URINARY DISORDER TREATMENTS

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.

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Description:

Artificial Urinary Sphincter (AUS):
AUS restores continence by keeping the urethra closed until the individual wants to urinate. The following components of the AUS are connected by tubing and filled with saline solution or a contrast medium:

- Cuff is surgically placed around the urethra to keep it closed
- Balloon is surgically placed near the bladder to control the amount of pressure exerted by the cuff
- Control pump is surgically placed in the scrotum to facilitate voiding

To urinate, the pump is squeezed to move fluid from the cuff to the pressure-regulating balloon. Afterward, the fluid automatically returns from the balloon to the cuff, restoring continence again.

Physical Therapy:
Techniques include pelvic floor muscle training and exercises designed to strengthen pelvic floor muscles.
URINARY DISORDER TREATMENTS (cont.)

Description: (cont.)

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

Criteria:

Artificial Urinary Sphincter:

- Implantation of an artificial urinary sphincter (AUS) for treatment of urinary incontinence is considered medically necessary with documentation of ALL of the following:

  1. Incontinence is secondary to permanent neurological dysfunction of bladder sphincter (i.e., radical prostatectomy)
  2. Failure to respond to 6 months of conservative treatment.
URINARY DISORDER TREATMENTS (cont.)

Criteria: (cont.)

Physical Therapy:

- Physical therapy for the treatment of stress urinary incontinence is considered *medically necessary*.

- Physical therapy for the treatment of urinary incontinence other than stress urinary incontinence is 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.

Vesicoureteral Reflux Treatments:

- Deflux for the treatment of individuals ages 1 through 18 with vesicoureteral reflux, grades II – IV is considered *medically necessary* when medical therapy has failed and surgical intervention is otherwise indicated.

- Deflux for all other indications not previously listed is considered *experimental or investigational* based upon lack of final approval from the Food and Drug Administration.
URINARY DISORDER TREATMENTS (cont.)

Resources:


URINARY DISORDER TREATMENTS (cont.)

Resources: (cont.)


URINARY DISORDER TREATMENTS (cont.)

Resources: (cont.)


FDA Premarket Approval Database for AMS Sphincter 800™ Urinary Control System:

- FDA-approved indication: Urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.

FDA Premarket Approval Database for Deflux® Injectable Gel:

- FDA-approved indication: Treatment of children with vesicoureteral reflux.

FDA 510K Summary for MyoTrac Infiniti™:

- FDA-approved indication: For acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: Inhibition of the detrusor muscle through reflexive mechanisms, strengthening of pelvic floor muscle. It is also indicated during incontinence treatment for assessing EMG activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles. It is also indicated for the ongoing treatment of the following conditions: relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, maintaining or increasing range of motion and stroke rehab by muscle re-education.
URINARY DISORDER TREATMENTS (cont.)

Resources: (cont.)

FDA 510K Summary for perineometer. Device names include, but are not limited to:

InCare™ Pelvic Floor Therapy System/Biofeedback Device
Periform® Perineometric Probe

- FDA-approved indication: Biofeedback. To improve the voluntary control and strength of the pelvic floor muscles for the treatment of urinary incontinence.

AMS Sphincter 800 is a trademark of American Medical Systems, an independent corporation that is not affiliated with BCBSAZ.
Deflux is a registered trademark of Galderma S.A, an independent corporation that is not affiliated with BCBSAZ.
InCare is a trademark of Hollister, Inc., an independent corporation that is not affiliated with BCBSAZ.
MyoTrac Infiniti is a trademark of Patterson Medical, an independent corporation that is not affiliated with BCBSAZ.
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