



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Extracorporeal
Electromagnetic Stimulation
for Urinary Incontinence**

Effective Date 3/15/2011
Next Review Date 3/15/2012
Coverage Policy Number 0041

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INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA does not cover extracorporeal electromagnetic stimulation for any type of urinary incontinence because it is considered experimental, investigational or unproven.

General Background

Urinary incontinence (UI), also called urinary voiding dysfunction, is the involuntary loss of urine. UI is not a disease, but a symptom that can be caused by various abnormalities that directly or indirectly affect bladder control. Depending on the type of malfunction, UI is generally classified as one of five conditions. Urge incontinence, a sudden and uncontrollable need to urinate, is characterized by urine leakage due to the inability of an individual to consciously inhibit the voiding reflex. It is often caused by involuntary contractions of the bladder wall and overactivity of the detrusor muscle. Urge incontinence is difficult to treat; approximately 60–70% of all cases are refractory.

Overflow incontinence is a condition in which the bladder overfills without feeling the sensation to urinate. This type of incontinence is characterized by an acontractile or hypotonic detrusor muscle. Drug therapy, fecal impaction, or disruption of the motor innervation of the detrusor muscle through neuropathies or spinal cord injuries may contribute to urinary retention, which in turn may lead to overflow incontinence.

Stress incontinence, the most common type of UI, involves the leakage of urine during exercise, coughing, sneezing, laughing, and other physical activities that increase pressure on the bladder. The combination of urge and stress incontinence is referred to as "mixed incontinence." The term "functional incontinence" refers to a person's inability to reach the bathroom due to chronic impairment of physical or mental functioning.

Treatment Options

Since UI may be a symptom of several disorders, accurate diagnosis is important to ensure that the appropriate treatment is prescribed. Treatment options for urinary voiding disorders include behavioral strategies, pharmacological interventions, and/or reconstructive surgery. After excluding infections, structural abnormalities, neurological problems, and tumors as the underlying cause of UI, the first choices for treatment are usually the less invasive behavioral and pharmacological interventions. Behavioral therapies include pelvic muscle exercises (e.g., Kegel exercises) and/or bladder training techniques. 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. Pharmacological interventions include antispasmodic medications as well as tricyclic antidepressants. Alpha-adrenergic drugs are often used to control stress incontinence.

Reconstructive surgery is advised only for patients who are refractory to all first-tier treatments. The most common surgical procedures for the treatment of UI include bladder neck suspension (i.e., sling procedure), periurethral collagen injections, and implantation of an artificial sphincter. Augmentation cystoplasty, which increases bladder volume by insertion of intestinal tissue, is often proposed for patients with severe detrusor instability who fail conservative therapies. Chronic sacral nerve stimulation (SNS), a minimally invasive therapy, is intended as an alternative to reconstructive surgery.

Extracorporeal Electromagnetic Stimulation (EMS)

EMS, also known as extracorporeal magnetic innervation (ExMI), has been proposed as a noninvasive therapy for the treatment of UI caused by pelvic floor weakness. Unlike electrical stimulation, which uses electrodes placed on the skin, EMS uses an electromagnetic field to induce natural contractions of the pelvic floor muscles. The goal of this therapy is to build strength, endurance and continence by rehabilitating the pelvic floor musculature. The process is similar to Kegel exercises without active participation by the patient. EMS is generally administered by a urologist during a regular office visit. The procedure is generally not painful and does not require anesthesia. 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.

U.S. Food and Drug Administration (FDA)

The NeoControl[®] Pelvic Floor Therapy System (Neotonus, Inc., Marietta, GA), formerly known as the Neotonus Model 1000 Magnetic Stimulator, was approved by the FDA 510(k) process on June 21, 2000. According to the FDA, the intended use for the NeoControl is to "provide entirely non-invasive electromagnetic stimulation of pelvic musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in women" (FDA, 2000).

Literature Review

The evidence in the published peer-reviewed literature evaluating the safety and effectiveness of EMS for urinary incontinence includes randomized controlled trials (RCTs) (Gilling, et al., 2009; Culligan, et al., 2005) and case series (Kang, et al., 2007; Voorham-van der Zalm, et al., 2006; Yokoyama, et al., 2004; Chandi, et al., 2004; Almeida, et al., 2004). Studies have primarily involved female patients with stress, urge or mixed incontinence with patient populations ranging from 11–111. Treatment protocols varied with respect to settings, duration of treatment, and device types. The results of some RCTs have demonstrated no statistically significant difference between treatment and control groups in outcomes such as pad tests and pelvic muscle strength.

A systematic review by Shamliyan et al. (2008) evaluated evidence on the management of urinary incontinence in women which included RCTs (n=96 studies) and other systematic reviews (n=3). Of the 96 RCTs published from 1990 through May 2007, 12 examined the effectiveness of magnetic or electrical stimulation. It was summarized that the inconsistent low-level evidence did not show that magnetic or electrical stimulation cured or improved urinary incontinence in women compared to sham stimulation or pelvic floor muscle training (PFMT).

A California Technology Assessment Forum (CTAF, 2004) review of the evidence on the use of magnetic stimulation for UI in women concluded that there is insufficient evidence from RCTs to conclude that pelvic floor magnetic stimulation is as beneficial as alternative effective therapies which include PFMT alone and anti-cholinergic medication (Felman, 2004).

Early studies reported that EMS might improve the number of incontinence episodes, decrease urine loss, and improve quality of life in women with urinary stress incontinence (But, 2003; Fujishiro, et al., 2002; Fujishiro, et al., 2000; Galloway, et al., 2000; Yamanishi, et al., 2000; Galloway, et al., 1999). However in general, the majority of studies have limitations of small patient populations, short-term follow-up and the use of patient-assessed outcome measures. It has not been proven that EMS is as effective as, or superior to, established treatment modalities.

Professional Societies/Organizations

A 2005 guideline from the American College of Obstetricians and Gynecologists (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.

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.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered when used to report extracorporeal electromagnetic stimulation for urinary incontinence:

CPT* Codes	Description
53899	Unlisted procedure, urinary system

ICD-9-CM Diagnosis Codes	Description
625.6	Stress incontinence, female
788.30- 788.39	Urinary incontinence

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0041	Extracorporeal Electromagnetic Stimulation for Urinary incontinence
Great-West Healthcare	3/12/2007	99.283.03	Incontinence, Extracorporeal Magnetic Stimulation (NeoControl®)

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