EXTRACORPOREAL MAGNETIC STIMULATION FOR URINARY INCONTINENCE

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersedes this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This policy describes the use of extracorporeal magnetic stimulation (EMS), a noninvasive therapy for the treatment of urinary incontinence (UI). EMS involves pulsed magnetic stimulation of the nerves in the pelvic and the corresponding muscles. The goal is to facilitate the contraction and rehabilitating of the pelvic floor musculature to reduce urinary incontinence.

**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Extracorporeal magnetic stimulation (EMS), sometimes referred to as extracorporeal magnetic innervation (ExMI), is considered EXPERIMENTAL AND/OR INVESTIGATIONAL for the treatment of stress, urge, and mixed urinary incontinence, due to inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature.

**Clinical Considerations: Treatment Options**

Since UI may be a symptom of several disorders, accurate diagnosis is important to ensure that the appropriate treatment is prescribed. For women with stress, urgency or mixed urinary incontinence, initial treatment includes appropriate lifestyle advice, physical therapy, a scheduled voiding regime, behavioral therapy and medication. Pelvic floor muscle training (e.g., Kegel exercises) and/or bladder training techniques are also used under special circumstances (e.g., pregnancy, post-partum). Biofeedback is commonly used as an adjunct to pelvic muscle exercises. Fluid restriction and dietary modification may also be employed to aid in adhering to a prescribed voiding schedule.

Reconstructive surgery is advised only for patients who are refractory to all first-tier treatments.

**Extracorporeal Magnetic Stimulation (EMS)**

EMS has been proposed as a noninvasive therapy for the treatment of UI caused by pelvic floor weakness. The effectiveness of EMS has not been proven in the published peer-reviewed scientific literature. The benefit of treatment varies and is of short-term duration. UI has been reported to worsen and/or return following EMS.

Side effects: Long-term safety data from randomized, controlled trials is scarce. However, current evidence suggests that magnetic stimulation is safe, with no or only few transient side effects. Reported side effects include: leg pain, abdominal pain, cystitis, bowel symptoms, backache, tingling sensation, perineal pain, and neck pain. It could also exacerbate preexisting lumbar ischialgia.

**BACKGROUND:**

Urinary incontinence (UI) is a major health problem at both the individual and population levels. An estimated 25 million people in the United States are, or have been, affected by UI (NAFC, 2009). UI affects 10% to 30% of all adults and 35% of people older than 60 years of age (NCQA, 2009; Fong and Nitti, 2010). The incidence of UI in women is 2 times greater than that in men (Fong and Nitti, 2010). UI is less prevalent in African-American, Hispanic, and Asian women compared with Caucasian women (Deng, 2011). UI is not a disease but a symptom that can be caused by a variety of conditions that directly or indirectly affect bladder control. Predisposing factors for UI include congenital defects, genetics, spinal stenosis, spinal cord injury, and
neurological abnormalities (e.g., Parkinson’s disease, stroke, multiple sclerosis, or herpes zoster infection). In women, pregnancy, childbirth, parity, pelvic surgery, pelvic radiation, pelvic organ prolapsed, and menopause are risk factors for UI (Deng, 2011). Risk factors in men include benign prostatic hyperplasia, benign prostate enlargement, and prostatectomy (Shaban et al., 2010). Obesity, smoking, advanced age, urinary tract infection, certain medications (e.g., diuretics, angiotensin-converting enzyme inhibitors, anticholinergic agents), and certain comorbidities (e.g., diabetes and cardiovascular disease) can increase a person’s risk of developing UI. The direct cost of treating incontinence was estimated at $19.5 billion in 2000 (Shaban et al., 2010).

UI is generally divided into the following categories, depending on the type of malfunction (Shaban et al., 2010; Deng, 2011):

- **Urge incontinence**: Urine leakage results from the inability to consciously inhibit the voiding reflex.
- **Overflow incontinence**: The bladder overfills without causing the sensation of the need to urinate.
- **Stress incontinence**: Characterized by the leakage of urine during physical activities that increase pressure on the bladder.
- **Mixed incontinence**: A combination of urge and stress incontinence.
- **Functional incontinence**: Patient is unable to reach the bathroom because of chronic physical or mental impairment.

