Pelvic Floor Electrical Stimulation for the Treatment of Urinary Incontinence

Policy Number: 2013M0028A          Effective Date: January 1, 2014

Table of Contents:  

<table>
<thead>
<tr>
<th><strong>Policy Section</strong></th>
<th><strong>Page</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY DESCRIPTION</td>
<td>2</td>
</tr>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>2</td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>4</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>5</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>5</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>6</td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>9</td>
</tr>
</tbody>
</table>

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 supersede 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 provides information on the use of pelvic floor electrical stimulation which involves the use of a non-implantable electrode, which is often a vaginal or anal internal probe, and an external pulse generator that delivers variable rates of current through the pelvic floor. The goal of pelvic floor electrical stimulation is to stimulate the nerves involved in bladder and sphincter function and to strengthen pelvic floor musculature to decrease or eliminate urge, stress, and mixed forms of urinary incontinence.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:
Non-implantable pelvic floor electrical stimulators may be considered MEDICALLY NECESSARY for stress and/or urge urinary incontinence when both of the following criteria are met:
1. Member is cognitively intact, AND
2. Member has failed a documented trial of pelvic muscle exercise program (a failed trial of pelvic muscle exercise program is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of PME designed to increase periurethral muscle strength).

Pelvic floor stimulators are considered EXPERIMENTAL/INVESTIGATIONAL for patients who do not have stress, urge or mixed incontinence.

Clinical Considerations:
- DHS requires documentation to include the type of incontinence and a trial of pelvic muscle exercises for a period of at least six months with no significant improvement in incontinence.
- CMS requires completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.
- A pelvic floor stimulator for urinary incontinence is covered as RENTAL ONLY up to the time the payments have reached the purchase price, at which time the machine becomes owned by the member.

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.

Urinary incontinence affects at least 13 million Americans and is twice as common in women as in men (NIDDK, 2004). Urinary incontinence affects 10% to 52% of adult women and is severe in 3% to 17% (Cody et al., 2003). For non-institutionalized persons older than 60 years, the prevalence ranges from 15% to 30%. For nursing home residents, the prevalence is ≥ 50%. Urinary incontinence is the involuntary loss of urine that is a social or hygienic problem. Urinary incontinence is categorized as transient, urge, stress, overflow, mixed, and functional.
The risk factors for the development of urinary incontinence in women include: Childbirth, mode of delivery, pregnancy, increased parity, hysterectomy, recurrent urinary tract infections, gastrointestinal factors, medications such as diuretics, sedatives and beta-blockers, smoking, alcohol and caffeine use, presence of two or more chronic diseases such as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), diabetes, advanced age, white race, and high body mass index.

Other causes of incontinence in both men and women include: Diseases that damage the cortical and subcortical inhibitory centers such as dementia, Alzheimer’s disease, normal pressure hydrocephalus, and multi-infarct disease.

There are three primary types of incontinence:

1. Urge incontinence, caused by an urgent need to urinate due to a sudden bladder contraction. Urge incontinence accounts for 50% to 70% of incontinence cases and involves the involuntary loss of urine preceded by an urge to void.

2. Stress incontinence, caused by a weakening of the pelvic floor muscles. Stress incontinence is characterized by the involuntary loss of urine associated with the lack of sustained constriction in the urethra and maneuvers, such as coughing, laughing, or running, that increase intra-abdominal pressure.

3. Overflow incontinence, caused by the bladder becoming too full yet unable to be emptied, usually due to obstruction or injury.

Mixed incontinence is common and usually includes characteristics of both stress and urge incontinence. Patients with stress incontinence may also need to void their bladders frequently to prevent leaking, a symptom that may also appear with urge incontinence. Urinary incontinence following radical prostatectomy affects between 6% and 63% of men greater than 6 months after surgery and is predominately stress or urge incontinence. Functional incontinence is caused by chronic impairment of physical and/or cognitive function, resulting in overactive bladder. A pure functional incontinence is a diagnosis of exclusion.

