

# Urinary Bladder Dysfunction



INDEPENDENT CARE HEALTH PLAN

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## Medicare Advantage Medical Coverage Policy

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#### **Disclaimer**

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. 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. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. 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 iCare.

## Related Medicare Advantage Medical/Pharmacy Coverage Policies

Benign Prostatic Hyperplasia Treatments

Botox [Botulinum Toxin]

Fecal Incontinence Evaluation and Treatments

## Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Biofeedback Therapy for the Treatment of Urinary Incontinence for the treatment	<a href="#">30.1.1</a>		
NCD	Bladder Stimulators (Pacemakers)	<a href="#">230.16</a>		
NCD	Incontinence Control Devices	<a href="#">230.10</a>		
NCD	Non-Implantable Pelvic Floor Electrical Stimulator	<a href="#">230.8</a>		
NCD	Sacral Nerve Stimulation for Urinary Incontinence	<a href="#">230.18</a>		
NCD	Uroflowmetric Evaluations	<a href="#">230.2</a>		
NCD	Durable Medical Equipment (DME) Reference List	<a href="#">280.1</a>		
LCD	Urological Supplies	<a href="#">L33803</a>	JB, JH – CGS Administrators, LLC (DME MAC)  JA, JD – Noridian Healthcare Solutions, LLC (DME MAC)	All States
LCA	Billing and Coding: Posterior Tibial Nerve Stimulation for Voiding Dysfunction	<a href="#">A57453</a>		
LCD	Posterior Tibial Nerve Stimulation for Voiding Dysfunction	<a href="#">L33396</a>	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
LCD	Urodynamics	<a href="#">L33576</a>		

LCA	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	<a href="#">A55835</a>		
LCD	Post-Void Residual Urine and/or Bladder Capacity by Ultrasound	<a href="#">L34085</a>	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD	Urodynamics	<a href="#">L34056</a>		
LCA	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	<a href="#">A53359</a>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCA	Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence	<a href="#">A53017</a>	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCA	Billing and Coding: Urodynamic Services - Non-invasive	<a href="#">A58543</a>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, VI
LCA	Billing and Coding: Posterior Tibial Nerve Stimulation for Voiding Dysfunction	<a href="#">A57453</a>		
LCD	Posterior Tibial Nerve Stimulation for Voiding Dysfunction	<a href="#">L33396</a>	JK - National Government Services, Inc. (Part A/B MAC)	CT, MA, ME, NY, NH, RI, VT
LCD		<a href="#">L33576</a>		

	Urodynamics			
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## Description

**Urinary bladder dysfunction** is a broad term that may encompass many 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, causing leakage if it 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 has been a postvoid residual (PVR) volume greater than 300 mL measured on 2 separate occasions and persisting for at least 6 months.<sup>85</sup> 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.

## 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 provides high resolution mapping of pressures and assesses the strength of the pelvic floor muscles within the vagina. A physician or surgeon can view this real-time data to potentially assist with evaluations.

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.

The **penile cuff test** (eg, UroCuff) is a noninvasive method to measure urinary pressure flow in an individual 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).

### **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 regarding exercises, muscle control and relaxation techniques to control incontinence.

**Biofeedback** is a training technique that uses an external sensor to indicate 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 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 or urethral bulb 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 to support the urethra and the bladder neck to prevent downward rotation of these structures.

- Sling procedures are also sometimes performed on an individual 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.

**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 stricture, transvaginal sling excision, urethral dilation, urethral reconstruction, urinary diversion and treatment of benign prostatic hyperplasia (BPH).

**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)**

**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.

**External urinary catheters or collection devices** are noninvasive products to purportedly manage urinary incontinence and prevent catheter associated urinary tract infections. There are two basic types, disposable and non-disposable. The PureWick Urinary Collection System and PrimaFit External Urinary System utilize suction and a soft, flexible wicking material to draw urine away from the body and into a sealed collection canister; the wicking material is disposable and needs to be replaced often. The TrueClr device acts similar to a meatal cup but utilizes a rubber sleeve that stays in place and draws urine out with light suction; the sleeve is reusable, being cleaned with soap and water.

