DRAFT Medical Coverage Policy | Saturation Biopsy for Diagnosis, Staging and Management of Prostate Cancer

EFFECTIVE DATE: 01|01|2027
POLICY LAST REVIEWED: 09|02|2026

OVERVIEW
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 individuals with prostate cancer.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans and Commercial Products
Saturation biopsy is covered in the diagnosis, staging, and management of prostate cancer.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Prostate cancer is a common cancer 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 (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, 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 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 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 may 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 may lead to missed cancers. Saturation biopsy may be performed transrectally or with a transperineally; 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 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 identify tumor grade more accurately than standard biopsy.

CODING

Medicare Plans and Commercial Products
The following CPT code(s) are covered for Medicare Advantage Plans and Commercial Products:

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

When performing saturation biopsy, claims should not be filed with codes 55700 (Code Deleted Effective 12/31/2025) or G0416, as these are not specific to saturation sampling.

RELATED POLICIES

None

PUBLISHED

Provider Update, November 2026
Provider Update, November 2025
Provider Update, October 2024
Provider Update, November 2023
Provider Update, January/December 2022

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. 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

DRAFT

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. 2018May; https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prostate- cancer-screening1. Accessed June 6, 2023.

DRAFT

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.