Accurate diagnosis of the type of UI is important for an appropriate selection of treatment options. The diagnosis of UI includes the history of UI; degree of bother to the patient; effect on lifestyle; medical and surgical history; neurological status; palpation to identify masses, hernias, or bladder distension; examination of external genitalia; prostate and rectal tone (in men); examination for pelvic organ prolapsed (in women); and urinalysis. In some cases, referral to a urologist is warranted and additional testing may include uroflowmetry, radiography, ultrasonography, determination of post void residual urine, pad tests, cystoscopy, and multichannel urodynamic testing (Fong and Nitti, 2010; Shaban et al., 2010).

Since UI is a symptom of several disorders, the treatment choices vary considerably depending on the underlying disorder. The treatment options for UI include behavioral strategies, pharmacological interventions, temporary electrical stimulation, and reconstructive surgery. After excluding infections, structural abnormalities, neurological problems, or tumors as the underlying cause for UI, the less invasive behavioral and pharmacological interventions are usually the first treatment choices. Behavioral therapies are often combined with temporary electrical stimulation before irreversible, reconstructive surgery is considered. Behavioral therapies include pelvic muscle exercises and/or bladder training techniques; Kegel exercises are the most basic pelvic muscle exercises. Bladder training uses a variety of strategies, including distraction, relaxation, and scheduled voiding, to teach patients with urge incontinence to inhibit contractions of the detrusor muscle. Fluid restriction and dietary modification may also be employed to aid in adhering to a prescribed voiding schedule. Pharmacological interventions include antimuscarinics, musculotropic relaxants, and tricyclic antidepressants. Antimuscarinics are the primary pharmacologic treatment for urge incontinence (Fong and Nitti, 2010; Shaban et al., 2010).

Second-line treatments for UI include neuromodulation, botulinum toxin, urethral bulking agents, surgery, or augmentation cystoplasty. Neuromodulation utilizes an electric current to stimulate the sacral nerves via leads from a neurostimulator that is implanted into the upper buttock. Urethral bulking agents, such as collagen, calcium hydroxyapatite, silicone particles, and polyacrylamide hydrogel, are injected into the submucosal tissues of the proximal urethra. These agents are intended to augment urethral closing; however, the difficulty of the procedure combined with the incidence of complications has caused this method to lose favor among
practitioners. The most common surgical procedure for the treatment of UI in women is the midurethral sling. Surgical procedures utilized in men include artificial urinary sphincter and perineal slings. Augmentation cystoplasty, during which bladder volume is increased by insertion of intestinal tissue, is often proposed for patients with severe detrusor instability who fail conservative therapies (Sassani and Aboseif, 2009; Fong and Nitti, 2010; Shaban et al., 2010).

Extracorporeal magnetic stimulation (EMS) has been introduced as a noninvasive therapy for the treatment of UI. During EMS therapy, a focused, time-varying magnetic field penetrates into the perineum and activates the motor neurons of the pelvic floor muscles. The pelvic muscles contract and relax with each magnetic pulse, thereby strengthening the muscles. The goal of this therapy is the rehabilitation of the pelvic floor musculature to reduce urinary incontinence (Kitalpha Med Ltd., 2009).

EMS treatment sessions typically last 20 to 30 minutes and are performed twice a week for an 8-week period. Although the patient can sense the muscle contractions, EMS is generally not painful and anesthesia is not required. Alternatively, continuous treatment may be conducted at home using a small EMS device (Pulsegen™; Power of Nature LLC), which is inserted into specially designed undergarments.

**Side effects:** Long-term safety data from randomized, controlled trials is scarce. However, current evidence suggests that magnetic stimulation is safe, with no or only few transient side effects. Reported side effects include: leg pain, abdominal pain, cystitis, bowel symptoms, backache, tingling sensation, perineal pain, and neck pain. It could also exacerbate preexisting lumbar ischialgia.

