Urinary Incontinence/ Voiding Dysfunction
Treatments and Devices
Policy Number: PG0497
Last Review: 02/25/2022

GUIDELINES

➢ This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.

➢ Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.

➢ This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

X Professional
X Facility

DESCRIPTION

Urinary incontinence is defined as the involuntary loss of urine, or the inability to hold urine. There are different types of urinary incontinence. This includes stress incontinence, urge incontinence, mixed incontinence, overflow incontinence, overactive bladder, functional incontinence, urinary retention, neurogenic bladder, urinary fistula, and psychogenic incontinence.

• Stress urinary incontinence (SUI) is the involuntary loss of urine without a bladder contraction that 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 coughs, sneezes, strains or laughs.

• 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. Factors such as infection, inflammation, strokes, dementia and prostate gland enlargement can stimulate the bladder to create spasms and cause urine loss.

• Mixed incontinence is present with symptoms due to types of incontinence simultaneously, that occurs when the bladder does not empty completely causing leakage if the bladder becomes overly full. Most often due to overactive bladder and stress incontinence.

• Overflow incontinence is the involuntary release of urine—due to a weak bladder muscle or to blockage—when the bladder becomes overly full, even though the person feels no urge to urinate. Overflow incontinence is the type of incontinence more common in elderly men who may have enlarged prostate glands.

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

• Functional incontinence (also known as, disability associated urinary incontinence) is when a person is unable to: recognize the need to go to the toilet, locate the toilet, access the toilet, manage their personal needs (e.g. remove clothing), recognize the toilet. When someone has functional incontinence, it often means there is a physical, intellectual or environmental issue that makes it difficult for him or her to use the toilet. Some of the causes of functional incontinence include problems with walking (arthritis or cerebral palsy), physical capabilities that have been affected by stroke or severe arthritis and problems with memory or learning (such as dementia, and intellectual disability).

• Urinary retention (UR) is the incomplete emptying of the bladder or cessation of urination. It may be acute
Neurogenic bladder is a condition in which problems with the nervous system affect the bladder and urination. Conditions like stroke and Parkinson's disease can result in neurogenic bladder.

A urinary fistula is an abnormal opening either within a urinary tract organ (such as the bladder) or an abnormal connection between a urinary tract organ and another organ (such as the colon).

Psychogenic incontinence is the kind of incontinence that results from a loss in mental function or emotional capacity. Most often, this condition occurs because of dementia due to acute diabetes or Alzheimer's, but sometimes can be a reflection of a severely depressed emotional state.

Examples of these various treatment options are listed below, not all-inclusive:

- **Conservative:** Includes medical treatment weight loss, fluid management/decrease caffeine intake, behavioral training, bladder training, pelvic floor rehabilitation, Kegel exercises and chronic catheterization. The American Urogynecologic Society recommends a minimum of three months conservative treatment.

- **Surgical Procedures:** Include, but are not limited to, periurethral bulking agents, augmentation cystoplasty, bladder denervation or detrusor myomectomy, enterocystoplasty, bladder diversion, artificial urinary sphincter and cystectomy. These may not be considered first line treatments for most patients and other conservative measures may be considered first.

- **Other measures and supportive devices for the management of urinary incontinence:** Include intermittent catheterization, indwelling urethral catheterization, suprapubic catheters, external collection systems, urethral insert devices (Attain), penile compression device, pelvic organ support devices, sling systems (MiniArcTM) and absorbent garments.

- **Pelvic Floor Stimulation (PFS)** (eg, Kegel exercises, pelvic muscle rehabilitation) (97110): There is a variety of electrical Kegel exercise assistance devices being marketed and made available over-the-counter for home use, which provide either vibrations or an electrical prompting (eg, Apex, Attain, Flyte, INNOVO). PFS is an off-label use for electrical stimulation devices. This involves the electrical stimulation of the pelvic floor muscles using a probe wired to a device controlling the electrical stimulation, or more recently, extracorporeal pulsed magnetic innervation. It is believed that electric or magnetic stimulation leads to PFS, which in turn stimulates the pudendal nerve to improve urethral closure by activating the pelvic musculature by enhancing the process of re-innervation. 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.

- **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.

