BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Bulking Agents (Urinary):
Bulking agents are endoscopically injected around the urethra or the ureter(s) to increase tissue bulk thereby increasing resistance to the outflow of urine. Types of bulking agents include:

- Calcium hydroxylapatite (Coaptite®)
- Collagen
- Deflux® Injectable Gel
- Durasphere® Carbon Coated Beads
- Macroplastique®
- Teflon (Polytef® Paste)
- Zuidex™ Implacer™ System
- Autologous fat or autologous ear chondrocytes (Fat is harvested from the lower abdomen or chondrocytes are grown from a tissue biopsy of the individual's ear cartilage. Food and Drug Administration (FDA) approval is not required for autologous materials.)
- Autologous cellular therapy with fibroblasts, myoblasts, adipose-derived or muscle-derived stem cells

INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE (cont.)

Description: (cont.)

Bulking Agents (Fecal):
Collagen bulking agent has been investigated as a treatment for fecal incontinence to increase tissue bulk, thereby increasing resistance to the outflow of feces.

Perianal bulking agents have been investigated as a treatment for fecal incontinence. 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. Perianal bulking agents include, *but are not limited to:*

- Durasphere®
- Gatekeeper
- Solesta®

Definitions:

Urgency-Frequency:
Uncontrollable urge to urinate that results in very frequent, small volumes.

Urinary Retention:
Inability to completely empty the bladder of urine.

Urinary Stress Incontinence:
Involuntary loss of urine from the urethra due to increased intra-abdominal pressure.

Urinary Urge Incontinence:
Leakage of urine when there is a strong urge to void.

Vesicoureteral Reflux (VUR):
Abnormal condition in which urine flows backward from the bladder to the kidneys. This condition causes recurrent urinary tract infections.

Grade I: Mild form and generally treated with antibiotics
Grade II – IV: Treated with bulking agents
Grade V: Treated with open surgery

INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE (cont.)

Criteria:

Urinary Incontinence:

Coaptite, Durasphere, and Macroplastique:

- Coaptite, Durasphere, or Macroplastique for the treatment of stress incontinence is considered ***medically necessary*** for individuals who have failed appropriate conservative therapy.

- Coaptite, Durasphere, or Macroplastique for all other indications not previously listed is considered ***experimental or investigational*** based upon lack of final approval from the Food and Drug Administration.

  These indications include, *but are not limited to:*

  - Urge incontinence

Polytef Paste (Teflon):

- Polytef paste for the treatment of urinary incontinence is considered ***experimental or investigational*** based upon a lack of final approval from the Food and Drug Administration.

Zuidex Implacer System:

- Zuidex Implacer system is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Autologous Fat and Ear Chondrocytes:

- Autologous fat or autologous ear chondrocytes for the treatment of urinary incontinence is considered ***experimental or investigational*** based upon a lack of scientific evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE (cont.)

Criteria: (cont.)

Urinary Incontinence: (cont.)

Autologous Cellular Therapy:

- Autologous cellular therapy for the treatment of urinary incontinence is considered ***experimental or investigational*** based upon a lack of scientific evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Fecal Incontinence:

Injectable Perianal Bulking Agents:

- Injectable perianal bulking agents for the treatment of fecal incontinence are considered ***experimental or investigational*** based upon:

    1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
    2. Insufficient evidence to support improvement of the net health outcome, and
    3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
    4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Resources prior to 05/22/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.19 BCBS Association Medical Policy Reference Manual. Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence. Re-issue date 03/13/2014, issue date 12/01/1995.

2. La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of faecal incontinence. *Colorectal Dis.* May 2013;15(5):569-574.

3. Lightner DJ, Fox J, Klingele C. Cystoscopic injections of dextranomer hyaluronic acid into proximal urethra for urethral incompetence: efficacy and adverse outcomes. *Urology.* Jun 2010;75(6):1310-1314.

INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE (cont.)

Resources: (cont.)

4. Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. *Cochrane Database Syst Rev.* 2013;2:CD007959.

5. Sangster P, Morley R. Biomaterials in urinary incontinence and treatment of their complications. *Indian J Urol.* Apr 2010;26(2):221-229.

FDA Premarket Approval Database for Coaptite®:

- FDA-approved indication: Treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult females.

FDA Premarket Approval Database for Durasphere®:

- FDA-approved indication: Treatment of adult women with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD).

FDA Premarket Approval Database for Macroplastique®:

- FDA-approved indication: For transurethral injection in the treatment of adult women diagnosed with stress urinary incontinence (sui) primarily due to intrinsic sphincter deficiency (ISD).

FDA Premarket Approval Database for Polytef® Paste:

- FDA-approved indication: Vocal cord augmentation.

FDA Premarket Approval Database for Solesta:

- FDA-approved indication: For the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications).