Early Prostate Cancer Detection

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

<table>
<thead>
<tr>
<th>Type</th>
<th>Title</th>
<th>ID Number</th>
<th>Jurisdiction Medicare Administrat ive</th>
<th>Applicable States/Territories</th>
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</table>
### Description

Prostate cancer in early stages often shows no identifiable signs or symptoms; therefore, early detection is key in finding prostate cancer while still in a potentially curable stage. **Prostate-specific antigen (PSA)** is a blood test to detect a marker for prostate cancer and is considered the gold standard for prostate cancer screening and management. **Digital Rectal Examination (DRE)** is a recommended complementary test done as part of prostate cancer screening along with PSA testing. However, only a biopsy of the prostate gland can establish a prostate cancer diagnosis.

Early detection of prostate cancer begins with a risk assessment which includes a baseline PSA and consideration of a baseline DRE. Repeat testing is then done at specific intervals based on level of risk, PSA value, and DRE results.

When prostate cancer is of concern, two common types of biopsies can be performed: **Fine Needle Aspiration (FNA)** and **Core Needle Biopsy (CNB)**. FNA is when a small sample of cell tissue is removed from an area of concern in the prostate and is performed with a very thin and hollow needle. CNB uses a larger hollow needle to remove the cell tissue sample. **Cytopathology** is the study of those removed cells to determine a diagnosis.

**Fluorescence in situ hybridization (FISH)** is an additional technique where a probe (a short, single-stranded nucleic acid sequence) targets a specific genetic sequence and is labeled/tagged with a fluorescent dye. If the target is found, the fluorescent dye becomes attached to that target and can be seen under microscopy or other related imaging. In oncology, FISH probes are used to evaluate many different genes for many different cancers.

### Coverage Determination

<table>
<thead>
<tr>
<th>Internet-Only Manuals (IOMs)</th>
<th>Medicare Manual</th>
<th>NCD</th>
<th>NCD</th>
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<tbody>
<tr>
<td>Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15- Covered Medical and Other Health Services</td>
<td>Medicare National Correct Coding Initiative (NCCI) Policy Manual</td>
<td>Prostate Specific Antigen</td>
<td>Prostate Cancer Screening Tests</td>
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<tr>
<td>§80.6.5-Surgical/Cytopathology Exception</td>
<td>Medicare NCCI Policy Manual</td>
<td>190.31</td>
<td>210.1</td>
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</table>
iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Please refer to the following CMS sources for guidance regarding prostate cancer screening:

- Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services, Section 80.6.5 - Surgical/Cytopathology Exception
- Medicare NCCI Policy Manual
- National Coverage Determination (NCD) 190.31 - Prostate Specific Antigen
- National Coverage Determination (NCD) 210.1 - Prostate Cancer Screening Tests

The following prostate cancer screening tests will be considered medically reasonable and necessary for the early detection of prostate cancer:

- **Screening digital rectal examination (DRE);**
  - covered at a frequency of once every 12 months for men who have attained age 50; **AND**
  - at least 11 months have passed following the month in which the last covered screening DRE was performed; **AND**

- **Screening prostate specific antigen (PSA) blood test;**
  - covered at a frequency of once every 12 months for men who have attained age 50; **AND**
  - at least 11 months have passed following the month in which the last covered screening PSA test was performed.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

### Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage
The following services will not be considered medically reasonable and necessary:

- BioVantra Integrated Prostate Cytomolecular Mapping; OR
- FISH testing of prostate tissue specimens for TMPRSS2-ERG rearrangement; OR
- Fine Needle Aspiration (FNA) for the diagnosis of prostate cancer

A review of the current medical literature shows that there is no evidence to determine that these services are standard medical treatments. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

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<tr>
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<td>84152</td>
<td>Prostate specific antigen (PSA); complexed (direct measurement)</td>
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<td>84153</td>
<td>Prostate specific antigen (PSA); total</td>
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<td>84154</td>
<td>Prostate specific antigen (PSA); free</td>
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<td>88172</td>
<td>Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site</td>
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<td>Cytopathology, evaluation of fine needle aspirate; interpretation and report</td>
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<tr>
<td>88177</td>
<td>Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)</td>
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<td>88377</td>
<td>Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure</td>
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**CPT Category III Codes(s)**

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**HCPCS Codes(s)**

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<tr>
<td>Prostate cancer screening; prostate specific antigen test (PSA)</td>
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References


Change Summary

- 01/01/2024 New Policy.