Clinical Policy Title: Surgical and invasive treatments for overactive bladder syndrome

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Coverage policy

Keystone First considers the use of the following surgical and invasive treatments for overactive bladder (OAB) syndrome to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

I. Appropriate candidate for surgical interventions:
   a. Conservative therapy should be considered prior to the initiation of medical or surgical treatment of urinary incontinence (UI) for a trial of six months to 12 months. These include:
      i. Behavioral modifications, such as scheduled voiding, diet modification, fluid restriction when appropriate, smoking cessation, avoidance of caffeine and bladder training.
      ii. Pelvic floor muscle training (PFMT).

II. One of the following surgical indications:
   a. Stress incontinence, demonstrated by physical examination or stress test (e.g., Marshall test cystography or urodynamic testing).
   b. Confirmation of urethral sphincter hypermobility by physical examination, cystography, ultrasound or cystoscopy.
   c. Acceptable post void residual (PVR) test.*
d. Absence of detrusor instability, urgency or frequency, as primary etiologies, which may require urodynamic studies.

e. Absence of fistula, urethral ectopy, bladder calculi, urethral diverticula or overflow incontinence etiology (unless well-treated stress incontinence, demonstrated by physical examination or stress test, such as the Marshall test, cystography, urodynamic testing).

f. Confirmation of urethral sphincter hypermobility, by physical examination, cystography, ultrasound or cystoscopy.

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* There is no universally accepted definition of a significant residual urine volume. Large PVR (> 200 ml – 300 ml) may indicate marked bladder dysfunction and may predispose to unsatisfactory treatment results if, for example, invasive treatment for bladder outlet obstruction (BOO) is undertaken. PVR does not seem to be a strong predictor of acute urinary retention and does not indicate presence of BOO specifically. Although the evidence base is limited, guidelines on assessment of lower urinary tract symptoms (LUTS) generally include PVR measurement (Asimakopoulos, et al., 2014).

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III. Surgical and invasive procedures for OAB clinically proven and medically necessary when criteria are met:
   a. Anterior colporrhaphy with bladder neck (Kelly-Kennedy) plication.
   b. Retropubic suspension (e.g., retropubic urethropexy or Burch procedure).
   c. Sling procedures (e.g., pubovaginal/suburethral sling; midurethral sling [transvaginal tapes (TVT), transobturator slings (TOT)]; bulbourethral sling).

IV. Artificial urinary sphincter implantation due to reduced outlet resistance (intrinsic sphincter deficiency) for males with severely symptomatic stress incontinence or following prostate surgery:
   a. Members who are six or more months post-prostatectomy who have had no improvement in the severity of UI despite trials of behavioral and pharmacological therapies.
   b. Injection of periurethral bulking* (collagen, carbon-coated beads or fat) as second-line therapy.

V. Periurethral bulking injections* including Botox for women ineligible for surgery when one or more criteria are met:
   a. The member has stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency (ISD) that persists despite at least 12 consecutive months of conventional therapy (for example, pelvic floor exercises, behavioral modification, or pessary).
   b. Post-traumatic or post-surgical injury.
   c. Urethral hypermobility in females with abdominal leak point less than 100 cm H2O that persists despite at least 12 consecutive months of conventional therapy (for example, exercise or to an anticholinergic medication).
   d. Stress urinary incontinence significantly limits activities of daily living.
   e. No other causes of stress urinary incontinence have been identified (e.g., urinary tract infection).
   f. Members whose incontinence does not improve after three treatments with bulking agents are considered treatment failures and are not likely to respond to this therapy. In such cases, further treatment with bulking agents is not considered medically necessary.

VI. Sacral nerve stimulation (SNS) or sacral neuromodulation (SNM) (e.g., InterStim® Medtronic):
   a. Patient has a diagnosis of urge incontinence, urgency frequency or non-obstructive urinary retention; and
b. Symptoms of incontinence have been present for at least 12 months and have resulted in insignificant disability, such as the limited ability to work or participate in activities outside of the home; and

c. Incontinence is not related to a neurologic condition; and

d. Previous behavioral* and pharmacological therapy have been unsuccessful for > six months; and

e. A percutaneous stimulation test to determine candidacy for a permanent implantation has provided at least a 50 percent reduction in incontinence symptoms as documented in voiding diaries.

f. The member has experienced urge UI or symptoms of urge frequency for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member’s ability to participate in daily activities.

* Members whose incontinence does not improve with five injection procedures (five separate treatment sessions) are considered treatment failures, and **no further treatment of urinary incontinence by collagen implant is covered.** Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., six months to 12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed, but must be supported by medical justification (CMS — National Coverage Determination-230). (see Summary of clinical evidence for citation on collagen)

Study

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1477593/

Limitations:

All other surgical interventions for the treatment of OAB syndrome are not medically necessary.

The following technologies for the treatment of OAB syndrome are considered experimental and investigational and, therefore, not medically necessary:

- Sacral nerve stimulator for stress incontinence or urge incontinence due to a neurologic condition, such as detrusor hyperreflexia, multiple sclerosis or spinal cord injury.
- Periurethral injections of the Teflon bulking agent.
- Exacorporeal magnetic innervation (ExMI) (e.g., NeoControl pelvic floor therapy system).
- Transvaginal radiofrequency/microwave surgery (e.g., SURx Transvaginal System).
- Transurethral radiofrequency tissue micro-remodeling (e.g., Renessa® System).
- Adjustable continence therapy (e.g., ACT® or ProACT™).
- Percutaneous tibial nerve stimulation (PTNS) (Urgent® PC Neuromodulation System).
- Other investigational bulking agents, (e.g., autologous fat and autologous ear chondrocytes FemSoft Insert for the control of adult female stress urinary incontinence).
Alternative covered services:

- Pharmacotherapy.
- Behavioral modification.
- PFMT.
- Bladder training.

Background

Previously referred to as “urge incontinence or detrusor instability,” the term “overactive bladder syndrome,” adopted by the International Continence Society (ICS), provides a more comprehensive and descriptive approach to the condition.

OAB is formally defined by ICS as:

- Urgency, which is the complaint of sudden need to void.
- With or without urge incontinence, involuntary loss of urine with urgency symptoms.
- Usually with frequency, which is the individual’s perception that he or she voids too often during the day, and is often defined as more than eight voids during waking hours.
- Usually with nocturia, which is awakening from sleep to empty the bladder.

According to the Treatment of Overactive Bladder in Women, Evidence Report #187, this operational definition was formally standardized as part of a consensus process of experts in 2002 by the ICS as part of an effort to promote health care professionals’ and researchers’ use of common terminology in the care and study of women with OAB.