**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.

**Indwelling intraurethral valve drainage prosthesis** (eg, inFlow Voiding Prosthesis) is a device that is designed for use in a female with impaired detrusor contractility (IDC). An individual diagnosed with IDC cannot spontaneously urinate due to insufficient bladder muscle contractions, which can be caused by conditions including multiple sclerosis, spinal cord injury or stroke. The prosthesis is initially inserted by a physician; it gets replaced at least every 29 days. 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.<sup>51</sup>

**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 systems also provide visual biofeedback. The 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 nonimplanted pelvic muscle stimulation devices being marketed and made available over the counter (OTC) for home use which either provide vibrations, motion sensing or electrical prompting (eg, Apex, Attain, Flyte, INNOVO, Ileva Pelvic Health System).

**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 initial stages of development.

- **Implanted PTNS** (eg, eCoin, Protect PNS, RENOVA iStim, 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.
- **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.<sup>44</sup>

**Periurethral bulking agents** (eg, Bulkamid, Coaptite, 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 SNM System, InterStim II, InterStim Micro, InterStimX) 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 stem cells under investigation include bone marrow-derived, mesenchymal, muscle-derived cells and umbilical cord blood cells.

**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.

**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.

**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 conditions may lead to urinary incontinence.

**Vaginal 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<sub>2</sub>. The controlled heat from the lasers reportedly causes reconstruction and remodeling of the collagen; thereby, providing support to the pelvic floor structures.<sup>43</sup>

**Vaginal pessaries** are rigid, intravaginal devices that support the bladder neck where the urethra joins the bladder to reduce incontinence. **Urethral inserts** (eg, Contino) similar support for males by obstructing the flow of urine from exiting the body.

## Coverage Determination

*iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:*

### URINARY INCONTINENCE (UI) AND OVERACTIVE BLADDER (OAB)

#### UI/OAB Evaluation

**Diagnostic evaluation for urinary incontinence (UI/OAB)** will be considered medically reasonable and necessary when the following requirements are met:

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

- History and physical exam; **AND**
- Measurement of postvoid residual volume (PVR) to exclude retention<sup>23</sup>; **AND**



- Urinalysis ruling out hematuria or urinary tract infection<sup>7,34</sup>; **AND**
- Positive cough stress test (during physical examination, cystometry or urodynamics) to identify stress urinary incontinence (not necessary for a suspected diagnosis of UII/OAB)

After [initial diagnostic evaluation](#) above has been performed, **urodynamic testing for UI/OAB** may be performed for the following indications<sup>24,25,33</sup>:

- As consideration for surgical intervention, particularly if there has been a previous failed surgery for the issue or the individual is considered a high-surgical risk; **OR**
- Etiology of incontinence is unclear; **OR**
- Incontinence refractory to [conservative management](#); **OR**
- Presence of other comorbid conditions which include, but may not be limited to:
  - Abnormal post-void-residual urinalysis; **OR**
  - History of previous incontinence surgery; **OR**
  - Neurologic condition affecting voiding (eg, multiple sclerosis, spinal cord lesions/injury); **OR**
  - Persistent symptoms of difficult bladder emptying; **OR**
  - Previous pelvic surgery or prostatectomy; **OR**
  - Prostate nodule (eg, asymmetry, other suspicion of prostate cancer); **OR**
  - Recurrent symptomatic urinary tract infection

After [initial diagnostic evaluation](#) above has been performed, **cystoscopy for UI/OAB** may be performed for the following indications<sup>24,25,33</sup>:

- 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, prostatectomy)<sup>7</sup>

### **Stress Urinary Incontinence (SUI) Treatments**

The **treatments listed below for SUI** will be considered medically reasonable and necessary when the following requirements are met:

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

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

**AND** all the following:

- [Diagnostic evaluation](#) has confirmed a diagnosis of SUI; **AND**
- Failure of or contraindication to [conservative management](#)

### **Suburethral Mesh Placement or Urethral Excision for Other Diagnoses**

The **procedures listed below** (without failure of conservative management) will be considered medically reasonable and necessary when the following requirements 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.<sup>15</sup>

### **Urge Urinary Incontinence (UUI)/Overactive Bladder (OAB) Treatments**

The **treatments listed below for UUI/OAB** will be considered medically reasonable and necessary when all the following requirements are met:

