Clinical Policy Title: Pelvic floor stimulation for incontinence

Clinical Policy Number: 13.02.02

Effective Date: July 1, 2016
Initial Review Date: April 19, 2017
Most Recent Review Date: April 19, 2017
Next Review Date: April 2018

Related policies:

CP# 13.03.02  Surgical and invasive treatments for overactive bladder syndrome
CP# 08.01.06  Cecostomy for fecal incontinence
CP# 08.02.04  Injectable bulking agents for fecal incontinence

ABOUT THIS POLICY: AmeriHealth Caritas Iowa has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Iowa’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Iowa when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Iowa’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Iowa’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Iowa will update its clinical policies as necessary. AmeriHealth Caritas Iowa’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Iowa considers the use of pelvic floor stimulation using non-implanted electrical devices for the treatment of urinary incontinence (UI) to be investigational or experimental and, therefore, not medically necessary.

AmeriHealth Caritas Iowa considers the use of pelvic floor stimulation using non-implanted electrical devices for the treatment of fecal incontinence (FI) to be investigational or experimental and, therefore, not medically necessary.

AmeriHealth Caritas Iowa considers the use of pelvic floor stimulation using extracorporeal magnetic innervation for the treatment of UI to be investigational or experimental and, therefore, not medically necessary.

For Medicare members only:
AmeriHealth Caritas Iowa considers the use of pelvic floor stimulation using non-implanted electrical devices to be clinically proven and, therefore, medically necessary for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training.

A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing four weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

**Limitations:**

All other uses of pelvic floor stimulation using non-implanted electrical devices and extracorporeal magnetic innervation are not medically necessary.

**Alternative covered services:**

- Behavioral training.
- Biofeedback.
- Bladder neck support prosthesis (pessary).
- Bladder training.
- Diet modification.
- Pelvic floor muscle training (PFMT).
- Pharmacotherapy (e.g., oxybutynin, tolterodine, darifenacin, solifenacin, fesoterodine, and trospium).
- Weight loss and exercise.

**Background**

Incontinence is a significant health problem in the United States and worldwide. Estimates of prevalence of UI vary widely due to inconsistencies in the definitions and differences in populations studied, but UI has a significant impact on the quality of life. UI is more common in women than men, and older women experience UI more often than younger women. Stress urinary incontinence (SUI) is the predominant type of UI in women and urge urinary incontinence (UUI) is the predominant type of UI in men, with the exception of UI related to radical prostatectomy, in which SUI predominates (Wu, 2014; Markland, 2011). UI in men and women is caused by bladder dysfunction, sphincter dysfunction, or both. Clinical presentation varies depending on the underlying mechanism causing or contributing to UI.

FI affects one in eight community adults with equal distribution among genders. The factors most commonly reported to be associated with FI include increasing age, diarrhea, chronic illness, and UI (Ng, 2015; Bharucha, 2015).
Treatment depends on the type of incontinence. For UI, treatment options include pelvic floor muscle training; physical therapies (e.g., vaginal cones); behavioral therapies (e.g., bladder training); mechanical devices (e.g., continence pessaries); drug therapies (e.g., anticholinergics and duloxetine) and surgical interventions, such as sling procedures and colposuspension (Imamura, 2013). For FI, nonsurgical treatment options include biofeedback, lifestyle and dietary modifications, bowel habit interventions, pelvic floor muscle training, rectal irrigation, and drug therapy. When noninvasive options fail, minimally invasive and surgical therapies may be considered (Bharucha, 2015).

Pelvic floor stimulation using non-implanted electrical or magnetic devices has been proposed as a nonsurgical option for the treatment of UI and FI. While the precise mechanism of action of pelvic floor electrical stimulation (PFES) in humans is unclear, the therapeutic intent is to stimulate the pudendal nerve to activate the pelvic floor musculature, which may lead to improved urethral closure. In addition, it may improve partially denervated urethral and pelvic floor muscles through the process of re-innervation.

PFES refers to the use of non-implanted electrodes, either adhesive pads placed on the skin near the vagina and anus, or a tampon-shaped device placed intra-vaginally or intra-anally, to deliver variable rates of electrical current to the pelvic floor musculature. Depending on the etiology of incontinence, PFES applies variations in electrical pulse amplitude and frequency to mimic and stimulate different physiologic mechanisms of the voiding response. Methods of PFES vary in location (e.g., vaginal or rectal), stimulus frequency, 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. Initial training occurs in an outpatient or office setting, followed by home treatment with a rented or purchased pelvic floor stimulator. As of January 16, 2016, the U.S. Food and Drug Administration (FDA) has given marketing clearance to 65 PFES devices (Class II, product code KPI) for the treatment of UI and FI (Hayes, 2016).