OAB is a common condition defined as urgency, with urgency incontinence (OAB wet) or without urgency incontinence (OAB dry), usually associated with increased daytime frequency and nocturia. In a recent Canadian population-based study, OAB symptoms were reported in 13.9 percent of respondents (13.1 percent of men and 14.7 percent of women). UI was reported by 28.8 percent of women with 68 percent having stress urinary incontinence (SUI), 21 percent mixed urinary incontinence (MUI) and 11 percent urgency urinary incontinence (UUI). In men, 5.4 percent of respondents had UI (26 percent SUI, 15 percent MUI and 58 percent UUI). The prevalence of OAB symptoms was similar in both sexes; however, OAB with UUI is more common in women (7.1 percent vs. 3.3 percent). Furthermore, OAB symptoms are more significant with increasing age (23.8 percent for > 60 years old versus 12.2 percent for < 60 years old.)

Less common categories of UI include total incontinence (associated with urinary tract fistula or ectopic ureter), functional (associated with psychiatric or mobility disorder), uncategorized, overflow, post-micturition dribble, radiotherapy, and climacturia.

Types of UI include:

- **Stress incontinence:**
  - Urine lost instantaneously with sudden increase in intra-abdominal pressure.
  - Coughing, laughing, sneezing, jumping, lifting, exercising and positional changes.
  - No leakage without activity or physical straining.
  - No leakage in supine position.
  - Infrequent in male unless previous pelvic or prostate surgery damaged sphincter or nerve.

- **Urge incontinence:**
  - Involuntary loss of urine after powerful and unexpected urge to void.
  - Patient complains about not making it to bathroom in time.
May occur several seconds after stress maneuver increases intra-abdominal pressure.
Unrelated to activity or position.
May mimic overflow incontinence with bladder outlet obstruction.

- Mixed incontinence:
  - Combination of urge and stress incontinence.
  - Identify and treat the most bothersome symptoms.
  - Overflow incontinence.
  - A small amount of urine dribbles out without urge or increase in abdominal pressure.
  - May mimic urge incontinence.
  - Bladder outlet obstruction due to benign prostatic hyperplasia (BPH) is most common cause.
  - Diabetes and chronic use of psychiatric medication are common causes.

- Total incontinence:
  - Loss of urine at all times and in all positions.
  - May be present in male after prostate surgery when sphincter damage has occurred.

- Reversible incontinence:
  - Impaired or restricted mobility and environmental barriers with inability to reach bathroom in a timely manner.
  - Exercise, especially high impact.
  - Cough.
  - Symptomatic urinary tract infection.
  - Symptoms of atrophic urethritis or vaginitis.
  - Medication.
  - Stool impaction or constipation.
  - Excess urine output:
    - Diuretics.
    - Excess fluid intake, including caffeine.
    - Metabolic abnormalities.
  - Delirium, dementia, depression and psychosis.

According to a citation on the Agency for Healthcare Research and Quality (AHRQ) website, at minimum, 11 million to 16 million women in the United States cope daily with symptoms that include sudden strong urges to urinate, difficulty delaying voids, frequent trips to the bathroom, and in many cases involuntary loss of urine when urgency strikes. They may wear pads for accidents, plan ahead for access to bathrooms, and modify their social and work lives to accommodate their symptoms. Some women are very distressed by the symptoms, whether mild or severe, and some find mechanisms to adapt, reporting little trouble with symptoms or interference with normal routines. Others report their symptoms negatively influence factors as varied as self-esteem, self-assessment of attractiveness and sexual function. Many women believe that some amount of incontinence is inevitable with aging and the majority of women with these symptoms do not talk with their health care providers about their concerns with bladder function. As a result, a small minority receive treatment.

Little is known about causes and most physiology and clinical research aimed at understanding etiology is now focused at the descriptive and hypothesis development and testing phase of investigation. The most promising theories postulate abnormalities in control of bladder function resulting from aberrations in neurologic signals from the bladder (sensation) and in central and peripheral nervous system regulation.
Components of the syndrome have had varied, and at times conflicting, nomenclature that include detrusor (bladder muscle) instability, detrusor dysfunction, detrusor dyssynergia, detrusor over activity (DO) and irritable bladder. In each case, these terms shared a causal model that hypothesizes that mistimed or poorly regulated bladder contractions create the sensation of a sudden need to void with or without leakage. However clinical study of bladder muscle function using urodynamic testing to measure characteristics like bladder capacity, pattern and timing of bladder contractions, and bladder volume at which women first experienced the urge to void, did not reveal uniform test results among women who had identical complaints. Lacking a reliable biologic marker to define and describe the severity of the condition with objective tests of the bladder itself, clinicians, researchers, pharmaceutical companies and others came to conceptualize the symptoms of OAB, which often appeared in combination, as a syndrome.

Diagnostic testing

Simple bladder testing is easily performed at the initial office visit and helps to formulate a diagnosis and appropriate treatment plan. This routinely involves a urinalysis and urine culture to rule out infection and a post void residual volume measured via bladder scanner or urethral catheterization. Further testing, including simple cystometrogram (CMG) and uroflow, can also be easily performed in the office. Complex uroflow may be performed with a full bladder before or after simple CMG and does require special equipment. The patient is asked to come to the office with a full bladder for uroflow. He or she then voids on a special commode that records volume voided, maximum flow rate, average flow rate, time to maximum flow and voiding time. A post void residual volume is then measured via bladder scanner or urethral catheterization. Simple CMG may then be performed. The bladder is catheterized to check post void residual volume and a urine specimen is sent for urine culture and/or cytology as indicated. A 50-mL syringe with the plunger removed is attached to the urethral catheter. Sterile water or saline is then used to slowly backfill the patient’s bladder. During backfill, the patient is asked questions to determine first urge to void, normal urge to void, urgent need to void and maximum bladder capacity. The patient is not filled beyond 500 mL to avoid ureteral reflux. At maximum capacity, the patient is asked to cough (with prolapse reduced if present) in lithotomy position, as well as standing. This will demonstrate any stress urinary incontinence. Patients with OAB typically demonstrate smaller bladder capacity (normal is 400 ml – 600 mL) and may also demonstrate DO during fill. This is objectively seen by increases in the level of fluid in the syringe during filling. He or she may also demonstrate large volumes of leakage during filling or when moving from lithotomy to standing positions.

Urodynamic testing and cystoscopy are usually performed by urology or urogynecology subspecialists. These tests are not required for first-line evaluation of OAB. Multichannel urodynamic testing requires special equipment and training. It allows precise measurement or calculation of intraurethral, intravesical and intra-abdominal pressures during filling and emptying of the bladder. Most patients with OAB will demonstrate reduced maximum bladder capacity and early sensations on testing. Some will show spontaneous detrusor contractions and reduced compliance during filling. Cystoscopy is usually normal in OAB patients. In some patients it may show trabeculations, stones, or abnormal masses or lesions associated with bladder cancer.

