Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

Description/Background

Saturation biopsy, 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.

PROSTATE CANCER

Prostate cancer is a common cancer 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 (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, since repeat biopsy specimens may be positive for cancer in a substantial percentage of patients.

In the early 1990s, use of sextant biopsies involving six random, evenly distributed biopsies became the standard approach to the diagnosis of 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 10–14 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%.[1]

Another approach to increase the number of biopsy tissue cores is use of the "saturation" biopsy. In general, saturation biopsy is considered as a minimum of 20 cores taken from the prostate, with improved sampling of the anterior zones of the gland, which may be under-sampled in standard peripheral zone biopsy strategies, and may lead to 17% of cancers being missed according to one study.[2] 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.

Surveillance
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.

Regulatory Status:

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

Medical Policy Statement

The safety and effectiveness of saturation biopsy (taking more than 20 samples) of the prostate have been established. It is a useful therapeutic option for patients meeting appropriate patient selection criteria.

Inclusionary and Exclusionary Guidelines

Inclusions:
Saturation biopsy of the prostate is considered established for the following indications in men with at least *two* prior extended transrectal prostate biopsies that are negative for invasive cancer AND:

- Elevated prostate specific antigen (PSA) that is persistently rising; OR
- Men with histologic evidence of atypia on prior prostate biopsy; OR
- Men with histologic findings of high-grade prostatic intraepithelial neoplasia (PIN) on prior biopsy.

Note: PSA values should be reported from the same laboratory as techniques for measuring these values may vary from lab to lab.

Exclusions:
Men who do not meet the above criteria.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

G0416 55706

Rationale

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

INITIAL OR REPEAT SATURATION BIOPSY

Clinical Context and Proposed Clinical Utility
The proposed clinical utility of saturation biopsy for diagnosis of prostate cancer is to improve health outcomes by detecting more clinically significant cancers and intervening appropriately. To evaluate the impact of saturation biopsy on the net health outcome, studies are needed that compare rates of clinically significant prostate cancers detected using saturation biopsy versus other biopsy methods.

The following **PICO** were used to select literature to inform this review. They apply to the first 2 indications-initial or repeat saturation biopsy.

Populations
The relevant population of interest are individuals with suspected prostate cancer.

Interventions
The relevant intervention of interest is initial or repeat saturation biopsy. 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. Saturation biopsy can be performed transrectally or transperineally; the transperineal approach is generally performed as a stereotactic template-guided procedure with general anesthesia.

Comparators
The comparator of interest is standard biopsy.

Outcomes

The general outcomes of interest are test accuracy, overall survival, disease-specific survival, and treatment-related morbidity.

Specific outcomes are improving the detection of clinically significant prostate cancer; increasing accurate risk stratification; and reducing the overdiagnosis of indolent tumors requiring only active surveillance. These are outcomes of primary interest because they would inform the individual's treatment plan and consequently, impact health outcomes.

Change in detection rate alone is not sufficient to determine the impact of saturation biopsy on health outcomes compared with other biopsy methods. With higher detection rates, there is the possibility of detecting clinically insignificant cancers, which could lead to unnecessary treatment. In addition, studies would ideally evaluate the impact of saturation biopsy on health outcomes such as disease progression or mortality.

Diagnostic accuracy is a short-term outcome. Survival outcomes would be measured over the long-term (e.g., 5- or 10-year survival).