- **Posterior tibial nerve stimulation (PTNS):** PTNS, also referred to as percutaneous tibial nerve stimulation, is the least invasive forms of neuromodulation used to treat overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency and urge incontinence.
  - 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.
  - 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 parameters in advance so that the individual can conduct treatments at home in 30 minute sessions each day. (Refer to Coverage
- **Artificial Urinary Sphincter**
  - The artificial urinary sphincter (AUS) involves the implantation of an artificial valve in the genitourinary tract to restore continence. The transfer of fluid within the device is controlled by a pressure-regulating balloon placed extraperitoneally in the individual's pelvis or abdominal cavity and a control pump placed in a subcutaneous pocket in the scrotum. Squeezing of the pump allows fluid within the closed-loop system to be transferred from the cuff to the balloon. It takes a few minutes before the cuff re-inflates automatically to the preset level, allowing the urethra to remain open for voiding. The valve then automatically re-tightens several minutes later, which closes the urethra, thereby enabling control of urine flow and continence to be achieved.
  - The artificial urinary sphincter (AUS) is the gold standard of treatment for geno typical male urinary incontinence following prostate surgery. It has withstood the test of time, being unsurpassed by any other device for decades. The AUS is particularly effective for the more severe type of geno typical male urinary incontinence, where circumferential compression of the urethra is required.

- **Transvaginal and transurethral radiofrequency energy**
  - Transurethral Radiofrequency is a non-surgical treatment for stress urinary incontinence (SUI) due to hypermobility. Radiofrequency energy is applied to tissues in the lower urinary tract using a transurethral probe. Upon healing, the treated sites reduce tissue compliance and increase resistance to involuntary leakage at times of increased intra-abdominal pressure. FDA approved devices include the Lyrette™ Transurethral SUI System, previously known as Renessa® Procedure.
  - Transvaginal Radiofrequency has been investigated as a technique to shrink and stabilize the endopelvic fascia, to improve support for the urethra and bladder neck. An incision is made through the vagina to expose the endopelvic fascia. Radiofrequency energy is applied over the fascia resulting in blanching and shrinkage of the tissue. FDA-approved devices include the SURx® LP Transvaginal System; however, the SURx is no longer marketed in the U.S.

- **Intraurethral Valve-Pump**
  - The inFlow intraurethral valve-pump and activator is a urinary device for women with incomplete bladder emptying, due to impaired detrusor contractility (IDC). The inFlow is promoted as an alternative to urinary catheters. The device consists of a small catheter with an internal, magnetically-activated pump-valve mechanism, which is placed in the female urethra for up to 29 days or less. Upon activation by a battery-powered wand held low over the pubic area, the valve opens and the pump induces urine flow. The device blocks urine flow when continence is desired, and an internal pump draws urine out of the bladder when activated by the user. Proper device sizing and initial insertion is done by a physician. Subsequent device replacements are self-inserted, or inserted by a caregiver, approximately every 29 days. This device obtained FDA clearance through the de novo approval process in 2014 and is indicated for, "Use in female individuals 18 years of age or older who have incomplete bladder emptying, due to impaired detrusor contractility of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers."

- **Adjustable Continence Therapy (The ACT, The ProACT)**
  - The ProACT system consists of two postoperatively adjustable silicone balloons placed under fluoroscopic guidance at the prostatic apex (in post-TURP individuals), or at the vesico-urethral anastomosis (in post prostatectomy subjects) in males. Balloon titration is via tubing connected to a titanium port in the scrotum to enable post-implantation adjustments. The balloons are filled with isotonic solution following implantation; 1 ml can be titrated monthly until optimum continence is achieved.

- **Tactile biomechanical sensor imaging**
  - 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.
  - The Kegel perineometer or vaginal manometer was developed as an instrument to measure the strength of voluntary contractions of the pelvic floor muscles. Using the perineometer ascertains the air pressure inside the vagina when asking the woman to squeeze as hard as possible, which indicates whether doing Kegel exercises would be beneficial. Assessment of the pelvic floor strength can also be performed digitally by the physician during a gynecological exam digitally to identify women with fascial defects of the pelvic floor. The Kegel perineometer and digital examinations are said to identify those women at risk of genital prolapse or urinary incontinence. Additional studies are needed to evaluate the applications, strengths, and limitations of this type of tactile imaging for diagnostic use. There are no

Limitations) face electrodes.
professional guidelines and position statements that support the use of vaginal tactile imaging or biomechanical tactile sensor imaging for any gynecological or non-gynecological condition.

