PERIURETHRAL BULKING AGENTS FOR THE TREATMENT OF URINARY INCONTINENCE

SUR710.008

BlueReview POSTED DATE: 11/17/2003
EFFECTIVE DATE: 10/24/2003

COVERAGE:

Periurethral bulking agents (cross linked collagen or carbon-coated spheres) are considered medically necessary for the treatment of Stress Urinary Incontinence (SUI), if the following conditions are met:

1. There is no improvement in incontinence for at least 12 months during which time, conventional and non-surgical treatments have been attempted and failed; and

2. A pre-treatment skin test is administered for cross link collagen bulking agents with no evidence of local hypersensitivity completed one month prior to the procedure.

Patients whose incontinence does not improve after 5 treatment procedures are considered treatment failures and additional treatment procedures will not be covered.

The following materials, when used for periurethral bulking agents, are considered experimental or investigational:

• Teflon (registered),
• Silicone Micro-Implants, or
• Autologous Fat.

DESCRIPTION:

Periurethral bulking agents are substances that are injected periurethrally either suburethrally through a cystoscopy with a spinal needle inserted percutaneously, or transvaginally with cystoscopic control. The bulking agent increases the tissue bulk, resulting in enhancement of the mucosal seal effect and enables the sphincter to protect against increases in intravesical pressure by increasing the resistance to the outflow of urine.

RATIONALE:

Periurethral bulking agents are recognized as treatment options for both men and women with stress incontinence. The Food and Drug Administration (FDA) has approved glutaraldehyde cross-linked (GAX) bovine collagen implantation, also known as Contigen® or Bard® for the use as a bulking agent in the treatment of (SUI). The 1996 Clinical Practice Guidelines for Urinary Continence in Adults, developed by the agency for Health Care Policy and Research (AHCPR) concluded that periurethral collagen is curative in 32% of men and 62% of women. Success may be maximized in men by assessing outcome after 4
injections and focusing treatment in those with milder degrees of incontinence. Carbon-coated beads (Durasphere) are a recently FDA approved alternative to cross-linked collagen. They are designed to provide a more durable effect. A double blind randomized study comparing the Durasphere to Contigen was reported to the FDA as part of the FDA-approval process. At the end of the 12-month study period the two agents reported equal effectiveness. There was also no difference in the number of treatments between the two groups. The trial length of twelve months might not have been long enough to assess comparative durability.

At this time, the FDA has not approved the following substances for the use as a periurethral bulking agent for the treatment of urinary incontinence:

- Teflon (registered),
- Silicone Micro-Implants, or
- Autologous Fat.

PRICING:
None

REFERENCES:


DISCLAIMER:

State and federal law, as well as contract language, including

Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company
Southwest Texas HMO, Inc., d/b/a HMO Blue® Texas
* Independent Licensees of the Blue Cross and Blue Shield Association
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Definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.
HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.