Medical Policy
Gene-Based Tests for Screening, Detection, and/or Management of Prostate Cancer

Table of Contents
- Policy: Commercial
- Policy: Medicare
- Authorization Information
- Coding Information
- Description
- Policy History
- Information Pertaining to All Policies
- References

Policy Number: 333
BCBSA Reference Number: 2.04.33

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members
Genetic tests for the screening, detection, and management of prostate cancer are INVESTIGATIONAL. This includes, but is not limited to the following:
- Single-nucleotide polymorphisms (SNPs) for risk assessment, or
- PCA3 for disease diagnosis and prognosis, or
- TMPRSS fusion genes for diagnosis and prognosis, or
- Multiple gene tests (gene panels) for prostate cancer diagnosis, or
- Gene hypermethylation for diagnosis and prognosis.

Prior Authorization Information

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

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. 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.

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S3721</td>
<td>Prostate Cancer Antigen 3 (PCA3) testing.</td>
</tr>
</tbody>
</table>

**Description**

Prostate cancer is a complex, heterogeneous disease. At the extremes of the spectrum, if left untreated, some prostate cancers behave aggressively, metastasize quickly, and cause mortality, while others are indolent and never progress to cause harm. In response to the need for better biomarkers for risk assessment, diagnosis, and prognosis, a variety of exploratory research is ongoing. Some products of this work have already been translated or are in the process of being translated into commercially available tests, including:

- Single-nucleotide polymorphisms (SNPs) for risk assessment,
- Prostate cancer antigen 3 (PCA3) for disease diagnosis and prognosis,
- Transmembrane serine protease (TMPRSS) fusion genes for diagnosis and prognosis,
- Multiple gene tests (gene panels) for prostate cancer diagnosis, and
- Gene hypermethylation for diagnosis and prognosis.

While studies using these tests generate much information that may help elucidate the biologic mechanisms of prostate cancer and eventually help design treatments, the above-mentioned tests are in a developmental phase.

Examples of genetic tests for the screening, detection, and management of prostate cancer include single-nucleotide polymorphisms (SNPs) and the prostate cancer antigen 3 (PCA3). All genetic tests for the screening, detection, and management of prostate cancer are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

**Summary**

The evidence for genetic tests related to prostate cancer screening, detection, and management variably but incompletely addresses clinical validity, i.e., the association of the test result with outcomes of interest expressed in terms of clinical performance characteristics such as sensitivity, specificity, predictive value, and comparisons to current standards using receiver-operating curve analysis and/or logistic regression. These data do not demonstrate clinical utility, i.e., that using a test will change treatment decisions and improve subsequent outcomes that matter to the patient such as mortality, morbidity, or quality of life. Thus, use of this testing for risk assessment, diagnosis, prognosis, and management of prostate cancer is considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2014</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>5/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
<tr>
<td>4/2012</td>
<td>Updated to add new non covered HCPCS code S3721.</td>
</tr>
</tbody>
</table>

**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
22. Perdona S, Cavadas V, Di Lorenzo G et al. Prostate cancer detection in the “grey area” of prostate-specific antigen below 10 ng/ml: head-to-head comparison of the updated PCPT calculator and


