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

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Saturation biopsy is generally considered obtaining more than 20 biopsy tissue cores from the prostate in a systematic manner; it is occasionally defined as obtaining more than 18 biopsy tissue cores.

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Saturation biopsy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

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. The 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 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 the effects of the technology on health outcomes.

For individuals who have suspected prostate cancer who receive repeat saturation biopsy, the evidence includes observational studies and a systematic review. The 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 one 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 the effects of the technology on health outcomes.

For individuals who have prostate cancer and are candidates for active surveillance who receive saturation biopsy, the evidence includes two nonrandomized comparative studies. The 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 one 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.
SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Comprehensive Cancer Network Guidelines

The National Comprehensive Cancer Network guidelines (v.2.2019) on early detection of prostate cancer state that routine use of advanced biopsy techniques, including saturation biopsy, is not recommended for initial biopsy. However, based on emerging evidence, the guidelines also state that saturation biopsy can be considered for "very high-risk" men with previous negative biopsies.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2012) recommendations on prostate cancer screening (now archived) did not address saturation biopsy. In May 2018, the Task Force released its updated recommendations on screening for prostate cancer. This update also did not address the use of saturation biopsy.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>September 2011</td>
<td>New policy</td>
<td>Policy updated with literature search; references 1, 2, 4-6 and 10 added. No change in policy statement.</td>
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<tr>
<td>October 2012</td>
<td>Replace policy</td>
<td>Policy updated with literature search; references 1, 2, 4-6 and 10 added. No change in policy statement.</td>
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<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature search; No change in policy statement.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review; reference 3, 4, 6, and 7 added. “Taking more than 20 core tissue samples at one time” removed from policy statement; guidance on this issue added to Policy Guidelines.</td>
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<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review. References 5 and 12-13 added. No changed to policy statement.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature search through May 7, 2018; references 3 and 14 added. Policy statement unchanged.</td>
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<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature search through May 29, 2019; no references added. Policy statement unchanged.</td>
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