>RCT with within subject comparison</td>
<td>30 children with SCI</td>
<td>Home FES cycling group, with passive cycling and electrical stimulation only controls</td>
<td>Oxygen uptake, rHR, forced vital Capacity, lipid profile</td>
<td>3 times per week for 6 months</td>
<td>There was no significant difference across groups. The FES group showed a greater percent increase in 1 of 4 measures compared to the control groups.</td>
<td>Early model of device that may not be representative of current devices</td>
</tr>
</tbody>
</table>
FES: functional electrical stimulation; RCT: randomized controlled trial; rHR: resting heart rate; SCI: spinal cord injury,

Six studies were identified on the ERGYS2 and its predecessors, the ERGYS1 and REGYS1 (see Table 14). Five studies were prospective within-subject comparisons and one was a retrospective matched comparison. Sadowsky et al (2013) evaluated motor and sensory recovery with long-term use of the ERGYS2. Individuals with SCI who were treated with FES had positive outcomes on motor and sensory scores compared to individuals who did not receive FES, but the retrospective study is limited by potential for selection bias. The within-subject comparisons in Table 14 uniformly show an improvement in aerobic capacity and metabolism with training. In a prospective study by Griffin et al (2009), cycling for 30 minutes, 2 to 3 times per week, for 10 weeks on the ERGYS2 resulted in improvements in a number of physiological measures of health (lean muscle mass, work capacity, glucose tolerance, insulin levels, inflammatory markers) along with an improvement in motor and sensory function. These positive results are notable for the relatively short training period. A reduction in bone mass and osteoporosis is common in individuals with SCI, but no studies have demonstrated an improvement in bone mineral density. A major limitation in relevance of the studies for the present evidence review is that they do not appear to have been conducted in the home environment. The REGYS and ERGYS cycle ergometers have a bulky integrated seat and require transfer from a wheelchair, which may be a significant limitation to home use. Sustained motivation to exercise for two to three times per week outside of the investigational setting is uncertain.

Table 14. Summary of Studies on the REGYS1, ERGYS1 and ERGYS2

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Participants</th>
<th>Treatment</th>
<th>Assessment</th>
<th>Training Duration</th>
<th>Outcome</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sadowsky et al (2013)</td>
<td>Retrospective matched comparison</td>
<td>25 adult individuals with chronic SCI who received FES cycling and 20 individuals with SCI who did not receive FES</td>
<td>Long-term rehabilitation on the ERGYS2</td>
<td>≥ 1 point improvement on the combined motor-sensory scores on the ASIA impairment scale</td>
<td>29 months [range, 3 to 168]</td>
<td>FES improved both motor and sensory scores compared to controls</td>
<td>Potential bias in who was referred for FES</td>
</tr>
<tr>
<td>Griffin et al (2009)</td>
<td>Prospective within subject comparison</td>
<td>18 adult individuals with SCI</td>
<td>Cycling for 30 min, 2 to 3 times per week on the ERGYS2</td>
<td>ASIA score, body composition, motor and sensory function, and metabolism</td>
<td>10 weeks</td>
<td>Improvement in lean muscle mass, cycling power, work capacity, endurance, glucose tolerance, insulin levels, inflammatory markers, and</td>
<td>10 week duration of study</td>
</tr>
<tr>
<td>Study Authors and Year</td>
<td>Study Design</td>
<td>Sample Size</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Device Note</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------</td>
<td>-------------</td>
<td>--------------</td>
<td>-----------</td>
<td>-------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutton et al (1997)</td>
<td>Prospective within subject comparison</td>
<td>11 adult individuals with SCI</td>
<td>Hybrid arm and leg exercise with the REGYS1 plus a Monark arm ergometer</td>
<td>Aerobic capacity and metabolism</td>
<td>LE FES 2 times per week for 18 weeks followed by 24 weeks of hybrid FES</td>
<td>Early model of device that may not be representative of current home devices. Separated arm ergometer.</td>
<td></td>
</tr>
<tr>
<td>BeDell et al (1996)</td>
<td>Prospective within subject comparison</td>
<td>12 adult individuals with chronic spastic SCI</td>
<td>Gradually increasing upper and lower cycling on the REGYS1</td>
<td>DEXA</td>
<td>6 mos</td>
<td>No improvement in BMD in the femoral neck and hip, trend in the lumbar spine</td>
<td></td>
</tr>
<tr>
<td>Hooker et al (1992)</td>
<td>Prospective within subject comparison</td>
<td>18 adult individuals with SCI</td>
<td>Monitored endurance training 3 times per week on the ERGYS1</td>
<td>Metabolism</td>
<td>12 weeks</td>
<td>23% increase in aerobic capacity with lower extremity testing but not upper-extremity testing</td>
<td></td>
</tr>
<tr>
<td>Pollack et al (1989)</td>
<td>Prospective within subject comparison</td>
<td>11 adult individuals with SCI C4 to T6</td>
<td>Gradually increasing resistance training on the REGYS1</td>
<td>Metabolism</td>
<td>13 to 28 mos</td>
<td>Exercise, but not resting, oxygen consumption and carbon dioxide production increased</td>
<td></td>
</tr>
</tbody>
</table>

Kressler et al (2014) conducted an analysis of data usage patterns and energy expenditure of 314 individuals over 20183 home activity sessions with Restorative Therapeutics FES cycle ergometers (e.g., RT300), (see Tables 15 and 16).35. With use categorized into low (< 2 days/week), medium (2 to 5 days/week) and high use (at least 5 days/week), 71% of individuals with SCI were considered low users. 

with an average of 0.9 days and 34 minutes of cycling per week. Seven (2%) of the 314 individuals were high users and 83 (27%) were medium users. Kressler et al (2014) noted that none of the users met the recommended 1000 kcals/wk, with maximal weekly expenditure was 43 kcals.

Table 15. Characteristics of Studies on Home Use of Restorative Therapeutics Cycle Ergometers

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Participants</th>
<th>Treatment Delivery</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kressler et al (2014)</td>
<td>US</td>
<td>314 individuals with SCI who had home network-connected Restorative Therapeutics FES cycle ergometers</td>
<td>Analysis of data on usage patterns and energy expenditure from 314 individuals across 20,183 activity sessions</td>
<td>NR</td>
</tr>
</tbody>
</table>

NR: not reported; SCI: spinal cord injury

Table 16. Results on Home Use of Restorative Therapeutics Cycle Ergometers

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>N (%)</th>
<th>Average days/wk (sd)</th>
<th>Average min/wk (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kressler et al (2014)</td>
<td>&lt;2 days per week</td>
<td>218 (71%)</td>
<td>0.9 (0.4)</td>
<td>34 (21)</td>
</tr>
<tr>
<td></td>
<td>2 to 5 days per week</td>
<td>83 (27%)</td>
<td>3.1 (0.7)</td>
<td>118 (50)</td>
</tr>
<tr>
<td></td>
<td>&gt; 5 days per week</td>
<td>7 (2%)</td>
<td>6.3 (1.0)</td>
<td>672 (621)</td>
</tr>
</tbody>
</table>

sd: standard deviation

Factors affecting compliance with recommended levels of activity on a home cycle ergometer was assessed by Dolbow et al (2012). Twenty-seven veterans with SCI were provided a rental RT300 and instructed to exercise for 40 to 60 minutes of continuous cycling, 3 times per week. If the participants achieved the recommended level of exercise, the Veterans Affairs Medical Center would purchase the device. Thus, there was a strong incentive to achieve the recommended level of exercise. Participants were monitored for another eight weeks after purchase to determine if compliance remained high without the incentive, although participation in a study is also known to improve adherence. Adherence rates were 71.7% for the first 8 weeks and 62.9% for the second 8 week period (not statistically different). The odds of adhering to the exercise program in the first 8 weeks were higher in younger participants (odds ratio: 4.86, p=0.02), in participants who were active prior to the study (odds ratio: 4.59, p = 0.02) and in participants with non-FES pain (odds ratio 2.22, p=0.01). Level of injury, time since injury, and history of depression were not significant factors in adherence. Five older participants dropped out of the study before the second eight week period began. The remaining participants were included in a subsequent report of the effect of the exercise on QOL over the eight weeks of the study.26.

