



## Clinical Review Criteria

### Electrical Stimulation and Devices

- Electrical Stimulation for the Treatment of Dysphagia
- Functional Neuromuscular Stimulation Unit (FNS or ENS)
- Galvanic Stimulation Device
- Gastric Electrical Stimulation (Enterra)
- H-wave Stimulation Device
- Microcurrent Stimulation Device (MENS)
- NESS Stimulators for Foot Drop and Paralyzed Hands
- Neuromuscular Electrical Stimulation Unit (NMES)
- Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis
- Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
- ReBuilder System
- Transcutaneous Electrical Nerve Stimulation (TENS) Unit
- Transcutaneous Electrical Joint Stimulation Devices (TEJSD)
- WalkAide System for Patients with Foot Drop
- Peripheral Nerve Stimulation

**A Separate Criteria Document Exists for the Following Devices:**

- [Central Nervous System Electrical Nerve Stimulator: Spinal Cord Stimulators for Pain, Deep Brain Stimulation](#)
- [Electrical Stimulation for Treatment of Wounds \(Wound Care Treatments\)](#)
- [Hypoglossal Nerve Stimulation \(Treatments for Obstructive Sleep Apnea\)](#)
- [Osteogenic \(Bone\) Stimulators](#)
- [Sacral Nerve Stimulator for Fecal and Urinary Incontinence](#)
- [Deep Brain Stimulation](#)
- [Vagus Nerve Stimulation](#)

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## Criteria

### For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	<a href="#">Electrical Nerve Stimulators 160.7</a> <a href="#">Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy 160.7.1</a> <a href="#">Neuromuscular Electrical Stimulation (NMES) (160.12)</a> <a href="#">Non-Implantable Pelvic Floor Electrical Stimulator (230.8)</a> <a href="#">Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13)</a> <a href="#">Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2)</a> <a href="#">Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27)</a>

	<a href="#">Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2)</a>
Local Coverage Determinations (LCD)	<a href="#">Transcutaneous Electrical Nerve Stimulators (TENS) (L33802)</a> <a href="#">Peripheral Nerve Stimulation (L37360)</a>  <a href="#">Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821)</a> *references code E0762
Local Coverage Article	<a href="#">Transcutaneous Electrical Nerve Stimulators (TENS) (A52520)</a>  <a href="#">Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (A52713)</a>

**For Non-Medicare Members**

Device	Criteria
<b>TENS unit</b>	<p>Kaiser Permanente has elected to use the MCG* (KP-0241) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p> <p><b>If requesting this service, please send the following documentation to support medical necessity:</b></p> <ul style="list-style-type: none"> <li>• Last 6 months of clinical notes from requesting provider or specialist to include any medications that were tried for pain relief</li> <li>• This service is dependent upon other measures of pain relief having been tried</li> </ul>
<b>NMES Unit – Neuromuscular Electrical Stimulation</b>	<p>Must meet <b>ALL of the following:</b></p> <ol style="list-style-type: none"> <li>1) Has durable medical equipment benefit</li> <li>2) Treatment of muscle atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves and other neurological reasons for disuse atrophy</li> </ol>

Device	Criteria
<b>FES unit – Functional Electrical Stimulation (e.g. Parastep I System)</b>	<p>Must meet <b>ALL of the following</b>:</p> <ol style="list-style-type: none"> <li>1. Has durable medical equipment benefit</li> <li>2. Spinal cord injury patients to achieve walking and not reverse or retard muscle atrophy with all of the following characteristics:               <ol style="list-style-type: none"> <li>a) Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerves);</li> <li>b) 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;</li> <li>c) Persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;</li> <li>d) Persons that possess high motivation, commitment and cognitive ability to use such device for walking;</li> <li>e) Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;</li> <li>f) Persons that can demonstrate hand and finger function to manipulate controls;</li> <li>g) Persons with at least 6-month post-recovery spinal cord injury and restorative surgery;</li> <li>h) Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and</li> <li>i) Persons who have demonstrated a willingness to use the device long-term.</li> <li>j) Persons without one of the following conditions:                   <ol style="list-style-type: none"> <li>i) Cardiac pacemaker;</li> <li>ii) Severe scoliosis or severe osteoporosis;</li> <li>iii) Skin disease or cancer at area of stimulation;</li> <li>iv) Irreversible contracture;</li> <li>v) Autonomic dysreflexia</li> </ol> </li> </ol> </li> </ol>
<b>Gastric Electrical Stimulation for the Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)</b>	<p>Kaiser Permanente has elected to use the <a href="#">FDA Humanitarian Device Exemption</a> approved indications for Diabetic Gastroparesis:</p> <ul style="list-style-type: none"> <li>• Chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years</li> </ul>
<b>Gastric Electrical Stimulation for the Treatment of Gastroparesis (other than diabetic gastroparesis)</b>	<p>Kaiser Permanente has elected to use the MCG* Gastric Stimulation, Electrical (A-0395) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p> <p><b>If requesting this service, please send the following documentation to support medical necessity:</b></p> <ul style="list-style-type: none"> <li>• Last 2 years of gastroenterology notes</li> <li>• Most recent clinical note from requesting provider</li> </ul>
<b>Electrical Stimulation for the Treatment of Dysphagia</b>	<p>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies</p>
<b>Galvanic Stimulation Device</b>	<p>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies</p>

Device	Criteria
<b>H-wave Stimulation Device</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>Microcurrent Stimulation Device (MENS)</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>NESS Stimulators for Foot Drop and Paralyzed Hands</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>ReBuilder System Threshold electrical stimulation</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>WalkAide System for Patients with Foot Drop</b>	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
<b>Peripheral Nerve Stimulator (i.e., StimRouter, Stimwave, Nalu)</b>	Peripheral nerve stimulation is not covered for any indication at this time. Under evidence review. All requests must be reviewed by the Medical Director.

**\*MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Evidence and Source Documents

[Electrical Stimulation for the Treatment of Dysphagia](#)  
[Gastric Electrical Stimulation \(Enterra\)](#)  
[Hypoglossal Nerve Stimulation](#)  
[NESS Stimulators for Foot Drop and Paralyzed Hands](#)  
[Percutaneous Neuromodulation Therapy \(PNT\) for Back Pain - Vertis](#)  
[Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee](#)  
[ReBuilder System](#)  
[WalkAide System for Patients with Foot Drop](#)

## Background

A transcutaneous electrical nerve stimulator (TENS) is a device that utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins.

These are not the same as neuromuscular electrical stimulators (NMES), which are used to directly stimulate muscles and are used to prevent disuse atrophy (not address pain).

The transcutaneous electrical nerve stimulator is a well-established technique with limited effect and efficacy for the control of chronic painful disorders. Patients with chronic pain are best treated with a multi-disciplinary approach that includes increasing their activity. A TENS unit may be useful for a few weeks to assist a patient in becoming more active. It is not recommended for acute pain management as medication is much more effective and is safe for short-term management. It may be used occasionally to assist with pain control in patients with acute pain.