- **Nonimplanted PTNS** (eg, NURO System, Urgent PC) when the following criteria are met<sup>17,22</sup>:
  - Absence of [contraindications](#); **AND**
  - [Diagnostic evaluation](#) confirms a diagnosis of UUI/OAB; **AND**
  - Failure of or contraindication [conservative management](#); **AND**
  - If the above criteria are met:
    - A total of 12 treatments (1 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 9 months of treatment (1 per month) may be approved subject to continued improvement; **OR**
- **Sacral nerve stimulation (SNS)** (eg, Axonics SNM System, InterStim II, InterStim Micro, InterStim X) with an FDA-approved device when all the following criteria are met <sup>18,19,20,32</sup>:
  - Absence of [contraindications](#); **AND**
  - [Diagnostic evaluation](#) confirms a diagnosis of UUI/OAB; **AND**
  - Failure of or contraindication to [conservative management](#); **AND**
  - Permanent implantation of a SNS requires a prior trial test stimulation for a minimum of 2 days that demonstrates a documented 50% or greater improvement in incontinence symptoms

**Removal of an SNS device** will be considered medically reasonable and necessary 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.

**Replacement of an SNS device using an FDA-approved device** will be considered medically reasonable and necessary when all the following requirements are met:

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

### **CHRONIC URINARY RETENTION (CUR)**

#### **Chronic Urinary Retention Evaluation**

**Diagnostic evaluation for CUR** will be considered medically reasonable and necessary when all the following requirements are met:

**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 100 mL to 200 mL warrant clinical correlation<sup>23, 88</sup>); **AND**
- Urinalysis ruling out hematuria or urinary tract infection<sup>7,34</sup>

After [initial diagnostic evaluation](#) above has been performed, **cystoscopy, cystourethroscopy, electromyography (EMG), penile cuff test or other urodynamic testing for CUR** may be performed for the following indications<sup>21,24,25,33</sup>:

- As consideration for urological surgical intervention, particularly if there has been a previous failed surgery for the issue or the individual is considered a high-surgical risk; **OR**
- CUR refractory to conservative management; **OR**
- Presence of other comorbid conditions which include, but may not be limited to:
  - Abnormal post-void-residual urinalysis; **OR**
  - History of previous incontinence surgery; **OR**
  - Neurologic condition affecting voiding (eg, multiple sclerosis, spinal cord lesions/injury); **OR**
  - Persistent symptoms of difficult bladder emptying; **OR**
  - Previous pelvic surgery or prostatectomy; **OR**
  - Prostate nodule (eg, asymmetry, other suspicion of prostate cancer); **OR**
  - Recurrent symptomatic urinary tract infection

### **Chronic Urinary Retention Treatments**

The **following treatments for CUR** will be considered medically reasonable and necessary when all the following requirements 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]); **OR**
- Indwelling intraurethral valve drainage prosthesis and replacement accessories (eg, inFlow Voiding Prosthesis) for those with urinary retention due to impaired detrusor contractility (IDC)<sup>27</sup>; **OR**
- Sacral nerve stimulation (SNS) (eg, Axonics SNM System, InterStim II, InterStim Micro, InterStim X) with an FDA-approved device when all the following criteria are met<sup>18,19,20,32</sup>:
  - Absence of [contraindications](#); **AND**
  - [Diagnostic evaluation](#) confirms a diagnosis of nonobstructive CUR; **AND**
  - Failure of or contraindication to [conservative management](#)
  - Permanent implantation of an SNS requires a prior trial test stimulation for a minimum of 2 days that demonstrates a documented 50% decrease in residual urine volume

**Removal of an SNS device** will be considered medically reasonable and necessary 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.

**Replacement of an SNS device** will be considered medically reasonable and necessary when all the following requirements are met:

- 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](#); **AND**
- FDA-approved device is being utilized as the replacement

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

### **Urinary Incontinence (UI)/Overactive Bladder (OAB)**

The following **UI/OAB treatments** will not be considered medically reasonable and necessary:

- Cryogen-cooled radiofrequency remodeling (eg, Viveve); **OR**
- Extracorporeal magnetic innervation (ExMI) (eg, NeoControl Pelvic Floor Therapy System); **OR**
- Implanted PTNS (eg, eCoin, Protect PNS, RENOVA iStim, StimRouter PNS); **OR**
- Vaginal laser therapy (eg, FemTouch, IncontiLase); **OR**
- Nonimplanted PTNS (eg, NURO System, Urgent PC) if any of the following contraindications are present:
  - Individual prone to excessive bleeding; **OR**
  - Individual with pacemaker or implantable defibrillator; **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**
- SNS (eg, Axonics SNM System, InterStim II, InterStim Micro, InterStimX) if any of the following contraindications are present<sup>18,19,20,32</sup>:
  - Permanent bilateral stimulation; **OR**
  - Bladder capacity less than 100 ml; **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**
- Transperineal implantation of permanent adjustable balloon continence device (eg, ProACT system, ACT system); **OR**
- Transurethral radiofrequency ablation (eg, Renessa procedure)

A review of the current medical literature shows that the evidence is insufficient to determine that these services (or for an individual with any of the above contraindications) are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

### **Summary of Evidence**

#### ***Cryogen-cooled Radiofrequency Remodeling***

Published evidence evaluating the Viveve System for treating SUI is limited to 6-month and 12-month follow-up studies of a small feasibility study evaluating 1 or 2 treatment sessions with the Viveve System in 37 women with SUI. Clinically meaningful reductions in urinary leakage volume and SUI symptoms were demonstrated, with no significant differences between 1 or 2 Viveve treatments. Additional published evidence from the larger randomized PURSUIT trial is needed to characterize the magnitude and duration of benefit of the Viveve System in reducing SUI symptoms.<sup>51</sup>

#### ***Extracorporeal Magnetic Innervation (ExMI)***

There is evidence from controlled and uncontrolled studies that extracorporeal magnetic stimulation can safely reduce the frequency of incontinence episodes and improve quality of life for women with UI. However, the effect was short lived and some studies failed to find an effect of EMS. Limitations of the studies included small sample size, no sham control group, and lack of long-term follow-up.<sup>66</sup>

#### ***Implanted PTNS***

Evidence from 3 pre-post treatment studies is at too high a risk of bias to determine eCoin's safety and effectiveness for treating UUI. Studies report that eCoin reduced UUI episodes and improved symptoms in most individuals up to 12-month follow-up; however, findings need validation in multicenter randomized controlled trials that report long-term (greater than 5 years) individual outcomes. Studies report mild or moderate device-related adverse events in up to 15% of patients. The existing studies are at substantial risk of bias from small sample size and lack of concurrent controls and randomization. Also, findings may not fully generalize across studies because authors used different measures to assess the same outcomes.<sup>37</sup>

### ***Vaginal Laser Therapy***

Limited evidence suggests laser therapy may work for some women with SUI or cystoceles. However, the safety and effectiveness of laser therapy has not been assessed in controlled trials, so determining how it compares with other treatments for SUI or cystoceles is not possible. Multicenter, randomized controlled trials with sufficient sample size and at least a 2-year follow-up are needed to establish the safety and effectiveness of this minimally invasive treatment. In 2018, the FDA issued a Safety Communication warning individuals and healthcare providers of problems involving procedures that use energy-based devices for treating vaginal conditions and symptoms (eg, urinary incontinence, menopause, sexual function).<sup>43</sup>

### ***Transperineal Implantation of Permanent Adjustable Balloon Continence Device***

The body of evidence identified for the ProACT device for treatment of post-prostate surgery UI lacks controlled studies to determine if the ProACT device is similar, better, or worse than other available treatments with respect to patient outcomes. Single-arm studies consistently reported improvements from baseline in some key clinical outcomes. Other outcomes were assessed by too few studies or assessed inconsistently across studies, precluding firm conclusions. Available evidence regarding potential harms suggests that the ProACT device may be associated with a moderate risk of complications, including revision and explantation; however, there is insufficient evidence to determine the relative safety of the ProACT device compared with other available treatments.<sup>60</sup>

### ***Transurethral Radiofrequency Ablation***

There is some evidence suggesting that transurethral RF energy-therapy is beneficial for carefully selected patients with refractory symptoms due to SUI and that most patients are satisfied with the treatment. Despite these positive findings, the strength of the existing data is weakened by flaws in study design and execution, particularly the loss of high numbers of patients to follow up, and the lack of controls in some studies. Although no serious adverse events were reported, minor complications occurred such as dysuria, urinary retention, and urinary tract infection. Additional independent studies are required to establish the long-term safety and efficacy of this technology since the manufacturer sponsored the existing studies.<sup>62</sup>

