Subject: Invasive Treatment for Urinary Incontinence

Background:
Urinary incontinence (the involuntary loss of urine) is a symptom that can be caused by a wide range of conditions including bladder dysfunction, sphincter incompetence, prostate problems (e.g., benign prostatic hypertrophy, prostatic carcinoma) or nerve damage. Symptoms of urinary incontinence (UI) can range from mild leaking to uncontrollable wetting. UI typically becomes more common with age, and women experience symptoms more often than men. There are four prevalent types of UI that occur in adults:

- **Stress Incontinence**: The most common type of leakage, stress incontinence typically occurs during physical movement or activity (e.g., coughing, sneezing, running, heavy lifting) that puts pressure on the bladder. The primary causes of stress incontinence are urethral sphincter weakness (intrinsic sphincter deficiency) or a hypermobile urethra that occurs when there is weakness of pelvic floor and poor support of the vesicourethral sphincter unit.

- **Urge incontinence**: Often referred to as "overactive bladder", urge incontinence is the unintentional loss of urine caused by the contraction of an overactive detrusor muscle (smooth muscle found in wall of bladder), usually associated with a sense of urgency. Urge incontinence is more commonly seen in men.

- **Overflow incontinence**: Characterized by frequent small urinations and dribbling, overflow incontinence occurs when the bladder is full and unable to empty. Overflow incontinence is most common in men with a history of surgery or prostate problems, and rare in women.

- **Mixed incontinence**: Mixed incontinence most commonly refers to a combination of stress and urge incontinence.

Diagnostic evaluation for UI includes a complete history and physical, urinalysis, and diagnostic testing including urodynamic testing (if indicated) to assess urinary tract function, bladder filling and storage, and bladder emptying. Conservative management may include Kegel exercises, behavioral therapies, mechanical devices, and pharmacotherapies. When conservative treatment fails to improve the condition, invasive and/or surgical intervention may be necessary.

Artificial Urinary Sphincter is a useful alternative when conservative interventions have failed. Implantation of an AUS is a commonly used surgical option for the management of male urethral deficiency especially following prostatectomy. To be considered for AUS implantation, the patient must be motivated and have sufficient physical and mental dexterity to operate the device. AUS may also be indicated in patients with epispadias-exstrophy (when bladder neck reconstruction has failed), women (when behavioral or pharmacologic therapies, or other surgical options have failed), and children with intractable UI who are refractory to pharmacologic therapies or unsuitable for other types of surgical procedures.

**Bladder Neck Suspension**: Bladder neck suspension surgery adds support to the bladder neck and urethra, reducing the risk of stress incontinence. The Burch procedure involves placing sutures in vaginal tissue near the neck of the bladder (where the bladder and urethra meet) and attaching them to ligaments near the pubic bone.

**Periurethral Bulking Agents**: Periurethral bulking agents have been widely used for incontinence in women; men with postprostatectomy incontinence have also been treated successfully. Injectable bulking agents are space-filling substances, injected periurethrally as a liquid that then solidifies into a spongy material, used to increase...
tissue bulk in the urethral wall, thereby increasing resistance to the outflow of urine. Bulking agents may be injected over a course of several treatments until the desired effect is achieved.

Sling Procedures: Sling procedures are the most common invasive treatment for stress incontinence. Although slings have traditionally been used in patients who fail primary incontinence surgery, they are becoming more common than primary procedures.

- Pubovaginal (Bladder neck/proximal urethral) sling procedures are performed through a vaginal incision and use a strip of tissue/fascia or mesh to support the bladder neck.
- Mid-urethral slings are newer procedures that use synthetic mesh materials placed midway along the urethra. The two general types of mid-urethral slings are retropubic slings (i.e., transvaginal/TVT tapes, and transobturator/TOT slings). The TVT procedure is a modification of the pubovaginal sling. The TOT procedure was developed as an alternative to the TVT procedure; its proposed advantage is the avoidance of a transpelvic introduction.
- The bulbourethral sling surgery uses a sling placed beneath the urethra and attached to either muscle tissue or the pubic bone. The sling compresses and elevates the urethra, giving the urethra greater resistance to pressure from the abdomen. It is usually used for men who have lost their urethral sphincter function because of prostate treatment, other surgery, or trauma.

