

Corporate Medical Policy

Systems Pathology for Predicting Risk of Recurrence in Prostate Cancer

File Name: systems_pathology_for_predicting_risk_of_recurrence_in_prostate_cancer
Origination: 10/2010
Last CAP Review: 11/2011
Next CAP Review: 11/2012
Last Review: 4/2012

Description of Procedure or Service

Systems pathology, an approach that combines cellular and biologic features to standard clinical parameters such as age, clinical or pathologic stage, grade, percent of cancer on biopsy cores, and prostate-specific antigen or its derivatives, is proposed as a way to estimate the probability of disease progression, either prior to or following prostatectomy.

Background:

Predicting risk of recurrence in patients undergoing treatment for prostate cancer is difficult, as it is for most malignancies. Over time, risk models for patients with prostate cancer have evolved from early efforts that relied on grade, stage, and prostate-specific antigen (PSA) levels to complex multivariate models. A publication in 2008 indicates that there are more than 65 published, externally validated prostate cancer nomograms and other tools that use standard clinical parameters such as age, clinical or pathologic stage, grade, percent of cancer on biopsy cores, and PSA or its derivatives to predict various clinical and pathologic outcomes.

Recent studies have begun to determine a different approach by adding both cellular and biologic features to the clinical and pathological information noted above. This approach has been called “systems pathology.”

Aureon Laboratories offered two pathology tests called the Prostate Px+ test and the Post-Op Px test (formerly called Prostate Px). Prostate Px+ was described as useful at diagnosis to patients considering surgery (radical prostatectomy) or other treatment options by providing physicians with objective information regarding the probability of disease progression. Post-Op Px estimated risk of PSA recurrence and disease progression after surgery. In October 2011, the company ceased operations and the tests are no longer offered.

Iris International gained U.S. Food and Drug Administration (FDA) 510(k) clearance in late 2011 for its Nadia ProsVue test, which combines immunoassay and real-time polymerase chain reaction (PCR) methodologies to determine the risk for recurrence of prostate cancer for 8 years after prostatectomy.

*****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

Systems pathology testing is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

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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 Systems Pathology for Predicting Risk of Recurrence in Prostate Cancer is covered

Not Applicable.

When Systems Pathology for Predicting Risk of Recurrence in Prostate Cancer is not covered

Systems pathology testing that determines cellular and biologic features of a tumor is considered investigational, including use for predicting risk of prostate cancer recurrence. BCBSNC does not cover investigational services.

Policy Guidelines

The current available studies do not address the clinical utility of this testing. Currently, it is not known whether models that use systems pathology result in changes in care that lead to improved patient outcomes. Additional data are needed to answer this important question.

In addition, studies are needed to determine which patients may benefit from this testing, as well as to determine when in the course of diagnosis and treatment the systems pathology assessment should be performed. There also should be further discussion about which outcomes are the best to be used in developing models; there can be substantial differences in models that predict PSA recurrence from those that predict metastatic disease and those that predict death. In addition, models may be needed that evaluate risk following treatments other than radical prostatectomy.

The value of using the systems pathology approach to determine risk is not known based on currently available studies. Thus, the impact on clinical outcomes is not known and the clinical utility of this testing is not known.

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: There is no specific CPT code for this test. CPT codes 88313, 88232, 88347 and 88399 may be reported.

Diagnosis code: 185

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.

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Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.64, 4/08/10

Senior Medical Director review 7/2010

Cordon-Cardo C, Kotsianti A, Verbel DA et al. Improved prediction of prostate cancer recurrence through systems pathology. *J Clin Invest* 2007; 117(7):1876-83. Retrieved on July 20, 2010 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1884691/?tool=pubmed>

Donovan MJ, Khan FM, Fernandez G et al. Personalized prediction of tumor response and cancer progression on prostate needle biopsy. *J Urol* 2009; 182(1):125-32. Retrieved on July 20, 2010 from [http://www.jurology.com/article/S0022-5347\(09\)00570-9/abstract](http://www.jurology.com/article/S0022-5347(09)00570-9/abstract)

Eggerer SE, Vickers AJ, Serio AM et al. Comparison of models to predict clinical failure after radical prostatectomy. *Cancer* 2009; 115(2):303-10. Retrieved on July 20, 2010 from <http://www3.interscience.wiley.com/cgi-bin/fulltext/121536185/PDFSTART>

Donovan MJ, Osman I, Khan FM. Androgen receptor expression is associated with prostate cancerspecific survival in castrate patients with metastatic disease. *BJU Int* 2010; 105(4):462-7. Retrieved on May 27, 2011 from <http://onlinelibrary.wiley.com/doi/10.1111/j.1464-410X.2009.08747.x/pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.64, 4/14/11

Medical Director review 6/2011

Specialty Matched Consultant Advisory Panel review 11/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.64, 3/8/12

Policy Implementation/Update Information

10/12/10 New policy implemented. Systems pathology testing is considered investigational for predicting risk of prostate cancer recurrence. BCBSNC does not cover investigational services. Notification given on 10/12/2010 for effective date 1/18/2011. (mco)

6/21/11 Medical Director review 6/2011. References updated. Revised policy statement as follows: "Systems pathology testing for predicting risk of recurrence of prostate cancer is considered investigational. BCBSNC does not provide coverage for investigational services or procedures." Intent of policy is unchanged. (mco)

12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. Policy Guidelines updated. No changes to Policy Statement. (mco)

5/1/12 Description section updated. "When not Covered" section revised to state: "Systems pathology testing that determines cellular and biologic features of a tumor is considered investigational, including use for predicting risk of prostate cancer recurrence. BCBSNC does not cover investigational services." Policy Guidelines updated. Billing/Coding section updated. References updated. Medical Director review 4/2012. (mco)

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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.