

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	6/19/2012	Policy Last Updated:	6/19/2012
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

A variety of gene based biomarkers have been associated with prostate cancer. These tests have the potential to improve the accuracy of risk prediction, diagnosis, staging, or prognosis of prostate cancer.

Prostate cancer is a complex, heterogeneous disease. At the extremes of the spectrum, if left untreated, some prostate cancers behave aggressively, metastasize quickly, and cause mortality, while others are indolent and never progress to cause harm. Current challenges in prostate cancer care are risk assessment; early and accurate detection; monitoring low-risk patients undergoing surveillance only; prediction of recurrence after initial treatment; detection of recurrence after treatment; and assessing efficacy of treatment for advanced disease.

In response to the need for better biomarkers for risk assessment, diagnosis, and prognosis, a variety of exploratory research is ongoing. Some products of this work have already been translated or are in the process of being translated into commercially available tests, including:

- single-nucleotide polymorphisms (SNPs) for risk assessment
- prostate cancer antigen 3 (PCA3) for disease diagnosis and prognosis
- transmembrane serine protease (TMPRSS) fusion genes for diagnosis and prognosis
- multiple gene tests (gene panels) for prostate cancer diagnosis
- gene hypermethylation for diagnosis and prognosis

While studies using these tests generate much information that may help elucidate the biologic mechanisms of prostate cancer and eventually help design treatments, the above-mentioned tests are in a developmental phase.

Although the PCA3 test has been approved by the FDA through the premarket approval process, it is not covered. At this time, evidence on the clinical validity of genetic tests related to prostate cancer screening, detection, and management is variable and incomplete, leaving considerable uncertainty regarding the clinical performance characteristics such as sensitivity, specificity, and predictive value. Some tests show evidence for predictive ability in the diagnosis or prognosis of prostate cancer, however, incremental accuracy in comparison to currently available tests has not been demonstrated. In addition, these data do not demonstrate clinical utility, i.e., that using a test will change treatment decisions and improve subsequent outcomes. Therefore, use of gene based testing for risk assessment, diagnosis, prognosis, and management of prostate cancer is not covered.

Medical Criteria:

Gene based testing for risk assessment, diagnosis, prognosis, and management of prostate cancer is not covered as there is a lack of conclusive data stating that using these tests will change treatment decisions and improve subsequent outcomes.

Policy:

Genetic tests for the screening, detection, and management of prostate cancer are considered **not medically necessary**. This includes, but is not limited to the following:

- single-nucleotide polymorphisms (SNPs) for risk assessment; or
- PCA3 for disease diagnosis and prognosis; or
- TMPRSS fusion genes for diagnosis and prognosis; or
- multiple gene tests (gene panels) for prostate cancer diagnosis; or
- gene hypermethylation for diagnosis and prognosis.

Coverage:

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for applicable not medically necessary benefits/coverage.

Codes:

The following code is **not medically necessary**:

S3721

Also known as:

Not applicable

Related topics:

Not applicable

Published:

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References:

American Urological Association (AUA). Prostate Cancer. Guideline for the management of clinically localized prostate cancer: 2007 update.

Blue Cross and Blue Shield Association. Medical Policy Reference Manual. Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer (2.04.33) 3:2012.

Blue Cross Blue Shield Technology Evaluation Center (TEC). Special Report: Recent Developments in Prostate Cancer Genetics and Genetic Testing. Volume 23, No. 7; January 2009.

Roobol MJ, Schroder FH, van Leeuwen P, et al. Performance of the Prostate Cancer Antigen 3 (PCA3) Gene and Prostate-Specific Antigen in Prescreened Men: Exploring the Value of PCA3 for a First-line Diagnostic Test. *European Urology*;5 8;2 0 1 0:4 7 5 - 4 8 1.

Wright JL, Lange PH. Newer Potential Biomarkers in Prostate Cancer. *Reviews in Urology*;2007(Fall);9(4):207–213.

Xie C, Kim HJ, Haw JG, et al. A novel multiplex assay combining autoantibodies plus PSA has potential implications for classification of prostate cancer from non-malignant cases. *Journal of Translational Medicine*;2011:9:43.

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