Authorization:
Prior authorization is required for all invasive procedures for urinary incontinence requested for members enrolled in commercial and Marketplace/Exchange (HMO, POS, PPO) products.

This policy utilizes InterQual® criteria and/or tools, which Harvard Pilgrim may have customized. You may request authorization and complete the automated authorization questionnaire via HPHConnect at www.harvardpilgrim.org/providerportal. In some cases, clinical documentation and/or color photographs may be required to complete a medical necessity review. Please submit required documentation as follows:

- Clinical notes/written documentation —via HPHConnect Clinical Upload or secure fax (800-232-0816)
- Photographs —HPHConnect Clinical Upload function, email (utilization_requests@harvardpilgrim.org), or mail (Utilization Management, 1600 Crown Colony Dr., Quincy, MA 02169). Please note that photographs should not be faxed as faxed photos cannot be utilized in making a medical necessity determination.

Providers may view and print the medical necessity criteria and questionnaire via HPHConnect for providers (Select Resources and the InterQual® link) or contact the commercial Provider Service Center at 800-708-4414. (To register for HPHConnect, follow the instructions here.) Members may access these materials by logging into their online account (visit www.harvardpilgrim.org, click on Member Login, then Plan Details, Prior Authorization for Care, and the link to clinical criteria) or by calling Member Services at 888-333-4742.

Policy and Coverage Criteria:
For this policy, Harvard Pilgrim Health Care (HPHC) draws upon the following 2020 InterQual® criteria:

- Bladder Neck Suspension/Sling, Female
- Urethral Sling, Male

HPHC requires the following criteria for the procedures listed below:

Artificial Urinary Sphincter (AUS) Surgery
Harvard Pilgrim Health Care (HPHC) considers artificial urinary sphincter (AUS) surgery as reasonable and medically necessary when documentation confirms member has urinary incontinence due to intrinsic urethral sphincter deficiency (IUSD) and ANY of the following:

- Female with on-going intractable incontinence, and history of failed behavioral therapy, pharmacological therapy, AND prior surgical treatment(s) for incontinence, OR

HPHC Medical Policy
• Male at least six months post-prostatectomy surgery with severe on-going incontinence following failed trials of behavioral and pharmacological therapies

**Periurethral Bulking Agents**

Harvard Pilgrim Health Care (HPHC) considers periurethral bulking agents approved by the U.S. Food and Drug Administration (FDA) for the treatment of stress urinary incontinence when documentation confirms ALL the following:
• Failure of 12 months of conservative therapy (e.g. exercise, pharmacotherapy); AND
• Abdominal leak point remaining < 100 cm H₂O for females;

A maximum of five treatment sessions are covered

**Exclusions:**

Harvard Pilgrim Health Care considers treatment for urinary incontinence as not medically necessary for all other indications.

**Supporting information:**

The use of bulking agents in women is restricted to women wanting to avoid surgical procedures and in women with recurrent/refractory incontinence despite a prior surgical procedure. Artificial urinary sphincter placement is a rare choice of treatment for women with stress incontinence and intrinsic sphincter deficiency and is restricted to cases not responding to other common treatments due to its high invasiveness and high revision rates.

Stress incontinence-males: Based on a 2019 UptoDate report, commonly used male stress incontinence interventions are transurethral bulking agents, perineal slings, and the artificial urinary sphincter. Bulking agents are preferred for men with mild stress incontinence and for men with contraindications for surgery. Artificial urinary sphincter is considered the most effective long-term treatment for men with severe stress incontinence.

UptoDate reported that a prior artificial urinary sphincter is associated with a higher sling failure, while prior sling placement is not associated with higher artificial urinary sphincter placement failures. History of bulking agent use does not seem to affect outcomes of either artificial sphincter or sling procedure.