## Medical Technology Assessment Committee (MTAC)

### *Transcutaneous Electrical Nerve Stimulation (TENS)*

#### **06/30/1998: MTAC REVIEW**

**Evidence Conclusion:** Jarzem et al., Transcutaneous Electrical Nerve Stimulation for Patients with Chronic Backpain, presented at the annual meeting of the American Academy of Orthopedic Surgeons, San Francisco, 1997. 350 patients with chronic back pain, randomized into 4 groups; (1) daily treatment with conventional TENS; (2) treatment with nu-wave form TENS; (3) treatment with acupuncture TENS; (4) and treatment with sham TENS. In addition, all underwent an identical exercise program by a single therapist, blinded. 26 patients dropped out. All patients improved over time, but there were no significant differences among treatment groups.

### *Electrical Stimulation for the Treatment of Dysphagia*

#### BACKGROUND

Dysphagia is the subjective sensation of difficulty or abnormality of swallowing. The term is derived from the Greek dys for bad or disorder, and phago for eat. Swallowing is a complex sensory-motor behavior that involves more than 25 pairs of muscles, 6 cranial nerves, and 2 cervical nerve roots to transport saliva, ingested solids, and fluids from the oral cavity to the stomach. It consists of three sequential, physiologically interconnected phases: oral preparatory and propulsive phase, pharyngeal phase, and esophageal phase. Dysphagia occurs when there is a problem with any part of this swallowing process. It can affect any age group, and may result from congenital abnormalities, stroke, head injury, neoplasms, and/or other medical conditions. Its incidence is higher in the elderly, in patients who have had strokes, and in patients who are admitted to acute care hospitals or chronic care facilities. Some may have trouble swallowing food, liquids, or saliva, and others are completely unable to swallow. Dysphagia can be a serious health threat due to the risk of aspiration pneumonia, bronchospasm, airway obstruction, pulmonary fibrosis, malnutrition, dehydration, and death (Leelamanit 2002, Blumenfeld 2006, Shaw 2007, Bulow 2008, Humbert 2012, Tan 2013). Functional dysphagia therapy aims at reducing the risk of aspiration and improving the physiology of the impaired swallowing mechanism to restore function. The traditional therapy incorporates diet modification, position adjustment, speech therapy, and exercise to alter the muscle structure and function. Percutaneous endoscopic gastrostomy tubes are often used in the management of dysphagia. Thermal tactile stimulation by the application of cold to the anterior faucal arch is also being used with some success. Existing treatments for dysphagia are usually unable to restore the complete swallow function among patients with the most severe disorders (Freed, 2001, Miller 2013, Tan 2013).

Transcutaneous electrical stimulation (ES) that involves the application of electric current across the skin to stimulate nerve or muscle tissue during a functional task is commonly used in physical and rehabilitation therapy. It is used to strengthen muscles after surgery, prevent disuse atrophy of denervated muscles, decrease spasticity, and accelerate wound healing. There are several variants of electrical stimulation therapy. Transcutaneous electrical nerve stimulation (TENS) is mainly used in an attempt to alleviate neuropathic or chronic musculoskeletal pains. This can be used on atrophied or denervated muscles but does not cause muscle

contraction. Functional electrical stimulation (FES) is the application of electrical current to excitable tissue to supplement or replace function that is lost in neurologically impaired individuals e.g. after spinal cord injury. Neuromuscular electrical stimulation (NMES) therapy is used on innervated muscles to recruit motor units and increase muscle strength. It selectively targets healthy innervated muscle fibers but does not always stimulate atrophied or denervated muscle. NMES may be considered as a FES in situations when a muscle contraction is facilitated during a functional task (Peckham 2005, Carnaby-Mann 2007, Tan 2013). Over the last 2-3 decades, NMES therapy has been proposed as a treatment option for pharyngeal dysphagia to initiate or re-establish the act of swallowing. The therapy involves the application of electric stimulation through a pair of surface electrodes located on the neck. These are usually placed in one of two configurations: one electrode above the lesser horn of the hyoid bone and the other roughly 4 cm below it, or both electrodes above the lesser hyoid bones bilaterally. Electric pulses are then delivered continuously at 80Hz for duration of 300  $\mu$ s and intensity ranging from 2.5 to 25 mA depending on the patient's tolerance. The therapy is usually given for 60-minute session every day, 5 days a week until swallowing has been restored or until the patient cannot tolerate it (Steele 2007). NMES has received great interest and raised much controversy since it was introduced. Over 9,000 speech pathologists in the US have been trained to use the technology. However, the underlying neurophysiologic basis for using the procedure that involves surface electrode placement on the external lateral neck is poorly defined. Challenge in designing a neuromuscular stimulation device for swallowing include selecting which muscles to target in the swallowing sequence, designing a device that triggers a chain of successive muscle excitations and inhibitions similar to normal swallowing process. Some scientists have argued that the current intensity delivered by NMES at the submental region is greatest at the skin surface and diminishes with depth through the platysma underlying the skin and subcutaneous fat. The deeper muscles which would pull the hyoid bone up and toward the mandible, and those that elevate the larynx to the hyoid bone, are much less likely to be activated by surface stimulation (Ludlow 2007, Steele 2007). Potential risks of NMES include arrhythmia, hypotension, laryngospasm, burns, glottic closure, and interference with pacemakers. The therapy is contraindicated in patients with pacemakers, superficial metal implants or orthotics, skin breakdown, cancer, history or cardiac disorders, seizures, impaired peripheral conduction system, pregnancy, significant reflux due to use of a feeding tube, or dysphagia due to drug toxicity (Leelamanit 2002, Blumenfeld 2006, Huckabee 2007).

Two NMES devices, the Freed Bioelectric Dysphagia Treatment Device and the Chattanooga VitalStim<sup>TM</sup> system, were cleared by the FDA for marketing in June 2001 and December 2002 respectively. Both are equivalent external electrical stimulation devices intended for re-education of the throat muscles, necessary for pharyngeal contraction, for the treatment of dysphagia from any etiology other than mechanical causes requiring surgery. The therapy treatment sessions last for 60 minutes and are most commonly administered by a speech and language pathologist. The FDA approval came with a warning that: 1. The long-term effects of chronic electric stimulation are unknown, 2. Stimulation should not be applied over the carotid sinus nerves, 3. Improper placement of the electrodes or improper use of recommended frequency, intensity or pulse, may cause laryngeal or pharyngeal spasm which may close the airway or cause difficulty in breathing.

#### **04/14/2004: MTAC REVIEW**

##### **Electrical Stimulation for the Treatment of Dysphagia**

**Evidence Conclusion:** The study reviewed provides insufficient evidence on the use of electrical stimulation in patients with dysphagia. It had potential selection and observation bias. The investigators compared electrical stimulation to tactile stimulation in a controlled study where patients were not randomized, but alternately assigned to electric stimulation using the Freed Bioelectric Dysphagia Treatment Device, or thermal tactile stimulation. Overall, the results of the study show that both treatment groups improved, but the final swallow scores were higher among the electrical stimulation group. The study has potential selection and observation biases and does not provide sufficient data on the long-term effectiveness of the treatment.

