Early Prostate Cancer Detection



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Medicare Advantage Medical Coverage Policy

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Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT[®] codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

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

Type Title IC	umber Jurisdiction Medicare Administrat ive s
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			Contractors (MACs)	
Internet- Only Manuals (IOMs)	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15- Covered Medical and Other Health Services	<u>§80.6.5-</u> Surgical/Cytopathology Exception		
Medicare Manual	Medicare National Correct Coding Initiative (NCCI) Policy Manual	Medicare NCCI Policy Manual		
NCD	Prostate Specific Antigen	<u>190.31</u>		
NCD	Prostate Cancer Screening Tests	<u>210.1</u>		

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

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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:

- <u>Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services</u>, Section 80.6.5 Surgical/Cytopathology Exception
- Medicare NCCI Policy Manual
- National Coverage Determination (NCD) <u>190.31</u> Prostate Specific Antigen
- National Coverage Determination (NCD) <u>210.1</u> Prostate Cancer Screening Tests
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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);
 - \circ 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;
 - o covered at a frequency of once every 12 months for men who have attained age 50; AND
 - $\circ~$ 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

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 -</u> <u>Particular services excluded from coverage</u>

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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 <u>no evidence</u> 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.

CPT Codes(s)	Description	Comments
84152	Prostate specific antigen (PSA); complexed (direct	
04152	measurement)	
84153	Prostate specific antigen (PSA); total	
84154	Prostate specific antigen (PSA); free	
88172	Cytopathology, evaluation of fine needle aspirate;	
	immediate cytohistologic study to determine adequacy	
	for diagnosis, first evaluation episode, each site	
88173	Cytopathology, evaluation of fine needle aspirate;	
	interpretation and report	
88177	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)	
88377	Morphometric analysis, in situ hybridization (quantitative	
	or semi-quantitative), manual, per specimen; each	
	multiplex probe stain procedure	
CPT Category III	Description	Comments
Codes(s)		•••••••
No code(s) identified		
HCPCS Codes(s)	Description	Comments
G0102	Prostate cancer screening; digital rectal examination	
G0103	Prostate cancer screening; prostate specific antigen test	
	(PSA)	

References

- Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 15 -Covered Medical and Other Health Services, Section 80.6.5 - Surgical/Cytopathology Exception. <u>https://www.cms.gov</u>. Published January 1, 2003. Updated January 11, 2008. Accessed November 17, 2023.
- Centers for Medicare & Medicaid Services (CMS). Medicare National Correct Coding Initiative (NCCI) Policy Manual. <u>https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-policy-manual</u>. Accessed November 17, 2023.
- Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Prostate Specific Antigen (190.31). <u>https://www.cms.gov</u>. Published November 25, 2002. Accessed November 17, 2023.
- Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Prostate Cancer Screening Tests (210.1). <u>https://www.cms.gov</u>. Published June 19, 2006. Accessed November 17, 2023.
- National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines Version 2.2023). Prostate Cancer Early Detection. <u>Prostate Detection.pdf</u> (nccn.org). Published September 26, 2023. Accessed November 17, 2023.

Change Summary

- 01/01/2024 New Policy.