

## Corporate Medical Policy

### Periurethral Bulking Agents for the Treatment of Urinary Incontinence

<b>File Name:</b>	periurethral_bulking_agents_for_the_treatment_of_urinary_incontinence
<b>Origination:</b>	8/1985
<b>Last CAP Review:</b>	11/2011
<b>Next CAP Review:</b>	11/2012
<b>Last Review:</b>	11/2011

#### Description of Procedure or Service

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Injecting material to increase the bulk around the urethra can improve the function of the urethral sphincter and make a better seal for the outside of the bladder area. Collagen is a natural protein substance made up of the white fibers of skin, tendon, bone, cartilage and all other connective tissue. Periurethral injection of collagen is used to treat stress urinary incontinence. Collagen injection uses a purified form of collagen derived from cow hide (e.g., Contigen®). A prefilled syringe is used to inject the cross-linked collagen around the urethra using an instrument called a cystoscope to guide placement. This procedure may be performed over the course of two to three visits to a physician. Since the body can slowly absorb collagen, retreatment may be necessary.

Carbon-coated spheres or beads (e.g., Durasphere™) and ethylene vinyl alcohol copolymer implant (e.g., URYX® marketed under the trade name Tegress® since 2005) have received approval by the United States Food and Drug Administration (FDA) as injectable periurethral bulking agents. These two agents are not absorbed over time, and are therefore thought to provide a more durable effect.

In 2005 a bulking agent composed of spherical particles of calcium hydroxylapatite (CaHA) in a gel carrier (Coaptite®) received FDA approval for use in women. Polydimethylsiloxane (silicone, Macroplastique®) received FDA approval in 2006 “for transurethral injection in the treatment of adult women diagnosed with stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency”. The FDA approvals are conditional on the enrollment of a minimum of 200-250 patients into a 5-year registry in order to further evaluate safety and efficacy.

Except for Contigen, bulking agents are FDA-indicated for use only in women with stress urinary incontinence due to intrinsic sphincter deficiency.

Polytetrafluoroethylene (Teflon®) is another implant material that has been investigated but has not received FDA approval.

A more recently explored alternative is cellular therapy with myoblasts, fibroblasts, or stem cells (muscle derived or adipose-derived). In addition to their use as periurethral bulking agents, it is hoped that transplanted stem cells will undergo self-renewal and multipotent differentiation, which could result in regeneration of the sphincter and its neural connections.

Note: Please refer to separate policy “Biofeedback” for treatment of stress urinary incontinence with biofeedback.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

# Periurethral Bulking Agents for the Treatment of Urinary Incontinence

## Policy

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**BCBSNC will provide coverage for Periurethral Bulking Agents for the Treatment of Urinary Incontinence, when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Periurethral Bulking Agents for the Treatment of Urinary Incontinence is covered

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Periurethral bulking agents for the treatment of urinary incontinence are covered when one of the following conditions is present:

1. For incontinence due to intrinsic sphincter deficiency where the patient has had no improvement in incontinence for at least 12 months;

**OR**

2. For stress urinary incontinence when all of the following are met:
  - a. incontinence has been present for 6 months; and
  - b. no other causes of stress urinary incontinence have been identified (e.g., urinary tract infection); and
  - c. stress urinary incontinence limits activities of daily living;

**AND** cross-linked collagen, carbon-coated spheres, ethylene vinyl alcohol copolymers, calcium hydroxylapatite or polydimethylsiloxane are used as the periurethral bulking agent.

## When Periurethral Bulking Agents for the Treatment of Urinary Incontinence is not covered

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- For conditions other than noted above.
- The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence is considered investigational.
- The use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells), autologous fat, and autologous ear chondrocytes as periurethral bulking agents is considered investigational and is not covered.
- The use of periurethral bulking agents to treat urge urinary incontinence is considered investigational.

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## Policy Guidelines

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There is a lack of large high-quality randomized controlled trials evaluating periurethral bulking agents for the treatment of urinary incontinence compared to placebo, conservative treatment, or one another. Existing evidence, although of moderate quality, suggests that the efficacy of carbon-coated spheres, calcium hydroxylapatite, and polydimethylsiloxane for treating incontinence may be similar to cross-linked collagen, an established treatment, and they may be considered medically necessary. There is insufficient published evidence on the efficacy of autologous cellular therapy, autologous fat, autologous ear chondrocytes, and other treatments such as Teflon; thus, these are considered investigational.