- Periurethral bulking agents
  - 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.

- Stem cell transplantation
  - 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.

- Laser therapy
  - 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, providing support to the pelvic floor structures.

**POLICY**

**HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage**

Procedures E0740, 0487T, 53451, 53452, 53453, 53454, 0587T, 0588T, 0589T, 0590T, 0596T, 0597T are non-covered for all product lines.

**HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan**

Transurethral Radiofrequency (53860) is non-covered.

**Advantage**

Transurethral Radiofrequency (53860) requires prior authorization for Advantage.

**HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage**

Transvaginal Radiofrequency is non-covered for all product lines.

Non-participating providers are required to obtain prior authorization BEFORE any services are rendered.

**COVERAGE CRITERIA**

**HMO, PPO, Individual Marketplace, Elite/ProMedica Medicare Plan, Advantage**

Treatment 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 member’s history, conducting a physical exam, performing a cough stress test, measuring post void 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.

**Periurethral injections of Bulking Agents (51715, L8603, L8604, L8606)**

Periurethral bulking agents that are cleared by the Food and Drug Administration (FDA) for UI (e.g., Bulkamid [polyacrylamide hydrogel], Coaptite [calcium hydroxylapatite], Contigen [glutaraldehyde crosslinked collagen], Durasphere [carbon-coated spheres/beads], Macroplastique [polymethylsiloxane], Uryx [ethylene vinyl alcohol copolymer]), may be considered medically necessary when the following criteria have been met:

- The patient has been diagnosed with stress incontinence due to intrinsic sphincter deficiency (ISD), or
- Post traumatic or surgical injury, or
- Urethral hypermobility in females with abdominal leak point less than 100 cm H2O which persists despite at least 12 consecutive months of conventional therapy (for example, exercise, medication), AND
- The patient has shown no improvement from at least 6 months of conservative measures (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy).
If collagen implant (Contigen) is used, a skin test is performed about a month prior to the implant to ensure that no hypersensitivity exists.

The only FDA approved product for the use in men is Contigen.

Up to five injection treatments may be considered medically necessary, beyond that, the patient would be considered a treatment failure and further treatment would be considered not medically necessary.

Bulking agents are not considered first line therapy. Conservative measures, including fluid management, smoking cessation, weight loss, vaginal exercises, and/or treatments of underlying causes of incontinence would be necessary for at least 6 months prior to the use of bulking agents.

The treatment of types of incontinence other than stress incontinence, with periurethral bulking agents is considered investigational.

Based upon literature, urethral bulking agents when used in the treatment of other types of urinary incontinence (e.g., urinary retention with overflow incontinence, functional incontinence, neurogenic bladder dysfunction, urinary fistulas and psychogenic incontinence), as yet, have not demonstrated a benefit to the patient.

**Artificial Urinary Sphincter (C1815, 53445, 53446, 53447, 53449)**

Implantation of an artificial urinary sphincter (AUS) device is considered medically necessary in genotypic male adults following prostate surgery to treat urinary incontinence due to reduced outlet resistance (Intrinsic Sphincter Deficiency [ISD])

- When the symptoms of incontinence have been refractory to at least 2 conventional conservative therapies for a minimum of 6 months (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy).

Artificial urinary sphincter implantation is not considered first-line treatment of refractory incontinence in genotypic male adults following prostate surgery. Examples of first-line conservative medical treatment may include one or more of the following: behavioral therapy, pharmacologic treatments, and intermittent self-catheterization.

Implantation of an artificial urinary sphincter device is considered not medically necessary for all other indications including, but not limited to:

- Treatment of intrinsic sphincter deficiency in genotypic women and children whose incontinence has been refractory to conservative medical treatment or other surgical treatments; and
- Treatment of intrinsic sphincter deficiency in genotypic men who have not undergone prostate surgery.

**Deflux (L8604)**

Subureteric injection of dextranomer/hyaluronic acid copolymer (Deflux) Deflux® is a gel-like liquid containing complex sugars, packaged in a syringe. It is used to treat children who have vesicoureteral reflux, an abnormal condition in which urine flows backwards from the bladder to the kidneys.

Indications include treatment of children with vesicoureteral reflux (VUR) grades II-IV. All other indications are considered investigational.

