

**Policy: MP090**

**Section: Medical Benefit Policy**

**Subject: Injectable Bulking Agents for Treatment of Urinary Incontinence**

---

### **I. Policy:** Injectable Bulking Agents for Treatment of Urinary Incontinence

### **II. Purpose/Objective:**

To provide a policy of coverage regarding Injectable Bulking Agents for Treatment of Urinary Incontinence

### **III. Responsibility:**

- A. Medical Directors
- B. Medical Management

### **IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

### **V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### **Medicaid Business Segment**

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**DESCRIPTION:**

Periurethral injections of bulking agents such as collagen and synthetic agents (e.g. Durasphere™) are used for the management of patients with urinary incontinence resulting from intrinsic sphincter deficiency.

**INDICATIONS:**

The use of injectable bulking agents may be considered medically necessary when documented evidence of urinary incontinence refractory to prior non-invasive treatments (e.g., Kegel exercises and pharmacologic agents). Types of injectable bulking agents that have received FDA approval include but are not limited to the following:

1. Collagen implants (e.g., Contigen)
2. Carbon-coated beads (e.g., Durasphere)
3. Silicone elastomer (e.g., Macroplastique)
4. Spherical particles of calcium hydroxylapatite (e.g., Coaptite)

**LIMITATIONS:**

A pre-treatment skin test for the bulking agent with no evidence of local bovine hypersensitivity is required prior to collagen implantation.

**EXCLUSIONS:**

There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of other agents, as periurethral bulking agents, including but not limited to Teflon®, autologous fat, or autologous ear chondrocytes. The Plan does **NOT** provide coverage of these agents because they are considered **experimental, investigational or unproven.**

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH:**

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

51715 Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck  
L8603 Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe  
L8606 Injectable bulking agent, synthetic implant, urinary tract, 1ml syringe  
95028 Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading

**ICD10 Codes:**

N39.3

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

Technology Evaluation Center, TEC Evaluation. "Collagen implantation for the treatment of stress urinary incontinence." June 1994;9 (14):1-12.

Echols KT. Chesson RR. Breaux EF. Shobeiri SA. Persistence of delayed hypersensitivity following transurethral collagen injection for recurrent urinary stress incontinence. *International Urogynecology Journal*. 13(1):52-4, 2002.

Herschorn S. Current status of injectable agents for female stress urinary incontinence. *Canadian Journal of Urology*. 8(3):1281-9, 2001 Jun.

Lightner D, Calvosa C, Andersen R, Klimberg I, Brito CG, Snyder J, Gleason D, Killion D, Macdonald J, Khan AU, Diokno A, Sirls LT, Saltzstein D. A new injectable bulking agent for treatment of stress urinary incontinence: results of a multicenter, randomized, controlled, double-blind study of Durasphere. *Urology*. 58(1):12-5, 2001 Jul.

Dmochowski RR, Appell RA. Injectable agents in the treatment of stress urinary incontinence in women: where are we now? *Urology*. 56(6 Suppl 1):32-40, 2000 Dec 4.

Winters JC, Chiverton A, Scarpero HM, Prats LJ Jr. Collagen injection therapy in elderly women: long-term results and patient satisfaction. *Urology*. 55(6):856-61, 2000 Jun

ECRI Hotline Response: Injectable Urethral Bulking Agents for the Treatment of Urinary Stress Incontinence. 6/4/02

Lee PE, Kung RC, Drutz HP. Periurethral autologous fat injection as treatment for female stress urinary incontinence: a randomized double-blind controlled trial. *J Urol*. 2001 Jan;165(1):153-8.

Haab F, Zimmern PE, Leach GE. Urinary stress incontinence due to intrinsic sphincteric deficiency: experience with fat and collagen periurethral injections. *J Urol*. 1997 Apr;157(4):1283-6.

Kuznetsov DD, Kim HL, Patel RV, Steinberg GD, Bales GT. Comparison of artificial urinary sphincter and collagen for the treatment of postprostatectomy incontinence. *Urology*. 2000 Oct 1;56(4):600-3.

Mayer R, Lightfoot M, Jung I. Preliminary evaluation of calcium hydroxylapatite as a transurethral bulking agent for stress urinary incontinence. *Urology*. 2001 Mar;57(3):434-8.

Koelbl H, Saz V, Doerfler D, Haeusler G, Sam C, Hanzal E. Transurethral injection of silicone microimplants for intrinsic urethral sphincter deficiency. *Obstet Gynecol*. 1998 Sep;92(3):332-6.

Zullo MA, Plotti F, Bellati F, Muzii L, Angioli R, Panici PB. Transurethral polydimethylsiloxane implantation: a valid option for the treatment of stress urinary incontinence due to intrinsic sphincter deficiency without urethral hypermobility. *J Urol*. 2005 Mar;173(3):898-902.

Corcos J, Collet JP, Shapiro S, Herschorn S, Radomski SB, Schick E, Gajewski JB, Benedetti A, MacRamallah E, Hyams B. Multicenter randomized clinical trial comparing surgery and collagen injections for treatment of female stress urinary incontinence. *Urology*. 2005 May;65(5):898-904.

Siddiqui ZA, Abboudi H, Crawford R, Shah S. Intraurethral bulking agents for the management of female stress urinary incontinence: a systematic review. *Int Urogynecol J*. 2017 Sep;28(9):1275-1284

Kocjanci, E., Mourad, S., & Acar, Ö. Complications of urethral bulking therapy for female stress urinary incontinence. *Neurourology and Urodynamics*, 2019;38 (Suppl 4), S12-S20

Toia, B., Gresty, H., Pakzad, M., Hamid, R., Ockrim, J., & Greenwell, T. Bulking for stress urinary incontinence in men: A systematic review. *Neurourology and Urodynamics*, 2020;38 (7):1804-1811.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 11/93 "Contigen Implant"

**Revised:** 6/96, 2/98, 12/02 revised as "Bulking Agents for Treatment of Urinary Incontinence"; 1/04 Coding, definition; 2/06; 2/07; 2/09 (key words); 2/20 (add product names)

**Reviewed:** 2/05, 2/08, 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/21, 2/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.