MEDICAL POLICY

Medical Policy Title	**Bulking Agents for Treatment of Urinary or Fecal Incontinence**
Policy Number	**7.01.22**
Current Effective Date	April 17, 2025
Next Review Date	April 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Urinary Incontinence

I. Urethral bulking agents for the treatment of urinary incontinence may be considered **medically appropriate** if approved by the U.S. Food and Drug Administration (FDA) and meet the required criteria for the following indications:

   A. Collagen implants when the following criteria are met:

      1. **BOTH** of the following criteria:

         a. Stress incontinence due to urethral sphincter dysfunction;

         b. Unresponsive to conservative therapy;

         AND

      2. **ONE** of the following indications:

         a. Patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;

         b. Patients with acquired sphincter weakness secondary to spinal cord lesion;

         c. Biological male patients following trauma, including prostatectomy and/or radiation;

         d. Biological female patients without urethral hypermobility and with abdominal leak point pressure of 100 cm H_2O or less.

   B. Bulking agents when the following criteria are met:

      1. **ALL** of the following criteria:

         a. Treatment of stress incontinence due to intrinsic sphincter deficiency (ISD);

         b. Only in biological female patients;

         c. Unresponsive to conservative therapy;

         AND

      2. **ANY** of the following bulking agents, including but not limited to:

a. Carbon-coated beads (Durasphere);
b. Polyacrylamide hydrogel (Bulkamid);
c. Spherical particles of calcium hydroxyapatite (Coaptite);
d. Polydimethylsiloxane (silicone elastomer) particles (Macroplastique).

II. Urethral bulking agents are considered **not medically necessary** in the treatment of other types of urinary incontinence including but not limited to the following:
   A. Urinary retention with overflow incontinence;
   B. Ectopic ureter;
   C. Neurogenic bladder dysfunction;
   D. Urinary fistulas;
   E. Psychogenic incontinence.

III. Additional Durasphere implants are considered **not medically necessary** when incontinence does not improve with five (5) separate injection sessions.

IV. Urethral bulking agents are considered **investigational** for the treatment of urinary stress incontinence. include, but are not limited to, **ANY** of the following:
   A. Polytetrafluoroethylene (Teflon);
   B. Autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, adipose-derived stem cells);
   C. Microballoons (UroVive).

Fecal Incontinence

V. Perianal bulking agents to treat fecal incontinence (FI) is considered **investigational.**

RELATED POLICIES

Corporate Medical Policy

1.01.55 Electrical Stimulation as a Treatment for Pain and other Medical Conditions

7.01.10 Sacral Nerve Stimulation

8.01.22 Tibial Nerve Stimulation (TNS) for voiding Dysfunction

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Use of Durasphere is restricted to prescription use by doctors trained in cystoscope use who have completed the appropriate implant training program.

DESCRIPTION

One physiologic cause of urinary incontinence is intrinsic sphincter deficiency (ISD). ISD describes a condition in which the urethral sphincter has been damaged by surgery, neurological disorders, or trauma. The result is sphincter incompetence and urinary leakage.

Intrinsic Sphincter Deficiency

There are two types of ISD:

- Total ISD is characterized by constant involuntary dripping of urine from the urethra day and night without bladder distention, as determined by physical examination of the abdomen and measurement of residual urine.
- Partial sphincter deficiency, also known as stress incontinence, affects patients who may experience involuntary loss of urine when coughing, bending, lifting or performing any maneuver that increases transabdominal pressure.

Urethral Bulking Agents

Urethral bulking agents are substances that have been developed for use in the treatment of stress incontinence due to ISD. These substances are injected at the area of the bladder neck and proximal urethra. The increased bulk caused by these substances enhances urethral resistance to the outflow of urine, thus reducing urine leakage. Urethral bulking agents may be injected over a course of several treatments until the desired effect is achieved. The procedure for injecting urethral-bulking agents is performed either in the doctor's office or the outpatient department of a hospital.

Pyrolytic Carbon-Coated Beads (Durasphere)

Datasphere are indicated for use in the treatment of adult women with stress urinary incontinence due to ISD. Carbon beads do not require skin testing, as there is no associated antigenicity. Durasphere is injected sub-mucosal at the bladder neck in females. The final bulking result is derived from the combination of the carbon-coated beads and the body's own collagen.

Coaptite

Coaptite is an injectable implant composed of spherical particles of calcium hydroxyapatite. It is indicated for the treatment of stress urinary incontinence due to (ISD) in adult females.

