Medical Policy
Extracorporeal Magnetic Innervation (ExMI) Therapy for Urinary Incontinence

Effective Date: July 15, 2017

Subject: Extracorporeal Magnetic Innervation (ExMI) Therapy for Urinary Incontinence

Background: Extracorporeal Magnetic Innervation (ExMI) is a noninvasive therapy aimed at improving urinary incontinence. The technology is based on pulsed magnetic stimulation of the sacral nerves and/or pudendal nerves, with the goal of rehabilitating the pelvic floor musculature to reduce urinary incontinence.

Policy and Coverage Criteria:

Harvard Pilgrim Health Care (HPHC) considers Extracorporeal Magnetic Innervation (ExMI) therapy experimental/investigational and is therefore not covered.

Supporting Information:

Urinary incontinence (UI) is generally defined as involuntary leakage of urine, also referred to as urinary voiding dysfunction. Depending on the pathophysiology involved, urinary incontinence can be classified into five groups: urge incontinence, overflow incontinence, stress incontinence, mixed incontinence and functional incontinence. Treatment options for urinary incontinence includes: behavioral strategies, pharmacological interventions, temporary or chronic electrical stimulations and reconstructive surgery.

Extracorporeal magnetic innervation (ExMI) is a noninvasive therapy aimed at improving urinary continence. The technology is based on Faraday's law of magnetic induction, which states that an electric current will flow in a conducting medium as a response to a pulsating magnetic field. Extracorporeal magnetic stimulation (EMS) induces controlled depolarization of neurons that innervate pelvic floor muscles, which causes the formation of action potentials that facilitate contraction of the corresponding muscle. The goal of this therapy is the rehabilitation of the pelvic floor musculature to reduce urinary incontinence.

A 2016 systematic review and meta-analysis of randomized controlled trials studied the conservative management of stress urinary incontinence (SUI). Results showed that magnetic stimulation with pelvic floor muscle training (PFMT) provided insufficient precision to determine whether the association was better, worse or no different when compared with pelvic floor muscle training alone.

Published peer-reviewed literature does not show consistent effectiveness of ExMI for the treatment of urinary incontinence. No studies have shown proven long-term effectiveness over other proven therapies. Sun et al. (2015) treated 32 women with demonstrable urinary tract dysfunction for at least 6 months following radical hysterectomy for uterine cervical cancer with 24 sessions of ExMI. The 1-h pad test weight decreased from 27.2 g pre-treatment to 12.1 g post-treatment. Median UDI-6 and IIQ-7 scores showed significant improvements at every stage of the ExMI treatment and in the 24.2 months mean follow-up after treatment. Symptoms of frequency, stress incontinence, urge incontinence and voiding difficulty showed significant improvements after 8 and 24 sessions of ExMI treatment. The urodynamic parameters between pre-treatment and post-treatment after 24 sessions revealed no significant changes. Based on the objective and subjective measures observed in this study, 24 sessions of twice-weekly ExMI treatment is an additional non-invasive therapy option for patients with...
the symptoms of lower urinary tract following RH. Wollner et al. (2012) treated 63 urinary incontinence patients with ExMI for 12 treatment sessions, 2 to 3 times per week. A significant reduction in the number of pads used per 24 hours was observed and persisted after a median follow up of 12.5 months. A 2010 study (Doganay et al.) found the beneficial effects of ExMI were temporary and had a high recurrence. Gilling et al. (2009) published results of a double-blind RCT comparing the efficacy of ExMI to sham in women with stress urinary incontinence. Results did not show significant differences between the two groups at the end of the 8-week trial. One study also reported worsening of symptoms in some patients after the treatment (Galloway et al., 2000).

A 2008 systematic review by Shamliyan et al. assessed studies for varying urinary incontinence treatments. Results found 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. Bakar et al. (2011) published results of a pilot study of ExMI for stress UI in older women. 13 patients between 61 and 69 were treated for SUI with ExMI. Treatments were twice a week for 6 weeks. At the end of treatment, urinary symptoms and incontinence conditions decreased. The authors felt ExMI should be considered as a non-invasive alternative.

A 2006 study of the effects of ExMI on 74 patients with varying forms of urinary incontinence showed no significant changes in pelvic floor function. Within all the incontinence subgroups treated, there were no significant changes in the data before and after treatment (Voorham-van der Salm et al. 2006). Quek (2005) reviewed the acute effects of magnetic stimulation on urodynamic parameters and its use in the management of urinary incontinence. Overall, Quek found that the data available varies too much in terms of treatment protocols, patient mix, and symptom severity to determine which group of patients might benefit the most. Beneficial effects appear to be temporary. Quek stresses further trials are needed to determine the optimum stimulation protocols for different situations and to compare magnetic stimulation with other forms of conservative pelvic floor therapy. Almeida et al. (2004) studied 91 female patients with varying forms of urinary incontinence. Immediately after the treatment, 34 of the 91 patients did not have leakage. However, at three months there was a progressive recurrence and at the end of 12 months almost all patients had lost any benefit of the treatment. A number studies showed initial improvement after treatment, but did not report follow up longer than three months (Chandi et al., 2004; Yokoyama et al. 2004).

There is no National Coverage Determination referencing ExMI for urinary incontinence.

**Coding:**

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0740</td>
<td>Non-implanted pelvic floor electrical stimulator, complete system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N39.41</td>
<td>Urge Incontinence</td>
</tr>
<tr>
<td>N39.42</td>
<td>Incontinence Without Sensory Awareness</td>
</tr>
<tr>
<td>N39.43</td>
<td>Post-Void Dribbling</td>
</tr>
<tr>
<td>N39.44</td>
<td>Nocturnal Enuresis</td>
</tr>
</tbody>
</table>
Continuous Leakage
Mixed Incontinence
Overflow Incontinence
Coital Incontinence
Postural (Urinary) Incontinence
Other Specified Urinary Incontinence
Other Specified Disorders of Urinary System
Hypermobility of Urethra
Intrinsic Sphincter Deficiency (Isd)
Combined Hypermobility of Urethra and Intrinsic Sphincter Deficiency
Functional Urinary Incontinence

References:

HPHC Clinical Medical Policy
ExMI Therapy for Urinary Incontinence

Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.


Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/17</td>
<td>Supporting information and references updated. ICD10 codes added for informational purposes. HCPCS code added.</td>
</tr>
</tbody>
</table>

Approved by UMPC: 03/22/17

Reviewed/Revised: 5/03; 2/09; 2/11; 2/13; 2/15; 3/17

Initiated: 5/03