Medical Policy

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Category: Surgery

Title: Breast Ductal Lavage

Procedure Code(s): 19499, A4649, 0046T, 0047T 7/1/03

Description / Background

Breast cancer originates in the epithelial cells that line the milk ducts of the breast. There are approximately 6-9 ductal systems in each breast, each of which is a separate structure terminating at the nipple surface. Progressive molecular and morphological changes may occur with these epithelial cells and the cells then become atypical. These atypical epithelial cells have an increased risk of becoming cancerous and may invade beyond the ductal system and into the surrounding tissue of the breast. The purpose of ductal lavage is to collect the atypical ductal epithelial cells for cytological analysis to assess a woman's risk for breast cancer.

At the present time, detection of atypical hyperplasia in the breast is the only readily identified, reliable marker of individualized risk for the development of breast cancer. The cytological analysis of the epithelial cells lining the milk ducts is an accepted procedure with established clinical utility. Ductal cells have been collected for several decades using the following techniques:

- Collection of spontaneous nipple discharge
- Collection of nipple discharge through aspiration, and
- Collection of cells by random fine needle aspiration.

Breast ductal lavage is superior to existing methods of collecting atypical epithelial cells in breasts that have no palpable or imageable lesions.

Breast ductal lavage is a minimally invasive office procedure to collect ductal epithelial cells for cytological analysis which is performed only on women who are defined as "at high risk" for

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developing breast cancer. Methods that assess a woman's risk for breast cancer currently include the following parameters:

- personal and family history
- Genetic mutation analysis, and
- statistical models (e.g., Gail Model)

The primary clinical utility in detecting atypical breast epithelial cells via ductal lavage at the current time is to improve risk stratification for women who already are at an elevated risk for developing breast cancer. Risk stratification can be defined as identifying individuals at particularly high risk for an outcome. This evaluation of epithelial cells from the breast provides a clinician with a pathway to refine current risk assessment by sub-stratifying patients who are at highest risk for developing breast cancer. The presence of cellular atypia along with historical risk factors such as family history, genetic markers along with the Gail Model refines and/or individualizes the patient's risk assessment, enabling further risk stratification.

Medical and surgical oncologists are presently offering ductal lavage clinically to their high-risk patients, not to detect cancer but to assess risk. The key difference is that the endpoint in the case of risk assessment is cytology. Unlike the case with cancer detection, where the gold standard is histology, there is no need in the risk assessment context to correlate cytology findings with underlying histology.

Identification of atypical cells in high-risk women offer a number of treatment options which include:

- Increased surveillance repeat physical exams, increased frequency of mammography
- Risk reduction through chemo-prevention (e.g., tamoxifen)
- Surgical intervention (prophylactic mastectomy)

The ductal lavage procedure involves the following:

- An anesthetic cream is applied to the nipple and surrounding areola for approximately thirty minutes prior to the procedure
- After self-massage of the breast an aspirator (suction cup) is centered directly over the nipple and a syringe is attached and gentle suction is applied to draw nipple aspirate fluid (NAF) droplets to the surface of the nipple
- The NAF droplet identifies the fluid-yielding ducts for lavage and also locates the natural openings of ducts on the surface of the nipple
- Once the ductal orifice has been located by the presence of the NAF droplet, a flexible microcatheter is inserted about one-half inch (1.5 cm) into the duct through its natural opening on the nipple surface. A small amount of anesthetic is infused intraductally through the catheter
- The ductal system is then infused with 2-4 ml of saline incrementally up to 10-20 ml. Saline rinses the duct and the epithelial cells are found in the rinse
- Breast massage by the physician facilitates ductal fluid collection through the catheter into a collection chamber
- The fluid collected from the duct is placed in a sterile vial and sent to the laboratory for analysis

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CPT / HCPCS Level II Codes and Description

19499 Unlisted procedure, breast * Use to bill until 7/1/2003

0046T Catheter lavage of a mammary duct(s) for collection of cytology specimen(s), in high-risk individuals (Gail risk scoring or prior personal history of breast cancer), each breast; single duct *Effective 7/1/2003.

0047T ….each additional duct *Effective 7/1/2003.
A4649 Surgical supply; miscellaneous

Diagnoses / Medical Conditions

Malignant neoplasms of female breast, including
- nipple and areola
- central portion
- upper-inner quadrant
- lower-inner quadrant
- upper-outer quadrant
- lower-outer quadrant
- axillary tail
- other specified sites of female breast

Three digit categories:
- Personal history of malignant neoplasm
- Family history of malignant neoplasm, classified to 174….Breast
- Family history of malignant neoplasm, classified to 183….Ovary and other uterine adnexa

Medical Policy Statement

Breast ductal lavage is a safe and minimally invasive office procedure that can provide a woman who is at elevated risk for developing breast cancer with additional information regarding that risk. The use of this technology is an adjunct to the present risk assessment tools in the evaluation of women at high risk for developing breast cancer.

Rationale

Breast cancer originates in the epithelial cells that line the milk ducts of the breast. Early molecular and morphological changes can be identified through cytological analysis of the ductal fluid using ductal lavage. A sufficient sample of fluid for analysis by ductal lavage is easier to obtain than through fine needle aspiration of a palpable lesion or from spontaneous

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nipple discharge. Ductal lavage is a safe and minimally invasive procedure that can provide a woman who is defined as high risk for developing breast cancer with additional information regarding that risk. This risk assessment tool assists the woman and her physician in weighing the risks and benefits of proposed treatment modalities and the next steps in the clinical management of her disease.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

Breast ductal lavage is a safe and minimally invasive office procedure that can provide a woman who is at elevated risk for developing breast cancer with additional information regarding that risk. The use of this technology is an adjunct to the present risk assessment tools in the evaluation of women at high risk for developing breast cancer.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Breast ductal lavage is a risk assessment tool and not a screening or diagnostic technology that should only be used in a category of women defined as high risk by any of the following parameters:

- Patients who demonstrate a documented pedigree consistent with the autosomal transmission (familial form) of breast cancer
- Patients who demonstrate the presence of genetic markers currently recognized as increasing the risk of developing breast cancer (e.g., BRCA1 and BRCA2)
- Patients with the histologic (tissue) diagnosis of lobular carcinoma in situ (LCIS) of the breast
- Patients with the histologic (tissue) diagnosis of atypical hyperplasia on breast biopsy, or determined to have the capacity to progress to cancer (histologic grade 3 lesions)
- A five-year risk of invasive breast cancer development of $\geq$1.7% according to the Gail model.

Related Policies

Genetic Testing for Inherited BRCA1 or BRCA2 Mutations

Medicare Information

CMS has no national policy for this procedure; Local Michigan Medicare does not have a policy for this procedure. Medicaid does not have a policy regarding this procedure and will review on an individual consideration (IC) basis.

(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.)

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- Winifred S. Hayes, Hayes Medical Technology Directory #A0103.12, "Breast Ductal Lavage for Cytological Examination in Women at High Risk for Breast Cancer", effective date July 2002.

The articles reviewed in this research includes those obtained in an internet based literature search for relevant medical references through January 27, 2003, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Date	Rationale
2/11/03	Joint medical policy established.
11/18/03	Policy retired; see comment below

Next Review: This is an established policy and no longer subject to periodic review

Pre-Consolidation Medical Policy History

Original Policy Date		Comments
BCN	N/A	Revised: N/A
BCBSM	N/A	Revised: N/A

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