Bulkamid

Bulkamid is a thick, permanent gel containing 2.5% cross-linked polyacrylamide and 97.5% apyrogenic water. It is injected into the wall of the urethra near the bladder to treat women who have stress urinary incontinence or stress predominant, mixed incontinence due to ISD.

Macroplastique

Macroplastique is an injectable soft-tissue urethral bulking agent for treating stress urinary incontinence primarily due to intrinsic sphincter deficiency. Macroplastique is made up of a water-soluble gel (polyvinylpyrrolidone) that is absorbed and removed from the body in urine; the synthetic, rubber-like, silicone elastomer implant material (cross-linked polydimethylsiloxane) is permanent and

not absorbed by the body. The silicone elastomer causes the bulking effect around the urethra after implantation.

Bulking agents injected into the anal canal have been proposed for treating fecal incontinence associated with internal anal sphincter (IAS) dysfunction. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Current treatment options for fecal incontinence include conservative measures, e.g., dietary changes, pharmacotherapy, pelvic floor muscle exercises, sacral nerve stimulation, and surgical interventions to correct an underlying problem.

SUPPORTIVE LITERATURE

Urinary Incontinence

Clinical trials investigating the safety and efficacy of Durasphere have shown that they have improved the net health outcomes of patients in the short term by achieving dryness or significant improvements in the symptoms of incontinence and provided benefits comparable to alternative treatments such as surgery.

Braga et al. (2022) conducted a systematic review, and meta-analysis on 11 articles to summarize the literature findings on the use of urethral bulking agents to manage recurrent stress urinary incontinence after failure of a mid-urethral sling. the overall cure and improvement rate ranged from 64% to 85% in the included studies, with a pooled value of 75%, compared with pooled failure and re-operation rates of 32% and 25%, respectively. A sub-group analysis was performed using bulking agents, bulkmamid and macroplastique. The pooled values of the cure and improvement rate were 84% and 80% for both of the bulking agents. While the study shows promise of using urethral bulking agents after failed mid-urethral sling, they suggest that further studies be completed.

Capobianco et al. (2019) conducted a systematic review, and meta-analysis to evaluate the efficacy and the effectiveness, safety and tolerability of urethral bulking agents (UBAs) in women with mixed or stress urinary incontinence. Out of 42 full articles only 21 were selected. The most frequently administered bulking agents were Bulkmamid and macroplastique, followed by urolastic, Macroplastique Implantation System (MIS) and durasphere. The improvement rate was higher than 50 %, with an estimated 57 % after a follow-up of>1 year. The outcome cure/dryness ranged from 9.1% to 56.7 %. The treatment success rate, assessed with different tools, ranged from 32.7% to 93.3%. The pooled objective treatment success rate was 7.0 % and 46.0 % in patients followed-up ≤12 and>12 months, retrospectively. There were several limitations based on quality, including the risk of selection bias. The study concluded that optimal injection technique has yet to be standardized. Overall, rates of complications that were associated with UBAs are low; however, long-term implications of permanent UBAs in the periurethral milieu is unknown.

Though autologous fat injections do not require FDA approval, results of clinical studies have shown poor health outcomes associated with reabsorption and fibrotic ingrowth.

Fecal Incontinence

Knowles et al., 2023, conducted a multicenter, prospective, non-randomized study of 48 participants. The objective of the study was to examine the safety and efficacy of iltamiocel, an investigational

cellular therapy of autologous muscle-derived cells, as treatment for FI. Each participant was injected with a single dose of iltamiocel. No serious adverse effects and only one product-related adverse effect of inflammation at the injection site were reported. A ≥ 50% reduction in FI episodes was observed in 53.7% of participants, and 24.4% had complete restoration of continence. Symptom severity and quality of life improved with mean Cleveland Clinic Incontinence Score reduction (-2.9; 95% CI: −3.7, −2.1), and Fecal Incontinence Quality of Life increased (2.2; 95% CI:1.4, 2.9). No significant changes were detected in anorectal manometry measurements. A history of episiotomy was significantly associated with treatment response in multivariate analysis. The administration of iltamiocel cellular therapy is safe. Iltamiocel shows promise for significantly improving fecal incontinence symptoms and quality of life.

