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

**POLICY**

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.

**CODING**

There is a CPT code for saturation biopsy:

55706 Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance.

This procedure may be reported with code 55700 (biopsy, prostate; needle or punch, single or multiple, any approach) when performed without stereotactic template guidance. This method may involve ultrasound guidance, which is reported with code 76942 (ultrasonic guidance for needle placement [eg, biopsy, aspiration, injection, localization device], imaging supervision, and interpretation).

There is also a HCPCS G code that can be reported for the surgical pathology associated with this procedure as well as other prostate needle biopsies:

G0416 Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method.
BENEFIT APPLICATION

BLUECARD/NATIONAL ACCOUNT ISSUES
State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only on the basis of their medical necessity.

BACKGROUND

PROSTATE CANCER
Prostate cancer is common and is the second leading cause of cancer-related deaths in men in the United States.

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 screening programs that identify cancer in prostates that are normal to palpation and to transrectal ultrasound. For patients with an elevated prostate-specific antigen 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 diagnose 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 specimens. 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; a sampling of the lateral horn might increase the cancer detection rate by approximately 25%.

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

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

RATIONALE
This evidence review was created in October 2009 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through May 29, 2019.

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 the 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 vs other biopsy methods.

The question addressed in this evidence review is: In individuals with suspected prostate cancer, does initial or repeat saturation biopsy improve the diagnosis of patients with clinically significant prostate cancer and lead to improved patient management decisions and health outcomes?

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

Patients
The relevant population of interest are patients with suspected prostate cancer.

Interventions
The therapy being considered is an initial or repeat saturation biopsy.

Comparators
The following practice is currently being used: standard biopsy.

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.

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

Setting

Patients would be tested in the primary or specialty care setting.

Initial Saturation Biopsy

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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).

The literature on diagnostic accuracy consists of studies reporting prostate cancer detection rates or diagnostic yields as a primary outcome. These data were summarized in a systematic review by Jiang et al (2013) on the utility of an initial transrectal saturation biopsy compared with an extended biopsy strategy. Eight studies (total n=11997 participants) met eligibility criteria (ie, compared 2 biopsy strategies on initial biopsy). Two of the studies were randomized controlled trials (RCTs), one used a paired design, and five were nonrandomized trials. Overall, prostate cancer was diagnosed in 2328 (42.4%) of 5486 men who underwent saturation biopsy compared with 2562 (39.3%) of 6511 men who had an extended biopsy. The detection rate was statistically significantly higher in the saturation biopsy group (risk difference, 0.004; 95% confidence interval [CI], 0.01 to 0.008; p=0.002). When only the higher-quality studies were analyzed (ie, the RCTs and prospective paired design), the detection rate remained statistically significantly higher for saturation biopsy (risk difference, 0.03; 95% CI, 0.01 to 0.05; p=0.01). Subgroup analysis found that the difference in detection rates between saturation and extended biopsy strategies was limited to the subgroup of men with prostate-specific antigen (PSA) levels less than 10 ng/mL. Within this group, prostate cancer was diagnosed in 998 (38%) of 2597 men who had saturation biopsies and in 1135 (34%) of 3322 men with extended biopsies (risk difference, 0.04; 95% CI, 0.01 to 0.07; p=0.002). Although the subgroup analyses included individual risk factors such as PSA level, they did not differentiate between detection of lower and higher risk prostate cancers. In addition, differences in health outcomes (eg, progression-free survival, overall survival [OS]) were not reported.

A related meta-analysis was published by Xue et al (2017). 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).

A retrospective nonrandomized study by Li et al (2014) reviewed data on 438 men who received an initial saturation biopsy and 3338 men who had an initial extended prostate biopsy. In an analysis stratified by PSA levels, there was a statistically significant higher rate of prostate cancer detection using a saturation biopsy strategy in men with a PSA level of less than 10 ng/mL. Detection rates among men with a PSA level of less than 4 ng/mL were 47.1% (40/85) with saturation biopsy and 32.8% (288/878)
with extended biopsy (p=0.008). Rates among men with PSA levels between 4 ng/mL and 9.9 ng/mL were 50.9% (144/283) with saturation biopsy and 42.9% (867/2022) with extended biopsy (p=0.011). There was no statistically significant difference in detection rates between groups when PSA levels were greater than 10 ng/mL. Detection rates at PSA levels greater than 10 ng/mL were 60% (42/70) with saturation biopsy and 61% (267/438) with extended biopsy (p=0.879).

A related study by Li et al (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 an extended prostate biopsy. 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 rates were 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 (ie, Gleason score ≤6, PSA density of ≤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 (ie, not low-risk) identified at first repeat biopsy was 4 (4.9%) of 81 in the initial saturation biopsy group and 85 (17.3%) of 490 in the initial extended biopsy group (p=0.048). The statistically significantly lower prostate cancer detection rate among men who initially underwent saturation biopsy would suggest that initial saturation biopsy might 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 evaluated 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 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 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.

Because the evidence is insufficient to demonstrate the detection of clinically significant cancers with saturation biopsy, 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 8 studies (2 were RCTs). The prostate cancer detection rate was significantly higher in men with saturation biopsy than in men 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 (eg, survival rate) were not reported. Although several studies were published after the systematic review, none showed that initial saturation biopsy detected more clinically significant cancers and none reported progression or survival outcomes.

