URINARY DISORDER TREATMENTS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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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URINARY DISORDER TREATMENTS (cont.)

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. FDA approved devices include AMS Sphincter 800™ Urinary Control System and ProACT™ Adjustable Continence Therapy for Men.

Physical Therapy:
Techniques include pelvic floor muscle training and exercises designed to strengthen pelvic floor muscles.

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. FDA-approved bulking agent includes Deflux® Injectable Gel.

Grade I: Mild form and generally treated with antibiotics
Grade II – IV: Treated with bulking agents
Grade V: Treated with open surgery
URINARY DISORDER TREATMENTS (cont.)

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 or transurethral resection of the prostate (TURP))
  2. Failure to respond to 6 months of conservative treatment

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 (prophylactic antibiotics) 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:

Literature reviewed 01/11/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


URINARY DISORDER TREATMENTS (cont.)

Resources: (cont.)


URINARY DISORDER TREATMENTS (cont.)

Resources: (cont.)


URINARY DISORDER TREATMENTS (cont.)

Resources: (cont.)

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.

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

InCare™ Pelvic Floor Therapy System/Biofeedback Device

- FDA-approved indication: Biofeedback. To improve the voluntary control and strength of the pelvic floor muscles for the treatment of urinary incontinence.
URINARY DISORDER TREATMENTS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah nilníígíí Blue Cross Blue Shield of Arizona haada yit’éęgo bína’ídiłkidgo éi doodago Háida bíjá aníyeedíígií t’áadoo le’é yína’ídiłkidgo beehaz’áníii hóó díí t’áa hazaadk’éhjí háká a’doowolgo bee haz’á doo bañí ilíígóó. Ata’ halne’ígí kojí bích’í’hodíílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話。在此插入數字 877-475-4799.

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تعتمد أسفلها خصوصية الضرورية بلغتك من دون أي تكلفة. للتحدث مع مترجم الصلب. 877-475-4799.
URINARY DISORDER TREATMENTS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang na makakuha ng tulong at impormasyon sa iyong wika ng walang gustos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하의 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동의사항에 따라하기 위해서는 877-475-4799로 전화해주세요.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi: اگر شما یا کسی که شما به او کمک می‌کنید، سوالی که در مورد اطلاعاتی به زبان خود را به طور رایگان دریافت می‌کنید 877-475-4799 یکی می‌دانید.

Assyrian: Blue Cross Blue Shield of Arizona یکی می‌دانید، یا کسی که شما به او کمک می‌کنید، سوالی که در مورد اطلاعاتی به زبان خود را به طور رایگان دریافت می‌کنید 877-475-4799 یکی می‌دانید.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่เก็บค่าใช้จ่าย โทรคุยกับเราที่ 877-475-4799.