Urinary Bladder Dysfunction

Humana

Medical Coverage Policy

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Disclaimer

Description

Urinary bladder dysfunction is a broad term that may encompass a myriad of lower urinary tract symptoms such as incontinence, overactive bladder and retention.

Urinary incontinence (UI) is the involuntary leakage of urine, which may be caused by aging, disease, postsurgical complications, trauma or other conditions.

- **Stress urinary incontinence (SUI)** is the involuntary loss of urine without a bladder contraction which occurs when the muscles and tissues around the bladder (eg, pelvic floor, sphincter) become weak or do not work. Urine may leak when there is pressure exerted on the bladder through actions such as coughing or sneezing.

- **Urge urinary incontinence (UUI)** is the involuntary loss of urine associated with a bladder contraction. It is a sudden, overwhelming urge to urinate due to involuntary contractions of the muscular wall of the bladder, which may cause an unintentional loss of urine. Frequent urination, including nocturia (awaken at night to urinate), can also occur.

Mixed incontinence may present with symptoms of both stress and urge incontinence.

Overflow incontinence occurs when the bladder does not empty completely causing leakage if the bladder becomes overly full.

Overactive bladder (OAB) is characterized as urgency, frequency and nocturia, with or without urge incontinence.

Urinary retention (UR) is the incomplete emptying of the bladder or cessation of urination. It may be acute or chronic in nature. The problem is considered chronic when there is an accumulation of urine that results in adverse clinical outcomes in the absence of intervention.[15] Some causes for **chronic urinary retention (CUR)** may include bladder outlet obstruction (related to urethral strictures following a surgery or injury), detrusor-sphincter dyssynergia (lack of coordination between bladder contraction and sphincter relaxation), impaired bladder contractility (underactive bladder [UAB] often related to neurologic conditions [neurogenic lower urinary tract dysfunction]) or a combination of factors.[23]

Evaluation

Treatment for UI or OAB depends on the type of incontinence and the underlying cause; therefore, prior to treatment, an evaluation must be performed. The initial assessment includes gathering the individual's history, conducting a physical exam, performing a cough stress test, measuring postvoid residual volume (PVR) and completing a urinalysis. Additional tests (eg, cystoscopy, urodynamic testing) may be necessary if surgical intervention is being considered.

Vaginal tactile imaging (or biomechanical transvaginal mapping) is a type of assessment which purportedly provides high resolution mapping of pressures and assesses the strength of the pelvic floor muscles within the vagina. This real-time

data can be viewed by a physician or surgeon to potentially assist with evaluations. **(Refer to Coverage Limitations section)**

Diagnosis for UR most often involves the measurement of PVR volumes which are obtained by catheterization or by bladder ultrasonography showing an elevated residual urine volume. Other tests (eg, blood tests, cystography, cystoscopy, ultrasonography, urinalysis, urodynamic testing) may be performed based on clinical findings.[23]

The **penile cuff test** (eg, UroCuff) is a noninvasive method to purportedly measure urinary pressure flow in individuals with lower urinary tract symptoms (LUTS). A small inflatable cuff is placed around the penile shaft and inflated during urination. As the cuff is deflated, a surge in urine flow returns followed by a steady urine flow. Bladder function is determined from interruption pressure versus flow rate. The maximum pressure for cuff interruption of urinary flow is plotted to reportedly diagnose bladder outlet obstruction (BOO) or benign prostatic hyperplasia (BPH). **(Refer to Coverage Limitations section)**

Treatments

Examples of **UI/OAB or UR treatments** include, but may not be limited to:

Artificial urinary sphincter involves the implantation of an artificial valve in the genitourinary tract to restore continence.

Behavioral training provides education in regards to exercises, muscle control as well as relaxation techniques to control incontinence.

Biofeedback is a training technique that uses an external sensor to provide an indication of bodily processes and teaches the individual to contract the urinary sphincter in response to the urge to urinate, which may help strengthen the sphincter. For information regarding **biofeedback**, please refer to Biofeedback Medical Coverage Policy.