The American Urological Association (AUA, 2019) states that urinary incontinence after prostate treatment is a clinically significant condition and supports the management of those who need treatment. The guidelines advise that individuals with bothersome stress urinary incontinence after prostate treatment should be offered surgical treatment one-year post-prostate treatment if conservative therapy has already been utilized unsuccessfully.

The American Urogynecologic Society (AUGS, 2018) guidelines note that urethral bulking is an FDA-approved therapy to treat adult female stress urinary incontinence due to intrinsic sphincter deficiency. Although urethral bulking is considered an acceptable treatment for urinary incontinence, individuals whose incontinence does not improve with five injection procedures (five separate treatment sessions) are considered treatment failures and no additional treatment should be attempted.

The National Institute for Health and Care Excellence (NICE, 2016) guidelines recommend conventional treatment (e.g. lifestyle changes, pelvic floor muscle training) for the management of urinary incontinence in women. When these conservative measures are unsuccessful, surgery may be considered. The guidelines note that when previous surgery has failed, insertion of an artificial urinary sphincter (AUS) may be required.
Afraa et al. 2011 conducted a retrospective review of 16 individuals (out of a cohort of 52 patients) who had stress urinary incontinence (SUI) pre- and post- artificial urinary sphincter (AUS) placement. The mean age was 68 ± 6.3 years, and the duration of incontinence was 3 ± 2.7 years. Data comparison pre- and post-AUS implantation revealed statistically significant improvement in bladder capacity from 271 ± 117 to 295.6 ± 151 mL (p = 0.05). The authors concluded that preoperative urodynamic irregularities improved after implantation of AUS.

**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>
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<tbody>
<tr>
<td>51715</td>
<td>Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck</td>
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<tr>
<td>51840</td>
<td>Anterior vesicourethropexy, or urethropexy (e.g., Marshall-Marchetti-Krantz, Burch); simple</td>
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<tr>
<td>51841</td>
<td>Anterior vesicourethropexy, or urethropexy (e.g., Marshall-Marchetti-Krantz, Burch); complicated (e.g., secondary repair)</td>
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<td>51845</td>
<td>Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., Stamey, Raz, modified Pereyra)</td>
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<tr>
<td>51990</td>
<td>Laparoscopy, surgical; urethral suspension for stress incontinence</td>
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<tr>
<td>51992</td>
<td>Laparoscopy, surgical; sling operation for stress incontinence (e.g., fascia or synthetic)</td>
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<tr>
<td>53440</td>
<td>Sling operation for correction of male urinary incontinence (e.g., fascia or synthetic)</td>
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<tr>
<td>53444</td>
<td>Insertion of tandem cuff (dual cuff)</td>
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<tr>
<td>53445</td>
<td>Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff</td>
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<tr>
<td>57288</td>
<td>Sling operation for stress incontinence (e.g., fascia or synthetic)</td>
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<tr>
<td>57289</td>
<td>Pereyra procedure, including anterior colporrhaphy</td>
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**Billing Guidelines:**
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

**References:**

Summary of Changes:

<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
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<tbody>
<tr>
<td>6/20</td>
<td>Annual review; InterQual® criteria adopted</td>
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<tr>
<td>6/19</td>
<td>Annual review; no changes</td>
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<tr>
<td>1/18</td>
<td>Bladder neck fascial sling and mid-urethral sling added with criteria;</td>
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<td></td>
<td>references updated, supporting information added</td>
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<tr>
<td>12/16</td>
<td>Add Background information, language and formatting changes, update</td>
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<tr>
<td></td>
<td>references. Add Coding disclaimer. Revise title.</td>
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Approved by Clinical Medical Policy Committee: 6/23/20
Approved by Clinical Policy Operational Committee: 1/15; 10/15, 12/16, 1/18, 6/19; 7/20
Policy Effective Date: 11/01/2020
Initiated: 7/1/20