PROSTATIC URETHRAL LIFT

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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PROSTATIC URETHRAL LIFT (cont.)

Description:

Benign Prostatic Hypertrophy (BPH):
BPH is a non-cancerous enlargement of the prostate. As the prostate enlarges, it presses against the urethra causing the urethra to narrow. The bladder wall becomes thicker and begins to contract even when there is only a small amount of urine in the bladder. Eventually the bladder weakens and loses ability to empty completely.

Prostatic urethral lift (PUL) is a minimally invasive procedure to relieve lower urinary tract symptoms (LUTS) associated with BPH. The prostatic urethral lift procedure includes placement of one or more implants in the lateral lobes of the prostate using a transurethral delivery device. The implants maintain an expanded urethral lumen. The UroLift® System has received FDA approval and includes 2 components: the delivery device and the implant.

Criteria:

- Prostatic urethral lift in individuals with moderate-to-severe lower urinary tract obstruction due to benign prostatic hyperplasia is considered medically necessary with documentation of ALL of the following:
  1. Individual has failed an adequate trial of medication therapy¹ or is intolerant to, or has a contraindication to a trial of medication.
  2. Prostate gland volume is ≤80 mL.
  3. Prostate anatomy demonstrates normal bladder neck without a median lobe predominant obstruction.
  4. No urinary tract infection or recent prostatitis.
  5. If prostate-specific antigen level greater than normal for age, appropriate testing has excluded diagnosis of prostate cancer.
  6. No contact dermatitis nickel allergy.
PROSTATIC URETHRAL LIFT (cont.)

Criteria: (cont.)

- Use of prostatic urethral lift for all other indications not previously listed or if above criteria not met 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Adequate medication is defined as one of the following:

- 7 days of a α-adrenergic blockers (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin)
- 3 months of a 5α-reductase inhibitor (e.g., finasteride, dutasteride)
- 3 months of a combination α-adrenergic blocker and 5α-reductase inhibitor.

Resources:

Literature reviewed 09/18/18. 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.


PROSTATIC URETHRAL LIFT (cont.)

**Resources:** (cont.)


PROSTATIC URETHRAL LIFT (cont.)

Resources: (cont.)


PROSTATIC URETHRAL LIFT (cont.)

Resources: (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: Dii kwe’ é atah nilíñígíí Blue Cross Blue Shield of Arizona haadá yíti’éego bina’ídilkidgo éí doodago Háida bíí jí aníllyeeédííi t’aadóo le’é yina’ídilkidgo beehaz’áanii hólo díí t’aá hazaadk’ehíí háká a’doowolgo bee haz’a doo báq bíí hínígóó. A’ hal’jíí koi di bíchí’í’ hodilííííh 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 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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viễn, xin gọi 877-475-4799.

Arabic: إن كان لديك أو أدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona الضرورية ببلاغ من دون أية تكلفة، للتحدث مع مترجم الصل ب 877-475-4799.
PROSTATIC URETHRAL LIFT (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay mga may katarungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang na may mga matutulungan tungkol sa iyong wika ng walang gastos. Upang malasag 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 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그러한 통역사와 얘기하기 위해서는 877-475-4799로 전화하십시오.

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:

 Persian: اگر شما یا کسی که شما به آن کمک می‌کنید، سوال‌های مربوط به Blue Cross Blue Shield of Arizona دارد، شما به آن کمک کنید، بهمراه که آنها در زبان خود را به طور رایگان دریافت نمایید. 877-475-4799.

Assyrian:

 Assyrian: Blue Cross Blue Shield of Arizona تل. 877-475-4799.

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

Thai: หากคุณ หรือคู่หูของคุณมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสมควรจะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่เสียเงิน สายด่วนฟรีที่ 877-475-4799.