Treatments

Treatments that have been formally investigated include pharmacologic treatments, such as prescription medications, both pills and patches; surgeries and procedures, such as sacral neuromodulation and botulinum injections; behavioral interventions, such as behavior modification programs; bladder training; and complementary and alternative medicine, such as acupuncture and reflexology.
The mainstay of treatment for overactive bladder and urge incontinence is medication. This consists of the use of bladder relaxants that prevent the bladder from contracting without the patient’s permission. When the symptoms are more severe or when conservative measures are not helping or are unsatisfactory, the treatment is surgery.

Two drugs, tolterodine tartrate and oxybutynin, were the only drugs approved in the United States specifically for OAB until 2004 when Trospium, Darifenacin and Solifenacin were introduced.

Fesoterodine, a metabolite of tolterodine was approved in October 2008. Oxybutynin is now available in a transdermal formulation. Thus, over roughly a decade — a very short time window in clinical medicine — both the condition of OAB and pharmaceutical treatments for OAB became part of the consciousness of the public and the general medical community alike.

Another treatment, pessary (bladder neck support prosthesis), which is a plastic device that fits into the vagina to help support the uterus and bladder, for the treatment of women with stress or mixed UI, and for the treatment of pelvic organ (uterine) prolapse has been used.

Sacral neuromodulation is a technique in which an electrical stimulus directly stimulates the S3 sacral nerve root. The technique has evolved over time, but typically it is performed as a staged procedure. The first stage involves a “test” stimulation using a percutaneous needle to stimulate the S3 nerve root. If there is a favorable response during the trial period, then long-term stimulation can be provided by surgically implanting a pulse generator. The pulse generator is usually placed in the fatty tissues overlying the buttocks, although abdominal placement was used with some of the earlier studies. Recent evolutions in this technique now permit a permanent lead to be used for the test stimulation. If the test is unsuccessful, the lead can be removed, but if it is successful, this lead is attached to the permanent implantable pulse generator. This has the advantage of ensuring that stimulation is provided in the exact location as during the test period. (Previously, a new lead was placed at the time of the implantable pulse generator placement.) The mechanism by which neuromodulation acts to improve symptoms is not completely understood. The technique is used for urinary urgency, frequency and urges incontinence refractory to other treatment modalities. It is also used for urinary retention. Given these seemingly contradictory applications, it is thought that the electrical stimulation affects the afferent nerves (which perceive bladder sensation), thus allowing them to appropriately transmit bladder sensations.

Peripheral neuromodulation techniques for neuromodulation involve stimulating the S3 nerve fibers more peripherally, at the posterior tibial nerve or cutaneous stimulation of the pudendal nerve via an anal or vaginal probe. For the posterior tibial nerve stimulation, a needle is placed percutaneously near the ankle and is attached to an external electrical device.

Instead of implanting a pulse generator, the patient returns for periodic sessions, often weekly for a series of treatments. Small case series suggest that posterior tibial nerve stimulation may improve OAB symptoms. There were no studies involving this technique that met our search criteria. One study evaluating neuromodulation of the pudendal nerve with anal and/or vaginal probes met our search criteria. Similarly, this is performed on an outpatient basis with weekly treatment sessions.

For the purposes of this report, sacral neuromodulation will refer to techniques that directly stimulate the S3 nerve root. Peripheral neuromodulation will refer to nerve stimulation peripherally, such as the use of an anal or vaginal probe to stimulate the pudendal nerve. These approaches are reviewed in the same section of this text.
Electromagnetic sacral nerve stimulation is yet another modality to modulate the neurologic control of the bladder. Most treatments involve large, powerful magnets that require a dedicated facility, as the magnets are not portable. The study included in this review evaluated the use of a smaller, portable electromagnetic system.

One randomized control trial (RCT) compared sacral neuromodulation to medical therapy. In this study, 98 participants were randomized to immediate sacral nerve stimulation or delayed sacral nerve stimulation. The delay group continued unspecified medical management for a six-month period before having the procedure.

This study, which randomized after successful test stimulation, found a reduction in daily urge incontinence episodes from 9.7 to 2.6 in the sacral neuromodulation group, compared to an increase of 9.3 to 11.3 in the medical management group at six months (p < 0.01) for patients with refractory OAB. At 18 months, 76 percent of participants receiving sacral neuromodulation reported they were completely dry or had experienced a reduction in symptoms of 50 percent or greater. Note that the comparison is not ideal, as subjects continuing to receive medical therapy had already failed medical management (Janknegt 2001).

The U.S. Food and Drug Administration (FDA) authorized the use of the sacral neuromodulation (SNM) device in 1997. SNM is now recommended to be a safe, effective, minimally invasive urological surgical technique for the treatment of a diverse spectrum of lower urinary tract diagnosis, including the refractory OAB. Additional usages of SNM, in urology, include disorders such as urinary urge incontinence, dysfunctional voiding and idiopathic urinary retention (Leng 2005).

Periurethral injection of bulking agents, such as cross-linked collagen (for example, Contigen® Bard Collagen Implant, C.R. Bard Inc., Covington, Georgia); carbon-coated beads (for example, Durasphere™ Advanced Uroscience Inc., St. Paul, Minnesota); calcium hydroxyapatite (for example, Coaptite® BioForm Medical Inc., San Mateo, California); and polydimethylsiloxane (for example, Macroplastique® Uroplasty Inc., Minneapolis, Minnesota) have been studied in randomized trials that established adequate safety and efficacy and have obtained clearance from the FDA for the treatment of adult women with stress urinary incontinence (SUI) due to intrinsic sphincteric deficiency.

Guidelines from the American Urologic Association (Gormley, et al., 2012) have concluded: “Clinicians may offer peripheral tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population. Option (evidence strength grade C; balance between benefits and risks/burdens uncertain).”

The injections are done under local anesthesia with the use of a cystoscope and a small needle. Bulking material is injected into the urethral sub-mucosal layer under direct vision. Unfortunately, the cure rate with this treatment is only 10 percent to 30 percent despite multiple formulations on the market for use. This treatment can be repeated and sometimes acceptable results are seen after multiple injections. The operation is minimally invasive, but the cure rates are lower compared to the other surgical procedures.

Typically botulinum toxin-A is used and can be injected directly into the wall of the bladder under cystoscopic guidance as a treatment for refractory OAB. It is FDA approved for this indication at the time of the writing of this document. A review of RCTs evaluating the use of intravesical botulinum toxin for OAB was published by the Cochrane Collaboration in 2007. Eight studies met their search criteria: five were published abstracts and three were full papers. Only one of the eight studies exclusively dealt with idiopathic OAB (the definition we used for our literature search). The remaining seven studies in the Cochrane review included subjects with neurogenic OAB.
The most common and the most popular surgery for stress incontinence is the sling procedure. Today, most of these procedures are being called TVT or TOT. In this operation, a narrow strip of material is used either from cadaveric tissue (from a cadaver), autologous tissue (from the patient’s body) or soft mesh (synthetic material). It is applied under the urethra to provide a hammock of support and improve urethral closure. The operation is minimally invasive and patients recuperate very quickly. For many years it was thought that biologic materials, the patient’s own fascia or cadaveric fascia, would create better more sustainable outcomes. We have found, however, that synthetic meshes have both the ease of use, with no need for harvest, as well as superior long-term results.

