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℠ and Medicare PPO Blue℠

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.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO Blue℠</td>
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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

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<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
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<td>5/2014</td>
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<tr>
<td>5/2013</td>
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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