

Medical Coverage Policy

Effective Date: 07/15/2021 Revision Date: 07/15/2021 Review Date: 12/10/2020 Policy Number: HCS-0407-036

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Change Summary: Updated Description, Coverage Determination

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the CMS website. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

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, post-surgical 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.

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• **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.

Other types of UI include, but may not be limited to, mixed incontinence which may present with symptoms of both stress and urge incontinence and overflow incontinence which occurs when the bladder does not empty completely causing leakage if the bladder becomes overly full.

Overactive bladder (OAB) represents the disruptive urge to urinate without urine leakage.

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.⁸⁷ 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 bladder]) or a combination of factors.⁷⁰

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 and performing a urinalysis. Additional tests may then be performed (ie, cystoscopy, urodynamic testing), especially for those where surgical intervention is being considered.

Vaginal tactile imaging 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)

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Diagnosis for UR most often involves the measurement of postvoid residual (PVR) volumes which are obtained by catheterization or by ultrasonography showing an elevated residual urine volume. Other tests (ie, blood tests, cystography, cystoscopy, ultrasonography, urinalysis, urodynamic testing) may be performed based on clinical findings.⁸⁶

Treatments

Examples of **UI**, **UR or OAB 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.

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**)

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.

Bladder support surgeries are performed using a variety of open, laparoscopic or needle suspension techniques to help restore continence.

- Procedures to secure the bladder neck using sutures (eg, Burch colposuspension, Marshall-Marchetti-Krantz [MMK]) and more outdated needle suspension techniques (eg, Stamey, Raz, modified Pereyra procedures) are performed to help obtain normal bladder position.
- Suburethral mesh placement (also referred to as a sling procedure) is far 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

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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 and recurrent posterior vaginal wall prolapse.

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 indwelling (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 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 the Benign Prostatic Hyperplasia (BPH) Treatments Medical Coverage Policy.)

Diet modification involves changing those things that may cause an increase in the urge to urinate which includes, but may not be limited to, eliminating caffeine in coffee, soda, tea and/or alcohol in addition to avoiding liquids at bedtime.

Extracorporeal magnetic innervation (ExMI) (eg, NeoControl Pelvic Floor Therapy System) purportedly utilizes magnetic fields to stimulate the nerves of the pelvic floor or the sacral nerve roots which supposedly 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 CO₂. The controlled heat from the lasers reportedly cause reconstruction and remodeling of the collagen; thereby,

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providing support to the pelvic floor structures.²⁶ (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 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. There are now two methods that have been introduced for this type of intervention, however one is still in the early stages of development.

- Nonimplanted PTNS (eg, NURO System, Urgent PC) With this 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.²⁷
- Implanted PTNS (eg, Protect PNS, RENOVA, StimRouter) is being explored as an option for those with OAB and associated symptoms. There are two versions for this technology one where the implantable lead is placed through a small surgical incision and another where the lead is injected through a special delivery system under ultrasound guidance. An external device or electrode is then worn around the ankle during treatment and the physician will set the stimulation

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parameters in advance so that the individual can conduct treatments at home in 30 minute sessions each day. (Refer to Coverage Limitations)

Periurethral bulking agents (eg, 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 (eg, Axonics Sacral Neuromodulation System, InterStim, InterStim II, InterStim Micro) is a procedure which involves the implantation of electrodes near the sacral nerve, which controls 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 being researched include, but may not be limited to, bone marrow-derived, mesenchymal, muscle-derived cells and umbilical cord blood cells.¹⁴ (Refer to Coverage Limitations section)

Transperineal implantation of permanent adjustable balloon continence device (eg, ProACT Therapy, ACT Therapy) consists of two adjustable balloon implants that are bilaterally placed via perineal approach. The fluid filled balloons reportedly provide pressure and support at the bladder neck, which purportedly prevents 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)**

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Urinary prosthesis (eg, inFlow Intraurethral Valve-Pump) is a device that reportedly 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. It is suggested 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, supposedly emptying the bladder. Purportedly, releasing the button closes the valve and stops the flow of urine. ⁵⁵ (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 <u>Direct-to-Consumer (DTC) Laboratory</u>
<u>Testing and Mobile Health (mHealth) Applications Medical Coverage Policy.</u>

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

Coverage Determination

All requests for PTNS and SNS for urinary bladder dysfunction for commercial Plan members only require review by a medical director.

Any services for urinary bladder dysfunction 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 urinary bladder dysfunction.