Section Summary: FES Exercise Equipment
The evidence on FES exercise equipment consists primarily of within-subject, pre-to post-treatment comparisons. Evidence was identified on 2 commercially
available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is a limited amount of evidence on the RT300 series. None of the studies showed an improvement in health benefits and 1 analysis of use for 314 individuals over 20000 activity sessions with a Restorative Therapeutics device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of six days per week, but caloric expenditure remained low. Compliance was shown in one study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function. A limitation of these studies is that they all appear to have been conducted in supervised research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain.

Summary of Evidence
For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive FES, the evidence includes case series. The relevant outcomes are functional outcomes and QOL. Evidence on FES for the upper limb in patients with SCI or stroke includes a few small case series. Interpretation of the evidence is limited by the low number of patients studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve the QOL. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have chronic foot drop who receive FES, the evidence includes RCTs and a systematic review. The relevant outcomes are functional outcomes and QOL. For chronic poststroke footdrop, two RCTs comparing FES with a standard AFO showed improved patient satisfaction with FES but no significant differences between groups in objective measures like walking. An RCT with 53 subjects examining neuromuscular stimulation for footdrop in patients with MS showed a reduction in falls and improved patient satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes a systematic review of small studies with within-subject designs. Further study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. The relevant outcomes are functional outcomes and QOL. No controlled trials were identified on FES for standing and walking in patients with SCI. However, case series are considered adequate for this condition, because there is no chance for unaided ambulation in this population with SCI at this level. Some studies have reported improvements in intermediate outcomes, but improvements in health outcomes (eg, ability to perform activities of daily
living, QOL) have not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective within-subject comparisons. The relevant outcomes are symptoms, functional outcomes, and QOL. The evidence on FES exercise equipment consists primarily of within-subject, pre- to post-treatment comparisons. Evidence was identified on 2 commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is a limited amount of evidence on the RT300 series. None of the studies showed an improvement in health benefits and 1 analysis of use for 314 individuals over 20000 activity sessions with a Restorative Therapeutics device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of six days per week, but caloric expenditure remained low. Compliance was shown in one study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function. A limitation of these studies is that they all appear to have been conducted in supervised in research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
The National Institute for Health and Care Excellence (2009) published guidance stating that the evidence on functional electrical stimulation for footdrop of neurologic origin appeared adequate to support its use. The Institute noted that patient selection should involve a multidisciplinary team. The Institute advised that further publication on the efficacy of functional electrical stimulation would be useful, specifically including patient-reported outcomes (eg, quality of life, activities of daily living) and these outcomes should be examined in different ethnic and socioeconomic groups.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Medicare (2002; updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation for ambulation in spinal cord injury patients consistent with the Food and Drug Administration labeling for the Parastep device. The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in its decision-making process. The decision memorandum noted that the available studies were flawed but concluded that the limited ambulation provided by the Parastep device
supported its clinical effectiveness and thus its coverage eligibility. The inclusion criteria outlined by Medicare are as follows:

1. "Persons with intact lower motor units (L1 and below)...;"
2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;
3. Persons who demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;
4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;
5. Persons that can transfer independently and can demonstrate standing tolerance for at least 3 minutes;
6. Persons that can demonstrate hand and finger function to manipulate controls;
7. Persons with at least 6-month post recovery spinal cord injury and restorative surgery;
8. Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and
9. Persons that have demonstrated a willingness to use the device long-term."

