# **Medical Coverage Policies**

### Systems Pathology in Predicting Prostate Cancer Treatment

EFFECTIVE DATE	11/17/2009	LAST UPDATED	11/17/2009

#### **Description:**

There are a number of predictive tools available to assess an individual patient's risk for prostate cancer. They include biopsy Gleason grade and score based on changes in tissue morphology, the number of positive tumor cores, preoperative prostate-specific antigen (PSA) level, and clinical tumor stage. Yet, no one risk assessment method can accurately predict a patient's outcome post treatment.

The current challenge to predicting an individual's risk is complicated by the subjectivity of these analysis and which cannot provide quantitative results. Systems pathology (Prostate PX) is an attempt at overcoming these deficiencies by integrating information from histologic, molecular, and clinical information to predict cancer recurrence by integrating three advanced technologies. 1). Image analysis in which a digital image of cancer tissue is used to generate various statistical measurements. 2). Biomarker detection, such as multiplexed in situ protein detection using fluorescently tagged antibodies and analysis via spectral imaging. 3). Clinical information, such as the Gleason score, pathologic stage, or PSA values. Data extracted from these tools provide results that can be analyzed by mathematic formulas or algorithms related to data mining, pattern recognition and statistical analysis. By using the patient's prostatectomy tissue, disease recurrence can be assessed, as either PSA recurrence or disease progression for up to 5 years post-surgery. The integration of all data sets pertaining to one patient can produce a personalized and individually predictive diagnosis and as a consequence, a therapy that is tailored to the individual.

At this time, the data reviewed to evaluate the effectiveness of this novel approach is insufficient to determine if systems pathology is more useful as an assessment tool to measure a patient's risk for prostate cancer as compared to other established methods.

#### Medical Criteria:

Not applicable.

#### **Policy:**

Systems pathology using Prostate PX testing as a predictive tool to determine cancer therapy is considered not medically necessary as the clinical data is insufficient to determine if it is more useful as an assessment tool to measure a patient's risk for prostate cancer as compared to other established methods.

#### Coverage:

There is not an established code which adequately describes the procedure therefore the provider should file using the unlisted code 88399. An "Unlisted Procedure Claim" form must be completed and the required supporting documentation provided.

## **Coding:** 88399

Also known as: Prostate PX Testing

#### Publications: Provider Update, January 2010

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