MASSACHUSETTS

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Medical Policy

Saturation Biopsy for Diagnosis, Staging and Management of Prostate Cancer

Table of Contents

Policy Number: 307

BCBSA Reference Number: 7.01.121 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Cryoablation of Prostate Cancer, #149

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Saturation biopsy is considered **INVESTIGATIONAL** in the diagnosis, staging, and management of prostate cancer.

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**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

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.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
55706	Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance

The following HCPCS code is considered investigational when submitted with the CPT code above for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method

Description

Prostate Cancer

Prostate cancer is common and is the second leading cause of cancer-related deaths in men in the U.S.

Diagnosis

The diagnosis of prostate cancer is made by biopsy of the prostate gland. The approach to biopsy has changed over time, especially with the advent of prostate-specific antigen screening programs that identify cancer in prostates that are normal to palpation and to transrectal ultrasound. For patients with an elevated prostate-specific antigen level but with a normal biopsy, questions exist about subsequent evaluation, because repeat biopsy specimens may be positive for cancer in a substantial percentage of patients.

In the early 1990s, use of sextant biopsies involving 6 random, evenly distributed biopsies became the standard approach to diagnose prostate cancer. In the late 1990s, as studies showed high false-negative rates for this strategy (missed cancers), approaches were developed to increase the total number of biopsies and to change the location of the biopsies. While there is disagreement about the optimal strategy, most would agree that initial prostate biopsy strategies should include at least 10 to 14 cores. Additional concerns have been raised about drawing conclusions about the stage (grade) of prostate cancer based on limited biopsy specimens. Use of multiple biopsies has also been discussed as an approach to identify tumors that may be eligible for subtotal cryoablation therapy.

At present, many practitioners use a 12- to 14-core "extended" biopsy strategy for patients undergoing initial biopsy. This extended biopsy is done in an office setting and allows for more extensive sampling of

the lateral peripheral zone; a sampling of the lateral horn might increase the cancer detection rate by approximately 25%.[1,]

Another approach to increasing the number of biopsy tissue cores is "saturation" biopsy. In general, saturation biopsy is considered as more than 20 cores taken from the prostate, with an improved sampling of the anterior zones of the gland, which may be undersampled in standard peripheral zone biopsy strategies and might lead to missed cancers. Saturation biopsy might be performed transrectally or transperineally; the transperineal approach is generally performed as a stereotactic template-guided procedure with general anesthesia.

Surveillance
In addition to the diagnosis of prostate cancer, some have suggested that saturation biopsy could be a part of active surveillance (a treatment approach that involves surveillance with prostate-specific antigen, digital rectal exam, and routine prostate biopsies in men whose cancers are small and expected to behave indolently). Saturation biopsy has the potential to identify tumor grade more accurately than standard biopsy.

Summary

Description
Saturation biopsy of the prostate, in which more cores are obtained than by standard biopsy protocol, has been proposed in the diagnosis (for initial or repeat biopsy), staging, and management of individuals with prostate cancer.

Summary of Evidence
For individuals who have suspected prostate cancer who receive initial saturation biopsy, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival (OS), disease-specific survival, test accuracy, and treatment-related morbidity. A 2013 systematic review found higher rates of cancer detection with saturation biopsy than with extended biopsy overall, but, in the subgroup of men with prostate-specific antigen (PSA) levels less than 10 ng/mL, the degree of difference was small and possibly not clinically significant. Health outcomes (eg, survival rate) were not reported. Although several studies were published after the systematic review, none showed that initial saturation biopsy improved the detection of clinically significant cancers and none reported progression or survival outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected prostate cancer who receive repeat saturation biopsy, the evidence includes observational studies and a systematic review. Relevant outcomes are OS, disease-specific survival, test accuracy, and treatment-related morbidity. Several studies have compared saturation with standard prostate biopsies in the repeat biopsy setting and have found significantly higher detection rates with saturation biopsy. However, at least 1 study found that about one-third of the positive findings with saturation biopsy were clinically insignificant cancers. Moreover, studies of saturation biopsy as the repeat prostate biopsy strategy focused on cancer detection rates and did not report health outcomes (eg, progression or survival). Evidence is lacking as to whether saturation biopsy leads to improved health outcomes, including the possibility of detecting clinically insignificant cancers, which could lead to unnecessary treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have prostate cancer and are candidates for active surveillance who receive saturation biopsy, the evidence includes 2 nonrandomized comparative studies. Relevant outcomes are OS, disease-specific survival, test accuracy, and treatment-related morbidity. Both studies retrospectively compared standard biopsy with saturation biopsy for selecting patients for active surveillance; neither found that saturation biopsy improved the ability to select patients. In 1 study, biopsy method was not a significant predictor of upstaging and, in the other study, biopsy method was not significantly associated with selecting patients with a high Gleason score. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
9/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2023	Clarified coding information.
8/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
8/2017	Annual policy review. New references added.
9/2016	Annual policy review. Policy title changed to Saturation Biopsy for Diagnosis, Staging, and Management of Prostate Cancer. References added. 9/1/2016
2/2016	Clarified coding information.
5/2015	Annual policy review. New references added.
1/2015	Clarified coding information.
4/2014	Annual policy review. Investigational indications clarified. Effective 4/1/2014.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group – Urology, Obstetrics and Gynecology. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group – Hematology and Oncology. No changes to policy statements.
1/19/2011	New policy effective 1/19/2011 describing ongoing non-coverage.

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

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