blue of california

Medical Policy

Urinary Incontinence Outpatient Treatment	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Medicine
Original Policy Date: January 11, 2008	**Effective Date:** July 3, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Urinary incontinence (UI), defined as the involuntary loss of urine, is common, particularly in women. While men and women may be affected by UI, women are twice as likely compared to men and prevalence increases with age. Urinary incontinence symptoms can range from mild leaking to uncontrollable wetting and the social burdens of UI can range from mildly bothersome

to debilitating. There are several types of UI including stress, urge, mixed, overflow and functional incontinence. The two predominant forms of UI are stress incontinence (sphincter failure during increases in abdominal pressure, as when coughing or with exertion) and urge incontinence (involuntary loss of urine accompanied by the urge to void, often associated with bladder detrusor muscle overactivity).

Less invasive treatments for UI include lifestyle changes, behavioral therapy, bladder training, pelvic floor muscle training (PFMT), and pharmacological therapy. More invasive or surgical interventions for UI are offered when behavioral or medical treatments do not provide enough relief.

This medical policy addresses the following treatments and devices for UI:

- Acupuncture*
- Adjustable continence therapy (ACT®, ProACT™)
- Biofeedback*
- Biomagnetic therapy
- Injectable periurethral bulking agents
- Pelvic floor stimulation (electrical /magnetic /extracorporeal electromagnetic)
- Posterior tibial nerve stimulation (PTNS) (Urgent® PC Neuromodulation System)
- Pudendal nerve stimulation (BION® device)
- Transurethral radiofrequency energy collagen micro-remodeling (e.g., Lyrette™ System [formerly Renessa® System])
- Transvaginal radiofrequency bladder neck suspension (e.g., SURx System®)
- Pelvic muscle trainer devices

Note: Please reference the following related Blue Shield Medical or Pharmacy policies for additional information:

- Biofeedback (Medical policy)
- OnabotulinumtoxinA, (Botox®) (Pharmacy policy)
- Sacral Nerve Neuromodulation/Stimulation (Medical policy)

Policy

Injectable Periurethral Bulking Agents

Injectable periurethral bulking agents cleared by the U.S. Food and Drug Administration (FDA) for urinary incontinence in men and women (e.g., Contigen [cross-linked collagen], Coaptite [calcium hydroxylapatite], Durasphere [carbon coated spheres/beads], or Macroplastique [polydimethlysiloxane] may be considered **medically necessary** when **both** of the following are met:

- Used for the treatment of stress urinary incontinence
- Failure, contraindication or intolerance to conservative therapy or therapies (See Policy Guideline)

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*Prior to any collagen implant (e.g., Contigen) therapy, a skin test for collagen sensitivity must be administered and evaluated over a four-week period. The skin test is not required for the other agents.

Treatment intervals, number of treatment sessions/injections, and treatment failure may vary by implant/product. Injections performed/requested after the maximal number of injections approved by the FDA in patients whose incontinence does not improve, are considered **not medically necessary** (See Policy Guideline).

Note: Patients who have reoccurrence of incontinence following a successful treatment series of injections (i.e., 6-12 months previously) may benefit from additional treatments and will require documentation of medical necessity.

The use of injectable periurethral bulking agents for the treatment of urge urinary incontinence is considered **investigational**.

The use of any other periurethral bulking agent is considered **investigational** for the treatment of urinary incontinence, including, but not limited to:

- Teflon® (polytetrafluoroethylene paste)
- Deflux® dextranomer/hyaluronic acid copolymer (excluding use in treatment of children with vesicoureteral reflux [VUR])
- Autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells)
- Autologous fat, and autologous ear chondrocytes

Transurethral Radiofrequency Energy Collagen Micro-Remodeling

Transurethral radiofrequency energy collagen micro-remodeling (e.g., Lyrette™ System [formerly Renessa® System]) may be considered **medically necessary** when both the following criteria are met:

- For the treatment of moderate-to-severe female stress urinary incontinence (See Policy Guideline)
- Non-pregnant women who have failed conservative treatment and who are either not medically able (e.g., poor surgical or anesthesia candidates) or not willing to undergo invasive surgery for their stress urinary incontinence

Other Procedures/Devices

The following urinary incontinence interventions are considered **investigational** for the treatment of any type of urinary dysfunction including, but not limited to, overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence and retention:

- Acupuncture*
- Adjustable Continence Therapy (ACT®, ProACT™ [Uromedica, Inc.])
- Biofeedback*
- Biomagnetic therapy
- Pelvic floor stimulation (electrical, magnetic, or extracorporeal electromagnetic stimulation of the pelvic floor muscles)

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- Posterior tibial nerve stimulation (PTNS) or percutaneous PTNS (Urgent® PC Neuromodulation System [Uroplasty, Inc.])
- Pudendal nerve stimulation for urinary incontinence (BION®device [Advanced Bionics Corp.])
- Transvaginal radiofrequency micro-remodeling (e.g., SURx Laparoscopic Probe Radiofrequency System [SURX, Inc.])

The use of pelvic muscle trainer devices (e.g., Kegelmaster, Gyneflex, Athena pelvic muscle trainer) for treatment of urinary incontinence is **not a covered benefit***.

***See Benefit Application Section**

Policy Guideline

Conservative Therapies for Urinary Incontinence

Patients should have had inadequate response to conservative therapy or therapies; in general, these treatments should have been used for at least 3 months. Conservative therapy for stress incontinence includes pelvic floor muscle exercises and behavioral changes, such as fluid management and moderation of physical activities that provoke incontinence. Additional options include intravaginal estrogen therapy, use of a pessary, and treatment of other underlying causes of incontinence in patients amenable to these treatments.

Injectable Periurethral Bulking Agents

Treatment Intervals, Number of Treatment Sessions/Injections, and Treatment Failure of Various Bulking Agents per the U.S. Food and Drug Administration (FDA):

Bulking Agent	FDA Information
Contigen®	Incontinence that does not improve at least one grade change following five injection procedures with Contigen (five separate treatment sessions) is considered a treatment failure, and further treatment of stress urinary incontinence with an implantable bulking agent is considered not medically necessary and, therefore, not covered. Individuals who have a recurrence of incontinence following successful treatment with Contigen in the past (e.g., 6 to 12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical documentation.
Coaptite®	The maximum total volume of Coaptite that can be injected during one treatment session is 15 ml. The maximum number of treatments is limited to five per individual. If a satisfactory improvement is not achieved after the initial treatment, additional injection procedures are considered medically necessary and, therefore, covered during the first six months after the initial injection, if the treating physician determines that they are necessary. All additional injection procedures should be scheduled a

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	minimum of seven days from the previous procedure.
Durasphere™	Durasphere™ can be given at 4-6 month intervals following the initial treatment.
Macroplastique®	Some individuals may require additional treatments to enhance their improvement or achieve dryness. It is recommended to delay additional treatment with Macroplastique for 12 weeks to allow the tissue to heal. The safety and effectiveness of more than one retreatment of Macroplastique®, and retreatment administered less than 12 weeks after the initial treatment, are unknown.
URYX® (withdrawn from the market)	Bulking agent therapy with URYX is a course of treatment that may require more than one injection procedure to achieve dryness or a desired level of improvement in incontinence. A minimum of four weeks should elapse between retreatment.

Coding for Periurethral Bulking Agents for Urinary Incontinence

The physician services associated with urethral bulking agents are described by CPT code:

- 51715: Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

There are HCPCS codes for the bulking agents used in this procedure.

- L8603: Describes collagen implant material, such as Contigen*
- L8606: Describes synthetic bulking agents, such as carbon-coated beads or copolymers (Durasphere or URYX)

*Prior to any collagen injection treatments, a skin test for collagen sensitivity musbe be administered and evaluated over a 4-week period represented by CPT code Q3031: Collagen skin test.

Transurethral Radiofrequency Energy Collagen Micro-Remodeling

Severity of Incontinence

There are many quality of life and symptom severity scales to evaluate the type and severity of urinary incontinence (e.g., International Consultation Incontinence Questionnaire (ICIQ), its short form (ICIQ-SF), the Incontinence Impact Questionnaire short form, and the Urogenital Distress Inventory short form). Scoring is different on each scale. For example, the International Quality of Life (IQOL) scoring tool defines female moderate-to-severe stress urinary incontinence as a score below 60. According to the American Urological Foundation (2009):

- Mild incontinence is light leakage with vigorous activity such as exercise or from sneezing, laughing, coughing or lifting
- Moderate/more severe incontinence is leakage with any movement such as standing up, walking, or bending over.