EMS devices include the NeoControl® Pelvic Floor Therapy System (Neotonus Inc., now defunct; system currently marketed by Kitalpha Med outside the United States), Magstim® Rapid (Magstim Co. Ltd.), BioCon-2000® (Mcube Technology), and Magther Incontinence Therapy System (EMD Medical Inc.).

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   There is only one extracorporeal magnetic stimulation (EMS) device approved for the treatment of urinary incontinence (UI), although there are a large number of electrical stimulation devices approved for this indication. The NeoControl® Pelvic Floor Therapy System (Neotonus Inc.) received 510(k) clearance from the FDA on October 29, 2000, for the treatment of urinary urge incontinence, urinary retention, and significant symptoms of urgency/frequency in women who have failed or could not tolerate more conservative treatments (CDRH, 2000a). The 510(k) clearance was modified in 2000 to remove the contraindication for patients with cardiac arrhythmia. The Magstim® Rapid with Dual 70-mm Coil and Circular 90-mm Coil (Magstim Co. Ltd.) received 510(k) clearance for stimulation of peripheral nerves on January 7, 2000; all other indications are considered as investigational (CDRH, 2000b).

   The MyoTrac Infiniti System (Thought Technology, LTD, Montreal, Quebec) was approved in March 2006 for acute and ongoing treatment of stress, urge, or mixed urinary incontinence.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**
   CMS has not established a National Coverage Determination (NCD) that addresses EMS for UI. In the absence of an NCD, coverage is left to the discretion of local Medicare carriers.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**
   Pelvic floor stimulators are covered with authorization for recipients with stress, urge or mixed incontinence who have undergone a documented trial of pelvic muscle exercises for a period of at least six
months with no significant improvement in incontinence. Pelvic floor magnetic stimulation devices (e.g. ExMI, NeoControl Pelvic Floor System) are considered investigative, therefore non-covered services.

CLINICAL EVIDENCE:

The evidence in the published peer-reviewed literature evaluating the safety and effectiveness of EMS for urinary incontinence consisted of 22 studies and included 9 randomized, sham-controlled, clinical trials; 2 randomized comparison trials; and 11 prospective uncontrolled studies, which evaluated the safety and efficacy of EMS for the treatment of UI. The studies primarily involved women patients with stress incontinence, although several studies also included women with urge or mixed incontinence, and some studies included a few men. There was one study of EMS for incontinence subsequent to radical prostatectomy and one study of urinary dysfunction in children. The patient populations were relatively small, ranging from 16 to 111 patients, and were heterogeneous with respect to age and duration of symptoms, and in some studies, also with respect to type of incontinence. The treatment protocols also varied with respect to device, settings, and duration of treatment. An armchair-based EMS device was utilized in most of the studies; however, two studies utilized EMS devices that fit into a specially designed undergarment for home-based treatment. Outcome measures included urodynamic parameters such as bladder capacity and urethral closure pressure, the mean number of incontinence episodes during the day and/or night, the mean number of pads used by the patient, mean pad weight, voided urine volume, and quality of life. Follow-up times were generally short and ranged from 1 week to 12 months.

The results of most, but not all, of the studies suggest that EMS is an effective but transient treatment for some types of urinary incontinence. In a number of the studies, frequency of leakage episodes, pad use, quality of life, frequency of urination, and certain urodynamic parameters were significantly improved after EMS treatment, and in several controlled studies, EMS treatment was more effective than sham treatment. However, the effect of EMS treatment was short lived; nearly all of the patients suffered relapse within a few months of treatment. EMS and functional electric stimulation were found to be equivalent in the two studies that compared these devices.

The results of three studies suggest that EMS does not improve UI. Two of these studies were uncontrolled, and the other was a randomized sham-controlled trial. Limitations of many of the studies included small sample size, lack of a sham control group, and no long-term follow-up.