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

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Stress Urinary Incontinence (SUI)

Humana members may be eligible for the following types of **diagnostic evaluation** for stress urinary incontinence (SUI):

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

- History and physical exam; AND
- Measurement of postvoid residual volume; AND
- Positive cough stress test (during physical examination and/or during cystometry); AND
- Urinalysis⁷

After <u>initial diagnostic evaluation</u> above has been performed, **urodynamic testing for SUI** *may* be performed for the following indications:

- Etiology of incontinence is unclear; OR
- Incontinence refractory to <u>conservative management</u>; OR
- Previous pelvic floor surgery or prostatectomy^{7, 14}

After <u>initial diagnostic evaluation</u> above has been performed, **cystoscopy for SUI** *may* be performed for the following indications:

- Acute onset incontinence; OR
- Incontinence refractory to <u>conservative management</u>; 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, 14}

Conservative management for **SUI** should include <u>a minimum of two therapies</u> over a consecutive 60 day period. Conservative management therapies for **SUI** include, but may not be limited to:

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- 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); **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

Humana members may be eligible under the Plan for the **following treatments for SUI** after <u>appropriate testing</u> as outlined above has confirmed a diagnosis of SUI and there has been a <u>failure of</u>* or contraindication to a minimum of two <u>conservative</u> <u>management</u> therapies over a consecutive 60 day period:

- Artificial urinary sphincter implantation; OR
- Bladder support surgeries (eg, Burch colposuspension, MMK procedure, modified Pereyra procedure, Raz procedure, Stamey procedure, suburethral mesh placement [sling procedure]**); OR
- Periurethral bulking agents (eg, Coaptite, Contigen, Durasphere EXP, Macroplastique)

*For individuals with a confirmed diagnosis of SUI, failure of two conservative management therapies are **not** required for suburethral mesh placement (sling procedures) **ONLY** when performed in conjunction with pelvic organ prolapse

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surgery (eg, anterior colporrhaphy [cystocele repair], posterior colporrhaphy [rectocele repair]). Additionally, for individuals with a confirmed diagnosis of pelvic organ prolapse **without** urinary incontinence, failure of two conservative management therapies are also **not** required for sling procedures to be performed.

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

<u>Urge Urinary Incontinence (UUI)/Overactive Bladder (OAB)</u>

Humana members may be eligible for the following types of diagnostic evaluation for urge urinary incontinence (UUI)/overactive bladder (OAB):

Initial diagnostic evaluation for UUI/OAB includes the following:

- History and physical exam; AND
- Urinalysis⁷

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

- Etiology of incontinence is unclear; OR
- Incontinence refractory to <u>conservative management</u>; OR
- Previous pelvic floor surgery or prostatectomy^{7, 14}

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

- Acute onset incontinence; OR
- Incontinence refractory to <u>conservative management</u>; **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, 14}

Conservative management should include <u>a minimum of two therapies</u>, one of <u>those being pharmacotherapy</u>, over a consecutive 60 day period. Conservative management therapies for **UUI/OAB** include, but may not be limited to:

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Pharmacotherapy (eg, anticholinergics, beta agonists, tricyclic antidepressants);

AND at least one of the following:

- 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); 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

Humana members may be eligible under the Plan for the **following treatments for UUI/OAB** after <u>appropriate testing</u> as outlined above 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)
- Nonimplanted PTNS (eg, NURO System, Urgent PC) when the following criteria are met (ALWAYS requires review by a medical director for commercial Plan members only):
- Absence of <u>contraindications</u> listed in the Coverage Limitations section; AND

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- 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 daily activities; AND
- Failure of or contraindication to a minimum of two <u>conservative management</u> therapies, including pharmacotherapy, over a consecutive 60 day period; **AND**
- If the above criteria are met:
 - o 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 (ie, record of bladder events, voiding diary), an additional nine months of treatment (one per month) may be approved subject to continued improvement
 - Treatments after 12 months are considered experimental/investigational (Refer to Coverage Limitations section); OR
- Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim, InterStim II, InterStim Micro) when all the following criteria are met (ALWAYS requires review by a medical director for commercial Plan members only):
 - Absence of <u>contraindications</u> 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 daily activities; AND
 - Failure of or contraindication to a minimum of two <u>conservative management</u> therapies, including pharmacotherapy, over a consecutive 60 day period; **AND**

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

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.

Urinary Retention (UR)

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

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

- History and physical exam; AND
- Measurement of postvoid residual volume (by catheterization and/or ultrasound); AND
- Urinalysis

After <u>initial diagnostic evaluation</u> above has been performed, **cystoscopy**, **cystourethroscopy**, **electromyography** (EMG) or **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 occasions¹⁵; AND
- UR refractory to <u>conservative management</u>

Conservative management therapies for **UR** 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

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- Pelvic floor exercise therapy (may be excluded by the member's individual certificate as educational therapy); OR
- Pharmacotherapy (ie, alpha-adrenergic blockers or 5-alpha reductase inhibitors)

Humana members may be eligible under the Plan for the **following treatments for CUR** after <u>appropriate testing</u> as outlined above has confirmed a diagnosis of CUR and the following criteria are met:

- Correction, reduction and/or removal of an anatomic obstruction (ie, 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 <u>Benign Prostatic Hyperplasia (BPH) Treatments</u> Medical Coverage Policy); OR
- Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim, InterStim II, InterStim Micro) when all the following criteria are met (ALWAYS requires review by a medical director for commercial Plan members only):
 - Absence of contraindications listed in the Coverage Limitations section; AND
 - Appropriate testing confirms a diagnosis of nonobstructive CUR; AND
 - At least 12 consecutive months of symptoms where the frequency and/or severity of CUR symptoms have impacted daily activities; AND
 - Failure of or contraindication to:
 - 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 a sacral nerve stimulator requires a prior trial test stimulation for a minimum of two days that demonstrates a documented 50% decrease in residual urine volume

