



MEDICAL COVERAGE GUIDELINES
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 05/09/17
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/04/18
ARCHIVE DATE:

PROSTATE-SPECIFIC ANTIGEN (PSA)

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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Description:

Prostate-specific antigen (PSA) is a glycoprotein that is expressed by both normal and neoplastic prostate tissue. The absolute value of serum PSA is useful for determining the extent of prostate cancer and assessing the response to prostate cancer treatment; its use as a screening method to detect prostate cancer is also common.



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Criteria:

- Prostate-specific antigen testing in males and in transgender male-to-female is considered **medically necessary**.
- Prostate-specific antigen testing 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.

Resources:

Literature reviewed 09/04/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. Bouvet JP, Gresenguet G, Belec L. Vaginal pH neutralization by semen as a cofactor of HIV transmission. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases*. Feb 1997;3(1):19-23.
2. Diamandis EP, Stanczyk FZ, Wheeler S, et al. Serum complexed and free prostate-specific antigen (PSA) for the diagnosis of the polycystic ovarian syndrome (PCOS). *Clinical chemistry and laboratory medicine*. Mar 31 2017.
3. Duraker N, Caynak ZC, Trabulus DC. Free/Total Serum Prostate-Specific Antigen Ratio in Women with Colorectal Cancer Has Prognostic Significance. *Journal of gastrointestinal cancer*. Mar 2017;48(1):8-12.
4. Gion M, Cardinali G, Trevisiol C, Zappa M, Rainato G, Fabricio ASC. Indicators of inappropriate tumour marker use through the mining of electronic health records. *Journal of evaluation in clinical practice*. Aug 2017;23(4):895-902.
5. Jahir ET, Devi R, Borthakur BB. Study of Serum Total PSA and Free PSA as an Oncological Marker in Breast Tumour. *Journal of clinical and diagnostic research : JCDR*. Mar 2017;11(3):Bc13-bc16.
6. Kulczycki A, Brill I, Snead MC, Macaluso M. Prostate-specific antigen concentration in vaginal fluid after exposure to semen. *Contraception*. Nov 2017;96(5):336-343.



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Resources: (cont.)

7. Li D, Radulescu A, Shrestha RT, et al. Association of Biotin Ingestion With Performance of Hormone and Nonhormone Assays in Healthy Adults. *Jama*. Sep 26 2017;318(12):1150-1160.
8. Musrap N, Diamandis EP. Prostate-Specific Antigen as a Marker of Hyperandrogenism in Women and Its Implications for Antidoping. *Clinical chemistry*. Aug 2016;62(8):1066-1074.
9. Roberts ST, Flaherty BP, Deya R, et al. Patterns of Gender-Based Violence and Associations with Mental Health and HIV Risk Behavior Among Female Sex Workers in Mombasa, Kenya: A Latent Class Analysis. *AIDS and behavior*. Mar 30 2018.
10. Rudnicka E, Radowicki S, Suchta K. Prostate specific antigen (PSA) in diagnosis of polycystic ovarian syndrome - a new insight. *Gynecological endocrinology : the official journal of the International Society of Gynecological Endocrinology*. Nov 2016;32(11):931-935.
11. Surie D, Yuhua K, Wilson K, et al. Association between non-barrier modern contraceptive use and condomless sex among HIV-positive female sex workers in Mombasa, Kenya: A prospective cohort analysis. *PloS one*. 2017;12(11):e0187444.
12. Suttipapit P, Wongwittayapanich S. Detection of prostate specific antigen and semenogelin in specimens from female rape victims. *Journal of forensic and legal medicine*. Feb 2018;54:102-108.
13. UpToDate.com. Measurement of prostate-specific antigen. 04/18/2017.
14. Wilson KS, Wanje G, Masese L, et al. A prospective cohort study of fertility desire, unprotected sex, and detectable viral load in HIV-positive female sex workers in Mombasa, Kenya. *Journal of acquired immune deficiency syndromes (1999)*. Mar 13 2018.



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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 nilínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínigóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 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 thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

