FEP 7.01.121 Saturation Biopsy for Diagnosis, Staging and Management of Prostate Cancer

**Effective Date:** October 15, 2018

**Related Policies:**
- 7.01.79 Cryoablation of Prostate Cancer

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**Saturation Biopsy for Diagnosis, Staging and Management of Prostate Cancer**

**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 patients with prostate cancer.

**OBJECTIVE**
The objective of this evidence review is to determine whether saturation biopsy improves the net health outcome in patients with suspected prostate cancer or patients with prostate cancer who are candidates for active surveillance.

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

**POLICY GUIDELINES**
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.

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

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

Summary of Evidence
For individuals who have suspected prostate cancer who receive initial saturation biopsy, the evidence includes randomized controlled trials, observational studies, and systematic reviews. 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 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. Relevant outcomes are overall survival, 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 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 2 nonrandomized comparative studies. Relevant outcomes are overall survival, 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Comprehensive Cancer Network Guidelines
National Comprehensive Cancer Network guidelines (v.2.2018) 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 2012 U.S. Preventive Services Task Force 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.
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Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

POLICY HISTORY

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<td>September 2011</td>
<td>New Policy</td>
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<td>October 2012</td>
<td>Update Policy</td>
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<td>Update 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</td>
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The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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<tr>
<td>September 2018</td>
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<td>Policy updated with literature search through May 7, 2018; references 3 and 14 added. Policy statement unchanged</td>
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