**Articles:** The search yielded 11 articles on electrical stimulation for the treatment of dysphagia. There was a longitudinal study with a control group, on electrical stimulation for swallowing disorders caused by stroke (Freed et al 2001), and another on effects of electrostimulation on salivary function of Sjogren's syndrome patients (Tala 1992). In the latter study, treatment aimed at increasing the production of saliva by an electrostimulation device placed on the tongue, which is different from the transcutaneous electric stimulating of the pharyngeal muscles. The search also revealed one case series with 23 patients, four small case reports, and four review articles. A larger study with 892 patients was submitted to the FDA but has not been published in a peer reviewed medical journal to date. *An evidence table was created for the following study:* Freed ML, Freed L, Chatburn RL et al. Electrical stimulation for swallowing disorders caused by stroke. *Respir Care* 2001;46:466-474. See [Evidence Table](#)

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **08/04/2008: MTAC REVIEW**

## **Electrical Stimulation for the Treatment of Dysphagia**

**Evidence Conclusion:** VitalStim was reviewed earlier by MTAC in April 2004. The best evidence at the time was the Freed et al (2001) nonrandomized controlled trial that compared electrical stimulation to tactile stimulation for the treatment of 110 patients with swallowing disorders caused by stroke. The study had its limitations and biases and did not provide sufficient evidence on the safety and effectiveness of neuromuscular electrical stimulation in treating dysphagia.

**Articles:** There is still a lack of published literature on the use of NMES for swallowing. The best published evidence to date is a very small (N=25) recent RCT with several limitations and a meta-analysis that included one small controlled trial (Freed, et al 2001), a retrospective study with a control group, and small case series. The results of the published controlled studies and case series are conflicting. Several case series with non-blinded subjective measures reported some improvement in swallowing. This positive effect was however not observed when more objective outcomes were used and blindly measured. The only published randomized controlled trial showed no significant differences between NMES and traditional swallowing therapy in treating patients with swallowing difficulties due to stroke. The trial was too small, unblinded, had insufficient statistical power, and no long-term follow-up. These limitations together with other methodological flaws do not allow making conclusions on the efficacy and safety of the therapy. In conclusion, there is insufficient published evidence to determine: 1. Whether patients treated with VitalStim will show more improvement in the oral and pharyngeal phases of swallowing compared to the traditional therapies used in the management of dysphagia. 2. If patients treated with VitalStim would have fewer dietary consistency restrictions compared to those receiving traditional means for dysphagia management, or 3. If patients treated with VitalStim would progress more rapidly from nonoral to oral nutrition compared to those receiving traditional means for dysphagia management.

The search yielded just over 30 articles on electrical stimulation for the treatment of dysphagia. Many were reviews and opinion pieces. There was one meta-analysis of non-randomized controlled studies and case series studies, a more recent small randomized controlled trial, and a number of case series on the effect of NMES therapy on improving swallowing. The literature search did not reveal any study on the effect of therapy on dietary restrictions, or progress from nonoral to oral nutrition. The meta-analysis and the RCT were selected for critical appraisal. Carnaby-Mann GD, Crary MA. Examining the evidence on neuromuscular electric stimulation for swallowing. A meta-analysis. *Arch Otolaryngol Head Neck Surg.*2007;133:564-571. See [Evidence Table](#) Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. *Dysphagia* April 2008. See [Evidence Table](#) Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. *Dysphagia* April 2008. See [Evidence Table](#)

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **06/16/2014: MTAC REVIEW**

## **Electrical Stimulation for the Treatment of Dysphagia**

**Evidence Conclusion:** NMES was reviewed earlier by MTAC in 2004 and 2008 and did not pass the evaluation criteria due to the lack of evidence on its safety and efficacy in the management of dysphagia. The best published evidence at the time was the Freed et al (2001) nonrandomized controlled trial that compared electrical stimulation to tactile stimulation for the treatment of 110 patients with swallowing disorders caused by stroke, a very small RCT with 25 patients (Bulow 2008) and a meta-analysis of small nonrandomized studies comprising 225 patients. More recently a number of randomized or quasi randomized RCTs were conducted to assess the efficacy of NMES in patients with dysphagia due to variable etiologies. The studies were small in size, had short follow-up durations, and varied widely in the patient selection, electrode positioning, stimulation protocols, combination with other therapies, and outcome measures. The results of the published trials as well as a meta-analysis of 7 trials are conflicting (evidence tables 1&2). Baijens, et al (2013) found no additional clinical benefit when submental NMES used in addition to the traditional dysphagia therapy in patients with dysphagia secondary to Parkinson's disease. Kushner, et al (2013) reported significantly better outcomes with NMES combined with traditional therapy vs. traditional therapy alone for patients with dysphagia following stroke. On the other hand Tan and colleagues' 2013 meta-analysis of RCTs suggest that NMES may be more effective than traditional therapy in patients with dysphagia due to different etiologies, except for post-stroke dysphagia. The conflicting results of the published studies, different stimulation protocols used, various underlying pathological conditions, and short follow-up durations, makes it hard to determine whether NMES provides additional therapeutic benefit for patients with dysphagia.

**Articles:** The literature search for studies on NMES published after the last 2008 MTAC review, revealed over 50 articles. There were two meta-analyses, 6 small randomized controlled trials, and a number of observational small studies related to the current review. One of the two meta-analyses (Geeganage et al, 2012) assessed feeding and swallowing treatment strategies including NMES in stroke patients and the other (Tan et al, 2013) evaluated NMES in patients with dysphagia caused by non-stroke conditions. The published RCTs identified by the search

examined the effect of NMES on treating dysphagia due to stroke, Parkinson's disease, or cancer. The following meta-analysis and the RCTs were selected for critical appraisal. Baijens LW, Speyer R, Passos VL, et al. Surface electrical stimulation in dysphagic Parkinson patients: a randomized clinical trial. *Laryngoscope*. 2013;123:E38-44. See [Evidence Table](#) Heijnen BJ, Speyer R, Baijens LW, et al. Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: effects on quality of life. *Dysphagia*. 2012; 27:336-345. See [Evidence Table](#) Lim KB1, Lee HJ, Lim SS, et al. Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomized controlled trial. *J Rehabil Med*. 2009;41:174-178. See [Evidence Table](#) Long YB, Wu XP. A randomized controlled trail of combination therapy of neuromuscular electrical stimulation and balloon dilatation in the treatment of radiation-induced dysphagia in nasopharyngeal carcinoma patients. *Disabil Rehabil*. 2013;35:450-454 See [Evidence Table](#) Permsirivanich W, Tipchatyotin S, Wongchai M, et al. Comparing the effects of rehabilitation swallowing therapy vs. neuromuscular electrical stimulation therapy among stroke patients with persistent pharyngeal dysphagia: a randomized controlled study. *J Med Assoc Thai*. 2009;92:259-265. See [Evidence Table](#) Ryu JS, Kang JY, Park JY, et al. The effect of electrical stimulation therapy on dysphagia following treatment for head and neck cancer. *Oral Oncol*. 2009;45:665-668. See [Evidence Table](#) Tan C, Liu Y, Li W, et al. Transcutaneous neuromuscular electrical stimulation can improve swallowing function in patients with dysphagia caused by non-stroke diseases: a meta-analysis. *J Oral Rehabil*. 2013; 40:472-480. See [Evidence Table](#) Xia W1, Zheng C, Lei Q, Tang Z, et al. Treatment of post-stroke dysphagia by VitalStim therapy coupled with conventional swallowing training. *J Huazhong Univ Sci Technolog Med Sci*. 2011;31:73-76. See [Evidence Table](#).

