BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

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

Effective Policy Date: October 1, 2023

Original Policy Date: September 2011

Related Policies:

None

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

Description

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.

RATIONALE

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines (v.1.2023) on early detection of prostate cancer state that despite emerging evidence, the panel does not recommend a saturation biopsy strategy for all individuals with previous negative biopsies given the benefits seen for magnetic resonance imaging (MRI) and MRI-targeted biopsy in this patient population.[12,] The emerging evidence cited included 1 prospective nonrandomized study (Zaytoun et al 2011)[9,] and uncontrolled observational studies published between 2006 and 2013.

NCCN guidelines on prostate cancer treatment (v.1.2023) do not mention saturation biopsy.[13,]

U.S. Preventive Services Task Force Recommendations

The **U.S. Preventive Services Task Force** (2018) recommendations on prostate cancer screening did not address saturation biopsy.[14,]

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

1. Zaytoun OM, Jones JS. Prostate cancer detection after a negative prostate biopsy: lessons learnt in the Cleveland Clinic experience. Int J Urol. Aug 2011; 18(8): 557-68. PMID 21692866
2. Jiang X, Zhu S, Feng G, et al. Is an initial saturation prostate biopsy scheme better than an extended scheme for detection of prostate cancer? A systematic review and meta-analysis. Eur Urol. Jun 2013; 63(6): 1031-9. PMID 23414775
3. Xue J, Qin Z, Cai H, et al. Comparison between transrectal and transperineal prostate biopsy for detection of prostate cancer: a meta-analysis and trial sequential analysis. Oncotarget. Apr 04 2017; 8(14): 23322-23336. PMID 28177897
4. Li YH, Elshafei A, Li J, et al. Transrectal saturation technique may improve cancer detection as an initial prostate biopsy strategy in men with prostate-specific antigen 10 ng/ml. Eur Urol. Jun 2014; 65(6): 1178-83. PMID 23768632
5. Li YH, Elshafei A, Li J, et al. Potential benefit of transrectal saturation prostate biopsy as an initial biopsy strategy: decreased likelihood of finding significant cancer on future biopsy. Urology. Apr 2014; 83(4): 714-8. PMID 24680442
6. Eichler K, Hempel S, Wilby J, et al. Diagnostic value of systematic biopsy methods in the investigation of prostate cancer: a systematic review. J Urol. May 2006; 175(5): 1605-12. PMID 16600713
7. Mabjeesh NJ, Lidawi G, Chen J, et al. High detection rate of significant prostate tumours in anterior zones using transperineal ultrasound-guided template saturation biopsy. BJU Int. Oct 2012; 110(7): 993-7. PMID 22394668
8. Lee MC, Moussa AS, Zaytoun O, et al. Using a saturation biopsy scheme increases cancer detection during repeat biopsy in men with high-grade prostatic intra-epithelial neoplasia. Urology. Nov 2011; 78(5): 1115-9. PMID 22054382
9. Zaytoun OM, Moussa AS, Gao T, et al. Office based transrectal saturation biopsy improves prostate cancer detection compared to extended biopsy in the repeat biopsy population. J Urol. Sep 2011; 186(3): 850-4. PMID 21788047
10. Linder BJ, Frank I, Umbreit EC, et al. Standard and saturation transrectal prostate biopsy techniques are equally accurate among prostate cancer active surveillance candidates. Int J Urol. Sep 2013; 20(9): 860-4. PMID 23278942
11. Quintana L, Ward A, Gerrin SJ, et al. Gleason Misclassification Rate Is Independent of Number of Biopsy Cores in Systematic Biopsy. Urology. May 2016; 91: 143-9. PMID 26944351
12. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection. Version 1.2023 https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf. Accessed June 5, 2023.
13. National Comprehensive Cancer Network. Prostate Cancer (v.1.2023). https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed June 6, 2023.

14. U.S. Preventive Services Task Force (USPSTF). Final Recommendation Statement: Prostate Cancer: Screening. 2018 May; https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate- cancer-screening1. Accessed June 6, 2023.

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

Date	Action	Description
September 2011	New policy	
October 2012	Replace policy	Policy updated with literature search; references 1, 2, 4-6 and 10 added. No change in policy statement.
June 2013	Replace policy	Policy updated with literature search; No change in policy statement.
September 2014	Replace policy	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.
September 2015	Replace policy	Policy updated with literature review. References 5 and 12-13 added. No changed to policy statement.
September 2016	Replace policy	Policy updated with literature review through June 10, 2016; references 10-13 added. Policy statement unchanged. Policy title changed to Saturation Biopsy for Diagnosis, Staging, and Management of Prostate Cancer.
September 2018	Replace policy	Policy updated with literature search through May 7, 2018; references 3 and 14 added. Policy statement unchanged.
September 2019	Replace policy	Policy updated with literature search through May 29, 2019; no references added. Policy statement unchanged.
September 2020	Replace policy	Policy updated with literature search through June 10, 2020; no references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature search through June 1, 2021; no references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature search through May 20, 2022; no references added. Policy statement unchanged.
September 2023	Replace policy	Policy updated with literature search through June 6, 2023; no references added. Policy statement unchanged.