A collagen skin test should be performed about a month prior to periurethral injection to rule out hypersensitivity. No skin test is required for carbon-coated beads, biocompatible copolymers, calcium hydroxylapatite or polydimethylsiloxane.

Patients whose incontinence does not improve with five injection procedures are considered treatment failures and should not receive further injections.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 51715, L8603, L8604, L8606, Q3031*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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### **Policy entitled: Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence**

BCBSA Medical Policy Reference Manual - 12/95

BCBSA Medical Policy Reference Manual - 7/97

Kumon H, Tsugawa M. Endoscopic correction of vesicoureteral reflux by subureteric Teflon (polytetrafluoroethylene) injection: review of 6-year experience. *Int J Urol.* 1997;4(6):541-5.

Belman Ab. Vesicoureteral reflux. *Pediatr Clin North Am.* 1997;44(5):1171-90.  
Medical Policy Advisory Group 3/99

### **New policy entitled: Treatment of Urinary Incontinence**

BCBSA TEC Evaluation, June 2000; Volume 15, No. 2

BCBSA TEC Evaluation, August 2000; Volume 15, No. 8

# Periurethral Bulking Agents for the Treatment of Urinary Incontinence

BCBSA Medical Policy Reference Manual, 12/15/00; 1.01.17

Specialty Matched Consultant Advisory Panel - 5/2001

Specialty Matched Consultant Advisory Panel - 9/2001

BCBSA Medical Policy Reference Manual, 2/15/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 1.01.17

BCBSA Medical Policy Reference Manual, 4/29/03; 7.01.19

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/15/04.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 11/9/04

Specialty Matched Consultant Advisory Panel - 5/2005

## **New policy entitled: Periurethral Bulking Agents for the Treatment of Urinary Incontinence**

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 4/1/05.

Specialty Matched Consultant Advisory Panel - 5/8/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 4/17/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 5/8/08

Specialty Matched Consultant Advisory Panel - 9/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 10/8/10

Specialty Matched Consultant Advisory Panel review 12/2010

Abrams P, Andersson KE, Birder L, et al. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse, and Fecal Incontinence. *Neurourology and Urodynamics* 29:213-240 (2010).

Lone F, Sultan AH, Thakar R. Long-term outcome of transurethral injection of hyaluronic acid/dextranomer (NASHA/Dx gel) for the treatment of stress urinary incontinence (SUI). *Int Urogynecol J* 2010

Davila GW. Nonsurgical outpatient therapies for the management of female stress urinary incontinence: long-term effectiveness and durability. *Adv Urol* 2011. Retrieved on November 1, 2011 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124122/?tool=pubmed>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 10/4/11

# Periurethral Bulking Agents for the Treatment of Urinary Incontinence

## Policy Implementation/Update Information

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### Policy entitled: Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence

- 8/85 Original Policy: Experimental/investigative for Teflon implant  
8/88 Reviewed: Investigational for Teflon implant
- 4/94 Evaluated: Use of GAX collagen implantation for the treatment of urinary stress incontinence due to intrinsic sphincter deficiency in patients who have urinary incontinence of greater than 12 months duration is eligible for coverage.
- 7/96 Reviewed: National Association reviewed 12/95. No changes.
- 5/99 Reaffirmed based on the MPAG review. No changes.
- 6/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 8/00 Coding system changes.
- 12/00 2001 HCPCS code added; L8606. System coding changes.