Bladder support surgeries are performed using a variety of open or laparoscopic techniques to help restore continence. Examples include, but may not be limited to:

- Procedures to secure the bladder neck using sutures (eg, Burch colposuspension, open or laparoscopic) are performed to help obtain normal bladder neck position

- Suburethral mesh placement (also referred to as a sling procedure) is more commonly performed and involves the use of synthetic (eg, single incision sling [SIS], tension-free vaginal tape [TVT], transobturator tape [TOT]) and nonsynthetic materials to aid in the support of the urethral sphincter. These devices are placed under the urethra and act as a hammock to support the urethra and the bladder neck to prevent downward rotation of these structures

  Sling procedures are also sometimes performed on individuals without incontinence during pelvic organ prolapse repairs to decrease the risk of postoperative SUI.

Bladder training is a method that includes timed voiding, keeping a diary and gradually increasing the time between voids so an individual can learn to manage UI.

Botox injection (For information regarding **Botox**, please refer to Botox [Botulinum Toxin] Pharmacy Coverage Policy).

Catheterization is a method used to drain the bladder. A urinary catheter may be in-dwelling (left in place for a specific amount of time) or be utilized intermittently to remove urine.

Correction, reduction and/or removal of an anatomic obstruction related to the cause of urinary retention may be necessary. There are a variety of procedure types depending on the nature of the obstruction including, but may not be limited to: mass removal, repair of pelvic organ prolapse, repair of urethral strictures, transvaginal sling excision, urethral dilation, urethral reconstruction, urinary diversion and treatment of benign prostatic hyperplasia (BPH). (For information regarding BPH treatments, please refer to Benign Prostatic Hyperplasia (BPH) Treatments Medical Coverage Policy.)

Cryogen-cooled radiofrequency remodeling (eg, Viveve) is a method proposed to reduce stress urinary incontinence by delivering radiofrequency (RF) energy to vaginal tissues around the urethra to improve structural integrity and increase

urethra support. **(Refer to Coverage Limitations section)** (For information regarding Viveve for vaginal rejuvenation, please refer to Cosmetic Surgery, Reconstructive Surgery, Scar Revision Medical Coverage Policy.)

Enuresis (bed wetting) **alarms** are devices that sense urine and set off an alarm so that an individual can wake up to use the toilet. **(Refer to Coverage Limitations section)**

Extracorporeal magnetic innervation (ExMI) (eg, NeoControl Pelvic Floor Therapy System) utilizes magnetic fields to stimulate the nerves of the pelvic floor or the sacral nerve roots which purportedly results in the contraction of the pelvic muscles. **(Refer to Coverage Limitations section)**

Laser therapy (eg, FemTouch, IncontiLase) has been proposed as a minimally invasive treatment for SUI as well as pelvic organ prolapse (POP). The two types of lasers currently being studied are Er: YAG and CO_2. The controlled heat from the lasers reportedly cause reconstruction and remodeling of the collagen; thereby, providing support to the pelvic floor structures.[29] **(Refer to Coverage Limitations section)**

Nonimplanted pelvic floor electrical stimulation (eg, Detrusan, UROSTYM) are rehabilitative devices that deliver small amounts of electrical stimulation to the nerves and muscles of the pelvic floor and bladder via a probe that is placed in the vagina, transurethral catheter or via surface electrodes. Some of the systems also provide visual biofeedback. The ultimate goal is that the electrical stimulation will strengthen muscles and retrain the bladder. These systems are utilized in clinic-based settings.

Pelvic floor exercises (eg, Kegel exercises, pelvic muscle rehabilitation) are a daily training program for the muscles that support the uterus, bladder and other pelvic organs to strengthen pelvic muscles to prevent accidental urine leakage. There are a variety of electrical Kegel exercise assistance devices being marketed and made available over-the-counter (OTC) for home use which either provide vibrations or an electrical prompting (eg, Apex, Attain, Flyte, INNOVO). **(Refer to Coverage Limitations)**

Percutaneous tibial nerve stimulation (PTNS) involves stimulation of the tibial nerve which travels to the sacral nerve plexus. This is believed to lead to improvements in voiding function, urgency and control. Two methods have been introduced for this type of stimulation, however one is still in the early stages of development.

