

Medica Central Coverage Policy

Policy Name: Urethral Bulking Agents for Urinary Incontinence MP9475

Effective Date: 09/01/2024

Important Information - Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

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Note: This policy is no longer scheduled for routine review of the scientific literature.

Urethral bulking agents which are FDA approved for stress incontinence are **COVERED** as a second line treatment for urinary incontinence due to sphincter deficiency or congenital anomalies.

Description

Urethral bulking agents are prosthetic devices used to treat stress urinary incontinence when the urethral sphincter is not able to contract sufficiently to hold back urine in the bladder. Implantation sites vary depending upon the mode of action of a particular agent, but are generally injected into the submucosal tissues of the urethra. Some agents may be injected into the bladder neck and/or into tissues adjacent to the urethra to add bulk to the bladder neck. This is intended to narrow the sphincter and increase resistance in order to reduce or eliminate urinary incontinence. Urethral bulking agents are intended only for patients who have shown no improvement in their incontinence for at least 12 months. Maximum effectiveness may require several injections over a period of time.

FDA Approval

The Contigen®/Bard® Collagen Implant (C. R. Bard, Inc., Murray Hill, NJ) received initial FDA approval on September 30, 1993 as a Class III device. Approval was granted for the treatment of urinary incontinence due to intrinsic sphincter deficiency that may be helped by a locally injected bulking agent. Supplemental approvals have been granted for the device.

Durasphere™ Injectable Bulking Agent (Advanced UroScience, Inc., St. Paul MN) received initial FDA approval on September 13, 1999, as a Class III device intended for the treatment of "adult women with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD)." Supplemental approvals have been granted for the device.



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The FDA approved Uryx® (Genyx Medical, Inc., Aliso Viejo, CA/C.R. Bard, Inc., Murray Hill, NJ) December 16, 2004 under a premarket approval (PMA) process. It is indicated for treatment of adult women diagnosed with stress urinary incontinence due to intrinsic sphincter deficiency.

Prior Authorization

Prior authorization is not required.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

• **51715** - Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

HCPC Codes:

- **L8603** Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
- L8604 Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract,
 1 ml, includes shipping and necessary supplies
- L8606 Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

	Committee/Source	Date(s)
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