

Corporate Medical Policy

Epithelial Cell Cytology and Breast Cancer Risk Assessment

File Name: epithelial_cell_cytology_and_breast_cancer_risk_assessment
Origination: 6/2001
Last CAP Review: 9/2008
Next CAP Review: 11/2011
Last Review: 4/2011

Description of Procedure or Service

Evaluation of breast duct epithelial cells is proposed as a technique to assess breast cancer risk and as a diagnostic tool for detecting breast cancer. Different collection systems have been investigated as techniques to obtain nipple aspirates; the collected epithelial cells are then examined cytologically. These techniques have been evaluated as a diagnostic and risk assessment tool in patients at high risk of breast cancer but without clinical or mammographic findings. For example, the finding of atypical hyperplasia may be associated with an increased risk of breast cancer. Malignant cells may also be identified in rare cases.

Ductal lavage of the breast is a minimally invasive method of collecting sample of cells (epithelial cells) from the individual milk (mammary) ducts of the breast for analysis under a microscope. The procedure can be performed in a physician's office or outpatient clinic. Breast ductal lavage involves the following steps:

Nipple aspiration. After application of an anesthetic cream to numb the nipple area, the patient gently massages the breast to bring any fluid in the mammary ducts to the nipple. A manual breast aspirator is centered directly over the nipple and gentle suction is used to draw tiny amounts of fluid (droplets) from the mammary ducts to the surface of the nipple.

Ductal cannulation. A tiny tube (microcatheter) is inserted into the natural nipple opening of the individual mammary ducts. A small amount of anesthetic is infused into the duct to numb the inside.

Cell Collection. Sterile saline (salt water) is slowly infused into the microcatheter to rinse (irrigate) the duct and collect cells. The ductal fluid is then withdrawn through the microcatheter and placed into a collection vial.

Cell analysis. The ductal fluid is checked under a microscope for the presence of cells that may indicate cancer or those that may increase the risk for breast cancer.

A suction collection system, the HALO NAF collection system (Neomatrix) has also received FDA clearance as a technique to collect ductal epithelial cells. In this system, small breast cups are placed on the woman's breast and adjusted to fit. The system is then engaged and automatically warms the breast and applies light suction to bring nipple aspirate fluid to the surface. Similar to ductal lavage, the fluid is then analyzed microscopically for cytologic abnormalities.

******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.***

Policy

Cytologic analysis of epithelial cells from nipple aspiration fluid is considered investigational as a technique to assess breast cancer risk and manage patients at high risk of breast cancer. Techniques of collecting nipple aspiration fluid include, but are not limited to, ductal lavage and suction.

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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 Epithelial Cell Cytology and Breast Cancer Risk Assessment is covered

Not applicable.

When Epithelial Cell Cytology and Breast Cancer Risk Assessment is not covered

It is not covered. It is considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

In 2007, the American Society of Breast Surgeons replaced their previous official statement regarding ductal lavage and cell-based risk assessment with "Ductal Cell-Based Risk Assessment", which reads in part:

"Ductal lavage is a minimally-invasive method of collecting breast epithelial cells for cytological examination. Cytologic interpretation of fluid obtained by ductal lavage is not an approved screening tool for the detection of breast cancer. The American Society of Breast Surgeons cautions that ductal lavage should not replace standard cancer screening methods. Long-term studies are necessary to better define the risk assessment contribution of cytologic atypia detected via these and other methods. The American Society of Breast Surgeons encourages participation in such trials."

According to the guidelines for Breast Cancer Screening and Diagnosis issued by the National Comprehensive Cancer Network, "Current evidence does not support the use of breast scintigraphy (eg, sestamibi scan) or ductal lavage, MRI in average risk women as routine screening procedures."

There is inadequate published literature that provides a detailed analysis of how cytologic analysis of epithelial cells from nipple aspiration fluid would be used in the clinical management of the patient. Clinical studies published in peer-reviewed journals are necessary to determine the value of the results in the screening, diagnosis and clinical management of breast cancer. (Refer to policy titled "Investigational (Experimental) Services.")

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: no specific code

There is no specific code for this procedure. To report, use the most appropriate unlisted procedure code such as 19499.

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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

From Policy Entitled: Breast Ductal Lavage:

TEC Clearinghouse, Technologica, April 2001

Obstetrics and Gynecology Supplement, April 30, 2001 (97(4 suppl):2S). *Detection of Premalignant and Malignant Breast Cells by Ductal Lavage*. William C. Dooley, M.D., Johns Hopkins School of Medicine, Baltimore, MD.

BCBSA Medical Policy Reference Manual - Policy 2.01.45 - Review date: 2/15/02

National Cancer Institute Online - Cancer Fact Sheet - Improving Methods for Breast Cancer Detection and Diagnosis dated 4/26/02

BCBSA Medical Policy Reference Manual - Policy 2.01.45 - Review date: 5/15/02

ECRI Windows on Medical Technology™ - Ductal Lavage and Nipple Aspiration for Identifying Women at High Risk of Breast Cancer - July 2002. Issue No. 80

Specialty Matched Consultant Advisory Panel review 8/02

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.45, 12/17/03.

ECRI Hotline Response - Ductal Lavage and Nipple Aspiration for Identifying Women at High Risk of Breast Cancer (04/27/2004) retrieved on 6/15/04 from http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc_id+7417&q=Breast+ductal&nm

Specialty Matched Consultant Advisory Panel - 8/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.45, 3/15/05.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.45, 12/14/05.

Specialty Matched Consultant Advisory Panel - 8/30/2006

Policy retitled: Epithelial Cell Cytology and Breast Cancer Risk Assessment:

National Comprehensive Cancer Network. Practice Guidelines in Oncology - v.1.2008. Breast Cancer Screening and Diagnosis retrieved on 6/25/08 from http://www.nccn.org/professionals/physician_gls/PDF/breast-screening.pdf

The American Society of Breast Surgeons. Official Statement. Ductal Cell-Based Risk Assessment retrieved on 6/2/08 from http://www.breastsurgeons.org/officialstmts/Ductal_Cell.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.45, 4/17/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.45, 6/12/08

Specialty Matched Consultant Advisory Panel - 9/4/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.45, 6/11/09

Policy Implementation/Update Information

From Policy Entitled: Breast Ductal Lavage

6/2001 Original policy issued.

11/01 Revised "Next Review Date". This was changed to 2003.

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- 1/03 Specialty Matched Consultant Advisory Panel review 8/15/02. Reaffirmed policy. Corrected typographical errors. Revised description section for clarity. System coding changes.
- 1/04 Benefits Application and Billing/Coding sections updated for consistency.
- 9/9/04 Removed 19499 from Billing Coding section, as it is designated for reporting "unlisted procedures", added codes 0046T and 0047T as these codes are specific to this policy. Specialty Matched Consultant Advisory Panel Review. No changes to criteria.
- 10/2/06 Added policy guidelines, key word and reference sources. No changes to criteria. (pmo)

Policy retitled: Epithelial Cell Cytology and Breast Cancer Risk Assessment

- 10/6/08 Description, Policy statement and Policy Guidelines revised, added key words, medical term definitions reference sources. Procedure remains investigational. Specialty Matched Consultant Advisory Panel 9/4/08. (pmo)
- 3/2/09 Under Billing/Coding section, removed CPT codes 0046T and 0047T-codes deleted as of 12/31/08. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 4/26/11 Updated description section. No change in Policy Statement or noncoverage criteria. Reference updated. (adn)

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.