- **Implanted PTNS** (eg, Protect PNS, RENOVA, StimRouter PNS) is being explored as an option for those with OAB and associated symptoms. The two approaches for this technology include implanting a lead through a small surgical incision or injecting a lead through an ultrasound-guided delivery system. An external device or electrode is then worn around the ankle during treatment and the physician will set the stimulation parameters in advance so that the individual can conduct treatments at home in 30 minute sessions each day. **(Refer to Coverage Limitations)**

- **Nonimplanted PTNS** (eg, NURO System, Urgent PC) is a minimally invasive technique, fine-needle electrodes are placed externally near the tibial nerve above the ankle. The electrode then carries electrical impulses from a stimulator to the sacral nerve plexus. This typically involves one 30 minute session per week, for 10-12 weeks, occurring in a clinical setting.[30]

Periurethral bulking agents (eg, Bulkamid, Coaptite, Contigen, Durasphere EXP, Macroplastique) is a procedure that involves the injection of collagen or other substances into the vicinity of the urinary sphincter which increases the tissue bulk, thereby increasing pressure in the urethra to maintain continence.

Sacral nerve stimulation (SNS) (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro) is a procedure which involves the implantation of electrodes near the sacral nerve to control the function of the muscles required for urination.

Stem cell transplantation is being proposed as a possible treatment for SUI. Examples of types of stem cells under investigation include, but may not be limited to, bone marrow-derived, mesenchymal, muscle-derived cells and umbilical cord blood cells.[17] **(Refer to Coverage Limitations section)**

Transperineal implantation of permanent adjustable balloon continence device (eg, ProACT Therapy, ACT Therapy) consists of adjustable balloon implants that are placed via a perineal approach. The fluid filled balloons reportedly provide pressure and support at the bladder neck to prevent bladder leakage. Titanium ports attached via tubing to each balloon are placed in the scrotum, which allows for postoperative volume adjustment. This device is indicated for adult men who have stress urinary incontinence arising from intrinsic sphincter deficiency of at least 12 months duration following radical prostatectomy or transurethral resection of the prostate (TURP) and who have failed to respond adequately to conservative therapy. ACT Therapy, for use in women, is not yet available in the United States. **(Refer to Coverage Limitations section)**

Transurethral radiofrequency ablation (eg, Renessa procedure) utilizes controlled heat that is applied from a radiofrequency device to supposedly denature the collagen in the tissues of the lower urinary tract. After healing, the tissue is reportedly firmer which increases resistance to involuntary leakage. **(Refer to Coverage Limitations section)**

Urethral excision involves the surgical removal of a urethral diverticulum or urogenital fistula. A urethral diverticulum is a localized outpouching which forms next to the urethra. A urogenital fistula tract is an abnormal connection between the genital tract and bladder, urethra or ureters. Both of these conditions may lead to urinary incontinence.

Urinary prosthesis (eg, inFlow Voiding Prosthesis) is a device that is designed for use in women with impaired detrusor contractility (IDC). Individuals diagnosed with IDC are unable to spontaneously urinate because of insufficient bladder muscle contractions, which can be caused from conditions including, but not limited to, multiple sclerosis, spinal cord injury or stroke. The prosthesis is initially inserted by a physician. In order to use the device, the individual sits on the toilet, holds the activator over the lower pelvic area and presses the button which opens the valve and activates the pump. This purportedly empties the bladder, while releasing the button closes the valve and stops the flow of urine.[41] **(Refer to Coverage Limitations section)**

Vaginal pessaries are rigid, intravaginal devices that support the bladder neck where the urethra joins the bladder in an effort to reduce incontinence.