**Posterior tibial nerve stimulation (PTNS) (also known as percutaneous tibial nerve stimulation) (64566)**

PTNS (64566) is covered for overactive bladder (OAB)/stress urinary incontinence (SUI)/urge urinary incontinence (UUI) after:

- all other causes of overactive bladder (OAB)/stress urinary incontinence (SUI)/urge urinary incontinence (UUI) have been ruled out (e.g. anatomical variances infections); and
- symptoms are not due to underlying neurologic condition (e.g., multiple sclerosis, Parkinson disease, spinal cord injury) ; and
- symptoms are persisting for at least 3 months; and
- failed behavioral therapy following an appropriate duration of 8 to 12 weeks without meeting treatment goals; and
- failed pharmacologic therapy following 4 to 8 weeks of treatment without meeting treatment goals or Member intolerance to anticholinergic drug therapy.

Treatment regimens consist of 30-minute weekly sessions for 12 treatments.
Limitations

- Patients must report an improvement in symptoms of urinary frequency, nocturia, and/or urinary urgency within 6 weeks (i.e., 6 sessions) of initiation of PTNS for continued coverage.
- After the initial 12 sessions, treatments will be allowed at a frequency of 1 every month for up to a total of two years. The 2 year time period begins with the initiation of PTNS treatment. Subsequent treatment will not be covered.
- After an initial ultrasound bladder evaluation, repeated ultrasound bladder evaluations will only be allowed if there is appropriate documentation of the medical necessity of this testing.
- Stress and neurogenic incontinence would not be expected to improve with PTNS.

Documentation Requirements

- The medical record must indicate the patient has the cognitive ability to understand and interact with the methodology of treatment.
- All indications must be clearly documented in the patient's medical record and made available upon request.
- Treatment beyond the initial 12 sessions will be allowed at a frequency of 1 every 1 to 2 months for up to two years when medical necessity is supported by documentation in the medical record.
- Beneficiaries must be ambulatory.

At this time, there is no evidence to support continued PTNS therapy after two years of treatment. PTNS treatments beyond 2 years from the initiation of treatment will not be covered.

PTNS for other types of incontinence (e.g. stress incontinence) are considered not medically necessary.

**Bladder support surgeries**

Bladder support surgeries are performed using a variety of open, laparoscopic or needle suspension techniques to help restore continence, may not be limited to:

- 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 urethra and the bladder neck to prevent downward rotation of these structures.

**Transurethral radiofrequency (53860) – Advantage only**

**Advantage**

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of Transurethral Radiofrequency (53860) in the treatment of SUI utilizing the Lyrette™ System, The Ohio Department of Medicaid requires this procedure be reviewed for medical necessity. Therefore, it may be covered with a prior authorization for Advantage members.

**Non-Covered**

The following treatments and devices are considered investigational for the treatment of urinary incontinence/urinary dysfunction, may not be limited to:

- Vaginal weight training with specially designed weights (cones) is considered investigational.
- Pelvic floor stimulation by any method, electrical or magnetic, is considered investigational. (E0740)
  - Extracorporeal magnetic innervation (ExMI) (eg, NeoControl Pelvic Floor Therapy System); or
Implanted percutaneous tibial nerve stimulation (PTNS) (eg, Protect PNS, RENOVA, StimRouter)

- Periurethral bulking agents other than those listed in the policy section above, including, but not limited to, Teflon®, autologous ear chondrocytes, autologous myoblast, and autologous fat tissue are all considered investigational.

- Transvaginal and transurethral radiofrequency energy therapies for bladder neck suspension, including, but not limited to, the Renessa® System, and the SURx Radiofrequency Bladder Neck Suspension System are all considered investigational. Exception: see above for transurethral radiofrequency (53860) coverage for the Advantage product line.

- Laser therapy (Genityte procedure, FemiLift, FemTouch, IncontiLase) is considered investigational.

- Stem cell therapy for the treatment of urinary incontinence is considered investigational.

- Autologous myoblast transplantation is considered experimental and investigational for the treatment of UI.

- Autologous muscle-derived cell therapy is considered experimental and investigational for the treatment of UI.

- Collagen porcine dermis mesh is considered experimental and investigational for the treatment of UI because its effectiveness for this indication has not been established.

- Transperineal Implantation of Permanent Adjustable Balloon Continence Device or Adjustable Continence Therapy (The ACT, ProACT) are considered investigational.

