STRIDEsm (HMO) MEDICARE ADVANTAGE

Effective Date: January 1, 2017

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 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 (AUS): The AUS has been shown to be effective for UI due to intrinsic urethral sphincter deficiency (IUSD), and 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; in a variation of this procedure (i.e., the Marshall-Marchetti-Krantz operation), sutures placed in vaginal tissue are secured directly to 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 increasingt 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 (suburethral) sling procedures are performed through a vaginal incision and use a strip of tissue/fascia or mesh to support the bladder neck.
- Midurethral slings are newer procedures that use synthetic mesh materials placed midway along the urethra. The two general types of midurethral 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 the following invasive and surgical procedures:

- Artificial urinary sphincter
- Bladder neck suspension/sling
- Periurethral bulking agents[1]
- Urethral sling

Requests for surgical procedures for members age 18 and over are reviewed using criteria listed below. (Requests for surgical procedures for members under age 18 are approved without review for medical necessity.)

Policy and Coverage Criteria:
Harvard Pilgrim Stride[SM] (HMO) Medicare Advantage covers invasive and surgical procedures listed below when medical record documentation confirms the procedure is reasonable and medically necessary to treat urinary incontinence in adults, and procedure-specific criteria are met.

Procedure	Criteria
Artificial Urinary Sphincter (AUS) Surgery	Member has urinary incontinence due to intrinsic urethral sphincter deficiency (IUSD), and ANY of the following: ▪ Epispadias-exstrophy with history of failed bladder neck reconstruction; ▪ Female with on-going intractable incontinence, and history of failed behavioral therapy, pharmacological therapy, AND prior surgical treatment(s) for incontinence; ▪ Male <u>at least 6 months post-prostatectomy surgery</u> with severe on-going incontinence following failed trials of behavioral and pharmacological therapies.
Bladder neck suspension/sling	Female member with mild to moderate urinary incontinence and a negative urine culture meets ALL the following: 1. Symptoms interfere with basic self-care tasks/ADLs (e.g., feeding, toileting, grooming, dressing, bathing, walking) and complex (instrumental) ADLs (e.g., shopping, housework, meal preparation, and basic home maintenance) for <u>at least</u> 6 months; 2. Urge incontinence has been excluded OR successfully

[1] Covered agents must be FDA-cleared.

Procedure	Criteria
	treated with medication; 3. Medications that can influence stress incontinence (e.g., alpha-blockers) are not contributing to symptoms.
Periurethral Bulking Agents • **Covered agents must be FDA-cleared for treatment of urinary incontinence.**	ANY of the following: • Urinary incontinence caused by intrinsic sphincter deficiency (IUSD), and ANY of the following: ○ Failure of 12 months of conservative therapy (e.g. exercise, pharmacotherapy); OR ○ Contraindication(s) to sling; OR ○ Previous sling failure in a member planning to have children, or a member with multiple co-morbidities) • Member with urethral hypermobility, and ANY of the following: ○ Documented abdominal leak point remaining < 100 cm H_2O after at least 12 months of conservative therapy (e.g. exercise, pharmacotherapy); OR ○ Contraindication(s) to sling; OR ○ Previous sling failure in a member planning to have children, or a member with multiple co-morbidities.
Urethral Sling Procedure	Male member with mild to moderate urinary incontinence meets ALL the following: 1. Negative urine culture; 2. Symptoms that interfere with basic ADLs and complex (instrumental ADLs) for at least 6 months; 3. Urge incontinence is excluded by cystometry or urodynamics, OR has been successfully treated with medication; 4. Medications that can influence stress incontinence (e.g., alpha-blockers) are not contributing to symptoms.

Exclusions:

Harvard Pilgrim Stride^{SM} (HMO) Medicare Advantage does not cover investigational or unproven invasive treatment for urinary incontinence. Procedures are considered investigational or unproven when criteria above are not met.

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.

CPT® Code	Description
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
51840	Anterior vesicourethropexy, or urethropexy (e.g., Marshall-Marchetti-Krantz, Burch); simple
51841	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); complicated (e.g., secondary repair)
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., Stamey, Raz, modified Pereyra)
51990	Laparoscopy, surgical; urethral suspension for stress incontinence
51992	Laparoscopy, surgical; sling operation for stress incontinence (e.g., fascia or synthetic)
53440	Sling operation for correction of male urinary incontinence (e.g., fascia or synthetic)
53442	Removal or revision of sling for male urinary incontinence (e.g., fascia or synthetic)
53444	Insertion of tandem cuff (dual cuff)
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
53448	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue
53449	Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
57287	Removal or revision of sling for stress incontinence (e.g., fascia or synthetic)
57288	Sling operation for stress incontinence (e.g., fascia or synthetic)

References:

1. National Coverage Determination (NCD) for INCONTINENCE Control Devices (230.10).

2. DuBeau, CE. Approach to women with urinary incontinence. In: UpToDate, Post TW (ed), UpToDate, Waltham, MA. (Accessed November 16, 2016).
3. DuBeau, CE. Treatment and prevention of urinary incontinence in women. In: UpToDate, Post TW (ed), UpToDate, Waltham, MA. (Accessed November 16, 2016).
4. Jelovsek, JE., Reddy, J. Surgical management of stress urinary incontinence in women: Choosing a primary surgical procedure. In: UpToDate, Post TW (ed), UpToDate, Waltham, MA. (Accessed November 16, 2016).
5. Nager, CW., Tan-Kim, J. Surgical management of stress urinary incontinence in women: Retropubic midurethral slings. In: UpToDate, Post TW (ed), UpToDate, Waltham, MA. (Accessed November 18, 2016).
6. Morgan, DM. Stress urinary incontinence in women: Persistant/recurrent symptoms after surgical treatment. In: UpToDate, Post TW (ed), UpToDate, Waltham, MA. (Accessed November 18, 2016).
7. Holroyd-Leduc JM, Straus SE. Management of urinary incontinence in women: Scientific review. JAMA. 2004;291(8):986-995.
8. Stav K, Dwyer PL, Rosamilia A, et al. Repeat synthetic mid urethral sling procedure for women with recurrent stress urinary incon_nence. J Urol. 2010;183(1):241-246.

Summary of Changes:

Date	Revisions
12/14/16	Add Background information, language and formatting changes, update references. Add Coding disclaimer. Revise title.
8/26/16	Minor language and formatting changes.

Approved by UMCPC: 12/14/16 (effective 1/1/17)

- **Revised 8/26/16**
- **Initial approval: 8/25/15 (effective 1/1/16)**