

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 (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.

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.
- ❖ 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; it's 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 requested for members enrolled in commercial and Marketplace/Exchange (HMO, POS, PPO) products:

- Artificial urinary sphincter
- Bladder neck suspension
- Periurethral bulking agents
- Perineal (male) sling
- Mid-urethral sling
- Bladder neck fascial slings

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 Health Care 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.

Artificial Urinary Sphincter (AUS) Surgery

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;
- Male at least 6 months post-prostatectomy surgery with severe on-going incontinence following failed trials of behavioral and pharmacological therapies.

Bladder Neck Suspension

Female member with mild to moderate urinary incontinence meets ALL the following:

- Urinary tract infection (UTI) ruled out with Urine analysis followed by reflex culture if required;
- Urge incontinence has been excluded (clinically or by simple office based voiding cystometrics volume measures) OR successfully treated with medication;
- History of failed conservative treatment (e.g. behavioral therapy, pharmacological therapy);

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 at least 6 months; 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 female 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 H₂O 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.

Perineal (male) Sling Procedure

Male member with mild to moderate stress urinary incontinence meets ALL the following:

- Urinary tract infection (UTI) ruled out with Urine analysis followed by reflex culture if required;
- Urge incontinence is excluded (clinically or by simple office based voiding cystometrics volume measures) OR has been successfully treated with medication;
- History of failed conservative treatment (e.g. behavioral therapy, pharmacological therapy);
- Symptoms that interfere with basic ADLs and complex (instrumental ADLs) for at least 6 months; Medications that can influence stress incontinence (e.g., alpha-blockers) are not contributing to symptoms

Mid-urethral slings [Transvaginal tapes (TVT), transobturator slings (TOT)]

Female member with stress urinary incontinence when members meet ALL the following:

- Urinary tract infection (UTI) ruled out with Urine analysis followed by reflex culture if required;
- Urge incontinence has been excluded (clinically or by simple office based voiding cystometrics volume measures) OR successfully treated with medication;
- History of failed conservative treatment (e.g. behavioral therapy, pharmacological therapy);
- Symptoms that interfere with basic ADLs and complex (instrumental ADLs) for at least 6 months;
- Medications that can influence stress incontinence (e.g., alpha-blockers) are not contributing to symptoms;
- The patient is counseled regarding expected benefit compared with risk of complications with mesh use and that polypropylene mesh is permanent.

Bladder neck fascial slings

Female member with stress urinary incontinence when members meet ALL the following:

- Urinary tract infection (UTI) ruled out with Urine analysis followed by reflex culture if required;
- Urge incontinence has been excluded (clinically or by simple office based voiding cystometrics volume measures) OR successfully treated with medication;
- History of failed conservative treatment (e.g. behavioral therapy, pharmacological therapy);
- Symptoms that interfere with basic ADLs and complex (instrumental ADLs) for at least 6 months;
- Medications that can influence stress incontinence (e.g., alpha-blockers) are not contributing to symptoms;
- Overflow incontinence has been excluded (normal post-void residual volume);
- Midurethral slings were contraindicated or were unsuccessful, or member decline to have a synthetic sling

Exclusions:

Harvard Pilgrim Health Care does not cover investigational or unproven invasive treatment for urinary incontinence. Procedures are considered investigational or unproven when criteria above are not met.

Supporting information:

Stress incontinence-female: A conservative therapy trial is always required prior to surgical treatment. Women without sufficient improvement with initial treatment can be considered for surgical approaches. An UptoDate report states that the mid-urethral sling (a minimally invasive surgical option) is an option that offers higher success rates than conservative therapy for women who wants a rapid and definitive treatment and are willing to accept surgical risks. Mid-urethral slings have become the procedure of choice for primary surgical treatment of Stress Urinary Incontinence since their introduction in 1990s. They are as effective with advantage of shorter operative duration and lower risk of adverse events than retropubic colposuspension and bladder neck slings. Long term follow-up studies have shown a cure rate of around 80% with mid-urethral slings. Both types of mid-urethral sling procedures (transobturator and transvaginal) seems to be comparable in efficacy and the final choice depends on the patient's preference taking into considerations that the transobturator procedure is more commonly associated with groin pain and the transvaginal procedure is more commonly associated with bladder perforation and voiding dysfunction. Use of Synthetic mesh is preferred over autologous fascia (e.g. bladder neck slings) despite contradictory advisory statements on mesh use, due to higher efficacy, lower morbidity and higher patient satisfaction rates with mesh procedures. Though the patient counselling on risk-benefit analysis should be done prior to any mesh-based procedure. Use of autologous fascia (e.g. bladder neck slings) should be reserved for women in whom mesh based slings are contraindicated or have failed or for patient preference. Situation where abdominal procedures (e.g. retropubic colposuspension) are preferred over mid-urethral slings, includes pelvic organ prolapse with repair planned via laparotomy in order to avoid two (abdominal and vaginal) incisions.

