

Corporate Medical Policy

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

File Name:	saturation_biopsy_for_diagnosis_and_staging_of_prostate_cancer
Origination:	11/2009
Last CAP Review:	11/2011
Next CAP Review:	11/2012
Last Review:	11/2011

Description of Procedure or Service

Saturation biopsy involves obtaining at least 20 biopsy tissue cores from the prostate in a systematic manner. Use of saturation biopsy has been proposed for use in the diagnosis (for initial or repeat biopsy), staging, and management of patients with prostate cancer.

Prostate cancer is a common cancer in men and is the second leading cause of cancer-related deaths in men in the US. 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 PSA (prostate-specific antigen) screening programs that identify cancer in prostates that are normal to palpation and to trans-rectal 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 1990's, use of sextant biopsies involving six random, evenly distributed biopsies became the standard approach to the diagnosis of prostate cancer. In the late 1990's 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 sub-total 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 the office setting.

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. While saturation biopsy can also be performed in an office-based setting, some perform this approach with general anesthesia.

Related Policies:

Cryosurgery Ablation of the Prostate

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

Policy

BCBSNC will not provide coverage for saturation biopsy of the prostate. It is considered investigational in the diagnosis, staging, and management of prostate cancer. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Saturation Biopsy for Diagnosis and Staging of Prostate Cancer is covered

Not Applicable

When Saturation Biopsy for Diagnosis and Staging of Prostate Cancer is not covered

Saturation biopsy for diagnosis, staging and management of prostate cancer is not covered. It is considered investigational and BCBSNC does not cover investigational services. In general, saturation biopsy is considered as a minimum of 20 cores taken from the prostate.

Policy Guidelines

Use of saturation biopsy has not been shown to improve detection or staging over use of extended biopsies. In addition, no studies have been done that link the information obtained through saturation biopsy with improvement in net health outcome. The impact of saturation biopsy on clinical decision making and long-term health outcomes, including prostate cancer mortality, is inconclusive at this time.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 55706, G0416, G0417, G0418, G0419

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

External Specialty-Matched Consultant Review 12/08.

Ashley RA, Inman BA, Routh JC et al. Reassessing the diagnostic yield of saturation biopsy of the prostate. *Eur Urol* 2008; 53(5):976-81.

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Simon J, Kuefer R, Bartsch G Jr et al. Intensifying the saturation biopsy technique for detecting prostate cancer after previous negative biopsies: a step in the wrong direction. *BJU Int* 2008; 102(4):459-62.

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* 2006; 175(5):1605-12.

Patel AR, Jones JS. Optimal biopsy strategies for the diagnosis and staging of prostate cancer. *Curr Opin Urol* 2009; 19(3):232-7.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology – v.2.2009 Prostate Cancer. Retrieved on October 28, 2009 from http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology – v.2.2010 Prostate Cancer Early Detection. Retrieved on October 28, 2009 from http://www.nccn.org/professionals/physician_gls/PDF/prostate_detection.pdf

External Specialty-Matched Consultant review 1/09.

Senior Medical Director review - 11/11/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.121, 10/8/10.

Specialty Matched Consultant Advisory Panel review 12/2010

National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Prostate Cancer (V.1.2011). retrieved on November 3, 2011 from http://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf.
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.121, 10/04/11

Specialty Matched Consultant Advisory Panel review 11/2011

Policy Implementation/Update Information

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| 12/7/09 | New policy issued. Saturation biopsy for diagnosis, staging and management of prostate cancer is not covered. It is considered investigational and BCBSNC does not cover investigational services. In general, saturation biopsy is considered as a minimum of 20 cores taken from the prostate. (pmo) |
| 6/22/10 | Policy Number(s) removed (amw) |
| 1/18/11 | Specialty Matched Consultant Advisory Panel review 12/2010. References updated. (mco) |
| 12/20/11 | Specialty Matched Consultant Advisory Panel review 11/2011. References updated. No changes to Policy Statement. (mco) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