There are three primary modes of treatment for urinary incontinence:

1. Non-pharmacologic:
   - Physical therapy, Kegel, or pelvic floor exercises, which involve repeated voluntary contraction of striated muscles, such as the levator ani, biofeedback, vaginal weights or cones, pessaries, urethral occlusion plugs, bladder training
   - Extracorporeal magnetic stimulation
   - Pelvic electrical stimulation

2. Pharmacologic treatments:
   - Anticholinergic
   - Beta-adrenergic agonists
   - Antimuscarinic agents such as oxybutynin, and tolterodine

3. Surgical therapies. The invasive surgical treatments include:
   - Retropubic colposuspension
   - Suburethral sling procedure
   - Tension-free tape procedure
Pelvic floor stimulation (PFS) involves the electrical stimulation of pelvic floor muscles using either a probe wired to a device for controlling the electrical stimulation, or more recently, extracorporeal pulsed magnetic innervation. It is thought that pelvic floor stimulation of the pudendal nerve will improve urethral closure by activating the pelvic floor musculature. In addition, PFS is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. The methods of PFS have varied in location (vaginal, rectal), stimulus frequency, stimulus intensity or amplitude, pulse duration, pulse to rest ratio, treatments per day, number of treatment days per week, length of time for each treatment session, and overall time period for device use between clinical and home settings. Variation in the amplitude and frequency of the electrical pulse is used to mimic and stimulate the different physiologic mechanisms of the voiding response, depending on the type of etiology of incontinence, e.g., either detrusor instability, stress incontinence, or a mixed pattern. Magnetic pelvic floor stimulation does not require an internal electrode; patients may sit, fully clothed, on a specialized chair.

Patients receiving PFS may undergo treatments in a physician’s office or physical therapy facility, or patients may undergo initial training in a physician’s office followed by home treatment with a rented or purchased pelvic floor stimulator. Magnetic PFS is delivered in the physician's office.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA): All devices with surface electrodes that are used for bladder stimulation are Class II devices. The 510(k) FDA-approved nonimplantable electrical stimulators include:
   - Detrusan 500 (Innovamed USA Inc.)
   - Pathway CTS 2000 (Prometheus Group)
   - Urostym (Laborie Medical Tech Corp.)
   - Elpha 2000 (Dan Med Inc.)
   - Athena Pelvic Muscle Trainer II (Athena Feminine Technologies Inc.)
   - evadri Bladder Control System (Hollister Inc.)
   - Urgent® PC Neuromodulation System (Uroplasty Inc.)
   - MyoTrac Infiniti™ (Thought Technology, Ltd.)
   - InCare PRS (Hollister Inc.)
   - NeoControl® Pelvic Floor Therapy System (Neotonus, Inc.)

   (FDA, 1999; FDA, 2001a; FDA 2003b; FDA, 2003c; FDA, 2003d; FDA, 2005a; FDA, 2005b).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
   National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator (230.8).
3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):


CLINICAL EVIDENCE:

SUMMARY:

Evidence regarding the effect of pelvic floor electrical stimulation with anal or vaginal electrodes is conflicting, with some randomized controlled trials reporting a beneficial effect for genuine stress incontinence compared with sham treatment, and others reporting minimal or no effect. There is less evidence regarding the efficacy of anal and vaginal electrical stimulation for urge and mixed urinary incontinence or postprostatectomy incontinence, or for other types of pelvic floor electrical stimulation methods, such as biofeedback-assisted electrical stimulation, or percutaneous or intravesical transurethral stimulation. In addition, optimal stimulation protocols have not been defined, and long-term effects are unknown.

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.

Note: There is no specific code for the administration of pelvic floor stimulation.

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<th>HCPCS Code</th>
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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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<td>625.6</td>
<td>Stress urinary incontinence, women</td>
</tr>
<tr>
<td>788.31</td>
<td>Urge urinary incontinence</td>
</tr>
<tr>
<td>788.32</td>
<td>Stress urinary incontinence, men</td>
</tr>
<tr>
<td>788.33</td>
<td>Mixed urinary incontinence (urge and stress incontinence), men and women</td>
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<th>ICD-10 Codes</th>
<th>Description</th>
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<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system</td>
</tr>
<tr>
<td>97014</td>
<td>Electrical stimulation (unattended)</td>
</tr>
<tr>
<td>97032</td>
<td>Application of modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
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**REFERENCES:**


### POLICY HISTORY:

<table>
<thead>
<tr>
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<th>ACTION/DESCRIPTION</th>
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<tr>
<td>06/27/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>11/15/2013</td>
<td>Published to UCare.org</td>
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