Table 1. Outcomes of Interest for Individuals with Suspicion of Prostate Cancer

Outcomes	Details
Test accuracy	Overall prostate cancer detection, clinically significant prostate cancer detection, sensitivity, and specificity. [Timing: ≥1 week]
Health Outcomes	Overall survival, disease-specific survival, treatment-related morbidity [Timing: 5 to 10 years]

Review of Evidence

Initial Saturation Biopsy

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews

The literature of diagnostic accuracy consists of studies reporting prostate cancer detection rates or diagnostic yields as the primary outcome. These data are summarized in a 2013 systematic review and meta-analysis by Jiang et al on the utility of an initial transrectal saturation biopsy compared with an extended biopsy strategy.[2] A total of 8 studies (Total N=11,997 participants) met eligibility criteria (i.e., compared the 2 biopsy strategies on initial biopsy). Two of the studies were randomized controlled trials (RCTs), one used a paired design, and 5 were non-RCTs. Overall, prostate cancer was diagnosed in 2328 of 5486 men (42.4%) who underwent saturation biopsy compared with 2562 of 6511 men (39.3%) who had extended biopsy. The detection rate was statistically significantly higher in the saturation biopsy group (risk difference [RD], 0.004; 95% confidence interval [CI], 0.01 to 0.008; p=0.002). When only the higher quality studies were included in the meta-analysis (i.e., the RCTs and prospective paired design), the detection rate was statistically significantly higher with saturation biopsy (RD=0.03; 95% CI, 0.01 to 0.05; p=0.01). For the analysis limited to

higher quality studies, the authors did not report the proportion of men in each group diagnosed with prostate cancer. Although the authors found statistically significantly higher rates of diagnosis in their overall pooled analyses, the degree of difference in diagnosis rates may not be clinically significant. In a subgroup analysis, in patients with prostate-specific antigen (PSA) less than 10 ng/mL, prostate cancer was diagnosed in 998 of 2597 men (38%) in the saturation biopsy group and 1135 of 3322 men (34%) in the extended biopsy group. The diagnosis rate was significantly higher in men receiving the saturation biopsy protocol (RD=0.04; 95% CI, 0.01 to 0.07; p=0.002). Although the analysis included subgroup analyses on individual risk factors such as PSA level, it did not differentiate between detection of lower and higher risk prostate cancers. In addition, differences in health outcomes (e.g., progression-free survival, overall survival (OS)) were not reported.

A related meta-analysis was published Xue et al in 2017.[3] Reviewers evaluated the literature comparing transrectal and transperineal biopsy approaches for the detection of prostate cancer. In an analysis stratified by the number of biopsy cores, there was no significant difference in the prostate cancer detection rate with the transrectal strategy or the transperineal biopsy strategy in studies using extended biopsy (odds ratio, 1.14; 95% CI, 0.89 to 1.45) or studies using saturation biopsy (odds ratio, 1.11; 95% CI, 0.92 to 1.34).

Observational Studies

A 2014 retrospective nonrandomized study by Li et al reviewed data on 438 men who received an initial saturation biopsy and 3338 men who had an initial extended prostate biopsy.[4] In an analysis stratified by PSA values, there was a statistically significantly higher rate of prostate cancer detection using a saturation biopsy strategy in men with a PSA less than10 ng/mL. Detection rates among men with PSA less than 4 ng/mL were 47.1% with saturation biopsy (40/85) and 32.8% with extended biopsy (288/878) (p=0.008). Rates among men with PSA between 4 and 9.9 ng/mL were 50.9% with saturation biopsy (144/283) and 42.9% with extended biopsy (867/2022) (p=0.011). There was not a statistically significant difference in detection rates between groups when PSA was greater than10 ng/mL. Detection rates in men with PSA greater than 10/ng/mL were 60% with saturation biopsy (42/70) and 61% with extended biopsy (267/438) (p=0.879).