### New policy entitled: Treatment of Urinary Incontinence

- 5/01 Policies combined and renamed. Added criteria for Pelvic Floor Stimulation as a Treatment of Urinary Incontinence. Specialty Matched Consultant Advisory Panel. No changes to policy.
- 9/01 Specialty Matched Consultant Advisory Panel review. Added description and coverage criteria for carbon-coated spheres or beads for Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence.
- 10/01 Coding format changes.
- 3/02 Added codes 64561 and 64581 to the Billing/Coding Section in Section II Sacral Nerve Stimulation for Urinary Incontinence and System Application Guidelines.
- 4/02 Format changes.
- 11/03 Specialty Matched Consultant Advisory Panel review 5/23/03. Benefits Application section revised. For Section I, Periurethral Injection of Implant Material, revised description for clarity; revised Policy Guidelines to indicate that "Patients whose incontinence does not improve with five injection procedures...". For Section II, Sacral Nerve Stimulation, removed codes 64555, 64575, E0751, E0753, E1399 and added codes 95971, E0752 and E0759. For Section III, Pelvic Floor Stimulation, revised description for clarity; added Innova Feminine Incontinence Treatment System to this section; added code 0029T to Billing/Coding section and removed codes 97014 and 97032. Deleted Section IV, Innova Feminine Incontinence Treatment System.
- 2/04 Added HCPCS codes L8603 and Q3031 to Billing/Coding section of Section I re: Periurethral Injection of Implant Material.
- 6/16/05 Specialty Matched Consultant Advisory Panel review 5/24/05. **Section I** - Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence; description

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revised, included biocompatible copolymer implant (e.g., URYX) in description; For “When Covered”- 2.d. “Cross-linked collagen or carbon-coated beads are used as the implantable material.” pulled out as a separate sentence so need 1 or 2 and use of listed materials; also added biocompatible copolymers as one of the approved materials; For “When not Covered” added “The use of autologous fat and autologous ear chondrocytes as periurethral bulking agents are considered investigational and are not covered.”; For “Policy Guidelines” removed sentence re: “15 ml of paste are injected...” since the procedure is included in the description. **Section II** - Sacral Nerve Modulation/Stimulation...description of procedure revised to provide additional information; For “When Covered” - changed #2 to indicate that the urinary incontinence conditions listed in #1 should not be related to a neurologic condition; #3 now reads: “Medical records document that the patient has failed at least a 3 month trial of conservative treatment such as behavioral therapy (i.e., diet modification, bladder training, biofeedback, Kegel exercises) and/or pharmacotherapy (i.e., 2 or more anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant); #4 is now re: the percutaneous test stimulation. For “When not Covered” #1 - added several examples of conditions “Any conditions other than those listed above including but not limited to the following: stress incontinence, urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis or spinal cord injury), other types of chronic voiding dysfunction, patients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture.” **Section III** - Pelvic Floor Stimulation...added policy guidelines re: investigational status: “Available data are insufficient to determine whether this treatment is as effective as alternatives. Additionally, the treatments lack standardization of delivery. There are minimal data for magnetic stimulation and no randomized trials. There is insufficient medical and scientific evidence to permit the Plan to evaluate the therapeutic value of pelvic floor stimulation as a treatment of urinary incontinence. For further information, please refer to separate policy number MED1263, Investigational (Experimental) Services.” Added - **Section IV** re: Transvaginal Radiofrequency Bladder Neck Suspension for Urinary Stress Incontinence as investigational. Notice given 6/16/05. Effective date 8/18/05.

- 1/5/06 Removed deleted codes E0752, E0756, E0757, E0758 & E0759 from appropriate Billing/Coding sections.
- 2/26/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 to Section II - Sacral Nerve Modulation/Stimulation for Urinary Incontinence. (pmo)

## **New policy entitled: Periurethral Bulking Agents for the Treatment of Urinary Incontinence**

- 6/4/07 Section I (Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence) of the policy entitled “Urinary Incontinence, Treatment“ issued as a separate policy entitled “Periurethral Bulking Agents for the Treatment of Urinary Incontinence”. Newly FDA approved bulking agents added to “Description” and “When Covered” sections. Reference Sources added. (pmo)
- 7/2/07 Reference source added. (pmo)
- 9/28/09 Under When Not Covered, third bullet - added autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells) to the list of investigational periurethral bulking agents. Reference sources added. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 1/18/11 Specialty Matched Consultant Advisory Panel review 12/2010. Added code L8604 to

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policy. Added statement to “When not covered” section: “The use of periurethral bulking agents to treat urge urinary incontinence is considered investigational.” Updated Description section. Updated Policy Guidelines section. Updated references. (mco)

- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. Revised the following statement in the “When not Covered” section: “Periurethral Teflon® injection for the treatment of urinary incontinence is considered investigational and is not covered.” to “The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence is considered investigational.” References updated. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.