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## 1.0 Description of the Procedure, Product, or Service

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 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 five-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.

### 1.1 Medical Term Definitions

- a. Autologous: derived from the same organism, i.e., self donation.
- b. Collagen: a protein substance made up of the white fibers of skin, tendon, bone, cartilage and all other connective tissue.
- c. Incontinence: an inability to control the body’s elimination of waste products through urination or defecation.
- d. Periurethral: around the urethra, the natural channel or tube through which urine passes from the bladder to outside the body.
- e. Sphincter: a ring-like band of muscle fibers that constrict a passage or close a natural opening.
- f. Urethra: the natural channel or tube through which urine passes from the bladder to outside of the body.
- g. Stress Urinary Incontinence: leakage of urine as a result of coughing, sneezing, laughing, straining, or some sudden voluntary movement, due to incompetence of the sphincteric mechanisms.

## 2.0 Eligible Recipients

### 2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

## 3.0 When the Procedure, Product, or Service Is Covered

### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### 3.2 Specific Criteria

- a. The use of periurethral bulking agents for the treatment of urinary incontinence is covered under the NC Health Choice Program, when it is determined to be medically necessary and one of the following conditions are present:
  1. Incontinence due to intrinsic sphincter deficiency where the recipient has had no improvement in incontinence for at least 12 months; **OR**
  2. Stress urinary incontinence when **ALL** of the following are met:
    - (a) incontinence has been present for six (6) months;
    - (b) no other causes of stress urinary incontinence have been identified (e.g., urinary tract infection);
    - (c) stress urinary incontinence limits activities of daily living; **AND**
- b. Cross-linked collagen, carbon-coated spheres, ethylene vinyl alcohol copolymers, calcium hydroxylapatite or polydimethylsiloxane are used as the periurethral bulking agent.

### 3.3 Policy Guidelines

- a. 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.
- b. Recipients whose incontinence does not improve with five (5) injection procedures are considered treatment failures and should not receive further injections.

## **4.0 When the Procedure, Product, or Service Is Not Covered**

### **4.1 General Criteria**

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

### **4.2 Specific Criteria**

Periurethral bulking agents for the treatment of urinary incontinence are not covered in the following situations:

- a. For conditions other than those listed in **Subsection 3.2**.
- b. Periurethral Teflon® injection for the treatment of urinary incontinence is considered investigational and is not covered.
- c. 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.

## **5.0 Requirements for and Limitations on Coverage**

### **5.1 Prior Approval**

Prior approval is not required for the use of periurethral bulking agents for the treatment of urinary incontinence.

## **6.0 Providers Eligible to Bill for the Procedure, Product, or Service**

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
September 30, 2011	Throughout	Policy Date of Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

CPT Code
51715

  

HCPCS Codes
L8603
L8606
Q3031

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s)

### F. Place of Service

Inpatient Hospital and Outpatient Hospital

### G. Co-payments

Co-payment(s) may apply to covered prescriptions and services.

### H. Reimbursement

Providers must bill their usual and customary charges.