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Coverage Limitations

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

- Extracorporeal magnetic innervation (ExMI) (eg, NeoControl Pelvic Floor Therapy System); OR
- Implanted percutaneous tibial nerve stimulation (PTNS) (eg, Protect PNS, RENOVA, StimRouter); OR
- Laser procedures (eg, FemTouch, IncontiLase); OR
- Nonimplanted percutaneous tibial nerve stimulation (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
 - Used longer than 12 months; OR
- Sacral nerve stimulation (eg, Axonics Sacral Neuromodulation System, InterStim, InterStim II, InterStim Micro) for any indication not listed above OR if the following contraindications are present:
 - o Bilateral stimulation; OR
 - Bladder capacity less than 100 ml; OR

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- Individual less than 16 years of age; OR
- Individual not capable of operating the device; OR
- Mechanical obstruction present (eg, benign prostatic hyperplasia, cancer, urethral stricture); OR
- Neurogenic bladder (eg, diabetic neuropathy, multiple sclerosis, spinal cord injury); OR
- o 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); OR
- Urinary prosthesis (eg, inFlow Intraurethral Valve Pump)

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 **enuresis** (bed wetting), **alarms.** This is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

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.

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

- Electrical Kegel exercise assistance devices (eg, Apex, Attain, Flyte, INNOVO); 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
- Urethral inserts

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

Background

Additional information about **urinary incontinence or 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:

 Absorbent products (may be excluded by the member's individual certificate as over-the-counter)

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- Catheters
- External collection devices (may be excluded by the member's individual certificate as over-the-counter)
- Penile clamps (eg, Cunningham clamp)

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

Codes

Provider Claims 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)	

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Laparoscopy, surgical; urethral suspension for stress incontinence Laparoscopy, surgical; sling operation for stress incontinence (eg., fascia or synthetic) Siling operation for correction of male urinary incontinence (eg., fascia or synthetic) Removal or revision of sling for male urinary incontinence (eg., fascia or synthetic) Insertion of tandem cuff (dual cuff) Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session 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 infleted tissue Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Unlisted procedure, urinary system Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg., fascia or synthetic)			
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fascia or synthetic) Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic) Insertion of tandem cuff (dual cuff) Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session 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 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Unlisted procedure, urinary system Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	51992		
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 8 Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff 8 Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session 8 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 8 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff 7 Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence 53899 Unlisted procedure, urinary system Not Covered if used to report any treatment outlined in Coverage Limitations section 8 Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53440	, , , , ,	
Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff	53442	, , ,	
placement of pump, reservoir, and cuff Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session 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 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Not Covered Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53444	Insertion of tandem cuff (dual cuff)	
pump, reservoir, and cuff Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session 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 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Unlisted procedure, urinary system Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53445		
sphincter including pump, reservoir, and cuff at the same operative session 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 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53446	, , , , ,	
sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53447	sphincter including pump, reservoir, and cuff at the same	
pump, reservoir, and cuff Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence Not Covered Not Covered Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53448	sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation	
bladder neck and proximal urethra for stress urinary incontinence Not Covered Not Covered if used to report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53449	1 .	
Unlisted procedure, urinary system report any treatment outlined in Coverage Limitations section Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	53860	bladder neck and proximal urethra for stress urinary	Not Covered
synthetic)	53899	Unlisted procedure, urinary system	report any treatment outlined in Coverage
57288 Sling operation for stress incontinence (eg. fascia or synthetic)	57287	_	
The special of the second of t	57288	Sling operation for stress incontinence (eg, fascia or synthetic)	

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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	Incision for 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 separate	
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 neurostim	

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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 neurostim	
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 neurostim	
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	Description	Comments
Code(s)		
0487T	Biomechanical mapping, transvaginal, with report	Not Covered
	Biomechanical mapping, transvaginal, with report Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy	Not Covered Not Covered
0487T	Transperineal periurethral balloon continence device; bilateral	
0487T 0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy Transperineal periurethral balloon continence device; unilateral	Not Covered
0487T 0548T 0549T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy Transperineal periurethral balloon continence device; removal,	Not Covered

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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 par	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 pa	Not Covered
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	Not Covered New Code Effective 07/01/2020
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	Not Covered New Code Effective 07/01/2020
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
		T
A4336	Incontinence supply, urethral insert, any type, each	Not Covered
A4336 A4520	Incontinence supply, urethral insert, any type, each Incontinence garment, any type, (e.g., brief, diaper), each	Not Covered Not Covered

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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 New Code Effective 10/01/2020

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K1010	Indwelling intraurethral drainage device with valve, patient	Not Covered New Code Effective
	inserted, replacement only, each	10/01/2020
K1011	Activation device for intraurethral drainage device with valve,	Not Covered
	replacement only, each	New Code Effective 10/01/2020
		Not Covered
K1012	Charger and base station for intraurethral activation device, replacement only	New Code Effective 10/01/2020
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	

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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, hospitalizatio	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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