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)**

#### **BACKGROUND**

Gastroparesis (GP) is a gastric motility disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. The most common etiologies of GP are diabetes mellitus, post-surgical often as the result of damage to the vagal nerve, and idiopathic. Other causes include Parkinson's disease, collagen vascular disorder, and any disease process that interferes with the neuromuscular function of the stomach. The characteristic symptoms of gastroparesis include early satiety, nausea, vomiting, bloating, and abdominal pain. These symptoms are typically driven by meal intake but can also be present continually at varying degrees of intensity. A severe gastroparesis can result in impaired quality of life, recurrent hospitalizations, malnutrition, and even death (Velanovich 2008, McCollum 2011). The standard medical management of gastroparesis involves dietary modification, glycemic control, and the use of antiemetic therapy combined with prokinetic agents such as metoclopramide and erythromycin. These therapies are generally effective for the symptomatic relief in the majority of patients with GP. However, some patients do not respond to, or cannot tolerate drug treatment, and may require palliative endoscopic or surgical therapies. Surgical options include feeding jejunostomy tubes, decompressing gastrotomy tubes, pyloroplasty, and gastrectomy as a last resort (McKenna 2008, Velanovich 2008, McCallum 2010). In the last decade, high frequency gastric electrical stimulation (GES) emerged as a potential treatment option for patients with medically refractory gastroparesis. The therapy involves delivering low-energy electrical stimuli in the muscularis propria of the stomach at a frequency significantly higher than the normal gastric slow wave frequency. This is different from gastric pacing that delivers high energy stimuli at a frequency slightly above the intrinsic slow wave activity. The Enterra® Therapy System (Medtronic, Minneapolis, MN), a stimulation device delivering high-frequency GES, was granted Humanitarian Device Exemption by the US Food and Drug Administration in 2000 for patient with chronic drug refractory nausea and vomiting secondary to gastroparesis of diabetes mellitus or idiopathic in origin (O'Grady 2009, Chu 2012). The Enterra® system consists of three main elements: a pair of leads, a pulse generator, and a programming system. The leads and pulse generator are implanted surgically via laparotomy or laparoscopically. The two leads are surgically implanted about 1 cm apart in the muscle wall of the greater curvature of the stomach, approximately 10 cm from the pylorus. They are anchored in place then connected to a pulse generator placed in a subcutaneous pocket created in the abdominal wall generally in the superior quadrant of the abdomen. The pulse generator is controlled by an external programmer that allows for interrogation and programming of stimulation via a radio-telemetry link. The battery life of the pulse generator is 5-10 years depending on the neurostimulator setting. It is sealed in the generator and thus the device must be replaced when the battery is depleted. The leads can be left in place and reused with the new pulse generator. The Enterra system produces intermittent bursts of high-frequency (~14 cycles per second) short duration pulses (~ 330 µs) that are three to four times faster than the native gastric slow wave frequency (Chu 2012, Guerci 2012, Soffer 2012). GES therapy is not without complications; researchers reported that 7-10% of the patients treated with the Enterra® system experience an adverse event mainly infection of the subcutaneous pocket. Other events include erosion of the abdominal wall by the device, leads dislodgment or penetration through the gastric wall, or tangling of wires in the generator pocket



and formation of adhesions (Soffer 2012). This technology was approved by the FDA as a humanitarian device based on data from one study consisting of 33 patients that was not published in the peer-reviewed literature at the time.

#### **02/14/2001: MTAC REVIEW**

##### **Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)**

**Articles:** There are currently no peer-reviewed articles on this technology. Therefore, it is not possible for the MTAC committee to review the Gastric Electrical Stimulation Enterra™ Therapy System at this time. No published evidence found.

The use of Gastric Electrical Stimulation Enterra Therapy System in the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* as there was no published evidence to review.

#### **02/11/2013: MTAC REVIEW**

##### **Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)**

**Evidence Conclusion:** There is insufficient published evidence to determine that gastric electrical stimulation (GES) may improve refractory nausea and vomiting symptoms in patients with gastroparesis secondary to diabetes mellitus. There is also insufficient evidence to determine that GES improves gastric emptying, or that it is superior to other therapies for the treatment of GP. The three published RCTs on GES had their limitations, had negative results, and could not rule out the placebo effect of the therapy. There was no, or very short washout periods between the ON/OFF modes of the experimental phases of the trials, no comparisons were made between GES and other therapies, medical therapy was tried for only one month in some cases, and the prokinetic/antiemetic agents and other therapies were not discontinued during the study periods. The Worldwide Anti-Vomiting and Electrical Stimulation Study (WAVESS) conducted by Abell and colleagues, 2003 (Evidence table 1) was the first published RCT that evaluated the efficacy of the implanted GES system for highly symptomatic patients with drug refractory nausea and vomiting secondary to gastroparesis of diabetes or idiopathic etiology. This trial together with two other observational studies were the basis for the US Food and Drug Administration Humanitarian Device Exemption approval of Enterra® Therapy System for patient with chronic drug refractory nausea and vomiting secondary to gastroparesis of diabetes mellitus or idiopathic origin. The study was a very small RCT with limitations. It was powered to enroll 80 subjects but could only recruit 33, and was changed from a RCT to an observational study after 2 months of randomization. After implantation of the device, patients were randomized to an ON or OFF stimulation of the device for one month, after which, they were crossed-over to the alternative ON/OFF mode without a washout period. All patients were kept on the prokinetic, antiemetic and other therapies they were using for the duration of the randomized and observational phases of the study. Overall, the results of the trial showed a significant decrease in the weekly vomiting frequency for all the patients combined, but not for the diabetic or idiopathic subgroups. It is to be noted that the published outcome data are different from the data presented to the FDA where no significant differences were found in the mean or median vomiting episodes between the ON and OFF modes. The total Symptom Scores (TSS) did not improve significantly during the RCT phase but showed significant improvement in the open-label phase. Side effects included infection, pacer migration, and stomach wall perforation. Another crossover RCT conducted by McCallum and colleagues, 2010 (evidence table 2) also had its methodological limitations and did not allow examining the placebo effect of GES. All study participants underwent GES for 1.5 months before randomization. There was no washout period after the initial GES or between the ON and OFF modes in the experimental randomized phases. The results of the study showed no significant difference in the (weekly vomiting frequency) WVF or other symptoms between the ON versus OFF periods but showed a significant improvement in WVF in the first 6-week unblinded period after implantation vs. baseline, which could have been carried over to the randomized phase, especially with a lack of washout period. There was a high rate of adverse events, many of which were serious, and three patients requires surgical intervention for infection requiring removal of the device, lead dislodgement, or device migration. At one year after the implant, when all patients had the device switched on, the WVF remained lower than baseline. One meta-analysis (Grady, 2009) combined the results of the first RCT (Abell 2003) together with 12 case series with no control groups, and a second meta-analysis (Chu 2012) pooled the results of two RCTs (Abell 2003, and McCallum 2010) together with 8 case series with no controls. The pooled results showed significant improvement in gastroparesis symptoms. The authors of the two meta-analyses indicated that the results of the analyses should be interpreted with caution due to the limitations and design of the studies included. The three most important complications reported were infection in the subcutaneous pocket affecting, electrodes detachment or displacement, and pulse generator migration, all of which require surgical intervention. Due to the unpredictable response of patients to GES, Abell and colleagues, 2011 (evidence table 3) investigated the effects of temporary electrical gastric stimulation therapy on gastroparesis symptoms to assess the response after a few days of therapy as a predictor of response to long-