Based on the results of a controlled trial with a two-year follow-up (n = 50), Meschia and colleagues (2004) stated that TVT can be recommended for patients with prolapse and occult SUI. In a comparison study (n = 61), deTayrac, et al. (2004), concluded transobturator suburethral tape appears to be equally efficient as TVT for surgical treatment of SUI in women, with no reduction of bladder outlet obstruction at one-year follow-up.

In a prospective observational, multicenter study (n = 90), Nilsson, et al. (2004), reported the TVT procedure for treatment of female SUI is effective over a period of seven years. This finding extends the observation of that by Abdel-Fattah and associates (2004), who concluded the Pelvicol pubovaginal sling is a safe procedure in the surgical management of SUI with similar success rate and patient satisfaction rate to TVT up to three years of follow up. An assessment by the National Institute for Clinical Excellence (NICE, 2003) concluded “the tension-free vaginal tape (TVT) procedure is recommended as one of a range of surgical options for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed.” The Ontario Health Technology Advisory Committee (2004) concluded that TVT be offered as one option to treat women who are affected by SUI severely enough to warrant a surgical treatment approach.

Retropubic colposuspension is abdominal surgery in which the vaginal tissues or periurethral tissues are affixed to the pubic bone. The long-term results are good but the surgery requires longer recuperation time and is generally only used when other abdominal surgeries are also required. While this procedure can also be performed laparoscopically, long-term results are not as good as with the open procedure.

With bladder neck needle suspension, a long needle is used to thread suture from the vagina to the abdominal wall. The suture incorporates paraurethral tissue at the level of the bladder neck. These procedures were found to be less effective than open retropubic suspensions and slings, and as a result are rarely done today.

Anterior vaginal repair is done when sutures are placed in the periurethral tissue and fascia to elevate and support the bladder neck. This procedure has also fallen out of favor for inferior long-term outcomes compared to open retropubic suspensions and slings.

The potential adverse outcomes of surgical treatment include bleeding, infection, pain, urinary retention or voiding difficulties, de novo urgency, pelvic organ prolapse, and failure of the surgery to fix the leakage. With the use of mesh materials there is a very small risk of erosion of the material into the bladder, urethra or vagina.

Additional surgical treatment options are available for stress incontinence in men. In male patients with stress incontinence, an alternative is to perform a urethral compression procedure, called a male sling. This is done with the use of a segment of cadaveric tissue or soft mesh to compress the urethra against the pubic bone. It is placed through an incision in the perineum (the area between the scrotum and the
rectum). The results show decent success rates in patients with low-volume incontinence; poor success is seen with severe incontinence. Long-term data are not currently available.

The most effective treatment for male incontinence is implantation of an artificial urinary sphincter. This device is made from silicone and has three components that are implanted into the patient. The cuff is the portion that provides circular compression of the urethra, and therefore prevents leakage of urine from occurring. This is placed around the urethra after an incision is made in the perineum. A small fluid-filled pressure-regulating balloon is placed in the abdomen and a small pump is placed in the scrotum to be controlled by the patient. The fluid in the abdominal balloon is transferred to the urethral cuff, closing the urethra and preventing leakage of urine. When the patient needs to urinate he presses the scrotal pump, which releases the fluid back to the abdominal balloon opening the urethra and allowing the patient to void.

In more difficult cases, the bladder can be made bigger using a segment of small intestine. This operation, called augmentation cystoplasty, is very successful in curing incontinence, but its main drawback is the need in 10 percent to 30 percent of the patients to perform self-catheterization to empty their bladders. It is extremely effective in curing bladder urgency and urge incontinence.

Reconstructive bladder surgery for refractory OAB involves enhancement of functional bladder capacity and reduction in spontaneous increments in intravesical pressure. Augmentation enterocystoplasty and detrusor myectomy are two bladder reconstructive surgical procedures, which are often performed for patients with refractory OABS with the potential of achieving the above aims.

In augmentation cystoplasty, the bladder capacity is increased by bivalving the bladder wall and replacing it with a segment of bowel. Incorporation of bowel segment also has the potential of diminishing detrusor contractility. In clinical practice, ileum is often the most commonly used segment of bowel in adult patients. No current RCTs, however, are available in the literature for evaluating the role of augmentation cystoplasty in the management of refractory OAB. A few case series in the current literature evaluate augmentation cystoplasty in patients with refractory OAB; however, within these papers most patients had additional pathologies, such as interstitial cystitis (Awad 1998) or stress urinary incontinence (Hasan 1995), rendering comparative analysis unreliable.

OAB symptoms are a key component of LUTS in many men with or without bladder outlet obstruction (BOO). Although a very important element in some, prostatic enlargement is not the sole factor contributing to LUTS, and many men may present with primary idiopathic OAB. Even in those men with BOO, treatment aimed at relieving the obstruction leads to resolution of OAB symptoms in only 35 percent. This supports the need for increased awareness of the existence of primary OAB in men presenting with LUTS, and must be considered in their management.

Post-prostatectomy urinary incontinence (PPUI) is usually due to direct damage to the external urethral sphincter. The incidence of SUI after treatment of prostatic benign disease, either using classical transurethral resection or laser therapy, is estimated to be less than 1 percent to 3 percent. The incidence of post-radical prostatectomy urinary incontinence (PPI) is variable depending on the definition, the evaluation tool, and the collection method used. In general, 1 percent to 40 percent of patients suffer from PPI. It may be caused by bladder dysfunction, sphincter dysfunction or a combination of both. Bladder dysfunction presenting as OAB wet may contribute to PPUI, but is rarely the sole cause (<10 percent). Sphincteric deficiency remains the major cause of UI in more than two-thirds of patients. A combination of both is present in at least one-third of patients. Only 6 percent to 9 percent of PPUI will ultimately require surgical intervention. New laparoscopic and robotic-assisted prostatectomy techniques use many of the
same surgical principles as open surgery. It was initially thought these techniques would lead to improved postoperative continence; however, comparative systematic reviews have not demonstrated this. Operative skills, bladder neck preservation and neurovascular bundle sparing technique may help to minimize the postoperative morbidity; however, no significant benefits have been confirmed to date.