- Urinary prosthesis, the inFlow™ intraurethral valve-pump implantation is considered investigational for all indications.

- Visual Biofeedback and Guided Exercise Program (eg. Attain) is considered investigational.
  - Real-time ultrasound imaging/biofeedback uses ultrasound imaging to provide the member with information on the effectiveness of voluntary contractions of the transverse abdominis and pelvic floor muscles with the goal of decreasing urinary incontinence. Real-time ultrasound imaging for incontinence is considered investigational or unproven and therefore not coverable.
  - Home biofeedback units and home combination electric stimulation/biofeedback units (e.g., InTone E0740, E1399) are not covered.

- Genetic testing for the identification, risk for, or management of urinary incontinence is considered investigational.

- Tactile biomechanical sensor imaging (transvaginal biomechanical imaging) is considered investigational for all indications, including but not limited to urinary incontinence.

- 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:
  - Member prone to excessive bleeding; OR
  - Member with nerve damage that could impact the percutaneous tibial nerve pelvic floor function; OR
  - Member with pacemaker or implantable defibrillator; OR
  - Pregnancy or plan to become pregnant while using the device; OR
  - Used longer than 12 months

- Radiofrequency micro-remodeling with the SURx System (paraurethral or transvaginal) for the treatment of UI is considered experimental and investigational because its effectiveness has not been established. (53860)

- Pudendal nerve stimulation is considered experimental and investigational.

- Adjustable transobturator male system is considered experimental and investigational for the treatment of stress urinary incontinence (SUI) because its effectiveness has not been established.

- Paramount does not cover the Athena pelvic muscle trainer, Gyneflex, Kegelmaster, Leva Pelvic Floor Trainer, or similar devices for the treatment of UI because these devices are considered exercise machines, and they do not meet the definition of covered durable medical equipment (DME).