term therapy with GES. The trial included 55 patients among whom only 13 had diabetes mellitus as the cause of GP. The study was a crossover RCT with only one day washout period between the two sessions in which the device was alternately turned ON and OFF. In the first 3 days after implantation of the electrodes (session 1) both groups experienced a significant improvement in vomiting, nausea, and all symptom scores, irrespective of stimulation, which may indicate a placebo effect. In conclusion, larger studies with a parallel group design, sufficient power, and long-term follow-up are needed to more accurately determine the efficacy and safety of gastric stimulation therapy for gastroparesis of diabetes mellitus or idiopathic etiology.

**Articles:** The literature search revealed over 100 articles on gastric electrical stimulation in patients with gastroparesis. The majority were review articles, articles on technical aspects of the therapy, or observational studies and case series with no comparison groups. The search identified three randomized controlled trials and two meta-analyses that pooled the results of case series together with the randomized controlled trial. The three RCTs were selected for critical appraisal. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. *Gastroenterol.* 2003; 125:421-428. See [Evidence Table](#) McCallum RW, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. *Clin Gastroenterol Hepatol.* 2010; 8:947-954. See [Evidence Table](#) Abell TL, Johnson WD, Kedar A, et al. A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis: *Gastrointest Endosc.* 2011; 74:496-503. See [Evidence Table](#)

The use of Gastric Electric Stimulation for the Treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

### **NESS Stimulators for Foot Drop and Paralyzed Hands**

#### BACKGROUND

Foot drop is a motor deficiency caused by partial or total paralysis of the muscles innervated by the peroneal nerve. It is not a disease but a symptom of an underlying problem. It is often caused by an injury to the peroneal nerve but can also be associated with a variety of conditions such as stroke, dorsiflexor injuries, neuropathies, drug toxicities, or diabetes. The problem may be temporary or permanent depending on the cause. Foot drop is characterized by the lack of voluntary control of ankle dorsiflexion, and subtalar eversion. Patients with foot drop are unable to walk on their heel, flex their ankle, or walk with the normal heel-toe pattern. They usually exhibit an exaggerated or high-stepping walk called steppage gait or foot drop gait in order to compensate for toe drop. This unnatural walking motion may result in subsequent damage to the hip, back or knee (Voigt 2000). Management of patients with foot drop varies and is dependent on the underlying cause. Some patients may be fitted with of ankle-foot orthoses (AFO) brace, which typically limit ankle plantarflexion to enhance foot clearance during swing. Patients may also undergo physical therapy for gait training. Surgery may be an option when the cause of foot drop is muscular or neurologic. Electrical stimulation was first proposed as a treatment for foot drop by Liberson in 1961. Liberson referred to the treatment as “functional electrotherapy” because its purpose was to replace a functional movement that was lost after injury or illness. There has been extensive development of functional stimulation devices since the early 1960s. The first devices were hard-wired surface stimulators, followed by hard-wired implanted electrical stimulators, and then microprocessor-based surface and implanted systems. In the 1990s, artificial and “natural” sensors were developed as a replacement for the foot-switch. More recently, testing has been done on a device in which both the sensor and stimulator are implanted (Lyons et al. 2002). The WalkAide system is an external neuromuscular functional stimulator. It contains a control unit attached to a flexible cuff that contains two electrodes. The unit is placed on the leg below the knee, near the head of the fibula. According to FDA materials, WalkAide stimulates the common peroneal nerve which innervates the muscles that cause dorsiflexion of the ankle. This stimulation is intended to produce a more natural and stable walking stride. It is indicated for individuals with foot drop due to central nervous system conditions including cerebral palsy, multiple sclerosis, traumatic brain injury, and cerebrovascular accident. It is contraindicated for patients with traumatic accidents to the leg, complications of back, hip or knee surgery, sciatica, peripheral neuropathy, spinal stenosis, post-polio syndrome and Guillain-Barre syndrome. In addition, patients with pacemakers or who experience seizures should not use WalkAide (FDA materials; Innovative Neurotronics website). The Innovative Neurotronics WalkAide System for foot drop was approved by the FDA in August 2005 to address the lack of ankle dorsiflexion in patients who have experienced damage to upper motor neurons or pathways to the spinal cord. The NESS L300 is another electrical stimulation system that received FDA clearance (in 2006) to provide ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease. It has the same intended use and same principal of operation as the WalkAide. The main technological difference however between the two systems, is the RF wireless communications between the components of NESS L300 versus the wired communication in the WalkAide system. NESS L300 is a neuroprosthesis device that consists of four main parts 1. A lower leg orthosis containing electrodes and a controlled stimulation unit, 2. A heel sensor 3. A control unit that is carried in the pocket, mounted on the waist, or on a neck strap, and 4. PDA to be used by the clinician to configure the control unit with functional parameters as appropriate for every patient. The system is intended