The exclusion criteria are as follows:

1. "Persons with cardiac pacemakers;
2. Severe scoliosis or severe osteoporosis;
3. Skin disease or cancer at area of stimulation;
4. Irreversible contracture; or
5. Autonomic dysreflexia."

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 17.

**Table 17. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03810963</td>
<td>Electrically Induced <strong>Cycling</strong> and Nutritional Counseling for Counteracting Obesity After SCI</td>
<td>17</td>
<td>May 2019</td>
</tr>
<tr>
<td>NCT02602639</td>
<td>Functional Electrical Stimulation with Rowing as Exercise after Spinal Cord Injury (FES)</td>
<td>6</td>
<td>Sep 2019</td>
</tr>
<tr>
<td>NCT03495986</td>
<td><strong>Spinal Cord Injury</strong> Exercise and Nutrition Conceptual Engagement (SCIENCE)</td>
<td>40</td>
<td>Jul 2022</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00890916</td>
<td>Hand Function for Tetraplegia Using a Wireless Neuroprosthesis</td>
<td>11</td>
<td>Dec 2017</td>
</tr>
<tr>
<td>NCT00583804</td>
<td>Implanted Myoelectric Control for Restoration of Hand Function in Spinal Cord Injury</td>
<td>10</td>
<td>Jan 2015</td>
</tr>
<tr>
<td>NCT03385005</td>
<td>Evaluating Neuromuscular Stimulation for Restoring Hand Movements</td>
<td>15</td>
<td>Mar 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

REFERENCES


Billing Coding/Physician Documentation Information

97116 Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)

97530 Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes

97760 Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes

97763 Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes

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

L5999 Lower extremity prosthesis, not otherwise specified

L8679 Implantable neurostimulator, pulse generator, any type

C1787 Patient programmer, neurostimulator

C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system

C1897 Lead, neurostimulator test kit (implantable)

ICD-10 Codes:

G35 Multiple sclerosis

G81.00- Hemiplegia and hemiparesis code range

G81.94

G82.20- Paraplegia (paraparesis) and quadriplegia (quadriparesis) code range

G82.54

G83.0- Other paralytic syndromes code range

G83.9

I63.00- Cerebral infarction code range

I63.9

I69.30- Sequelae of cerebral infarction code range

I69.398

M21.371- Foot drop (acquired) code range

M21.379

Additional Policy Key Words

N/A
Policy Implementation/Update Information

10/1/08  New policy titled *Functional Neuromuscular Stimulation*. The treatment of paralyzed muscles in stroke or spinal cord injury patients, multiple sclerosis or other motor function disorders is considered investigational.

7/1/00  No policy statement changes.
7/1/01  No policy statement changes.
4/1/02  No policy statement changes. Title changed to *Functional Neuromuscular Stimulation for the Treatment of Paralysis (FNS)*
4/1/03  No policy statement changes.
4/1/04  No policy statement changes.
4/1/05  Policy statement revised to read, “Functional neuromuscular stimulation as a technique to provide ambulation is considered investigational.”
4/1/06  No policy statement changes.
4/1/07  No policy statement changes.
4/1/08  Policy statement revised to specifically include patients with spinal cord injury and post-stroke. This therapy remains investigational.
8/1/08  Added information to the description section regarding the WalkAide.
4/1/09  No policy statement changes.
11/1/09  Additional applications (hand and foot) added to policy statement; policy title changed to “Functional neuromuscular electrical stimulation”. This change is effective 10/6/09.
4/1/10  No policy statement changes.
4/1/11  Policy combined with policy 1.01.503 Neuromuscular Stimulation for Muscle Rehabilitation. Policy statement added indicating all other uses of neuromuscular stimulation as investigational.
4/1/12  No policy statement changes.
4/1/13  Policy statement revised; cerebral palsy added to investigational policy statement.
4/1/14  No policy statement changes.
4/1/15  No policy statement changes.
4/1/16  No policy statement changes.
4/1/17  No policy statement changes.
4/1/18  No policy statement changes.
4/1/19  No policy statement changes.
4/1/20  No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating healthcare providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.