

Corporate Medical Policy

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

File Name: gene_based_tests_for_screening_detection_or_management_of_prostate_cancer
Origination: 4/2009
Last CAP Review: 8/2011
Next CAP Review: 8/2012
Last Review: 4/2012

Description of Procedure or Service

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.

SNP testing as part of genome-scanning tests with risk assessments for prostate cancer are offered by a variety of laboratories including Navigenics, LabCorp (23andme), and ARUP (deCode) as laboratory-developed tests. The PCA3 test is offered in the U.S. by a number of reference laboratories including ARUP, Mayo Medical Laboratories, and LabCorp. The reagents used in testing are developed by Gen-Probe. The Prostate Gene Expression Profile was widely announced as available from Clariant, Inc. in January 2009; as of March 2011, the test no longer appears on the listing at the company website. A test for hypermethylation of GSTP1 is currently available from LabCorp (“Glutathione S-transferase Gene [GSTP1, pi-class] Methylation Assay”), and the required specimen is formalin-fixed, paraffin-embedded tissue. The test is stated to be an adjunct to histopathology. Epigenomics AG (Frankfurt, Germany) has entered licensing agreements with two U.S. laboratories (Quest and Predictive Biosciences) to establish and commercialize laboratory-developed tests for its proprietary methylation biomarker GSTP1. This test is not yet available, and it is unclear what matrices will be used.

Regulatory Status

Only PCA3 has been submitted to the U.S. Food and Drug Administration (FDA) for premarket approval.

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The Gen-Probe PROGENSA® PCA3 Assay was approved by the FDA on February 15, 2012 through the premarket approval process. According to the company's press release, this assay is "indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on the current standard of care, before consideration of PROGENSA PCA3 assay results."

The other tests mentioned in this policy, if available, are offered as laboratory-developed tests under the Clinical Laboratory Improvement Amendments (CLIA) licensed laboratories

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

Genetic tests for the screening, detection, and management of prostate cancer are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Gene-Based Tests for Screening, Detection, or Management of Prostate Cancer are covered

Not applicable

When Gene-Based Tests for Screening, Detection, or Management of Prostate Cancer are not covered

Gene-based tests for screening, detection, and/or management of prostate cancer are considered investigational. These include but are not limited to the following:

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

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

Policy Guidelines

The 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: S3721

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.33, 2/15/2007.

Senior Medical Director - 2/2009

Specialty Matched Consultant Advisory Panel - 8/2009

Medical Director – 8/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.33, 4/14/2011

Specialty Matched Consultant Advisory Panel – 8/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.33, 3/8/2012

Medical Director – 4/2012

Policy Implementation/Update Information

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- 4/13/09 Evidence based guideline adopted from the BCBS Association. Reviewed with the Senior Medical Director 3/16/2009. "The available evidence does not permit conclusions regarding the clinical utility of gene-based tests for the screening, detection, and management of prostate cancer, therefore this test is not recommended." (btw)
- 10/12/09 Specialty Matched Consultant Advisory Panel review 8/28/09. No changes to evidence based guideline. (btw)
- 6/22/10 Policy Guideline Number(s) removed (amw)
- 9/14/10 "Description" section rewritten. Added examples of tests under the "Not Recommended" section to include; single-nucleotide polymorphisms (SNPs) for risk assessment, PCA3 for disease diagnosis, TMRSS fusion genes for diagnosis and prognosis, multiple gene tests (gene panels) for prostate cancer diagnosis, gene hypermethylation for diagnosis and prognosis". Updated the rationale. Reviewed by Medical Director 8/10/2010. References added. (btw)
- 9/30/11 Evidence Based Guideline converted to Corporate Medical Policy. "Description" section updated. "Policy" statement added indicating "Genetic tests for the screening, detection, and management of prostate cancer are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures." Specialty Matched Consultant Advisory Panel review 8/31/2011. References added. Notification given 9/30/2011 Policy effective 1/1/2012. (btw)
- 3/30/12 Added HCPCS code S3721 to the Billing/Coding section. (btw)
- 5/1/12 Revised "Description" section. Added "and prognosis" to the second bullet under the "When Not Covered" section. No change to policy intent. Policy Guidelines updated. Reference added. Medical Director review 4/18/2012. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.