For information regarding **smartphone apps for incontinence training programs or devices** (eg, leva app), please refer to the Digital Therapeutics Medical Coverage Policy.

For information regarding **fecal incontinence**, please refer to Fecal Incontinence Evaluation and Treatments Medical Coverage Policy.

Coverage Determination

URINARY INCONTINENCE (UI) AND OVERACTIVE BLADDER (OAB)
Commercial Plan members: requests for PTNS and SNS for UI and OAB require review by a medical director.

Any services for UI/OAB that are considered primarily educational or training in nature are generally NOT covered under most Humana Benefit Plans.

Please refer to the member's applicable pharmacy benefit to determine benefit availability and the terms and conditions of coverage for medication for the treatment of UI/OAB.

Services provided by a psychiatrist, psychologist or other behavioral health professionals are subject to the provisions of the applicable behavioral health benefit.

UI/OAB Evaluation
Humana members may be eligible for the following types of **diagnostic evaluation for urinary incontinence (UI/OAB)**:

Initial diagnostic evaluation for **UI/OAB** includes the following:

- History and physical exam; **AND**
- Measurement of postvoid residual volume (PVR) to exclude retention; **AND**
- Positive cough stress test (during physical examination and/or during cystometry); **AND**

- Negative urinalysis[7,24]

After initial diagnostic evaluation above has been performed, **urodynamic testing for UI/OAB** may be performed for the following indications:

- Etiology of incontinence is unclear; **OR**
- Incontinence refractory to conservative management; **OR**
- Previous pelvic floor surgery or prostatectomy[7,14]

After initial diagnostic evaluation above has been performed, **cystoscopy for UI/OAB** may be performed for the following indications:

- Acute onset incontinence; **OR**
- Incontinence refractory to conservative management; **OR**
- Presence of microscopic hematuria; **OR**
- Recurrent urinary tract infection; **OR**
- Suspicion of bladder neck contracture, foreign body or urethral stricture after a previous surgery (eg, gynecologic surgery or prostatectomy)[7]

Stress Urinary Incontinence (SUI) Treatments
Humana members may be eligible under the Plan for the **following treatments for SUI** when the following criteria are met:

- Artificial urinary sphincter implantation; **OR**

- Bladder support surgeries (eg, Burch colposuspension [laparoscopic or open], suburethral mesh placement [sling procedure]*****) using a US Food & Drug Administration (FDA) approved device; **OR**

- Periurethral bulking agents (eg, Bulkamid, Coaptite, Contigen, Durasphere EXP, Macroplastique);

AND all of the following:

- Appropriate diagnostic evaluation has confirmed a diagnosis of SUI; **AND**

- Failure of or contraindication to a minimum of two conservative management therapies over a consecutive 60 day period

Suburethral Mesh Placement or Urethral Excision for Other Diagnoses
Humana members may be eligible under the Plan for the following procedures without failure of conservative management when the following criteria are met:

- **Urethral excision** when a urethral diverticulum or urogenital tract fistula is present and causing urinary incontinence; **OR**

- **Suburethral mesh placement** (sling procedures)***** using an FDA-approved device **AND** either of the following:

  - Pelvic organ prolapse without urinary incontinence; **OR**

  - Performed in conjunction with pelvic organ prolapse surgery (eg, anterior colporrhaphy [cystocele repair], posterior colporrhaphy [rectocele repair])

*****Per the American Urological Association (AUA), intraoperative cystoscopy should be performed during all synthetic sling procedures to identify urinary tract injury.[11]

Urge Urinary Incontinence (UUI)/Overactive Bladder (OAB) Treatments
Humana members may be eligible under the Plan for the **following treatments for UUI/OAB** after appropriate diagnostic evaluation has confirmed a diagnosis of UUI/OAB and the following criteria are met:

- **Botox injection** (for information regarding coverage determination/limitations, please refer to Botox [Botulinum Toxin] Pharmacy Coverage Policy); **OR**