to provide ankle dorsiflexion in individuals with foot drop following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot. According to the manufacturer it may also facilitate muscle reduction, prevent/retard disuse atrophy, maintain or increase joint range of motion and increase local blood flow (FDA materials; Ness 300 website). NESS H200 or Bioness is another new muscle stimulation device developed Bioness Inc. to restore function to paralyzed muscles. It is a brace like apparatus, equipped with electrodes to stimulate and activate muscles that have been affected by stroke, injury, multiple sclerosis or cerebral palsy. The H 200 is worn on the forearm and hand and holds the hand in a functional position. According to the manufacturer, the functional electrical stimulation is used to move affected areas through repetitive exercises which would strengthen the muscles, reduce spasticity, improve blood flow, and increase range of movement. A microprocessor allows the therapist to program the device with a sequence of exercises customized to each patient. The system may be also used in the home setting (Bioness Inc. web page). Stroke is one of the leading causes of disability and impairment in the United States. It is reported that only 12-18% stroke survivors will regain complete functional recovery of the upper extremity, and that about 30% to 66% of those with paretic arms will still have an impaired upper limb function after six months with routine rehabilitation. Arm dysfunction impairs the daily activities of the individual as writing, dressing, bathing, self-care, and in turn reduces the functional independence, occupational performance, and quality of life (de Kroon 2002, Meilink 2008, and Kwakkel 2008). Loss of upper extremity function following stroke is a major rehabilitation challenge. Occupational and physical therapies which are commonly used in the rehabilitation of stroke patients have not always been satisfactory in improving the reaching, grasping, holding, or releasing functions of the paralyzed limb. Investigators are now focusing on therapies that will lead to regaining and improving upper extremity functional activity rather than only minimizing the impairment (Alon 2008). Electrical stimulation (ES) has been studied and used clinically for about 40 years in different neurological conditions such as cerebrovascular accidents, multiple sclerosis, cerebral palsy, and other events. Its use for the upper limb is getting increased attention as a therapeutic modality in poststroke rehabilitation. It provides continuous low voltage stimuli which enable repetitive exercise to the neuromuscular system. ES has two modalities: 1. Therapeutic electrical stimulation (TES) which applies higher frequency (36 Hz) with the aim of activating the reduced muscle strength and preventing or lowering the pain and spasticity of the muscles, and 2. Functional electrical stimulation (FES) which applies lower frequency ES (18 HZ) in order to improve activity during the stimuli. TES includes neuromuscular electrical stimulation (NMES), EMG-triggered electrical stimulation, positional feedback stimulation training (PFST), and transcutaneous electrical nerve stimulation (TENS). These have different indications, mechanisms of action, and are applied by multiple devices with a range of possibilities for the adjustment of stimulation parameter (Berner 2004, Kroon 2002). FES on the other hand, is the application of neuromuscular electrical stimulation concurrently with the training of task specific or functional activity i.e. provoking muscle contraction in order to assist the performance of functional activities during stimulation. In the last decades, several research groups have been working on the development of FES systems for the upper extremity, and currently multiple devices aiming at restoring the upper limb function are commercially available (Snoek 2000, Alon 2008). The NESS H200, formerly known as "The Handmaster", (NESS Ltd Ra'anana, Israel) is a portable, non-invasive, hybrid wrist/hand orthosis and electrical stimulation device that is designed to be used in hemiplegic as well as C5 tetraplegic patients. It provides an instrument for both the treatment at the level of impairment (neuromuscular and articular properties) and disability (functional handgrip with stabilized wrist). The system contains an external control unit connected by a cable to a below the elbow splint. The splint contains a body with front spiral end and a wing which pivots about the body and can be opened by lifting a release handle. Five surface electrodes are attached to the splint and correspond with the motor points in finger and thumb muscles. The control unit allows the user to select from among three exercise modes and three functional modes. The exercise modes provide stimulation to the targeted finger and thumb extensor and flexor muscles. The functional mode provides sequential key grip or palmer grasp and release patterns. The spiral design of the system allows wrist stabilization in a functional position of 10 -20° of extension. The system is also designed to permit reproducible accurate electrode positioning by the patient. Once fitted into the orthosis, the electrodes remain in position for all subsequent applications and allow consistent replication of the grasp, hold and release hand functions. The patient is provided with a progressive home exercise program and is required to follow a conditioning paradigm using the system's exercise modes. Training periods start at 10 minutes twice daily and gradually increase to 45 minutes 2 times a day (Hara 2008, Snoek 2000). The NESS system and the Handmaster device received FDA clearance in September 2002, and August 2003 respectively, to be used to maintain or increase the range of motion, reduce muscle spasm, prevent retardation of disuse atrophy, muscle reduction, increase local blood circulation, and provide hand active range of motion and function in patients suffering from upper limb paralysis due to C5 spinal cord injury, or hemiplegia due to stroke.

**12/03/2007: MTAC REVIEW**  
**NESS Stimulators for Foot Drop and Paralyzed Hands**

**Evidence Conclusion:** There is insufficient published evidence to determine the efficacy and safety of the Ness L300 system for patients with foot drop. There is insufficient published evidence to determine the efficacy and safety of the Ness H200 system for the restoration of hand movements.

**Articles:** The search did not reveal any published studies, on Bioness, NESS L300, or NESS H200. Information about the devices was obtained from the FDA and/or the manufacturer's Web sites.

The use of the NESS L300 or NESS H200 in the treatment of foot drop or paralyzed hands does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### 10/06/2008: MTAC REVIEW

##### **NESS Stimulators for Foot Drop and Paralyzed Hands**

**Evidence Conclusion:** The two published RCTs (Alon 2007, and Alon 2008) were conducted by the same group of investigators in the same center, using the same eligibility criteria, procedures, and outcome measures. One of the studies (Alon 2007) included patients with mild/moderate paresis (Fugl- Meyer score 11-40), and the other (Alon 2008) included patients with severe motor loss of the upper extremity (Fugl-Meyer score 2-10). The two trials compared the standard physical and occupational therapies plus FES using NESS H200 versus the standard physical and occupational therapies alone. The trials were small, unblinded, and had no extended follow-up after the end therapy. Their overall results showed some improvement in movement and function in the patients randomized to the NESS H200. The observed differences vs. standard therapy were statistically significant in patients with mild/moderate paresis but not in those with severe motor loss (Alon 2008). The lack of statistical power in the latter study, as well as open-label design, short duration, and absence of follow-up do not allow making any definitive conclusion regarding the effectiveness of the therapy or the persistence of the improvements observed in patients with severe motor impairment. Ring and colleagues' trial (2005) were a comparative study with blinded assessment of outcomes, but had the disadvantage of inappropriate randomization, small number of patients, and absence of follow-up after the six weeks of therapy. The authors categorized the participants into those with or without active voluntary motion of the fingers and wrist at baseline. Patients were assigned to receive rehabilitation with or without NESS Handmaster. The overall results of the trial showed significant improvement in spasticity, motion, and function in all participants receiving the NESS Handmaster device vs. those who did not receive the device. The observed differences were statistically significant for all variables studies for patients who had active partial range of movement at baseline. For those with no active voluntary motion in the fingers and wrist at baseline, decrease in finger spasticity was the only statistically significant improvement observed.

**Conclusion:** There is poor evidence to determine that the use of NESS H200 may improve upper extremity function in patients with mild or moderate paresis/paralysis with similar eligibility criteria as those in the trials, compared to standard physical and occupational therapies. There is insufficient evidence to determine whether the benefits observed would persist after therapy is ended. There is insufficient published evidence to determine that the use of NESS H200 would improve function in patients with severe motor loss in the upper extremity. There is insufficient published evidence to determine if the use of NESS H 200 would lead to a faster motor and functional recovery vs. standard therapy alone. There is fair evidence that NESS H200 is safe to use among patients with upper limb impairment due to stroke, and who has eligibility criteria similar to those of the published studies.

The search revealed a large number of published articles on the use of FES in general, but very limited publications on use the use NESS H200 (NESS Handmaster) for patients with cervical spinal cord injury or stroke. The majority of studies on NESS H200 were case reports or case series with less than 30 patients. There were two small (N=15, and N= 26) randomized controlled trials and one quasi-randomized study, that compared the outcomes of FES using NESS H200 or NESS Handmaster devices in addition to the standard rehabilitation vs. standard rehabilitation alone in stroke survivors with impaired upper extremity. All three were critically appraised.