**Repeat Saturation Biopsy**

**Technically Reliable**

Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

**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).

Eichler et al (2006) published a systematic review of cancer detection rates and complications of various prostate biopsy strategies. They pooled data that compared various extended biopsy schemes for studies involving 20698 patients. Reviewers 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.

Representative studies of saturation biopsy in repeat prostate biopsies follow. These studies focused on cancer detection rates and did not report health outcomes (eg, OS, 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. Prostate cancer was detected in 24 (26%) of the 92 patients, predominantly in the anterior zones. A median of 30 cores was taken in the saturation biopsies. Gleason scores of 7 or higher were detected in 11 (46%) of the diagnosed men. Most tumors (83.3%) were found in the anterior zones of the gland, with a significantly higher number of positive cores than in 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 diagnosed by extended biopsy. From 1999 to 2009, 314 men had at least 1 or more repeat biopsies due to the presence of exclusive high-grade prostatic intraepithelial neoplasia (without any other pathologic finding) in a previously 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 status, and multifocal prostatic epithelial neoplasia. Pathologic findings on repeat biopsies demonstrated similar Gleason scores, 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 on the results of a prospective, nonrandomized comparative study of extended biopsy vs office-based transrectal saturation biopsy in a repeat biopsy population. After an
initial negative biopsy, 1056 men underwent 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 the second biopsy included a previous suspicious pathologic finding and/or clinical indications such as an abnormal digital rectal exam, persistently increased PSA level, and PSA level increasing more 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% vs 24.9% in the extended biopsy group (p=0.008). Of the 315 positive biopsies, 119 (37.8%) revealed clinically insignificant cancer (defined as Gleason score <7, a total of ≤3 positive cores, and maximum of ≤50% of cancer in any positive core). There was a trend toward increased clinically insignificant cancer detection for saturation biopsy (40.1%) vs extended biopsy (32.6%; 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 RCTs.

No direct evidence from studies comparing the impact of saturation biopsy with standard biopsy for patient management decisions or health outcomes in patients requiring a repeat biopsy for 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.

Because the evidence is insufficient to demonstrate the detection of clinically significant cancers with saturation biopsy, no inferences can be made about clinical utility.

Subsection Summary: Repeat Saturation Biopsy

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).

Active Surveillance

Clinical Context and Proposed Clinical Utility

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

The question addressed in this evidence review is: In individuals with prostate cancer who are candidates for active surveillance, does saturation biopsy improve the identification of tumor grade and improve health outcomes compared with standard biopsy?

The following PICOTS were used to select literature to inform this review.
Patients
The relevant population of interest are patients with prostate cancer who are potential candidates for active surveillance.

Interventions
The test being considered is a saturation biopsy.

Comparators
The following practice is currently being used: standard biopsy.

Outcomes
The 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 a sufficiently low-risk that active surveillance is an appropriate approach to patient management.

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

Setting
Patients would be tested in the primary or specialty care setting.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires a review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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).

Several studies have evaluated the accuracy of saturation biopsy for identifying patients who might be suitable candidates for active surveillance. Linder et al (2013) 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 a 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 of at least 0.4 ng/mL) did not differ significantly between groups: rates were 97% for standard biopsy and 95% for saturation biopsy (p=0.11).

Quintana et al (2016) compared 12-core biopsy with saturation biopsy (18-33 cores; median, 20 cores) in 375 patients to determine the Gleason score accurately.11 The authors stated that patients with Gleason scores of four 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 (ie, ≥4),
there were no statistically significant differences in the sensitivity, specificity, negative predictive value, or positive predictive value of 12-core vs saturation biopsies. The areas under the receiver operating characteristic 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.

Because the evidence is insufficient to demonstrate that saturation biopsy improves the identification of tumor grade, no inferences can be made about clinical utility.

**Summary of Evidence**

For individuals who have suspected prostate cancer who receive initial saturation biopsy, the evidence includes RCTs, observational studies, and systematic reviews. The relevant outcomes are 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

Clinical Input From Physician Specialty 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 from 3 physician specialty societies and 3 academic medical centers while this policy was under review in 2014. There were five responses from one specialty society, four responses from another, and one response from the third, for a total of ten specialty society responses. Most reviewers stated that saturation biopsy is considered investigational and did not think that saturation biopsy in patients with two prior negative biopsies and persistently rising prostate-specific antigen level is considered medically necessary. Clinicians proposed various options that could be used in the situation of prior negative biopsies and rising prostate-specific antigen level: there was no consensus on the best approach. Suggestions included magnetic resonance imaging with transrectal ultrasound, multiparametric magnetic resonance imaging, and 3T pelvic magnetic resonance imaging. There was near consensus that there is insufficient evidence to support the use of any of these techniques for the indications being considered.

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.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in June 2019 did not identify any ongoing or unpublished trials that would likely influence this review.
ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state. States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntarily offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES


**CODES**

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<th>Description</th>
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<td>CPT</td>
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<td>Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance</td>
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<td>HCPCS</td>
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**POLICY HISTORY**

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**MP 7.01.121**

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

- Literature search through May 7, 2018; reference 14 added. Policy statement unchanged.

- 07/22/19: Replace policy
  
  Blue Cross of Idaho adopted changes as noted, effective 07/22/2019. Policy updated with literature search through May 29, 2019; no references added. Policy statement unchanged.