- **Nonimplanted PTNS** (eg, NURO System, Urgent PC) when the following criteria are met:**(Commercial Plan members: requests for PTNS require review by a medical director)**

  - Absence of contraindications listed in the Coverage Limitations section; **AND**

  - Appropriate diagnostic evaluation confirms a diagnosis of UUI/OAB; **AND**

- At least 12 consecutive months of symptoms when the frequency and/or severity of UUI/OAB symptoms have impacted the ability to perform activities of daily living; **AND**

- Failure of or contraindication to a minimum of two conservative management therapies, one of those being pharmacotherapy, over a consecutive 60 day period; **AND**

- If the above criteria are met:

  - A total of 12 treatments (one per week) will be initially approved

  - If there is a 50% decrease in symptoms as evidenced by a daily urolog (record of bladder events, voiding diary), an additional nine months of treatment (one per month) may be approved subject to continued improvement (for information regarding treatment beyond 12 months, **refer to Coverage Limitations section**); **OR**

- **Sacral nerve stimulation (SNS**) (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro) with an FDA-approved device when all the following criteria are met: **(Commercial Plan members: requests for SNS require review by a medical director)**

  - Absence of contraindications listed in the Coverage Limitations section; **AND**

  - Appropriate testing confirms a diagnosis of UUI/OAB; **AND**

  - At least 12 consecutive months of symptoms where the frequency and/or severity of UUI/OAB symptoms have impacted the ability to perform activities of daily living; **AND**

  - Failure of or contraindication to a minimum of two conservative management therapies, one of those being pharmacotherapy, over a consecutive 60 day period; **AND**

- Permanent implantation of a SNS requires a prior trial test stimulation for a minimum of two days that demonstrates a documented 50% or greater improvement in incontinence symptoms

Humana members may be eligible for **removal of an SNS device** when a previously implanted device and/or its associated components cause complications or unintended negative outcomes (eg, adverse change in voiding function, infection, new pain, undesirable stimulation) for the individual.

Humana members may be eligible for **replacement of an SNS device** when the following criteria are met **(Commercial Plan members: requests for SNS require review by a medical director)**:

- Previously implanted device and/or its associated components are no longer functioning appropriately (eg, defective pulse generator, lead migration) and are no longer under warranty; **AND**
- Absence of contraindications listed in the Coverage Limitations section; **AND**
- FDA-approved device is being utilized as the replacement

Note: The criteria for **urinary incontinence treatments** are not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations

Urinary Incontinence (UI)/Overactive Bladder (OAB)

Humana members may **NOT** be eligible under the Plan for **UI/OAB treatments** for any indications other than those listed above including, but may not be limited to:

- Cryogen-cooled radiofrequency remodeling (eg, Viveve); **OR**
- Extracorporeal magnetic innervation (ExMI) (eg, NeoControl Pelvic Floor Therapy System); **OR**
- Implanted PTNS (eg, Protect PNS, RENOVA, StimRouter PNS); **OR**

- Laser procedures (eg, FemTouch, IncontiLase); **OR**
- Nonimplanted PTNS (eg, NURO System, Urgent PC) for any indication not listed above **OR** if any of the following contraindications are present:
  - Individual prone to excessive bleeding; **OR**
  - Individual with nerve damage that could impact the percutaneous tibial nerve or pelvic floor function; **OR**
  - Individual with pacemaker or implantable defibrillator; **OR**
  - Pregnancy or plan to become pregnant while using the device; **OR**
  - Treatment duration longer than 12 months; **OR**
- SNS (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro) for any indication not listed above **OR** if the following contraindications are present:
  - Bilateral stimulation; **OR**
  - Bladder capacity less than 100 ml; **OR**
  - Individual 15 years of age or younger; **OR**
  - Individual not capable of operating the device; **OR**
  - Mechanical obstruction present (eg, benign prostatic hyperplasia, cancer, urethral stricture); **OR**
  - Neurogenic lower urinary tract dysfunction (NLUTD) (eg, diabetic neuropathy, multiple sclerosis, spinal cord injury); **OR**
  - Pregnancy or plan to become pregnant while using the device; **OR**
- Stem cell transplantation; **OR**