A related study by Li et al, published in 2014, evaluated the potential benefit of saturation biopsy as the initial prostate biopsy strategy by examining the yield of repeat saturation biopsy in men with initial negative findings by either saturation or extended prostate biopsy.[5] A total of 561 men were included in the study; the initial strategy was saturation biopsy in 81 men and extended biopsy in 480 men. In all cases, saturation biopsy was used for the first repeat biopsy. The overall prostate cancer detection rate was 19.8% in the group with initial saturation biopsy and 34.8% in the group with initial extended biopsy (p=0.008). Low-risk prostate cancer was defined using the Epstein criteria (i.e., Gleason score $\leq$6, PSA density of $\leq$0.15 g/mL per gram, <3 positive cores, and >50% cancer involvement in a single core). The number of intermediate- and/or high-risk prostate cancers identified at first repeat biopsy was 4 of 81 (4.9%) in the initial saturation biopsy group and 85 of 490 (17.3%) in the initial extended biopsy group (p=0.048). The statistically significantly lower prostate cancer detection rate among men who initially underwent saturation biopsy suggests that initial saturation biopsy may be less likely to miss prostate cancer than extended biopsy, and, in this study, prostate cancer diagnosed by repeat saturation after negative initial saturation biopsy was more likely to be clinically insignificant. However, the study indirectly evaluates the initial biopsy, and the number of events in men who underwent an initial saturation biopsy was relatively small.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence from studies comparing the impact of saturation biopsy with standard biopsy for patient management decisions or health outcomes in patients with suspected prostate cancer was identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Subsection Summary: Initial Saturation Biopsy
Studies on saturation biopsy as the initial prostate biopsy strategy were summarized in a 2013 systematic review of eight studies, two of which were RCTs. The prostate cancer detection rate was significantly higher in men with saturation biopsy than with standard biopsy. In a subgroup analysis, the systematic review found that the higher detection rate was limited to men with PSA levels less than 10 ng/mL. Health outcomes (e.g., survival rate) were not reported. Although several studies were published after the systematic review, none showed that initial saturation biopsy detects more clinically significant cancers and none reported progression or survival outcomes.

Repeat Saturation Biopsy

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Review
In 2006, Eichler et al published a systematic review of cancer detection rates and complications of various prostate biopsy schemes.[6] They pooled data that compared various extended biopsy schemes in studies involving 20,698 patients. The authors concluded that prostate biopsy schemes consisting of 12 cores that add laterally directed cores to the standard sextant scheme seem to have the right balance between the cancer detection rate and adverse events and that taking more than 12 cores added no significant benefit.

Observational Studies
Representative studies on saturation biopsy in repeat prostate biopsies follow. The studies focused on cancer detection rates and did not report health outcomes such as overall survival or progression-free survival.

Mabjeesh et al (2012) reported on a high-risk group of men with at least 2 previous negative transrectal biopsies who then underwent transperineal template-guided saturation biopsy.[7] Prostate cancer was detected in 26% of the 92 patients, predominantly in the anterior zones. A median of 30 cores was taken in the saturation biopsies. Gleason score ≥7 was detected in 46% of the diagnosed men. Most of the tumors (83.3%) were found in the anterior zones of the gland, with a significantly higher number of positive cores vs. the posterior zones (mean 4.9 vs. 1.5, p= 0.015).

Lee et al (2011) evaluated the role of transrectal saturation biopsy for cancer detection in men with high-grade prostatic intraepithelial neoplasia (HGPIN) diagnosed by extended biopsy.[8] From 1999 to 2009, 314 men had at least 1 or more repeat biopsies due to the presence of exclusive HGPIN (without any other pathologic finding) in a previous extended biopsy. They were divided into 2 groups according to the initial follow-up biopsy scheme; 178 men were followed using a second standard extended biopsy scheme, and 136 were followed using the saturation biopsy scheme. In the standard repeat biopsy group, 35 (19.7%) of 178 men had cancer on initial repeat biopsy. In the saturation biopsy group, 42 (30.9%) of 136 had cancer on initial repeat biopsy (overall, p=0.04). Multivariate analysis demonstrated that the biopsy scheme on repeat biopsy was an independent predictor of prostate cancer detection (odds ratio, 1.85; 95% CI, 1.03 to 3.29), exclusive of age, PSA level, days from initial biopsy, digital rectal exam (DRE) status, and multifocal prostatic epithelial neoplasia. Pathologic findings on repeat biopsies demonstrated similar Gleason grades, regardless of biopsy technique: a Gleason score of 6 was present in 74.3% and 73.1% of specimens in the standard and saturation schemes, respectively. The presence of a Gleason score of 8 or higher was 8.6% and 9.5%, respectively.

