

## Bulking Agents for the Treatment of Urinary Stress Incontinence and Vesicoureteral Reflux

<b>Policy ID:</b>	HHO-DE-MP-1188
<b>Approved By:</b>	Highmark Health Options – Market Leadership
<b>Provider Notice Date:</b>	
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<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
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### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary bulking agents for the treatment of urinary stress incontinence and vesicoureteral reflux.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

**Vesicoureteral Reflux (VUR)** – The retrograde flow of urine from the bladder upward toward the kidney. Bulking agents can be injected into tissue around the ureteral orifices to minimize reflux.

### PROCEDURES

1. A prior authorization is required.
2. Urinary stress incontinence

The use of United States Food and Drug Administration (U.S. FDA) approved bulking agents for the treatment of urinary stress incontinence may be considered medically necessary in individuals who have failed appropriate conservative therapy for at least three (3) months.

- Note: Conservative therapy for stress urinary incontinence may include:
  - Pelvic floor muscle exercises (Kegel exercises); or
  - Behavioral changes, such as:
    - Fluid management; or
    - Smoking cessation; or
    - Weight loss; or
    - Moderation of physical activities that provoke stress urinary incontinence; or
  - Additional options may include:
    - Intravaginal estrogen therapy; or
    - Use of a pessary; or
    - Treatment of other underlying causes of stress incontinence in individuals amenable to these treatments.

Additional treatments for reoccurrence of stress urinary incontinence with a periurethral bulking agent may be considered medically necessary following successful treatment in the past six (6) to 12 months.

Further treatment of stress urinary incontinence with a bulking agent is considered not medically necessary when there is failure to improve after five (5) separate treatment sessions.

The use of bulking agents to treat stress urinary incontinence not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the published peer-reviewed literature including but not limited to the following:

- Teflon; and
- Autologous fat; and
- Autologous ear chondrocytes; and
- Autologous cellular therapy, including but not limited to:
  - Myoblasts; and
  - Fibroblasts; and
  - Muscle derived stem cells; and
  - Adipose derived stem cells.

### 3. Vesicoureteral reflux

The use of U.S. FDA approved periureteral bulking agents for the treatment of pediatric individuals with VUR grades II, III, or IV may be considered medically necessary when medical therapy has failed, and surgical intervention is otherwise indicated.

The use of periurethral bulking agents for VUR not meeting the criteria as indicated in this policy is considered not medically necessary.

The use of bulking agents is contraindicated in individuals with:

- Nonfunctioning kidney(s); or
- Hutch diverticuli; or

- Active voiding dysfunction; or
- Ongoing urinary tract infection.

4. Post-payment audit statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

5. Place of service: inpatient/outpatient

Experimental/investigational (E/I) services are not covered regardless of place of service.

The treatment of urinary stress incontinence and/or vesicoureteral reflux is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

### CODING REQUIREMENTS

CPT code	Description
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck.
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 MI syringe, includes shipping and necessary supplies.
52327	Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material.

### COVERED DIAGNOSIS CODES FOR 51715, L8606

Codes						
N36.42	N36.43	N39.3				

### COVERED DIAGNOSIS CODES FOR 52327

Codes						
<b>N11.0</b>	N13.70	N13.71	N13.72	N13.721	N13.722	N13.729
<b>N13.73</b>	N13.731	N13.732	N13.739			

### REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

### POLICY SOURCE

**American Urological Association et al – 2017.**

The 2017 joint guidelines on surgical treatment of female stress urinary incontinence from the American Urological Association and Society of Urodynamics, Female Pelvic Medicine and Urogenital

Reconstruction stated that bulking agents are an option for patients considering surgery for stress urinary incontinence (SUI). The guidelines also stated that there are few long-term data on the efficacy of bulking agents and that retreatment is common.

In 2017, the American Urological Association reviewed and confirmed the validity of its 2010 published guideline on the management of primary VUR in children. The Association recommended that [individuals] older than one (1) year of age who have a febrile breakthrough urinary tract infection while receiving continuous antibiotic prophylaxis be considered for open surgery or endoscopic injection of bulking agents.

## Reference

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**POLICY UPDATE HISTORY**

<Date>	<Event>
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