

MEDICAL POLICY



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| SUBJECT: BULKING AGENTS FOR TREATMENT OF URINARY OR FECAL INCONTINENCE | EFFECTIVE DATE: 09/16/99 REVISED DATE: 08/16/01, 06/20/02, 07/17/03, 06/17/04, 06/16/05, 06/15/06, 06/21/07, 06/19/08, 05/22/14 ARCHIVED DATE: 05/28/09, 06/18/15 EDITED DATE: 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/25/16, 05/18/17, 05/17/18 |
| POLICY NUMBER: 7.01.22 CATEGORY: Technology Assessment | PAGE: 1 OF: 4 |
| <ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare 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.</i> | |

POLICY STATEMENT:

- I. Based upon our criteria and review of the peer-reviewed literature, the use of urethral bulking agents for the treatment of urinary incontinence has been medically proven to be effective. Types of urethral bulking agents that have received FDA approval include:
- A. Collagen implants have been medically proven to be effective and therefore, can be considered a **medically appropriate** treatment option in the management of stress incontinence due to urethral sphincter dysfunction that is unresponsive to conservative therapy, for the following:
 1. Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
 2. Male or female patients with acquired sphincter weakness secondary to spinal cord lesion;
 3. Male patients following trauma, including prostatectomy and/or radiation; and
 4. Female patients without urethral hypermobility and with abdominal leak point pressure of 100 cm H₂O or less.
 - B. The following bulking agents have been medically proven to be effective, and therefore, are considered a **medically appropriate** treatment option in the management of only women with stress incontinence due to intrinsic sphincter deficiency (ISD) that is unresponsive to conservative therapy:
 1. Carbon-coated beads (Durasphere)
 2. Spherical particles of calcium hydroxylapatite (Coaptite®); and
 3. Polydimethylsiloxane (silicone elastomer) particles (Macroplastique®).
- II. Based upon our criteria and assessment of 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:
- A. Polytetrafluoroethylene (Teflon®),
 - B. Autologous fat, and
 - C. Microballoons (UroVive®).
- III. Based upon our criteria and assessment of peer-reviewed literature, urethral bulking agents when used in the treatment of other types of urinary incontinence (e.g., urinary retention with overflow incontinence, ectopic ureter, neurogenic bladder dysfunction, urinary fistulas and psychogenic incontinence), as yet, have not demonstrated a benefit to patient outcomes and are considered **not medically necessary**.
- IV. Based upon our criteria and assessment of peer-reviewed literature, the use of perianal bulking agents to treat fecal incontinence is considered **investigational**.

Refer to Corporate Medical Policy #7.01.68 regarding Endoscopic Injection of Bulking Agents for the Treatment of Vesicoureteral Reflux.

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POLICY GUIDELINES:

- I. Use of Durasphere® is restricted to prescription use by doctors trained in cystoscopy use who have completed the appropriate implant training program.
- II. Patients whose incontinence does not improve with 5 injection procedures (e.g., 5 separate treatment sessions) are considered treatment failures and further treatment of urinary incontinence by Durasphere® implant is considered **not medically necessary**.
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 exam 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 either performed 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-mucosally 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 hydroxylapatite. It is indicated for the treatment of stress urinary incontinence due to (ISD) in adult females.

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, and the man-made, rubber-like, silicone elastomer implant material (cross-linked polydimethylsiloxane) that 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 SUI, 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 and pelvic floor muscle exercises, sacral nerve stimulation, and surgical interventions to correct an underlying problem.

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

RATIONALE:

Urinary Incontinence

Cross-linked collagen, carbon-coated beads (Durasphere®), Coaptite®, and Macroplastique® have been approved by the FDA, but only for the treatment of urinary stress incontinence due to ISD. Durasphere®, Coaptite®, and Macroplastique® are approved only for use in women. 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. 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. Long-term effectiveness of these urethral-bulking agents has yet to be established.

Fecal Incontinence

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. Dextranomer in stabilized hyaluronic acid (NASHA Dx) was better than sham injections at six months (65/136, 48% versus 48/70, 69%) participants not improved, defined as less than 50% reduction in incontinence episodes, (RR 0.70, 95% CI 0.55 to 0.88); with more incontinence free days (3.1 days compared with 1.7 in the sham treatment group, median 1.40 days, 95% CI 0.33 to 2.47). 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 carboncoated beads (Durasphere®) in the short term. Similarly, there were short term benefits from injections delivered under ultrasound guidance compared with digital guidance. No long term evidence on 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 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: Number Description

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.

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| <u>CPT:</u> | 51715 | Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck |
| | 0377T (E/I) | Anoscopy with directed submucosal injection of bulking agent for fecal incontinence |

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| HCPCS: | L8603 | Injectable bulking agent, collagen implant, urinary tract, per 2.5 ml syringe, includes shipping and necessary supplies |
| | L8604 | Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies |
| | L8605 | 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: | N36.42-N36.43 | Urethral functional and muscular disorders (code range) |
| | N39.3 | Stress incontinence (female) (male) |
| | N39.41-N39.46, N39.44-N39.46 | Other specified urinary incontinence (code range) |
| | N39.498 | Other specified urinary incontinence |
| | R32 | Unspecified urinary incontinence |

REFERENCES:

BlueCross BlueShield Association. Periurethral bulking agents for the treatment of urinary and fecal incontinence. Medical Policy Reference Manual Policy #7.01.19. 2017 Aug 10.

Maeda Y, et al. Perianal injectable bulking agents as a treatment for faecal incontinence in adults. Cochrane Database Syst Rev. 2013 Feb 28;2:CD007959.

Maslekar S, et al. Injectable collagen for the treatment of fecal incontinence: long-term results. Dis Colon Rectum 2013 Mar;56(3):354-9.

U.S. Food and Drug Administration. Summary of safety and effectiveness data for Coaptite®. Available at [http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040047b.pdf] accessed 4/25/18.

U.S. Food and Drug Administration. Durasphere injectable bulking agent. Available at [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980053S016] accessed 4/25/18.

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KEY WORDS:

Autologous fat, periurethral, Bovine collagen, Carbon coated beads, Coaptite®, Collagen, GAX, Macroplastique®, Microballoons, Teflon®, Uryx®, Tegress®, Solesta.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Incontinence Control Devices. 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=AgAAgAAAAA&>