- Transperineal implantation of permanent adjustable balloon continence device (eg, ProACT system, ACT system); **OR**

- Transurethral radiofrequency ablation (eg, Renessa procedure)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **vaginal tactile imaging** (or biomechanical transvaginal mapping). This is considered experimental/ investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the following **UI devices or supplies** for any indication including, but may not be limited to:

- Electrical Kegel exercise assistance devices (eg, Apex, Attain, Flyte, INNOVO); **OR**

- Enuresis (bed wetting) alarms; **OR**

- External urine collection systems (eg, PrimaFit External Urinary System, PureWick Urine Collection System); **OR**

- Hygienic items and/or incontinence garments (eg, briefs, diapers, pads, penile wraps, underpads); **OR**

- Penile clamps; **OR**

- Urethral inserts

Although they may be prescribed by a health care practitioner, these **UI devices and supplies** are available without a prescription and may be obtained over-the-counter (OTC) and are generally contractually excluded. In the absence of a contractual

exclusion for OTC items, these **UI devices and supplies** are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Coverage Determination

CHRONIC URINARY RETENTION (CUR)

Commercial Plan members: requests for SNS for CUR require review by a medical director.

Any services for CUR that are considered primarily educational or training in nature are generally NOT covered under most Humana Benefit Plans.

Please refer to the member's applicable pharmacy benefit to determine benefit availability and the terms and conditions of coverage for medication for the treatment of CUR.

Chronic Urinary Retention Evaluation

Humana members may be eligible for the following types of **diagnostic evaluation for CUR**:

Initial diagnostic evaluation for **CUR** includes the following:

- History and physical exam; **AND**
- Measurement of PVR by catheterization and/or bladder ultrasound (PVR greater than 200 mL is abnormal and PVR between 100mL to 200 mL requires clinical correlation[70]); **AND**
- Negative urinalysis

After initial diagnostic evaluation above has been performed, **cystoscopy, cystourethroscopy, electromyography (EMG) or other urodynamic testing for CUR** may be performed for the following indications:

- PVR of greater than 300 mL that has persisted for at least six months documented on two or more separate occasions[15]; **AND**

- CUR refractory to conservative management

Chronic Urinary Retention Treatments

Humana members may be eligible under the Plan for the **following treatments for CUR** after appropriate diagnostic evaluation has confirmed a diagnosis of CUR and the following criteria are met:

- Correction, reduction and/or removal of an anatomic obstruction** (eg, mass removal, repair of pelvic organ prolapse, repair of urethral strictures, transvaginal sling excision, urethral dilation, urethral reconstruction, urinary diversion, treatment of benign prostatic hyperplasia [BPH], etc.) (for information regarding coverage determination/limitations of BPH procedures, please refer to Benign Prostatic Hyperplasia (BPH) Treatments Medical Coverage Policy); **OR**

- Sacral nerve stimulation (SNS) (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro) with an FDA-approved device when all the following criteria are met: **(Commercial Plan members: requests for SNS require review by a medical director)**

- Absence of contraindications listed in the Coverage Limitations section; **AND**

- Appropriate diagnostic evaluation confirms a diagnosis of nonobstructive CUR; **AND**

- At least 12 consecutive months of symptoms when the frequency and/or severity of CUR symptoms have impacted the ability to perform activities of daily living; **AND**

- Failure of or contraindication to conservative management including:

  - Intermittent catheterization (in both males and females) over a consecutive 60 day period; **AND**

  - Pharmacotherapy (for males only) over a consecutive 60 day period; **AND**

- Permanent implantation of an SNS requires a prior trial test stimulation for a minimum of two days that demonstrates a documented 50% decrease in residual urine volume

Humana members may be eligible for **removal of an SNS device** when a previously implanted device and/or its associated components cause complications or unintended negative outcomes (eg, adverse change in voiding function, infection, new pain, undesirable stimulation) for the individual.