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Urinary Incontinence Severity Grades (Classification grading system of symptoms)

- **Grade 0 -** Continent
- **Grade I -** Patient loses urine with sudden increase in prone position but not in supine
- **Grade II -** Patient loses urine with physical stress (walking; changing from a reclining to a standing position; sitting up in bed)
- **Grade III -** Patient with total incontinence; urine loss unrelated to physical activity and/or position

There is a specific CPT code for this procedure:

- 53860: Transurethral, radiofrequency micro-remodeling of the female bladder neck and proximal urethra for stress urinary incontinence

Adjustable Continence Therapy Device (ACT®, ProACT™)

The ACT® system (Uromedica, Inc., Minnetonka, MN) is an implantable device developed as a minimal invasive option for treatment-resistant stress urinary incontinence in women. The ProACT™ system (Uromedica, Inc., Minnetonka, MN) has been developed for men. Currently, these devices are not approved by the FDA and are being studied in clinical trials.

The following codes may be used to describe the ACT or ProACT system:

- A4356: External urethral clamp or compression device (not to be used for catheter clamp), each
- A4360: Disposable external urethral clamp or compression device, with pad and/or pouch, each

Biofeedback

Biofeedback for urinary incontinence is described by the following CPT and HCPCS codes:

- 90911: Biofeedback training by any modality
- E0746: Electromyography (EMG), biofeedback device

Biomagnetic Therapy

There are no specific codes identifying biomagnetic therapy devices. A miscellaneous durable medical equipment (DME) code (e.g., HCPCS code: E1399) may be used.

Pelvic Floor Stimulation Devices

Examples of U.S. FDA approved pelvic floor muscle stimulation devices for urinary incontinence include, but are not limited to:

- Minnova™ Pelvic Floor Stimulation System (Empi®, St. Paul, MN)
- MyoTrac Infiniti™ (Thought Technology, Ltd.)
- Pathway™ CTS 2000 (The Prometheus Group)
- InCare® PRS (Hollister, Inc.)
- NeoControl® Pelvic Floor Therapy System (Neotonus, Inc) formerly the Neotonus Model 1000 Magnetic Stimulator

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Coding for Pelvic Floor Stimulation and Devices:

- 53899: Unlisted procedure, urinary system (when used for pulsed magnetic stimulation)
- 97014 or 97032: Application of a modality to one or more areas; electrical stimulation (unattended)
- G0283: Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
- E0740: Incontinence treatment system; pelvic floor stimulator, monitor, sensor and/or trainer

Posterior Tibial Nerve Stimulation (PTNS)

There is a specific CPT code for this procedure:

- 64566: Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

Note: CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64565) are not appropriate since PTNS uses percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PTNS and percutaneous neuromodulation therapy (PNT) are not implanted, therefore CPT code 64590 is not appropriate.

Pudendal Nerve Stimulation (BION® device)

There is no specific code for the pudendal nerve stimulation for the treatment of urinary incontinence. The following CPT codes may be used:

- 97014 or 97032: Application of a modality to one or more areas; electrical stimulation (unattended)

The following HCPCS code may be used for the BION microstimulator device:

- E0740: Incontinence treatment system; pelvic floor stimulator, monitor, sensor and/or trainer

Transvaginal Radiofrequency Micro-Remodeling

There are no specific CPT codes describing the transvaginal radiofrequency micro-remodeling (i.e., SURx system). The manufacturer recommends the use of CPT code 53899 (unlisted procedure, urinary system). As of 2006, the SURx is no longer marketed in the United States.

Pelvic Muscle Trainer Devices

There are no specific codes for the pelvic muscle trainer devices. A miscellaneous durable medical equipment code (e.g., HCPCS code: E1399) may be used.

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

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Documentation Required for Clinical Review

• History and physical and/or urology consultation report including:
  o Type and severity of urinary incontinence
  o Prior conservative treatment(s), duration and response(s)
  o Procedure/device/treatment requested and medical necessity justification
  o Treatment plan
  o Additionally, for periurethral bulking agent injections include:
  ▪ Type of substance to be injected, amount, and proposed number of injections and treatment intervals
  ▪ Additionally, for reoccurrence of incontinence, prior treatment response and medical justification
Post Service
• Procedure report(s) (if applicable)
• Device invoice (if applicable)

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

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