



## MASSACHUSETTS

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# Medical Policy Systems Pathology in Prostate Cancer

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### Policy Number: 250

BCBSA Reference Number: 2.04.64A

ND/LCD: NA

### Related Policies

Saturation Biopsy of the Prostate, #[307](#)

### Policy

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity  
Medicare Members: Managed Care HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup>**

Tests utilizing systems pathology that include cellular and biologic features of a tumor, including use in predicting risks of recurrence in patients with prostate cancer are [INVESTIGATIONAL](#).

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

## CPT Codes

There are no specific CPT codes for this service.

## Description

Predicting risk of recurrence in patients undergoing treatment for prostate cancer is difficult, as it is for most malignancies. 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.

Examples of system pathology tests include Prostate Px+ test and the Post-Op Px test (formerly called Prostate Px) from Aureon Laboratories. All systems pathology tests are considered investigational regardless of the commercial name or the laboratory performing the test.

## Summary

Currently it is not known whether use of these models that use systems pathology will result in changes in care that lead to improved patient outcomes. Additional data are needed to answer this important question.

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. Therefore, this testing is considered investigational.

## Policy History

Date	Action
5/2015	New references added from BCBSA National medical policy.
5/2014	New references from BCBSA National medical policy; titled changed.
5/2013	New references from BCBSA National medical policy.
11/2011-04/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
09/27/2011	Medical Policy Group – Urology, Obstetrics and Gynecology No changes to policy statements.
07/2011	2011 Medical Policy Group – Hematology and Oncology No changes to policy statements.
12/01/10	New policy. Effective 12/1/2010.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Shariat SF, Karakiewicz PI, Margulis V et al. Inventory of prostate cancer predictive tools. *Curr Opin Urol* 2008; 18(3):279-96.
2. Donovan MJ, Hamann S, Clayton M et al. Systems pathology approach for the prediction of prostate cancer progression after radical prostatectomy. *J Clin Oncol* 2008; 26(24):3923-9.
3. 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.
4. 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.
5. Eggener SE, Vickers AJ, Serio AM et al. Comparison of models to predict clinical failure after radical prostatectomy. *Cancer* 2009; 115(2):303-10.
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7. Klein EA, Stephenson AJ, Raghavan D et al. Systems pathology and predicting outcome after radical prostatectomy. *J Clin Oncol* 2008; 26(24):3916-7.
8. Donovan MJ, Osman I, Khan FM et al. Androgen receptor expression is associated with prostate cancer-specific survival in castrate patients with metastatic disease. *BJU Int* 2010; 105(4):462-7.
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11. Moul JW, Lilja H, Semmes OJ et al. NADiA Prosvue prostate-specific antigen slope is an independent prognostic marker for identifying men at reduced risk of clinical recurrence of prostate cancer after radical prostatectomy. *Urology* 2012; 80(6):1319-25.
12. Moul JW, Sarno MJ, McDermed JE, et al. NADiA Prosvue prostate-specific antigen slope, CAPRA-S, and prostate cancer--specific survival after radical prostatectomy. *Urology*. Dec 2014;84(6):1427-1432. PMID 25432832
13. Moul JW, Chen DY, Trabulsi EJ, et al. Impact of NADiA Prosvue PSA slope on secondary treatment decisions after radical prostatectomy. *Prostate Cancer Prostatic Dis*. Sep 2014;17(3):280-285. PMID 25027863