



**PROSTATE Px® TEST FOR PREDICTION OF  
RECURRENCE OF PROSTATE CANCER  
HS-156**



*Harmony Behavioral Health, Inc.*

*Harmony Behavioral Health of Florida, Inc.*

*Harmony Health Plan of Illinois, Inc.*

*HealthEase of Florida, Inc.*

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*WellCare Prescription Insurance, Inc.*

**Prostate Px® Test for  
Prediction of Recurrence of  
Prostate Cancer**

**Policy Number: HS-156**

**Original Effective Date: 2/18/2010**

**Revised Date(s): 2/18/2011; 2/2/2012**

**DISCLAIMER**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## **BACKGROUND**

Prostate Px® is a prognostic test, which has been developed in an attempt to improve the accuracy of prediction of prostate cancer risk. This test relies on partially automated analysis of microscopic images of stained tissue samples. Specially trained pathologists select representative digital microscopic images of the tissue samples that are analyzed by a computer program to detect features that may be associated with prostate cancer severity. Potential information about current disease and likelihood of recurrence are also obtained from staining with labeled antibodies to detect specific proteins that may be associated with worse cases of prostate cancer. These data are combined with results of standard testing such as prostate-specific antigen levels and scoring of prostate cancer severity by a pathologist. The Prostate Px test is typically prescribed by a urologist or urological surgeon and performed with tissue samples that are collected during an inpatient or outpatient prostatectomy.

### *Cost Analysis*

According to a cost-effectiveness analysis from a payer perspective that was performed by the test provider, in 2006, the cost of the Prostate Px test was \$1968. Although this analysis found that use of the Prostate Px test improved cost-effectiveness, this conclusion does not seem to be reliable since the postoperative surveillance strategy in the analysis relied exclusively on PSA testing rather than the standard approach of PSA testing, digital rectal exams, and repetition of prostate biopsy at regular intervals.

### *Summary Statement*

Results of the available studies suggest that the Prostate Px test is not a suitable replacement for existing methods for prediction of prostate cancer recurrence. In addition to a lack of standardization of its criteria for determination of risk, the only available study that compared the Prostate PX test with existing standard methods found no significant differences in predictive accuracy for this test versus standard methods. The Prostate Px test seems to be undergoing a process of development and refinement. Additional studies of an improved, standardized version of this test are needed to determine whether it can enhance prediction of prostate cancer risk compared with current standard methods.

Adoption of this technology would likely have little or no effect on inpatient and outpatient facility utilization for management of patients who have prostate cancer. The available evidence suggests that the Prostate Px test provides information that is essentially identical to the information provided by current standard methods for prediction of the risk of prostate cancer recurrence. Demand for the Prostate Px test for prediction of prostate cancer recurrence will likely rise slowly or decline since this test has not been found more accurate than standard methods of risk prediction (Hayes, 2010).

## **POSITION STATEMENT**

The Prostate Px® test for the prediction of the recurrence of prostate cancer **is considered experimental and investigational and is NOT a covered benefit.**

## **CODING**

### **Non-Covered CPT®\* Codes for Prostate PX Testing**

<b>88305</b>	Level IV – Surgical Pathology, gross and microscopic examination; Prostate
<b>88305-TC</b>	Level IV – Surgical Pathology, gross and microscopic examination; Prostate; <i>Technical Component Only</i>
<b>88323</b>	Consultation and report on referred material requiring preparation of slides
<b>88347</b>	Immunofluorescent study, each antibody; indirect method



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**88399** Unlisted surgical pathology procedure

**ICD-9-CM Procedure Codes** - No applicable codes

**HCPCS Codes**- No applicable codes

**Non-Covered ICD-9-CM Diagnosis Codes**

**185** Cancer of the Prostate

\*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

**REFERENCES**

**Peer Reviewed**

1. Cordon-Cardo, C., Kotsianti, A., Verbel, D.A., & et al. (2007). Improved prediction of prostate cancer recurrence through systems pathology. *Journal of Clinical Investigation*, 117(7), 1876-1883.
2. Donovan, M.J., Khan, F.M., Fernandez, G., & et al. (2009). Personalized prediction of tumor response and cancer progression on prostate needle biopsy. *Journal of Urology*, 182(1), 125-132.
3. Eggener, S.E., Vickers, A.J., Serio, A.M., & et al. (2009). Comparison of models to predict clinical failure after radical prostatectomy. *Cancer*, 115(2), 303-310.
4. Hayes Directory. (2010, January 5). Prostate Px® (Aureon Laboratories Inc.) for prediction of recurrence of prostate cancer. Retrieved from <http://www.hayesinc.com>

**Government Agencies, Professional and Medical Organizations**

N/A

**HISTORY AND REVISIONS**

<b>Date</b>	<b>Action</b>
2/2/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
2/18/2011	• Approved by MPC.