MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Bulking Agents for Treatment of Urinary or Fecal Incontinence**
Policy Number	**7.01.22**
Category	**Technology Assessment**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, the use of **urethral bulking agents** for the treatment of urinary incontinence has been medically proven to be effective and, therefore, may be considered **medically appropriate** if approved by the U.S. Food and Drug Administration and meet **EITHER** of the following criteria:

A. Collagen implants are considered a **medically appropriate** treatment option in the management of stress incontinence due to urethral sphincter dysfunction that is unresponsive to conservative therapy, for **ANY** of the following:

1. Patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
2. Patients with acquired sphincter weakness secondary to spinal cord lesion;
3. Biological male patients following trauma, including prostatectomy and/or radiation;
4. Biological female patients without urethral hypermobility and with abdominal leak point pressure of 100 cm H_2O or less.

B. Bulking agents are considered **medically appropriate** for the treatment of stress incontinence due to intrinsic sphincter deficiency (ISD) only in biological female patients that are unresponsive to conservative therapy. These agents include, but not limited to, **ANY** of the following:

1. Carbon-coated beads (Durasphere);
2. Polyacrylamide hydrogel (Bulkamid);
3. Spherical particles of calcium hydroxyapatite (Coaptite);
4. Polydimethylsiloxane (silicone elastomer) particles (Macroplastique).

II. Based upon our criteria and assessment of the peer-reviewed literature, the use of **urethral bulking agents** in the treatment of other types of urinary incontinence (e.g., urinary retention with overflow incontinence, ectopic ureter,

neurogenic bladder dysfunction, urinary fistulas, or psychogenic incontinence) have not demonstrated a benefit to patient outcomes and, therefore, are considered **not medically necessary.**

III. Patients whose incontinence does not improve with five (5) injection procedures (i.e., five (5) separate treatment sessions) are considered treatment failures; further treatment of urinary incontinence in these patients by Durasphere implant is considered **not medically necessary**.

IV. Based upon our criteria and assessment of the peer-reviewed literature, the following **urethral bulking agents** have not been medically proven to be effective and, therefore, are considered **investigational** for the treatment of urinary stress incontinence. These treatments 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).

V. Based upon our criteria and assessment of the peer-reviewed literature, the use of **perianal bulking** agents to treat **fecal incontinence (FI)** is considered **investigational.**

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

Refer to Corporate Medical Policy #1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

POLICY GUIDELINE

I. 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.

There are two types of ISD:

I. 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.
II. 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 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. The goal of this procedure is to create enhanced urethral coaptation by insertion of a bulking agent that is nonimmunogenic and will not migrate from where it is injected. 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) 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 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 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 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.

Following the success of periurethral bulking agents for treating stress urinary incontinence, 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.

Several agents identical or similar to those used for urinary incontinence (e.g., Durasphere, silicone biomaterial) have been studied for the treatment of fecal incontinence. Solesta (Q-Med), a formulation of non-animal, stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx), has received FDA approval for treating fecal incontinence.

RATIONALE

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. 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. Other synthetic urethral bulking agents do not have FDA approval.

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

Cell therapy has been proposed as an alternative treatment option for urinary incontinence. The AUA guidelines (2017; amended 2023) for the Surgical Treatment of Female Stress Urinary Incontinence (SUI) states “Physicians should not offer stem cell therapy for stress incontinent patients outside of investigative protocols.” (Expert Opinion).

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.

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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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
R32	Unspecified urinary incontinence

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*Key Article

KEY WORDS

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

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Incontinence Control Devices (230.10). Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=241&ncdver=1&bc=AgAAgAAAAAAA&] accessed 02/26/24.