The experience of Hasan, et al. (1995), in the use of augmentation enterocystoplasty in patients with refractory OAB has been encouraging. We evaluated the role of augmentation cystoplasty in 48 patients, of whom 35 (73 percent) patients had a refractory OAB. Early symptomatic outcome was good in 40 (83 percent) patients, moderate in seven (15 percent) patients and unsatisfactory in one (2 percent) patient. The mean symptom scores before and three months after surgery were 10 (range 2 – 14) and 3 (range 2 – 14), respectively ($P < 0.001$). There was a significant increase in total bladder capacity (307 ± 140 to 588 ± 217 mL; $P < 0.001$) and bladder compliance (37 ± 50 to 169 ± 162 mL/cm H$_2$O; $P < 0.001$). Clean intermittent self-catheterization (CISC) was performed by 36 (75 percent) patients. On urodynamic analysis, DO persisted in 15 (31 percent) patients. Quality-of-life scores revealed significant improvements in all domains. Late complications (> 30 days) included incisional hernia (three patients), anastomotic perforation (one patient), calculus formation (one patient) and urethral stricture (one patient). The long-term outcome was good or moderate in 12 patients (92 percent) with neurogenic bladder dysfunction and good or moderate in 19 patients (58 percent) with DO.

On reviewing the additionally published literature on augmentation cystoplasty, the complication rate associated with the procedure continues to be high, including the specific side effects of recurrent urinary tract infections (UTIs), mucus retention, urinary tract calculus formation, metabolic disturbances, long-term deteriorating renal function and risk of bladder perforation (Greenwell, 2001).

Detrusor myectomy aims to improve bladder function by excising bladder muscle from the fundus of the bladder while leaving the bladder mucosa intact. The segment is commonly covered with omentum, which carries the potential of creating a permanent wide-neck diverticulum. All current cases reports in the literature indicate an unclear stratification in clinical improvement; hence this procedure is not well established (Kumar, 2005).

**Searches**

Keystone First 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 9, 2016. Search terms were: “MeSH overactive bladder,” “stress incontinence” and “surgical treatment MeSH.”

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

In 2014, the American Urologic Association (AUA), in collaboration with the Society of Urodynamics, Female Pelvic Medicine, and Urogynecological Society (SUFU) issued updated Guidelines for the Diagnosis and Treatment of Non-Neurogenic Overactive Bladder. Insufficient evidence was retrieved regarding diagnosis, so this portion of the guideline is based on clinical principles and expert opinion. The majority of the treatment portion is evidence-based. When sufficient evidence existed, articles relevant to treatment were assigned a strength rating of A (well-conducted RCTs or exceptionally strong observational studies); B (RCTs with some weaknesses of procedure or generalizability, or generally strong observational studies); or C (observational, have other problems that potentially confound interpretation of data). Additional treatment information is provided as clinical principles and expert opinion when insufficient evidence existed. AUA standards are directive statements that an action should or should not be undertaken based on Grade A or Grade B evidence. Recommendations are directive statements that an action should or should not be undertaken based on Grade C evidence. Options are nondirective statements that leave the decision to take an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears relatively equal or unclear. Options may be supported by Grade A, B or C evidence (Gormley, et al., 2014).

NICE has issued a full guidance to the National Health Service (NHS) in England, Wales, Scotland and Northern Ireland titled “Percutaneous Posterior Tibial Nerve Stimulation for Overactive Bladder Syndrome.” The NICE guidance states “Current evidence on percutaneous posterior tibial nerve stimulation (PTNS) for overactive bladder (OAB) syndrome shows that it is efficacious in reducing symptoms in the short and medium term. There are no major safety concerns” (NICE, 2010, p. 3). Further recommendations have been made as part of the “Clinical Guideline on Urinary Incontinence in Women” (CG171) published in September 2013 (NICE, 2013).

The American Urogynecologic Society (AUGS) supports the use of electrical stimulation as a unique, low-risk therapy, and states that electrical stimulation is noninvasive and provides a potential cure at a relatively low cost (AUGS, 2003).

The American College of Obstetricians and Gynecologists (ACOG) states that, although there are many unanswered questions regarding the effectiveness of electrical stimulation, the technique may be efficacious for both stress and urge incontinence for women in whom traditional treatment modalities have failed. However, electrical stimulation may not be superior to other therapies, including pelvic muscle exercises, bladder retraining and medications. ACOG acknowledges additional, well-designed trials are needed to establish the efficacy of electrical stimulation for urinary incontinence (ACOG, 1995).

Berghmans, et al. (1998), evaluated the efficacy of physical therapies for first-line use in the treatment and prevention of stress urinary incontinence in women. They identified six trials that reported electrical stimulation to be more effective than sham stimulation and identified five trials that compared electrical stimulation with any other intervention, such as vaginal cones, pelvic floor muscle exercise and both treatments combined. None of the five trials showed electrical stimulation to be more effective than pelvic floor muscle exercises alone, vaginal cones or PFM exercises with vaginal cones. The authors concluded that due to differences in the type of stimulation (extravaginal versus intravaginal, neurotrophic versus interferential) and stimulation parameters used in these trials, the interpretation of the results was
inconclusive.

The AUA formed a committee to examine the scientific evidence regarding electrical stimulation for urinary incontinence. The committee concluded there was not a strong consensus about the effectiveness of vaginal, suprapubic and/or anal electrical stimulation for stress, urge or mixed incontinence. The AUA urges that further randomized trials are conducted, including a comparative study of electrical stimulation versus behavioral modification.

The one RCT comparing sacral neuromodulation to medical therapy found a reduction in daily incontinence episodes from 9.7 to 2.6 in the intervention group, compared to an increase of 9.3 to 11.3 in the medical management group at six months (P < 0.01). Of note, all subjects receiving medical therapy had already failed medical management; no benefit from continued medical therapy would be expected. The remaining six case series that reported on change in UUI had decreases in mean incontinence episodes per day of 51 percent to 80 percent, and from a median of five down to zero incontinence episodes a day. Length of follow-up in these studies ranged from six months to five years.

Ghoniem, et al. (2009), evaluated the effectiveness and safety of Macroplastique as minimally invasive endoscopic treatment for female SUI primarily due to intrinsic sphincter deficiency. A total of 247 females with intrinsic sphincter deficiency were randomized 1:1 and treated with a transurethral injection of Macroplastique or Contigen (served as the control). Repeat treatment was allowed after the three-month follow up. Effectiveness was determined 12 months after the last treatment using Stamey grade, pad weight and Urinary Incontinence Quality of Life Scale scores. Safety assessment was recorded throughout the study. After 12 patients were excluded from the study, 122 patients received Macroplastique injection and 125 received Contigen injection. Mean patient age was 61 years and the average history of incontinence was 11.2 years. Of the patients, 24 percent had undergone prior incontinence surgery. At 12 months after treatment, 61.5 percent of patients who received Macroplastique and 48 percent of controls had improved one Stamey grade. In the Macroplastique group the dry/cure rate was 36.9 percent compared to 24.8 percent in the control group (p < 0.05). In the Macroplastique and control groups the one-hour pad weight decrease was 25.4 and 22.8 ml from baseline (p = 0.64), and the mean improvement in Urinary Incontinence Quality of Life Scale score was 28.7 and 26.4 (p = 0.49), respectively. The authors concluded that Macroplastique injection was statistically more effective than Contigen for SUI primarily due to intrinsic sphincter deficiency with a 12.1 percent cure rate difference.