Preoperative evaluations for mid-urethral sling procedure should include confirmation of the stress urinary incontinence and exclusion of other causes for incontinence, confirmation of normal bladder emptying, and general surgical risk assessment. Women with mixed urinary incontinence (both stress and urgency components) may be given a trial of anticholinergic medication preoperatively, if urgency component is predominant and help delay the surgery. The absolute contraindications to mid-urethral sling are: Current urinary tract infection, Current pregnancy, and current anticoagulation therapy; whereas the relative contraindications are future plans for pregnancy and an increased risk of injury to retropubic structures due to prior surgery or a current hernia with viscera or major vessels in the retropubic space.

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.

UptoDate report states that following procedures are no longer recommended for stress incontinence in women

- Anterior colporrhaphy (even with Kelly-Kennedy plication)
- Transabdominal paravaginal repair.
- Transvaginal needle suspensions (e.g. Raz, Stamey, or Gittes procedures) (based on a meta-analysis of 10 trials showing a significantly higher one-year failure rate at one-year compared to retropubic colposuspension)
- Marshall-Marchetti-Krantz (MMK) procedure (based on a meta-analysis of four randomized trials showing a lower 1 and 5-year failure rate with Burch procedure compared with MMK as well as based on additional advantages of Bruch procedure compared with MMK such as shorter duration of postoperative bladder catheterization, lower rates of post-operative osteitis pubis, and stronger support.

Stress incontinence-males: As per the 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. The perineal sling techniques involves a technique similar to the sling technique used in females for stress urinary incontinence using synthetic mesh to compress the urethra. The International Consultation on Incontinence (ICI) and the United

Kingdom National Institute for Health and Clinical Excellence (NICE) supports the safety and efficacy of male slings for postprostatectomy stress incontinence. However, the safety of the procedure is not as well established as in females and should be used only in males who have failed more conservative approaches. Following prostatectomy, it is advisable to wait for at least 6-12 months before considering surgical options to allow for spontaneous resolution of stress incontinence with conservative treatments. With regards to choosing between the sling and artificial urinary sphincter apart from patient preference, one should consider that slings may be used in men with limited manual dexterity with difficulty manipulating the artificial urinary sphincter, and in milder incontinence, whereas artificial urinary sphincter may be used for men with history of previous pelvic radiation therapy or severe incontinence. Sling is a preferred choice for most men if given an option as suggested by data.

One should keep in mind an important point highlighted by UptoDate report 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.

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 (eg, Marshall-Marchetti-Krantz, Burch); simple
51841	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); complicated (eg, secondary repair)
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, Stamey, Raz, modified Pereyra)
51990	Laparoscopy, surgical; urethral suspension for stress incontinence
51992	Laparoscopy, surgical; sling operation for stress incontinence (eg, fascia or synthetic)
53440	Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)
53442	Removal or revision of sling for male urinary incontinence (eg, 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 (eg, fascia or synthetic)
57288	Sling operation for stress incontinence (eg, fascia or synthetic)

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.

HPHC Medical Policy

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HPHC policies are based on medical science, and written to apply to the majority of people with a given condition. Individual members' unique clinical circumstances, and capabilities of the local delivery system are considered when making individual UM determinations. 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.

References:

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Summary of Changes:

Date	Revisions
06/14/19	Annual review; no changes
01/11/18	Bladder neck fascial sling and mid-urethral sling added with criteria; references updated, supporting information added
12/14/16	Add Background information, language and formatting changes, update references. Add Coding disclaimer. Revise title.

Approved by Clinical Medical Policy Committee: 06/12/2019

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