Medical Policy
Saturation Biopsy for Diagnosis, Staging and Management of Prostate Cancer

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Policy Number: 307
BCBSA Reference Number: 7.01.121
NCD/LCD: N/A

Related Policies
Cryoablation of Prostate Cancer, #149

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM 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.

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

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>55706</td>
<td>Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance</td>
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</table>

The following CPT and HCPCS codes are 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:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
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<tr>
<td>88305</td>
<td>Level IV - Surgical pathology, gross and microscopic examination Abortion - spontaneous/missed Artery, biopsy Bone marrow, biopsy Bone exostosis Brain/meninges, other than for tumor resection Breast, biopsy, not requiring microscopic evaluation of surgical margins Breast, reduction mammoplasty Bronchus, biopsy Cell block, any source Cervix, biopsy Colon, biopsy Duodenum, biopsy Endocervix, curettings/biopsy Endometrium, curettings/biopsy Esophagus, biopsy Extremit, amputation, traumatic Fallopian tube, biopsy Fallopian tube, ectopic pregnancy Femoral head, fracture Fingers/toes, amputation, non-traumatic Gingiva/oral mucosa, biopsy Heart valve Joint, resection Kidney, biopsy Larynx, biopsy Leiomyoma(s), uterine myomectomy - without uterus Lip, biopsy/wedge resection Lung, transbronchial biopsy Lymph node, biopsy Muscle, biopsy Nasal mucosa, biopsy Nasopharynx/oropharynx, biopsy Nerve, biopsy Odontogenic/dental cyst Omentum, biopsy Ovary with or without tube, non-neoplastic Ovary, biopsy/wedge resection Parathyroid gland Peritoneum, biopsy Pituitary tumor Placenta, other than third trimester Pleura/pericardium - biopsy/tissue Polyp, cervical/endoembryonic Polyp, colorectal Polyp, stomach/small intestine Prostate, needle biopsy Prostate, TUR Salivary gland, biopsy Sinus, paranasal biopsy Skin, other than cyst/tag/debridement/plastic repair Small intestine, biopsy Soft tissue, other than tumor/mass/lipoma/debridement Spleen Stomach, biopsy Synovium Testis, other than tumor/biopsy/castration Thyroglossal duct/brachial cleft cyst Tongue, biopsy Tonsil, biopsy Trachea, biopsy Ureter, biopsy Urethra, biopsy Urinary bladder, biopsy Uterus, with or without tubes and ovaries, for prolapse Vagina, biopsy Vulva/labia, biopsy</td>
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<th>HCPCS Codes</th>
<th>Code Description</th>
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<tr>
<td>G0416</td>
<td>Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method</td>
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**Description**
Prostate cancer is common and is the second leading cause of cancer-related deaths in men in the United States. 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 (PSA) screening programs that identify cancer in prostates that are normal to palpation and to transrectal ultrasound. For patients with an elevated PSA 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 diagnosis 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 material. 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; sampling of the lateral horn may increase the cancer detection rate by approximately 25%.

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

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

**Summary**
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 patients with prostate cancer.

For individuals who have suspected prostate cancer who receive initial saturation biopsy or repeat saturation biopsy, the evidence includes randomized and nonrandomized diagnostic accuracy studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and treatment-related morbidity. A 2013 systematic review found higher rates of cancer detection with saturation biopsy than 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. The use of saturation biopsy as a repeat biopsy after prior negative biopsies in men with persistent clinical suspicion of prostate cancer appears to increase the detection rate of cancer, particularly in the anterior zones. However, evidence is lacking as to whether this 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 the effects of the technology on health outcomes.

For individuals who have prostate cancer and are potential candidates for active surveillance who receive saturation biopsy, the evidence includes 2 nonrandomized comparative studies. Relevant outcomes are
overall survival, disease-specific survival, test accuracy, and treatment-related morbidity. Both studies retrospectively compared standard biopsy and 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 the effects of the technology on health outcomes.

Clinical input obtained in 2014 supported the investigational policy statement.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>8/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>2/2016</td>
<td>Clarified coding information.</td>
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<tr>
<td>5/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>1/2015</td>
<td>Clarified coding information.</td>
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<tr>
<td>1/19/2011</td>
<td>New policy effective 1/19/2011 describing ongoing non-coverage.</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**