Long-term safety data from randomized controlled trials is scarce. However, current evidence suggests that magnetic stimulation is safe, with no or only few transient side effects. Seven of the studies that were reviewed for this report had follow-up durations of 6 months or longer, and none reported complications related to EMS. Only two of the studies reported any complications. One patient withdrew from the study because of exacerbation of preexisting lumbar ischialgia that was deemed to be device related. Over half of the 48 patients in one study reported side effects, which included leg pain, abdominal pain, cystitis, bowel symptoms, backache, tingling sensation, perineal pain, and neck pain.

Definitive patient selection criteria for EMS for treatment of UI have not been established. EMS is contraindicated in patients with overflow incontinence, patients with cardiac pacemakers or other implanted metal or electronic devices, and in pregnant patients.
EXTERNAL SOURCES/ GROUPS POLICY:

- The American College of Obstetricians and Gynecologists (ACOG): The 2005 guideline from ACOG on UI in women states the following regarding treatment options:
  1. Behavioral therapy, including bladder training and prompted voiding, improves symptoms of urge and mixed incontinence and can be recommended as a noninvasive treatment in many women.
  2. Pelvic floor training appears to be an effective treatment for adult women with stress and mixed incontinence and can be recommended as a noninvasive treatment for many women.
  3. Pharmacologic agents, especially oxybutynin and tolterodine, may have a small beneficial effect on improving symptoms of detrusor overactivity in women.

The guideline does not mention the use of EMS in the treatment of UI.

- American Urogynecologic Society (AUGS): AUGS has a policy statement, which states that “pelvic floor rehabilitation therapy, including pelvic floor stimulation and biofeedback guided pelvic floor exercises, used alone or in combination, are a proven method used to treat symptoms of UI and pelvic floor dysfunction” (AUGS, 2011).

- Blue Cross Blue Shield Association: BCBSA TEC Assessment evaluated the use of electromagnetic pelvic floor stimulation. At the time, minimal data regarding these devices was available, and no randomized trials had isolated and validated the effectiveness of the treatment. Galloway and colleagues presented the results of a multicenter prospective nonrandomized trial in 83 patients with stress urinary incontinence. Patients were treated for 20 minutes twice a week for six weeks. A total of 66% of patients were either dry or using no more than one pad per day after a 3-month follow-up. The TEC Assessment concluded that these preliminary results require confirmation in randomized trials.

SUMMARY

There is limited data in the published, peer-reviewed, evidence-based literature supporting the efficacy of extracorporeal electromagnetic stimulation (EMS). Limitations of the studies include small patient populations, lack of a control group, lack of long-term results, and inconsistencies in procedural protocol. The studies do not demonstrate that the use of EMS results in improved health outcomes in patients with urinary incontinence (UI) when compared to either sham devices or proven treatment methods such as behavioral and pharmacological therapies.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<tr>
<td>E0740</td>
<td>Incontinence treatment system, pelvic floor stimulator, monitor, sensor, and/or trainer</td>
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<tr>
<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
</tr>
<tr>
<td>G0295</td>
<td>Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses</td>
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ICD-9-CM | Description
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625.6 | Stress incontinence, female
788.30 | Urinary incontinence, unspecified
788.31 | Urge incontinence
788.32 | Stress incontinence, male
788.33 | Mixed incontinence, (male) (female)
788.34 | Incontinence without sensory awareness
788.35 | Post-void dribbling
788.36 | Nocturnal enuresis
788.37 | Continuous leakage
788.38 | Overflow incontinence
788.39 | Other urinary incontinence

ICD-10 Codes | Description
--- | ---
N39.3 | Stress incontinence
N39.4 | Other specified urinary incontinence (includes overflow incontinence, reflex incontinence, and urge incontinence)

CPT® Codes | Description
--- | ---
53899 | Unlisted procedure, urinary system
64550 | Application of surface (transcutaneous) neurostimulator
97014 | Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032 | Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

CPT® is a registered trademark of the American Medical Association.

REFERENCES:

10. Center for Devices and Radiological Health (CDRH). K001903. NeoControl Pelvic Floor Therapy System. October 29,


POLICY HISTORY:

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<td>01/30/2013</td>
<td>New policy 2013M0016A. Approved by the Interim Medical Policy Committee.</td>
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