Humana members may be eligible for **replacement of an SNS device** when the following criteria are met **(Commercial Plan members: requests for SNS require review by a medical director)**:

- Previously implanted device and/or its associated components are no longer functioning appropriately (eg, defective pulse generator, lead migration) and are no longer under warranty; **AND**

- Absence of contraindications listed in the Coverage Limitations section; **AND**

- FDA-approved device is being utilized as the replacement

**While conservative management may be utilized prior to correction, reduction and/or removal of an anatomic obstruction for CUR, documented failure of conservative management is not required in these instances.

Note: The criteria for **chronic urinary retention** are not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

Coverage Limitations

Chronic Urinary Retention (CUR)

Humana members may **NOT** be eligible under the Plan for the **penile cuff test** (eg, UroCuff). This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **CUR treatments** for any indications other than those listed above including, but may not be limited to:

- SNS (eg, Axonics Sacral Neuromodulation System, InterStim II, InterStim Micro) for any indication not listed above **OR** if the following contraindications are present:
  - Bilateral stimulation; **OR**
  - Bladder capacity less than 100 ml; **OR**
  - Individual 15 years of age or younger; **OR**
  - Individual not capable of operating the device; **OR**
  - Mechanical obstruction present (eg, benign prostatic hyperplasia, cancer, urethral stricture); **OR**
  - Neurogenic lower urinary tract dysfunction (NLUTD) (eg, diabetic neuropathy, multiple sclerosis, spinal cord injury); **OR**
  - Pregnancy or plan to become pregnant while using the device; **OR**
- Urinary prosthesis (eg, inFlow Voiding Prosthesis)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **supplies used with urinary catheters** (eg, leg bags, securing devices). Although they may be prescribed by a health care practitioner, these **CUR supplies** are available without a prescription and may be obtained OTC and are generally contractually excluded. In the absence of a contractual exclusion for OTC items, these **CUR supplies** are considered not medically necessary as defined in the member's individual

certificate. Please refer to the member's individual certificate for the specific definition.

Background

Additional information about **urinary incontinence, overactive bladder or chronic urinary retention** may be found from the following websites:

- American Urological Association
- National Association for Continence
- National Institute of Diabetes and Digestive and Kidney Diseases
- National Library of Medicine

Medical Alternatives

Alternatives to **urinary bladder dysfunction treatments** include, but may not be limited to:

- Diet modifications (eg, avoiding liquids at bedtime, eliminating caffeine and/or alcohol)
- Weight loss

Physician consultation is advised to make an informed decision based on an individual's health needs.

Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor	**Not Covered if used to report any treatment outlined in Coverage Limitations section**

38241	Hematopoietic progenitor cell (HPC); autologous transplantation	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
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)	
53230	Excision of urethral diverticulum (separate procedure); female	
53235	Excision of urethral diverticulum (separate procedure); male	
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	
53451	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance	**Not Covered** **New Code Effective 01/01/2022**
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance	**Not Covered** **New Code Effective 01/01/2022**
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon	**Not Covered** **New Code Effective 01/01/2022**
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	**Not Covered** **New Code Effective 01/01/2022**
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	**Not Covered**
53899	Unlisted procedure, urinary system	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
55899	Unlisted procedure, male genital system	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
57287	Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	
57288	Sling operation for stress incontinence (eg, fascia or synthetic)	

58999	Unlisted procedure, female genital system (nonobstetrical)	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	
64585	Revision or removal of peripheral neurostimulator electrode array	
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)	

95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	**Not Covered if used to report any treatment outlined in Coverage Limitations section**

97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
CPT® Category III Code(s)	**Description**	**Comments**
0487T	Biomechanical mapping, transvaginal, with report	**Not Covered**
0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	**Not Covered** **Deleted Code Effective 12/31/2021**
0549T	Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy	**Not Covered** **Deleted Code Effective 12/31/2021**
0550T	Transperineal periurethral balloon continence device; removal, each balloon	**Not Covered** **Deleted Code Effective 12/31/2021**
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	**Not Covered** **Deleted Code Effective 12/31/2021**
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	**Not Covered**
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	**Not Covered**