**Vaginal tTctile imaging** (biomechanical transvaginal mapping) will not be considered medically reasonable and necessary. A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

### **Summary of Evidence**

***Vaginal Tactile Imaging (VTI)***

VTI may provide biomechanical data which can be applied for computer simulation of surgical procedures for treatment effectiveness or custom pessary design, however it is important to note that the VTI is not intended as a diagnostic device. It is not intended to be used to diagnose any specific diseased conditions, such as pelvic organ prolapse or UI. Image interpretation must be completed by a clinician and is subjective, utilizing their knowledge of general and functional pelvic anatomy and or clinical experience. There have not been many conclusive findings in studies.

The following **UI devices** will not be considered medically reasonable and necessary:

- Enuresis (bed wetting) alarms; **OR**
- External urinary catheters or collection devices (eg, PrimaFit External Urinary System, PureWick Urine Collection System, TrueClr)

Although they may be prescribed by a health care practitioner, these **UI devices** are not covered by Medicare as they are disposable and/or do not meet the CMS definition of Durable Medical Equipment (DME).

**Chronic Urinary Retention (CUR)**

**SNS** (eg, Axonics SNM System, InterStim II, InterStim Micro, InterStimX) **for CUR** will not be considered medically reasonable and necessary if the following contraindications are present <sup>18,19,20,33</sup>:

- Permanent bilateral stimulation; **OR**
- Bladder capacity less than 100 ml; **OR**
- Individual not capable of operating the device; **OR**
- Mechanical obstruction present (eg, benign prostatic hyperplasia [BPH], 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

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for an individual with any of the above contraindications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

**Coding Information**



Any codes listed on this 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	
38241	Hematopoietic progenitor cell (HPC); autologous transplantation	
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	
53452	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance	
53453	Periurethral transperineal adjustable balloon continence device; removal, each balloon	
53454	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	
53860	Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence	
53899	Unlisted procedure, urinary system	
55899	Unlisted procedure, male genital system	
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)	
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	
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	
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	
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	
<b>CPT® Category III Code(s)</b>	<b>Description</b>	<b>Comments</b>
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	
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	
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	

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	
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	
0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence	<b>Not Covered</b>
0811T	Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); set-up and patient education on use of equipment	
0812T	Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); device supply with automated report generation, up to 10 days	
0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous	
0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial	
0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous	
0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial	
<b>HCPCS Code(s)</b>	<b>Description</b>	<b>Comments</b>
A4290	Sacral nerve stimulation test lead, each	
A4327	Female external urinary collection device; meatal cup, each	
A4328	Female external urinary collection device; pouch, each	

A4335	Incontinence supply; miscellaneous	
A4336	Incontinence supply, urethral insert, any type, each	
A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each	
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each	
A4520	Incontinence garment, any type, (e.g., brief, diaper), each	<b>Not Covered</b>
A4553	Nondisposable underpads, all sizes	<b>Not Covered</b>
A4554	Disposable underpads, all sizes	<b>Not Covered</b>
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each	
A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month	
A6591	External urinary catheter; non-disposable, for use with suction pump, per month	
A9286	Hygienic item or device, disposable or nondisposable, any type, each	<b>Not Covered</b>
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)	
C1816	Receiver and/or transmitter, neurostimulator (implantable)	
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	
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	
E1399	Durable medical equipment, miscellaneous	
K1006	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system	
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	

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## Appendix

### Appendix A

#### Conservative Management for UI/OAB

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

- Behavioral training; **OR**
- Biofeedback; **OR**
- Bladder training; **OR**
- Diet modification (eg, fluid management, decrease caffeine intake); **OR**
- Nonimplanted pelvic floor electrical stimulators utilized in a clinical setting (eg, Detrusan, UROSTYM); **OR**
- Pelvic floor exercise 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; **OR**
- Catheterization, indwelling or intermittent; **OR**
- Pelvic floor exercise therapy; **OR**
- Pharmacotherapy (eg, alpha-adrenergic blockers or 5-alpha reductase inhibitors)

**Change Summary**

- 01/01/2024 New Policy.
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