Policy updates:
Added botox as a treatment:

**BOTOX® (ONABOTULINUMTOXINA) is medically necessary**

- Urinary incontinence due to neurogenic bladder after documented failure, intolerability, or contraindication to medical therapy (eg, pelvic floor exercises, diet/fluid management, anticholinergics, intermittent catheterization)
- Urinary incontinence due to overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
  - The individual has a documented failure, intolerability, or contraindication to an anticholinergic medication.
- Botox® (onabotulinumtoxinA) was approved on August 24, 2011 for the treatment of urinary incontinence due to neurogenic bladder; additionally, on January 18, 2013, Botox® (onabotulinumtoxinA) was approved for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency

U.S. Food and Drug Administration (FDA) approve Botox to treat overactive bladder. FDA NEWS RELEASE. Jan. 18, 2013.
Added information regarding Botox:

American Academy of Neurology (AAN): The AAN prepared a technology assessment in 2008 that addressed the safety and efficacy of BTX for various indications. Based on the evidence provided by two small RCTs and a small randomized crossover trial, this assessment concluded that BTX had been established as an effective and safe treatment for neurogenic detrusor over activity in adults. The AAN assessment stated that the evidence concerning BTX for detrusor over activity is limited by lack of comparison of BTX with other treatment options (Naumann et al., 2008). Several of the authors of the AAN assessment have financial relationships with at least one of the manufacturers of BTX.

**BTX-A for Treatment of Neurogenic Detrusor Over activity**: The largest available RCT that evaluated BTX-A for neurogenic detrusor over activity enrolled 275 patients and compared dosages of 200 and 300 U onaBTX-A with placebo. At 12 weeks after treatment compared with placebo, both BTX-A treatment groups had statistically significant decreases in mean number of episodes of UI per week, which decreased from 33 to 12 for the 200 U group and 31 to 11 for the 300 U group versus a decrease from 37 to 25 for the placebo group. Complete cessation of UI 12 weeks after treatment occurred in a larger percentage of the 200 U group (38%), and the 300 U group (40%) compared with the placebo group (8%), which was also statistically significant. BTX-A treatment was associated with increases in urinary retention (20% and 32% of the BTX-A treatment groups versus 3% of the placebo group) and urinary tract infection (56% and 64% of the BTX-A treatment groups versus 40% of the placebo group) (Cruz et al., 2011).

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Hartmann KE, et al. (2007) The Vanderbilt Evidence-Based Practice Center systematically reviewed evidence on treatment of OAB, UUI and related symptoms. | Key points: Treatment of overactive bladder:  
- The Vanderbilt Evidence-Based Practice Center systematically reviewed evidence on treatment of OAB, UUI and related symptoms. They focused on prevalence and incidence, treatment outcomes, comparisons of treatments, modifiers of outcomes, and costs.  
- Studies published in English from January 1966 to October 2008 were included. Studies were excluded with fewer than 50 participants, fewer than 75 percent women, or lack of relevance to OAB. Of 232 included publications, 20 were good quality, 145 were fair and 67 were poor. They calculated weighted averages of outcome effects and conducted a mixed-effects meta-analysis to investigate outcomes of pharmacologic treatments across studies.  
- OAB affects more than 10 percent to 15 percent of adult women, with 5 percent to 10 percent experiencing UUI monthly or more often. Six available medications are effective in short-term studies. Estimates from meta-analysis models suggest extended release forms (taken once a day) reduce UUI by 1.78 (95 percent confidence interval (CI): 1.61, 1.94) episodes per day, and voids by 2.24 (95 percent CI: 2.03, 2.46) per day. Immediate release forms (taken twice or more a day) reduce UUI by 1.46 (95 percent CI: 1.28, 1.64), and voids by 2.17 (95 percent CI: 1.81, 2.54). As context, placebo reduces UUI episodes by 1.08 (95 percent CI: 0.86, 1.30), and voids by 1.48 (95 percent CI: 1.19, 1.71) per day. No one drug was definitively superior to others, including comparison of newer more selective agents to older antimuscarinics.  
- Current evidence is insufficient to guide choice of other therapies, including sacral neuromodulation, instillation of oxybutynin, and injections of botulinum toxin. |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Acupuncture was the sole complementary and alternative medicine treatment, among reflexology and hypnosis, with early evidence of benefit. The strength of the evidence is insufficient to fully inform choice of these treatments. Select behavioral interventions were associated with symptom improvements comparable to medications. Limited evidence suggests no clear benefit from adding behavioral interventions at the time of initiation of pharmacologic treatment.</td>
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</tbody>
</table>
| Hassouna MM, et al. (2000) Sacral neuromodulation in the treatment of urgency-frequency symptoms: a multicenter study on efficacy and safety | Key points:  
- A total of 51 patients from 12 centers underwent baseline assessment, including a detailed voiding diary, urodynamic evaluation and percutaneous test stimulation of the sacral nerves at S3 and/or S4. All patients enrolled in the study had undergone prior conventional treatment, such as pharmacotherapy, hydrodistention and surgical intervention, which failed. All patients demonstrated a satisfactory response to trial stimulation and were randomly divided into a stimulation group (25 patients) and a control group (26). A sacral nerve stimulation device was implanted after six months in the control group. Patients were followed at one, three and six months, and at six-month intervals for up to two years after implantation of a neuroprosthetic InterStim system. Dagger. The study variables included the number of voids daily, volume voided per void and degree of urgency before void.  
- Compared to the control group, six-month voiding diary results demonstrated statistically significant improvements (p <0.0001) in the stimulation group with respect to the number voids daily (16.9 +/- 9.7 to 9.3 +/- 5.1), volume per void (118 +/- 74 to 226 +/- 124 ml.), and degree of urgency (rank 2.2 +/- 0.6 to 1.6 +/- 0.9). Patients in the control group showed no significant changes in voiding parameters at six months. Significant improvements in favor of the stimulation group were noted in various parameters with respect to water cystometry and quality of life (SF-36). At six months after implantation, neurostimulators were turned off in the stimulation group and urinary symptoms returned to baseline values. After reactivation of stimulation, sustained efficacy was documented at 12 months and 24 months.  
- Neuromodulation of the sacral nerves is an effective, safe therapy that successfully treats significant symptoms of refractory urgency-frequency. |
| Nowakowski L, et al. (2014) The influence of mesh pelvic floor reconstructive surgery on OAB symptoms | Key points:  
- The working hypothesis was that pelvic organs prolapse can induce overactive bladder symptoms. Therefore, restoration of pelvic anatomy with accompanying proper urodynamic parameters (cystometric volume, micturition volume and uroflow) should resolve OAB symptoms.  
- Forty-eight women, ages 51 — 77 years (mean 62.4+7.32), with stage II, III or IV prolapse (POP-Q scale) were included in the study. Patients with LUTS (infiammation, infection and pain) were excluded. Each patient underwent clinical evaluation and full urodynamic examination (cystometry and uroflowmetry MMS Libra +). Depending on the type of the anatomical defect on the POP-Q scale — anterior defect, posterior defect or both anterior and posterior — a repair using polypropylene monofilament mesh was performed (TVM anterior, TVM posterior or TVM total). Patients were asked to complete King's Health questionnaire before and after the reconstructive surgery. Statistical analysis was performed using Kolmogorov-Smirnov and U Mann-Whitney tests.  
- OAB symptoms were diagnosed in 27 patients. DO was found in 10 patients. In 17 patients, out of 27 with OAB before surgery, over activity symptoms completely resolved after the surgery (63%). On the other hand, post-op de novo OAB symptoms appeared in two patients (4.1%).  
- Half of the patients with OAB symptoms after surgery had DO before mesh repair while only 30% of patients without OAB symptoms after surgery had DO before the surgical procedure. Micturition volume in the group of patients with OAB significantly increased after the surgery (293.78 ml vs. 364.15 ml; P=0.006).  
- Maximal cystometric capacity in patients with overactive bladder also significantly increased after surgery (774.68 ml vs. 968.58 ml; P=0.004). |
Increased after the surgery (318.78 ml vs. 407 ml; \( p = 0.0001 \)). Quality of life measured by King’s questionnaire improved in the group of patients with resolution of OAB symptoms in incontinence impact, role limitations, and sleep or emotions, \( p < 0.05 \).
- Correction of pelvic organ prolapse stage II, III and IV in patients with OAB symptoms leads to an improvement in bladder conditions in half of the patients. Such treatment also resulted in symptom resolution of DO ascertained in urodynamic studies. OAB syndrome with DO was more resistant to surgical treatment as compared to OAB without DO. Quality of life improved in patients who did not present with OAB bladder symptoms after the mesh surgery. Restoration of proper anatomy might also cure or improve bladder symptoms in patients with OAB symptoms, coexisting with advanced pelvic organ prolapse.