Extracorporeal magnetic innervation (ExMI) delivers nerve impulses to the pelvic floor area to increase muscular contractions in an attempt to improve bladder control. The FDA has approved one device, the NeoControl® Pelvic Floor Therapy System for the treatment of UI in women (Neotonus, North Attleboro, MA; Class II, product code KPI). The system consists of a control unit and treatment chair. The chair’s therapeutic head generates pulsed magnetic fields that stimulate the perineal tissues, nerves, and muscles, reportedly increasing contractions and improving circulation. The treatment is typically performed twice a week, with each session lasting approximately 20 minutes. A complete course of treatment may take eight weeks or more depending on the condition of the pelvic floor muscles when therapy is started.

**Searches**

AmeriHealth Caritas Iowa searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).
We conducted searches on March 14, 2017. Search terms were: "urinary incontinence/therapy" (MeSH), "fecal incontinence/therapeutic use" (MeSH), "fecal incontinence/therapy" (MeSH), "electric stimulation therapy" (MeSH) and "pelvic floor."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews**.

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The National Institute for Health and Care Excellence recommends against the routine use of electrical stimulation of women with overactive bladder syndrome, alone or in combination with pelvic floor muscle training. The group does recommend that PFES be considered in women who cannot actively contract pelvic floor muscles in order to aid motivation and adherence to therapy (NICE, 2013).

The European Association of Urology recommended PFES as an adjunct to behavioral therapy in patients with urgency UI. The Association does not recommend PFES as monotherapy for SUI, or ExMI for the treatment of UI or overactive bladder in adult women (EAU, 2015).

The American Society of Colon and Rectal Surgeons recommended dietary management, medical management and biofeedback as first-line nonsurgical treatments for patients with FI and some preserved voluntary sphincter contraction, but made no mention of PFES in the guideline (Paquette, 2015).

The American College of Physicians guideline on the nonsurgical management of UI in women did not mention either PFES or ExMI in its 2014 recommendations of nonsurgical management of urinary incontinence in women (Qaseem, 2014).

The most recent systematic review for PFES for overactive bladder included 63 trials, 44 of which did not report a primary outcome of cure or improvement. While some evidence found PFES was more effective than pelvic floor muscle training, it was unclear if it was more effective than placebo. The low or very low quality of evidence limits any confidence in results (Stewart, 2016).

A Hayes review assessed 15 randomized controlled trials (RCTs), including 11 of women with SUI and three of men following a prostatectomy. The study concluded that a moderate-sized body of low-quality evidence exists showing benefits to some women with SUI, and a limited amount of low-quality evidence shows
improved outcomes in men after radical prostatectomy (Hayes, 2016).

Other systematic reviews include:

- Thirteen studies assessed efficacy of biofeedback and/or PFES for adult FI (young mothers and elderly men and women needing second-line treatment). It concluded that these therapies combined were consistently superior to either as monotherapy, using moderate-to-high quality evidence (Vonthin, 2013).
- Nine trials found PFES increased continence rates more than did placebo, but only one in nine treated women achieved continence (Shamlyan, 2012).
- Fifty-five trials (n = 6,608 women with SUI) evaluated efficacy of five interventions; PFES was less effective than biofeedback and pelvic floor muscle training, and no more effective than placebo (Imamura, 2010).
- Thirty-seven studies (n = 1058 women with SUI) documented electrical stimulation improved quality of life more than placebo, but results of individual studies were inconsistent (Moroni, 2016).
- Forty studies of 210 post-prostatectomy males treated for six to 12 months with pelvic floor muscle training with or without PFES found a non-significant (3 percent) difference in risk ratio (Zhu, 2012).
- Ninety-six RCTs and three systematic reviews found PFES did not resolve UI in women (Shamlyan, 2008).

An RCT of 208 men ages 51 – 84 with incontinence post-prostatectomy found that mean incontinence episodes per week after eight weeks of treatment decreased from 28 to 13 after behavioral therapy alone, and a similar reduction of 26 to 12 after behavioral therapy plus PFES; these reductions were better than controls (25 to 21), but adding PFES to behavioral therapy did not improve outcomes (Goode, 2011).

A recent study of 60 women with overactive bladder syndrome found PFES did not reduce daily micturitions and nocturnia episodes as effectively as percutaneous tibial nerve stimulation (Scaldazza, 2017).

The multiple systematic reviews discussed here do not address any long-term effects of PFES, while limited evidence of PFES effectiveness has prevented any cost-effectiveness studies to date.