Zaytoun et al (2011) reported the results of a prospective, non-randomized comparative study of extended biopsy versus office-based transrectal saturation biopsy in a repeat biopsy population.[9] After an initially negative biopsy, 1,056 men underwent either a repeat 12- to 14-core biopsy (n=393) or a 20- to 24-core repeat biopsy (n=663) at the discretion of the attending urologist's practice pattern. Indications for second biopsy included a previous suspicious pathologic finding and/or clinical indications such as abnormal digital rectal examination, persistently increased prostate-specific antigen (PSA) and PSA increasing greater than 0.75 ng/mL annually. Prostate cancer was detected in 29.8% (n=315) of repeat biopsies. The saturation biopsy group had a detection rate of 32.7% versus 24.9% in the extended biopsy group (p=0.0075). Of the 315 positive biopsies, 119 (37.8%) revealed clinically insignificant cancer (defined as Gleason sum <7, a total of 3 or fewer positive cores, and a maximum of 50% or less of cancer in any positive core). There was a trend toward increased detection of clinically insignificant cancer detection in the saturation versus the extended biopsy cases, 40.1% versus 32.6%, respectively (p=0.02).

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Subsection Summary: Repeat Saturation Biopsy

Several studies have compared saturation and 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 cancer. Moreover, studies of saturation biopsy as the repeat prostate biopsy strategy focused on cancer detection rates and did not report health outcomes (e.g., progression or survival).

ACTIVE SURVEILLANCE

Clinical Context and Test Purpose

The proposed clinical utility of saturation biopsy is to improve health outcomes by better identifying individuals with prostate cancer who are appropriate candidates for active surveillance through more accurate determination of the Gleason score.

The following **PICO** were used to select literature to inform this review.

Populations

The relevant population of interest is individuals with prostate cancer who are potential candidates for active surveillance.

Interventions

The relevant intervention of interest is saturation biopsy. 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. Saturation biopsy can be performed transrectally or transperineally; the transperineal approach is generally performed as a stereotactic template-guided procedure with general anesthesia. Patients would be tested in the primary or specialty care setting.

Comparators

The comparator of interest is standard biopsy.

Outcomes

Gleason score is a criterion used to select men for active surveillance. More accurate selection of patients for active surveillance could lead to better health outcomes by reducing misclassification of patients as being sufficiently low-risk that active surveillance is an appropriate approach to patient management.

Diagnostic accuracy is a short-term outcome. Survival outcomes would be measured over the long term (e.g., 5- or 10-year survival).

Review of Evidence
Several studies have evaluated the accuracy of saturation biopsy for identifying patients who might be suitable candidates for active surveillance. In 2013, Linder et al reviewed data on 500 consecutive patients who underwent standard template prostate biopsy (12 cores) or saturation biopsy (at least 18 cores) before radical prostatectomy.[10] They identified 218 patients who would have been candidates for active surveillance. Criteria were Gleason score no greater than 6, clinical stage T1 or T2a, PSA level less than 10 ng/mL, and involvement of no more than 33% of cores. Among these 218 patients, 124 had undergone standard biopsy and 94 underwent saturation biopsy. In a multivariate analysis, biopsy method was not a significant predictor of upstaging on analysis of pathologic findings (p=0.26). In addition, the 5-year biochemical failure-free survival rates (defined as PSA level at least 0.4 ng/mL) did not differ significantly in the 2 groups: rates were 97% for standard biopsy and 95% for saturation biopsy (p=0.11).