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
</table>
| Kerr L. (2005) Special Patient Populations: Collagen as a Case Study | Key point:  
  - McGuire and Appell reported on their observation of 98 women and 89 men at 1 year after surgery and 45 women and 33 men at 2 years after surgery.  
  - They concluded that collagen implants dramatically improved the ability of the urethra to resist abdominal pressure increases without changing the voiding pressure required to allow bladder emptying.  
  - After implantation, male patients similarly demonstrated an increase in abdominal pressure required to cause leakage; however, the data for men were not supported in further reports. Overall, men had lower success rates and required more collagen to render them dry. |

**Glossary**

**Artificial sphincter** — A patient-controlled device made of silicone rubber that has an inflatable cuff that fits around the tube through which urine leaves the body (urethra), a balloon that regulates the pressure off the cuff and a bulb to control inflation and deflation of the cuff. The balloon is placed within the pelvic space, and the control bulb is placed in the scrotum of a male or the external vaginal lips of a female. The cuff is inflated to keep urine from leaking. When urination is desired, the cuff is deflated, allowing urine to drain out.

**Biofeedback** — A procedure that uses electrodes to help individuals gain awareness and control of their pelvic muscles. Also, involves training patients to control involuntary physiological processes, such as muscle tension, blood pressure or heart rate by using visual or auditory feedback.

**Burch colposuspension** — An operation to support the bladder neck by elevating the vagina using dissolvable sutures.

**Bladder neck** — Area of thickened muscle fiber where the bladder joins the urethra. Acting on signals from the brain, bladder neck muscles can either tighten to hold urine in the bladder or relax to allow urine out and into the urethra. These muscles also tighten during ejaculation to prevent backflow of semen into the bladder.

**Bulking agents** — Substance injected under the urethra to improve urinary control.

**Collagen implant** — A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). ISD is a cause of stress urinary
incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

**Cystometry** — Measures the bladder pressure by measuring how much the bladder can hold and how much pressure builds up inside the bladder as it stores urine, and how full it is when an individual feels the urge to urinate.

**Detrusor instability** — A bladder that contracts and empties out urine even though it is not full, or when the person does not intend to urinate.

**Electrical stimulation** — An application of an electric current or impulse to the pelvic floor muscles and bladder to cause a muscle contraction. This treatment is used in people who have nerve damage to the bladder or pelvis.

**Intrinsic sphincter deficiency (ISD)** — A cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

**Kegel exercises** — Pelvic muscle exercises that assist in bladder and bowel control, as well as sexual function.

**Mesh** — A net, web or screen material used to support the bladder in certain surgeries for stress urinary incontinence.

**Mixed incontinence** — Mixed incontinence refers to a combination of stress and urge incontinence. Many patients experience symptoms of both types.

**Nerve stimulation** — Small, electrical impulses of the nerves that signal the need to urinate. A small, pacemaker-like device is implanted under the skin, usually in the buttock. Attached to the device — called a stimulator — is a thin, electrode-tipped wire that carries electrical impulses to the sacral nerve. These electrical impulses block messages sent by an overactive bladder to the brain, telling it the body needs to urinate. Nerve stimulation may help with urge incontinence, but these procedures aren’t effective for treating stress urinary incontinence.

**Neuromodulation** — The alteration of nerve activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body.

**Periurethral** — Lining of the urethra.

**Overactive bladder (OAB)** — OAB is defined by urgency, which is the complaint of sudden need to void, with or without urge incontinence and involuntary loss of urine with urgency symptoms; and usually with frequency, which is the individual’s perception of voiding too often during the day. OAB is often defined as more than eight voids during waking hours. OAB is usually accompanied by nocturia, which is awakening from sleep to empty the bladder, is carried out to normalize — or modulate — nerve function.

**Overflow incontinence** — Overflow incontinence occurs as a result of poor bladder emptying and an always-full bladder. In these patients, leakage occurs because the cup is already full and as more urine is produced it overflows and leaks out. Frequent small urinations and constant dribbling are symptoms. This is rare in women and more common in men with a history of surgery or prostate problems.
Reversible incontinence — Includes both functional and transient incontinence. Continence requires adequate mobility, mentation, motivation and manual dexterity in addition to integrated control of the urinary tract. The causes of reversible incontinence, often outside the bladder, may give rise to prolonged incontinence.