Maeda et al., in a Cochrane Review (2013), determined the effectiveness of perianal injection of bulking agents for the treatment of fecal incontinence in adults. Five eligible randomized trials with a total of 382 patients were identified. Four of the trials were at an uncertain or high risk of bias. Most trials reported a short-term benefit from injections regardless of the material used, including placebo saline injection. One study demonstrated dextranomer in stabilized hyaluronic acid (NASHA Dx) to be more effective than sham injection, but with more adverse effects. Another study comparing silicone material (PTQ) to saline injections was too small to demonstrate a clinical benefit compared to the control injection of normal saline. A silicone biomaterial (PTQ) was shown to provide some advantages and was safer in treating fecal incontinence than carbon coated beads (Durasphere) in the short term. Similarly, there were short-term benefits from injections delivered under ultrasound guidance compared with digital guidance. No evidence on long-term outcomes was available, and further conclusions were not warranted from the available data. None of the studies reported patient evaluation of outcomes, and, thus, it is difficult to gauge whether the improvement in incontinence scores matched practical symptom improvements that mattered to the patients. The authors concluded that one large, randomized, controlled trial has shown that this form of treatment using dextranomer in stabilized hyaluronic acid (NASHA Dx) improves continence for a little over half of patients in the short term. However, the number of identified trials was limited, and most had methodological weaknesses.

PROFESSIONAL GUIDELINE(S)

Urinary Incontinence

American Urological Association (AUA) guidelines (2017; amended 2023) for the Surgical Treatment of Female Stress Urinary Incontinence (SUI):

- "Physicians should not offer stem cell therapy for stress incontinent patients outside of investigative protocols." (Expert Opinion).
- Clinicians should counsel index patients considering surgery for SUI regarding the efficacy and safety of bulking agents (Strong recommendation; Evidence Level: Grade A).

American Urogynecologic Society 2024 Clinical Practice Statement in Urethral Bulking recommend the following:

- "Urethral bulking agents are indicated in cases of stress urinary incontinence (SUI), and that intrinsic sphincter deficiency is not predictive of patient outcomes" (Grade B evidence; strength [SOR]: strong recommendation).
- "Urethral bulking agents may be considered for initial management of SUI, however the grade of evidence and strength of the recommendation were weaker" (Grade C evidence; SOR: recommendation).

Fecal Incontinence

The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management Fecal Incontinence (Bordeianou et al., 2023) state that injection of biocompatible bulking agents into the anal canal is not routinely recommended for the treatment of FI.

American Gastroenterological Association 2017 clinical practice update for Surgical Interventions and the use of Device-Aided Therapy for the Treatment of Fecal Incontinence and Defecatory Disorders suggest the following:

- "Perianal bulking agents such as intra-anal injection of dextranomor may be considered when conservative measures and biofeedback therapy fail."

REGULATORY STATUS

Urinary Incontinence

Cross-linked collagen, carbon-coated beads (Durasphere), Coaptite, Bulkamid, and Macroplastique have been approved by the FDA, but only for the treatment of urinary stress incontinence due to ISD. Durasphere, Coaptite, Bulkamid, and Macroplastique are approved only for use in biologic females. Other synthetic urethral bulking agents do not have FDA approval.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0963T (*E/I)	Anoscopy with directed submucosal injection of bulking agent into anal canal (effective 07/01/25)
46999 (*E/I)	Unlisted procedure, anus *E/I when used for Fecal incontinence ICD10 code range R15.0-R15.9
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

HCPCS Codes

Code	Description
L8603	Injectable bulking agent, collagen implant, urinary tract, per 2.5 ml syringe, includes shipping and necessary supplies
L8604 (E/I)	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1ml, includes shipping and necessary supplies
L8605 (E/I)	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

ICD10 Codes

Code	Description
N36.42-N36.43	Urethral functional and muscular disorders (code range)
N39.3	Stress incontinence (female) (male)
N39.41-N39.46	Other specified urinary incontinence (code range)
N39.498	Other specified urinary incontinence
R15.0-R15.9	Fecal incontinence of feces (code range)
R32.0	Unspecified urinary incontinence

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SEARCH TERMS

Autologous fat, periurethral, bovine collagen, carbon coated beads, Coaptite, collagen, dextranomer/hyaluronic acid, GAX, Macroplastique, microballoons, Teflon, Uryx, Tegress, Solesta, Zuidex.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Incontinence Control Devices (NCD 230.10). [accessed 2025 Mar 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
10/18/01, 06/20/02, 07/17/03, 06/17/04, 06/16/05, 06/15/06, 06/21/07, 06/19/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 06/18/15, 05/25/16, 05/18/17, 05/17/18, 05/16/19, 05/21/20, 05/20/21, 05/19/22, 05/18/23, 05/16/24, 04/17/25	
Date	**Summary of Changes**
04/17/25	• Annual review; policy intent unchanged. Codes 46999 and 0963T added.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date