0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters	**Not Covered**
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters	**Not Covered**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	**Not Covered**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	**Not Covered**
0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence	**Not Covered** **New Code Effective 01/01/2022**
HCPCS Code(s)	**Description**	**Comments**
A4290	Sacral nerve stimulation test lead, each	
A4328	Female external urinary collection device; pouch, each	**Not Covered if used to report any device/treatment outlined in Coverage Limitations section**
A4335	Incontinence supply; miscellaneous	**Not Covered**
A4336	Incontinence supply, urethral insert, any type, each	**Not Covered**
A4520	Incontinence garment, any type, (e.g., brief, diaper), each	**Not Covered**

A4553	Nondisposable underpads, all sizes	**Not Covered**
A4554	Disposable underpads, all sizes	**Not Covered**
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each	**Not Covered if used to report any device/treatment outlined in Coverage Limitations section**
A9286	Hygienic item or device, disposable or nondisposable, any type, each	**Not Covered**
C1762	Connective tissue, human (includes fascia lata)	
C1763	Connective tissue, nonhuman (includes synthetic)	
C1767	Generator, neurostimulator (implantable), nonrechargeable	
C1771	Repair device, urinary, incontinence, with sling graft	
C1778	Lead, neurostimulator (implantable)	
C1787	Patient programmer, neurostimulator	
C1815	Prosthesis, urinary sphincter (implantable)	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
C1816	Receiver and/or transmitter, neurostimulator (implantable)	
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	
C1897	Lead, neurostimulator test kit (implantable)	
C2631	Repair device, urinary, incontinence, without sling graft	
E0740	Nonimplanted pelvic floor electrical stimulator, complete system	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
E1399	Durable medical equipment, miscellaneous	**Not Covered if used to report any device outlined in Coverage Limitations section**
K1006	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system	**Not Covered**

L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies	
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies	
L8680	Implantable neurostimulator electrode, each	
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	
L8682	Implantable neurostimulator radiofrequency receiver	
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement	
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension	
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	
S2142	Cord blood-derived stem-cell transplantation, allogeneic	**Not Covered if used to report any treatment outlined in Coverage Limitations section**

S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and posttransplant care in the global definition	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
S8270	Enuresis alarm, using auditory buzzer and/or vibration device	**Not Covered**
T4545	Incontinence product, disposable, penile wrap, each	**Not Covered**

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Appendix A – Conservative Management for UI/OAB

Conservative management therapies for **UI/OAB** include, but may not be limited to:

- Behavioral training (may be excluded by the member's individual certificate as educational therapy); **OR**
- Biofeedback (may be excluded by the member's individual certificate as alternative medicine) (please refer to Biofeedback Medical Coverage Policy); **OR**
- Bladder training (may be excluded by the member's individual certificate as educational therapy); **OR**
- Diet modification (eg, fluid management, decrease caffeine intake) (may be excluded by the member's individual certificate as educational therapy); **OR**
- Nonimplanted pelvic floor electrical stimulators utilized in a clinical setting (eg, Detrusan, UROSTYM); **OR**
- Pelvic floor exercise therapy (may be excluded by the member's individual certificate as educational therapy); **OR**
- Pessary devices; **OR**
- Pharmacotherapy (eg, anticholinergics, beta agonists, tricyclic antidepressants)

Appendix B – Conservative Management for CUR

Conservative management therapies for **CUR** include, but may not be limited to:

- Bladder training (may be excluded by the member's individual certificate as educational therapy); **OR**
- Catheterization, indwelling or intermittent; **OR**
- Pelvic floor exercise therapy (may be excluded by the member's individual certificate as educational therapy); **OR**
- Pharmacotherapy (eg, alpha-adrenergic blockers or 5-alpha reductase inhibitors)