Sling procedure — Surgical methods for urinary incontinence involving the placement of a sling, made either of tissue obtained from the person undergoing the sling procedure or from a synthetic material.

Stress incontinence — Also referred to as stress urinary incontinence. The most common type of incontinence involves the leakage of urine caused by actions, such as coughing, laughing, sneezing, running and lifting, that put pressure on the bladder from inside the body. Can result from either a fallen bladder or weak sphincter muscles.

Suspension procedure — A bladder neck suspension reinforces the urethra and bladder neck so they won't sag, and provides something for the urethra to compress against to help prevent leakage.

Total incontinence — Results from total loss of sphincter control or from a fistula that bypasses the sphincter.

Trabeculated bladder — Characterized by thick wall and hypertrophied muscle bundles. Typically seen in instances of chronic obstruction.

Transurethral surgery — Surgical procedure where a lighted tube is inserted through the urethra into an organ. Serves a diagnostic and therapeutic role in the treatment of various conditions.

Urge incontinence — Also referred to as urge urinary incontinence. Wetting. Involuntary urinary leakage when the bladder contracts unexpectedly by itself. The inability to hold urine long enough to reach a restroom.

Urge incontinence — Also referred to as overactive bladder, urge incontinence is another form of leakage. This can happen when a person has an uncontrollable urge to urinate but cannot reach the bathroom in time and has an accident. At other times, running water or cold weather may cause such an event. Some people have no warning and experience leakage just by changing body position (e.g., getting out of bed).

Urinary continence — Ability to control urination.

Urinary incontinence — Involuntary loss of urine associated with a sudden strong urge to urinate.

Urodynamics — A series of tests that measures the bladder's ability to hold and release urine.

References

Professional society guidelines/other:


National Institute for Clinical Excellence (NICE, UK) interventional procedures (IP) guidance aimed to evaluate the efficacy and safety of permanent SNS for the refractory OAB. (NICE 2004).


Peer-reviewed references:


**Clinical trials:**

Searched clinicaltrials.gov on <date> using terms overactive bladder, incontinence | Open Studies. 98 studies found, four relevant.


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


National coverage Analyses (NCA) - Sacral Nerve Stimulation for the treatment of Urinary Urgency/Frequency in Adults (August 2000). Surgical interventions for urgency/frequency patients include augmentation cystoplasty or a cystectomy with or without diversion or orthotopic augmentation. Surgery generally is reserved for difficult-to-treat cases that do not respond to less-invasive intervention (Couillard and Webster 1995; Wall 1990; Langer et al. 1988; Pontari et al. 1997). In augmentation cystoplasty, part or most of the bladder is removed and a new bladder is formed with a section of the patient’s bowel, intestine or stomach. Urine continues to be stored in the neobladder and emptied through the existing urethra or surgically formed opening. http://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?. Accessed February 3, 2016.
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>Comment</th>
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<tbody>
<tr>
<td>51840</td>
<td>Anterior vesicourethropexy, or urethropexy (e.g., MarChetti-Krantz, Burch); simple</td>
<td></td>
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<tr>
<td>51841</td>
<td>Anterior vesicourethropexy, or urethropexy (e.g., MarChetti-Krantz, Burch); complicated (eq. secondary repair)</td>
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<tr>
<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>51992</td>
<td>Laparascopy; surgical; sling operation for stress incontinence</td>
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<tr>
<td>53440</td>
<td>Sling operation for correction of male urinary incontinence</td>
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<tr>
<td>53448</td>
<td>Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, cuff through an infected field in the same operation session including irrigation and debridement of infected tissue</td>
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<tr>
<td>57220</td>
<td>Plastic operation on urethral sphincter, vaginal approach (e.g., Kelly urethral plication)</td>
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<tr>
<td>57240</td>
<td>Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele</td>
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<tr>
<td>57267</td>
<td>Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach</td>
<td>Add-on code</td>
</tr>
<tr>
<td>57287</td>
<td>Removal or revision of sling for stress incontinence (e.g., fascial or synthetic)</td>
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<tr>
<td>57289</td>
<td>Pereyra procedure, including anterior colporrhaphy</td>
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<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode; sacral nerve, including imaging guidance if performed.</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>N32.81</td>
<td>Overactive bladder</td>
<td></td>
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<tr>
<td>N39.3</td>
<td>Stress incontinence (male/female)</td>
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<tr>
<td>N39.41</td>
<td>Urge incontinence</td>
<td></td>
</tr>
<tr>
<td>N39.46</td>
<td>Mixed incontinence (urge and stress)</td>
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<tr>
<td>R32</td>
<td>Unspecified urinary incontinence</td>
<td></td>
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<tr>
<td>HCPCS Level II</td>
<td>Description</td>
<td>Comment</td>
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<td>NA</td>
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Appendix A


Major recommendations:
The grades of evidence (I – III) and levels of recommendation (A – C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

Behavioral therapy, including bladder training and prompted voiding, improves symptoms of urge and mixed incontinence and can be recommended as a noninvasive treatment in many women.

Pelvic floor training appears to be an effective treatment for adult women with stress and mixed incontinence and can be recommended as a noninvasive treatment for many women.

Pharmacologic agents, especially oxybutynin and tolterodine, may have a small beneficial effect on improving symptoms of DO in women.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

Cystometric testing is not required in the routine or basic evaluation of urinary incontinence.

Bulking agents are a relatively noninvasive method of treatment for stress incontinence and can be used in women for whom any form of operative treatment is contraindicated.

Long-term data suggest that Burch colposuspension and sling procedures have similar objective cure rates; therefore, selection of treatment should be based on patient characteristics and the surgeon's experience.

The combination of a hysterectomy and a Burch colposuspension does not result in higher continence rates than a Burch procedure alone.

Tension-free vaginal tape and open Burch colposuspension have similar success rates.

Anterior colporrhaphy, needle urethropexy and paravaginal defect repair have lower cure rates for stress incontinence than Burch colposuspension.

The following recommendations are based primarily on consensus and expert opinion (Level C):

After the basic evaluation of urinary incontinence, simple cystometry is appropriate for detecting abnormalities of detrusor compliance and contractibility, measuring post void residual volume, and determining capacity.

Patients with urinary incontinence should undergo a basic evaluation that includes a history, physical examination, measurement of post void residual volume and urinalysis.
Definitions

Grades of evidence:

I: Evidence obtained from at least one properly designed randomized controlled trial.
II-1: Evidence obtained from well-designed controlled trials without randomization.
II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3: Evidence obtained from multiple-time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
III: Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees.

Levels of recommendations:
Level A — Recommendations are based on good and consistent scientific evidence.
Level B — Recommendations are based on limited or inconsistent scientific evidence.
Level C — Recommendations are based primarily on consensus and expert opinion.