**Articles:** Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation (FES) may modify the poor prognosis of stroke survivors with severe motor loss of the upper extremity. *Am J Rehabil Med* 2008;87:627-636 See [Evidence Table](#) Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: A pilot study. *Neurorehabil Neural Repair* 2007;21:207-215 See [Evidence Table](#) Ring H, and Nechama Rosenthal. Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. *J Rehabil Med* 2005;37:32-36 See [Evidence Table](#)

The use of the NESS H200 in the treatment of paralyzed hands does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### ***Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System***

##### **BACKGROUND**

The Vertis percutaneous neuromodulation therapy (PNT) system, manufactured by Vertis Neuroscience, is a minimally invasive, nonsurgical therapy. It is based on the premise that chronic back pain is caused by increased

sensitization of the nerve cells that transmit pain signals. The Vertis PNT system delivers electrical stimulation to the deep tissues near the spine to alter the “hypersensitivity” of nerve pathways that cause persistent pain. Treatment consists of a series of outpatient treatment sessions performed in a clinic setting. It is intended for use by a physician or other clinician (e.g. physical therapist), not for patient use. The device includes three major components: Control unit - A software driven, five-channel, AC powered nerve stimulator which generates the electrical stimulus, Sterile, needle electrodes, A cable that connects the needles to the control unit. The FDA approved Verdis PNT in September 2001 for the following indications: Symptomatic relief and management of chronic or intractable low back pain and/or as an adjunctive treatment in the management of post-surgical low back pain and post-traumatic low back pain.

#### **10/09/2002: MTAC REVIEW**

##### **Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System**

**Evidence Conclusion:** There is insufficient evidence to determine the effect of percutaneous neuromodulation therapy on back pain.

**Articles:** There were no published articles evaluating the effect of PNT on back pain. Two articles that were submitted for publication were identified on the manufacturer’s website. The manufacturer indicated that the articles are not yet published.

The use of percutaneous neuromodulation therapy in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee**

##### **BACKGROUND**

There are three main types of arthritis that can affect the knee joint: osteoarthritis, rheumatoid arthritis and post-traumatic arthritis. Osteoarthritis, the most common type, is generally a slowly progressing degenerative disease that involves the gradual wearing away of the joint cartilage. Symptoms include pain and swelling. Pain often increases after activities such as walking and stair climbing and is the principal symptom for which patients with osteoarthritis seek medical attention. The main goal of treatment is pain control, although maintaining and/or improving joint function are also goals. A stepwise approach to management of osteoarthritis of the knee is generally recommended. Initial conservative measures include weight reduction, exercise, and the use of supportive devices. Medications, including anti-inflammatories and corticosteroids, can be used to supplement the conservative approaches. For patients who fail medical management, surgical treatments are available. Pulsed electrical stimulation is a potential non-invasive alternative to surgery for patients who do not respond to medical treatment. The BioniCare Stimulator has been approved by the FDA as an adjunctive treatment for osteoarthritis of the knee. It is a portable battery-operated device that delivers a low frequency (100 Hz) electrical signal to the knee via skin electrodes. Other types of electrical stimulation including electro-acupuncture, transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES) with the Respond Select device have also been used to treat osteoarthritic knee pain.

#### **08/01/2005: MTAC REVIEW**

##### **Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee**

**Evidence Conclusion:** There was one randomized controlled trial on BioniCare for treating osteoarthritis (Zizic et al. 1995). The authors reported that the active treatment group had significantly better outcomes than the placebo group two weeks after completing a 4-week treatment period. However, the statistical analysis may have been biased. The authors used a one-sided p-value at  $p < 0.05$ . If they had used the commonly accepted method of dividing the p-value in half for a one-sided p-value (in this case  $p < 0.025$ ), two of the three primary efficacy variables would not have been significant. Another limitation of the study is that, although the authors reported statistically significant differences, the clinical significance is unclear. There was approximately a 10% difference in the change from baseline in patient perception of pain and patient perception of function (approximately 30% change in the treatment group and 20% change in the placebo group for each outcome variable).

**Articles:** The single RCT was published in 1995 and has not been replicated. In addition, no studies were identified that compared BioniCare to other treatments such as medication or TENS. Patients in the Zizic study were not required to have failed other treatments. One empirical study on the BioniCare system was identified (Zizic, 1995). This was a placebo-controlled randomized controlled trial and was critically appraised. No studies were identified that compared BioniCare to other treatments such as exercise or medication, or to different forms of electrical stimulation such as TENS. *The Zizic study was critically appraised: Zizic TM, Hoffman KC, Holt PA et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. J Rheumatol 1995; 22: 1757-1761. See [Evidence Table](#)*

The use of Pulsed electrical stimulation in the treatment of osteoarthritis of the knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **ReBuilder System**

### **BACKGROUND**

Peripheral neuropathy is a disorder of the peripheral nervous system characterized by impaired function of sensory, motor and/or autonomic nerves. It results from damage to the cell body, nerve fiber, or to the surrounding myelin sheath of peripheral nerves. Manifestations include pain, numbness, tingling, extreme sensitivity to touch, lack of coordination, muscle weakness or paralysis, and bowel or bladder problems. Treatment relies on addressing the underlying cause and various treatments for pain. ReBuilder is a handheld, battery-powered nerve stimulator that delivers an electrical impulse, similar to a normal nerve signal, to specific regions of the body to alleviate pain, burning, tingling, and numbness from a variety of conditions. The ReBuilder is an FDA class II, neurologic therapeutic medical device that first received FDA 510(k) approval in 1987 for marketing as a TENS unit for pain relief. In 1989, the FDA cleared ReBuilder for other indications. The FDA approval is for the symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain relief, relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle reeducation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and maintaining or increasing range of motions. The FDA has written warning letters to manufacturer of ReBuilder against marketing the device for any off-label indications, including peripheral neuropathy.

### **12/19/2011: MTAC REVIEW**

#### **ReBuilder System**

**Evidence Conclusion:** The literature studies did not identify any studies that evaluated the ReBuilder System for any indication. The search did identify a 2011 technology assessment from Kaiser Permanente. Their literature search also did not identify any studies that evaluated the safety or efficacy of the ReBuilder System (Kaiser 2011). Conclusion: There is insufficient evidence to determine the safety or efficacy of the ReBuilder System for the treatment of chronic intractable pain for any condition.

**Articles:** The literature studies did not identify any studies that evaluated the ReBuilder System for any indication. The search did identify a 2011 technology assessment from Kaiser Permanente. Their literature search also did not identify any studies that evaluated the safety or efficacy of the ReBuilder System (Kaiser 2011). See [Evidence Table](#).