Few journal articles have been published on efficacy of extracorporeal magnetic innervation (ExMI). One study that followed 137 women treated for SUI and UUI found that 47 percent were dry after six months, but with high recurrence after three years (Doganay, 2010). Another study of 30 women with SUI treated with ExMI found 77.8 percent were cured or improved after three months, a figure that was unchanged for one year; however, a gradual decrease occurred in the second year (Hoscan, 2008). A Hayes review of 22 studies found a similar pattern of any improvements not lasting past the short term (Hayes, 2015).

**Policy updates:**

A total of 1 guideline/other and 11 peer-reviewed references have been added to this policy.
**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stewart (2016)</strong></td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| PFES for adults with overactive bladder | - Cochrane review of 63 trials (n = 4,424) of adults treated for overactive bladder with PFES.  
- 44 of 63 trials did not have outcomes of perception of cure or improvement.  
- Moderate-quality evidence indicated PFES was better than pelvic floor muscle training (RR = 1.60), drug treatment (RR = 1.20), and placebo (RR = 2.26) for perception of improvement.  
- Not clear if PFES better than placebo for urgency urinary incontinence.  
- Low-quality evidence (n = 51) that PFES added to pelvic floor muscle training was superior than when PFES was not added. |
| **Hayes (2016)**          | **Key points:**                   |
| PFES as treatment of UI   | - Systematic review of 15 RCTs; 11 RCTs evaluated PFES in 895 women with SUI and 308 women with UUI, and three RCTs evaluated PFES in 258 men with SUI following radical retropubic prostatectomy (RP).  
- Overall quality: low. Heterogeneity in patient populations, specific treatment protocols, and comparators and short follow-up.  
- PFES appears to be safe and well tolerated in the short term. Most common adverse effects were pain or discomfort with the electrical stimulation.  
- For women with SUI or UUI or men with UUI, PFES offers limited benefit at best.  
- The optimal number of sessions or duration of treatment is unclear. |
| **European Association of Urology (2015)** | **Key points:**                   |
| Guidelines on UI          | - Evidence synthesis of two health technology assessments and three systematic reviews, comprising 15 trials that used different comparison methods.  
- Overall quality: low. Heterogeneous stimulation parameters, treatment regimens and outcome parameters.  
- Most evidence on PFES refers to women with SUI.  
- No evidence found for electromagnetic stimulation.  
- In adults with UI, conflicting evidence of effectiveness of PFES versus sham stimulation or pharmacotherapy, and whether PFES adds to the benefit of PFMT alone. |
| **Vonthein (2013)**       | **Key points:**                   |
| PFES and/or BF for FI     | - Systematic review and meta-analysis of 13 RCTs comparing BF alone or in combination with PFES; PFES alone to other treatments. Two populations represented were 1) young mothers and 2) predominately elderly men and women in need of a second-line conservative treatment and no obvious need for surgery.  
- Overall quality: moderate to high quality. Heterogeneity with respect to spectrum of patients and treatment protocols, poor reporting of technological details and safety outcomes.  
- No trial showed superiority of control, BF alone or PFES alone when compared with BF + PFES. Superiority of BF + PFES over any monotherapy was demonstrated in several trials.  
- High-quality evidence suggests AM-MF PFES plus electromyography BF is the best second-line treatment for FI. |
| **Shamliyan (2012)**      | **Key points:**                   |
For the Agency for Healthcare Research and Quality

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Nonsurgical treatments for UI in community-dwelling women | • Systematic review of nine RCTs of intra-vaginal PFES and five RCTs of ExMI.  
• Overall quality: high for PFES, low to moderate for ExMI. Poor adherence.  
• PFES increased continence rate, improved SUI and improved quality of life compared to sham.  
• For UUI, MUI, or overactive bladder (OAB), comparable outcomes between PFES as monotherapy or combination therapy versus other nonsurgical treatments or pharmacological treatments.  
• ExMI improved UI but did not increase urinary continence more than sham stimulation. Evidence of improved quality of life was low. |

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>53899</td>
<td>Extracorporeal magnetic innervation</td>
<td></td>
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<tr>
<td>97014</td>
<td>Application of a modality to one or more areas; electrical stimulation unattended</td>
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<tr>
<td>97032</td>
<td>Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes, requiring direct patient contact by the provider</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>N39.3</td>
<td>Stress incontinence (female) (male)</td>
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<tr>
<td>N39.41-N39.498</td>
<td>Other specified urinary incontinence (code range)</td>
<td></td>
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<tr>
<td>R15.0-R15.9</td>
<td>Fecal incontinence (code range)</td>
<td></td>
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<tr>
<td>R32</td>
<td>Unspecified urinary incontinence</td>
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<tr>
<td>HCPCS Level II Code</td>
<td>Description</td>
<td>Comments</td>
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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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