**CODING/BILLING INFORMATION**

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1815</td>
<td>Prosthesis, urinary sphincter (implantable)</td>
</tr>
<tr>
<td>E0740</td>
<td>Non-implanted pelvic floor electrical stimulator, complete system</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>E0746</td>
<td>Electromyography (EMG), biofeedback device</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable Medical Equipment, miscellaneous</td>
</tr>
<tr>
<td>L8603</td>
<td>Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies</td>
</tr>
<tr>
<td>L8604</td>
<td>Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies</td>
</tr>
<tr>
<td>L8606</td>
<td>Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies</td>
</tr>
<tr>
<td>38240</td>
<td>Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor</td>
</tr>
<tr>
<td>38241</td>
<td>Hematopoietic progenitor cell (HPC); autologous transplantation</td>
</tr>
<tr>
<td>51715</td>
<td>Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck</td>
</tr>
<tr>
<td>51840</td>
<td>Anterior vesicourethropexy, or urethropexy (eg, MarshallMarchetti-Krantz, Burch); simple</td>
</tr>
<tr>
<td>51841</td>
<td>Anterior vesicourethropexy, or urethropexy (eg, MarshallMarchetti-Krantz, Burch); complicated (eg, secondary repair)</td>
</tr>
<tr>
<td>51845</td>
<td>Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, Stamey, Raz, modified Pereyra)</td>
</tr>
<tr>
<td>51990</td>
<td>Laparoscopy, surgical; urethral suspension for stress incontinence</td>
</tr>
<tr>
<td>51992</td>
<td>Laparoscopy, surgical; sling operation for stress incontinence (eg, fascia or synthetic)</td>
</tr>
<tr>
<td>53440</td>
<td>Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)</td>
</tr>
<tr>
<td>53442</td>
<td>Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)</td>
</tr>
<tr>
<td>53444</td>
<td>Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)</td>
</tr>
<tr>
<td>53445</td>
<td>Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff</td>
</tr>
<tr>
<td>53446</td>
<td>Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff</td>
</tr>
<tr>
<td>53447</td>
<td>Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session</td>
</tr>
<tr>
<td>53448</td>
<td>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</td>
</tr>
<tr>
<td>53449</td>
<td>Repair of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff</td>
</tr>
<tr>
<td>53451</td>
<td>Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance (experimental/investigational)</td>
</tr>
<tr>
<td>53452</td>
<td>Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance (experimental/investigational)</td>
</tr>
<tr>
<td>53453</td>
<td>Periurethral transperineal adjustable balloon continence device; removal, each balloon (experimental/investigational)</td>
</tr>
<tr>
<td>53454</td>
<td>Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume (experimental/investigational)</td>
</tr>
<tr>
<td>53860</td>
<td>Transurethral radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence</td>
</tr>
<tr>
<td>53899</td>
<td>Unlisted procedure, urinary system (specifically for ExMi) Non-Covered when utilized for transvaginal radiofrequency</td>
</tr>
<tr>
<td>57287</td>
<td>Removal or revision of sling for stress incontinence (eg, fascia or synthetic)</td>
</tr>
<tr>
<td>57288</td>
<td>Sling operation for stress incontinence (eg, fascia or synthetic)</td>
</tr>
<tr>
<td>58999</td>
<td>Unlisted procedure, female genital system (nonobstetrical)</td>
</tr>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrode array</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td>90912</td>
<td>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</td>
</tr>
<tr>
<td>90913</td>
<td>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)</td>
</tr>
<tr>
<td>95970</td>
<td>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</td>
</tr>
<tr>
<td>95971</td>
<td>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</td>
</tr>
<tr>
<td>95972</td>
<td>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</td>
</tr>
<tr>
<td>97014</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (unattended)</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
</tr>
<tr>
<td>97039</td>
<td>Unlisted modality (specify type and time if constant attendance)</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes</td>
</tr>
<tr>
<td>0487T</td>
<td>Biomechanical mapping, transvaginal, with report</td>
</tr>
<tr>
<td>0548T</td>
<td>Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy (Deleted Code 1/1/2022, see procedures 53451, 53452, 53453, 53454 effective 1/1/2022)</td>
</tr>
<tr>
<td>0549T</td>
<td>Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy (Deleted Code 1/1/2022, see procedures 53451, 53452, 53453, 53454 effective 1/1/2022)</td>
</tr>
<tr>
<td>0550T</td>
<td>Transperineal periurethral balloon continence device; removal, each balloon (Deleted Code 1/1/2022, see procedures 53451, 53452, 53453, 53454 effective 1/1/2022)</td>
</tr>
<tr>
<td>0551T</td>
<td>Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume (Deleted Code 1/1/2022, see procedures 53451, 53452, 53453, 53454 effective 1/1/2022)</td>
</tr>
<tr>
<td>0587T</td>
<td>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</td>
</tr>
<tr>
<td>0588T</td>
<td>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</td>
</tr>
<tr>
<td>0589T</td>
<td>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</td>
</tr>
<tr>
<td>0590T</td>
<td>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 parameter</td>
</tr>
<tr>
<td>0596T</td>
<td>Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement</td>
</tr>
<tr>
<td>0597T</td>
<td>Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement</td>
</tr>
</tbody>
</table>
Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/services/providers/medical-policies/.

REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 07/01/2021

<table>
<thead>
<tr>
<th>Date</th>
<th>Explanation &amp; Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/2021</td>
<td>• Policy Created&lt;br&gt;• Achieved medical policies PG0197 Posterior Tibial Nerve Stimulation (PTNS) and PG0191 Transurethral &amp; Transvaginal Radiofrequency for Urinary Incontinence – documentation/criteria incorporated into this new medical policy PG0497 Urinary Incontinence/ Voiding Dysfunction Treatments and Devices&lt;br&gt;• Procedures E0740, 0487T, 0548T, 0549T, 0550T, 0551T, 0596T, 0597T, 0587T, 0588T, 0589T, 0590T, 0596T, 0597T are non-covered for all product lines&lt;br&gt;• Transurethral Radiofrequency (53860) is non-covered for HMO, PPO, Individual Marketplace and Elite/ProMedica Medicare Plan.&lt;br&gt;• Transurethral Radiofrequency (53860) requires prior authorization for Advantage.&lt;br&gt;• Transvaginal Radiofrequency is non-covered for all product lines.</td>
</tr>
<tr>
<td>02/25/2022</td>
<td>• Policy reviewed and updated to reflect most current clinical evidence&lt;br&gt;• Deleted procedure codes 0548T, 0549T, 0550T, 0551T removed&lt;br&gt;• New 2022 replacement procedure codes 53451, 53452, 53453, 53454 added as non-covered, considered experimental/investigational</td>
</tr>
</tbody>
</table>

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets


Industry Standard Review

Hayes, Inc.

Industry Standard Review