The use of ReBuilder System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **WalkAide System for Patients with Foot Drop**

### **BACKGROUND**

Foot drop is defined as a significant weakness in the muscles involved in flexing the ankle and toes (dorsiflexion). The specific muscles affected include the tibialis anterior, extensor hallucis longus and extensor digitorum longus. These muscles allow the toes to swing upward during the beginning of a walking stride and the planting of the heel towards the end of the stride. In patients with foot drop, the foot droops or drags along the ground during the swing phase. The condition is also called steppage gait because patients often raise their thigh excessively high to compensate for toe drop, and they appear as though they are walking up stairs. The unnatural walking motion may result in subsequent damage to the hip, back or knee. Foot drop is associated with a number of conditions such as peripheral nerve injuries, stroke, diabetes, neuropathies and drug toxicity. The causes can be divided into three categories, which may overlap: nerve damage, muscle damage, and/or a skeletal or anatomic abnormality. The conventional treatment for foot drop is the use of ankle-foot orthoses (AFO). These typically limit ankle plantar flexion to enhance foot clearance during swing. Disadvantages of AFOs are that they can be uncomfortable and limiting to wear. Surgery is sometimes beneficial when the cause of foot drop is muscular or neurologic. Electrical stimulation was first proposed as a treatment for foot drop by Liberson in 1961. Liberson referred to the treatment as "functional electrotherapy" because its purpose was to replace a functional movement that was lost after injury or illness. There has been extensive development of functional stimulation devices since the early 1960s. The first devices were hard-wired surface stimulators, followed by hard-wired implanted electrical stimulators, and then microprocessor-based surface and implanted systems. In the 1990s, artificial and "natural" sensors were developed as a replacement for the foot-switch. More recently, testing has been done on a device in which both the sensor and stimulator are implanted (Lyons et al. 2002). The WalkAide system is an external neuromuscular functional stimulator. The system contains a control unit attached to a flexible cuff that contains two electrodes. The unit is placed on the leg below the knee, near the head of the fibula. According to FDA materials, WalkAide stimulates the common peroneal nerve which innervates the muscles that cause dorsiflexion of the ankle. This stimulation is intended to produce a more natural and stable walking stride. WalkAide is indicated for individuals with foot drop due to central nervous system conditions including cerebral palsy, multiple sclerosis, traumatic brain injury and cerebrovascular accident. It is contraindicated for patients with traumatic accidents to the leg, complications of back, hip or knee surgery, sciatica, peripheral neuropathy, spinal stenosis, post-polio syndrome and Guillain-Barre syndrome. In addition, patients with pacemakers or who experience

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seizures should not use WalkAide (FDA materials; Innovative Neurotronics Web site). The Innovative Neurotronics WalkAide System for foot drop was approved by the FDA in August 2005 to address the lack of ankle dorsiflexion in patients who have experienced damage to upper motor neurons or pathways to the spinal cord.

**10/02/2006: MTAC REVIEW**

**WalkAide System for Patients with Foot Drop**

**Evidence Conclusion:** There is insufficient published evidence to determine the efficacy and safety of the Innovative Neurotronics WalkAide System for patients with foot drop. A randomized controlled trial comparing WalkAide to ankle-foot orthoses is underway. The only empirical study identified was a case study, reporting on one patient. The patient used a bionic nerve (BION) implant and a portable BIONic foot drop stimulator that the authors called a "WalkAide2". It is not clear whether this is the same technology as the Innovative Neurotronics WalkAide system.

**Articles:** There are no published randomized or non-randomized controlled studies. According to ClinicalTrials.gov and the Innovative Neurotronics website, an RCT is underway comparing the Innovative Neurotronics WalkAide System to an ankle-foot orthosis (AFO) in patients with cerebrovascular accident. No data from this study are available at this time.

The use of the WalkAide system in the treatment of foot drop does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

**Applicable Codes**

**TENS--**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HPCP Codes	Description
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)

**NMES/FES--**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HPCP Codes	Description
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

**Gastric Neurostimulation--**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach

<b>43881</b>	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
<b>64590</b>	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
<b>64595</b>	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
<b>95980</b>	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
<b>95981</b>	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
<b>95982</b>	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

**Other Electrical Stimulation--**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

<b>CPT/HCPC Codes</b>	<b>Description</b>
<b>64566</b>	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
<b>64575</b>	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
<b>64580</b>	Incision for implantation of neurostimulator electrode array; neuromuscular
<b>C1820</b>	Generator, neurostimulator (implantable), with rechargeable battery and charging system
<b>C1822</b>	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
<b>L8678</b>	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
<b>L8682</b>	Implantable neurostimulator radiofrequency receiver
<b>L8683</b>	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
<b>L8685</b>	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
<b>L8686</b>	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
<b>L8687</b>	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
<b>L8688</b>	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

**Peripheral Nerve Stimulator- i.e., StimRouter--**

**Medicare** - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

**Non-Medicare** – Considered Not Medically Necessary ***\*\*All requests must be reviewed by the Medical Director***

<b>CPT® Codes</b>	<b>Description</b>
<b>64555</b>	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
<b>64575</b>	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)

**Electrical Stimulation for the Treatment of Dysphagia**  
**Galvanic Stimulation Device**  
**H-wave Stimulation Device**  
**Microcurrent Stimulation Device (MENS)**



**Percutaneous Neuromodulation Therapy (PNT) for Back Pain  
Vertis PNT System  
ReBuilder System Threshold Electrical Stimulation--**

**Considered Not Medically Necessary:**

CPT® or HCPC Codes	Description
No specific codes	

**Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee--**

**Medicare: Considered Not Medically Necessary - experimental, investigational or unproven**  
**Non-Medicare: Considered Not Medically Necessary**

HCPC Codes	Description
<b>E0762</b>	Transcutaneous electrical joint stimulation device system, includes all accessories

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
06/30/1998	02/02/2010 <sup>MDCRPC</sup> , 12/07/2010 <sup>MDCRPC</sup> , 10/04/2011 <sup>MDCRPC</sup> , 01/03/2012 <sup>MDCRPC</sup> , 08/07/2012 <sup>MDCRPC</sup> , 03/05/2013 <sup>MDCRPC</sup> , 04/02/2013 <sup>MDCRPC</sup> , 01/07/2014 <sup>MPC</sup> , 07/01/2014 <sup>MPC</sup> , 05/05/2015 <sup>MPC</sup> , 03/01/2016 <sup>MPC</sup> , 01/03/2017 <sup>MPC</sup> , 11/07/2017 <sup>MPC</sup> , 09/04/2018 <sup>MPC</sup> , 09/03/2019 <sup>MPC</sup> , 09/01/2020 <sup>MPC</sup> , 09/07/2021 <sup>MPC</sup> , 09/06/2022 <sup>MPC</sup> , 09/05/2023 <sup>MPC</sup>	09/01/2020

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
06/14/2016	Added NCD 160.7.1
06/02/2015	TENS: MPC approved recommendation of adopting the MCG hybrid criteria
09/28/2017	Added Gastric Neurostimulation codes
06/28/2018	Removed G0283
07/12/2018	Corrected the FES and NMES criteria
10/03/2018	Added LCD L37360 Peripheral Nerve Stimulator
06/24/2020	Added HCPC code C1823 (ESD)
09/01/2020	Removed HCPC codes A4570, C1823, E0766, E0769, G0281 and G0282. Removed CPT codes 63650, 63655, 63685, 64550, 64565, 95971, 95972, 95973, 95974, 95975, 95976, 95977, 95978 and 95979. Added HCPC code E0762. Removed Hypoglossal Nerve Stimulation indications – noted on <i>Sleep Apnea Treatments</i> criteria.
11/06/2023	Updated Medicare coverage links. Added L34821 transcutaneous Electrical Joint Stimulation Devices (TEJSD)