

# Medical Coverage Policy



## Breast Ductal Lavage

Device/Equipment  Drug  Medical  Surgery  Test  Other

Effective Date:	9/1/2001	Policy Last Updated:	12/6/2011
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**Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

**Prospective review is not required.**

### Description:

All ductal and lobular breast cancers originate in a single layer of epithelial cells that line the ductal/lobular system of all milk ducts. Ductal lavage enables the retrieval of these cells using a microcatheter inserted into the milk ducts through the nipple orifices. A saline solution is flushed through the catheter into the ducts to wash out cells for cytological examination. The ductal lavage technique is directed at patients identified as being at high risk for breast cancer utilizing the Gail index, a personal history of breast cancer or evidence of BRCA mutation and have no mammographic abnormality.

The gold standard for examination of these cells has been nipple aspiration with cytopathological examination of the specimen. Ductal lavage is designed to harvest an increased number of cells with the ability to gather cells from individual milk ducts. Each breast has 6 to 8 milk ducts. The technique is based upon decades of research indicating that breast cancer originates in the epithelial lining of the milk ducts and involves a series of molecular changes from normal to abnormal to malignant. As long as the abnormal cells are contained within the ducts or lobules, they are termed preinvasive disease. Once they have invaded surrounding tissue, they are considered invasive cancer.

The procedure has been dubbed "breast pap smear" because like the test for cervical cancer, it is a nonsurgical approach to identifying abnormal cells prior to their development into cancer. Mammography is the standard for early detection for breast cancer. However, by the time an abnormality is detected via mammography, the lesion has grown to a size of 1 to 2 cm and may have been present for 6 to 8 years.

The value of cytopathological examination of specimens from the breast, especially from nipple aspiration is well documented. However, no studies utilizing cells acquired via ductal lavage have been reported. There is as yet no consensus among practicing cytopathologists as to the criteria for interpreting specimens obtained by ductal lavage. While the technique may be theoretically interesting and even promising in early studies, it has yet to be the subject of sufficient controlled studies to allow for a determination of its effectiveness, accuracy and safety in both an absolute sense and in comparison to more established techniques for acquisition and evaluation of breast cytology. It is not presently known how the technique will modify management of the high risk patient.

Fiber optic ductoscopy is a technique that provides direct visual examination of the breast ducts through nipple orifice cannulation and exploration. It has been explored in the following clinical situations:

- Diagnostic technique in women with spontaneous nipple discharge (as potential alternative to surgical exploration)
- A follow-up to atypical cytology from ductal lavage specimen
- Delineation of ductal disease to define margins for surgical resection
- Direct delivery of therapeutic agents

**Medical Criteria:**

Not applicable

**Policy:**

Breast ductal lavage is considered **not medically necessary** as there is insufficient controlled studies to allow for a determination of its effectiveness, accuracy and safety in comparison to more established techniques for acquisition and evaluation of breast cytology.

Fiber optic Ductoscopy is considered **not medically necessary** for the detection, diagnosis or treatment of breast cancer.

**Coverage:**

Benefits may vary between groups/contracts. Please refer to individual Evidence of Coverage or Subscriber Agreement for the applicable "services not medically necessary" coverage.

**Codes:**

There is not a CPT code which specifically describes breast ductal lavage or fiber optic ductoscopy.

**19499** Unlisted procedure, breast

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Policy Update, July 2006

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**References:**

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