In 2016, Quintana et al compared the utility of 12-core biopsy and saturation biopsy (18-33 cores; median, 20 cores) in 375 patients for accurately determining the Gleason score.[11] The authors stated that patients with Gleason scores of 4 or higher were generally not considered candidates for active surveillance. Gleason score was confirmed by pathologic analysis of prostate specimens. For detecting a high Gleason grade (i.e., ≥4), there were no statistically significant differences in the sensitivity, specificity, negative predictive value, or positive predictive value of 12-core versus saturation biopsies. The areas under the receiver operating curve were 0.82 for saturation biopsy and 0.84 for 12-core biopsy (p value not reported).

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No direct evidence from studies comparing the impact of saturation biopsy with standard biopsy for patient management decisions or health outcomes in patients with prostate cancer being considered for active surveillance was identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Section Summary: Active Surveillance
Several studies have compared saturation with standard prostate biopsies in the active surveillance setting and have failed to find differences between these methods. 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.

SUMMARY OF EVIDENCE

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.

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.

Although an overabundance of evidence is lacking as to whether this leads to improved health outcomes, it is possible that clinically significant cancers could be detected earlier using this technique. Therefore, the use of saturation biopsy has been established as an additional tool for active prostate cancer surveillance.

SUPPLEMENTAL INFORMATION

Clinical Input Received Through Physician Medical Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 3 physician specialty societies and 3 academic medical centers while this policy was under review in 2014. There were 5 responses from 1 specialty society, 4 responses from another, and 1 from the third for a total of 10 specialty society responses. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless

otherwise noted. Most reviewers stated that saturation biopsy is considered investigational and did not think that saturation biopsy in patients with 2 prior negative biopsies and persistently rising PSA level is considered medically necessary. Clinicians proposed various options that could be used in the situation of prior negative biopsies and a rising PSA: there was no consensus on the best alternative approach. Suggestions included magnetic resonance imaging (MRI) with transrectal ultrasound, multiparametric MRI, and 3T pelvic MRI. There was near consensus that there is insufficient evidence to support use of any of these techniques in the situation being considered

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Comprehensive Cancer Network (NCCN) Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines (v.4.2024) on early detection of prostate cancer state that despite emerging evidence, the panel does not recommend a saturation biopsy strategy for all men 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) and uncontrolled observational studies published between 2006 and 2013.

NCCN guidelines on prostate cancer treatment (v.4.2024) do not mention saturation biopsy.[13]

U.S. Preventive Services Task Force Recommendations
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.[14]

Government Regulations
National/Local:

There is no national or local coverage determination on this topic. There are fees for the procedure codes listed in this policy.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Cryosurgical Ablation of the Prostate (Retired)

References

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17. HAYES Medical Technology Directory. Prostate Saturation Biopsy for Diagnosis of Prostate Cancer. Lansdale, PA: HAYES, Inc., July 2, 2010, updated June 29, 2012. Archived August 2015.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through November 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/13	2/19/13	3/4/13	Joint policy established
3/1/15	12/12/14	12/29/14	Routine maintenance. References and rationale updated.
3/1/16	12/10/15	12/10/15	Routine maintenance. References and rationale updated. Codes updated.
3/1/17	12/13/16	12/13/16	Routine policy maintenance. Updated rationale/references.
3/1/18	12/12/17	12/12/17	Routine policy maintenance. Updated rationale, added reference #3. No change in policy status.
3/1/19	12/11/18		Routine policy maintenance. No change in policy status.
3/1/20	12/17/19		Routine policy maintenance. No change in policy status.
3/1/21	12/15/20		Routine policy maintenance. No change in policy status.
3/1/22	12/14/21		Routine policy maintenance. No change in policy status.
3/1/23	12/20/22		Updated rationale section, removed two references. No change in policy status.
3/1/24	12/19/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
3/1/25	12/17/24		Routine policy maintenance, no change in status. Vendor managed: N/A (ds)

Next review date: 4th Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SATURATION BIOPSY FOR DIAGNOSIS AND STAGING OF PROSTATE CANCER

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.