Medical Coverage Policy | Breast Ductal Lavage for Detection of Breast Cancer

EFFECTIVE DATE: 09|01|2001
POLICY LAST UPDATED: 01|22|2016

OVERVIEW
Ductal lavage is a method of collecting breast ductal epithelial cells for cytological analysis. It can be used as a risk assessment tool in women with a higher risk of breast cancer. It is sometimes called the "breast Pap smear."

MEDICAL CRITERIA
BlueCHiP for Medicare and Commercial Products
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Breast ductal lavage is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective in comparison to more established techniques for acquisition and evaluation of breast cytology.

Fiberoptic ductoscopy is considered not medically necessary for the detection, diagnosis, or treatment of breast cancer as the data is insufficient to permit scientific conclusion regarding the role of breast duct endoscopy in the evaluation and management of patients with known or suspected breast 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" benefits/coverage.

BACKGROUND
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. The HALO®

Breast Pap Test (Halo Healthcare, Inc, Irvine, CA) is a U.S. Food and Drug Administration (FDA)-approved, noninvasive device that is positioned on the nipple and acquires ductal fluid by applying heat, cyclic compression, and suction. This device is discussed in one small study funded by the manufacturer and concludes that although the device can collect the duct fluid noninvasively, well-designed randomized controlled studies are required to determine the utility of cytological analysis of breast ductal fluid (Proctor, 2007). 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.

Fiberoptic 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

There is minimal published information about how fiberoptic ductoscopy would be used in the management of the patients either in determining the need for other diagnostic tests, such as mammography or ductography, determining the need for biopsy or excision, or determining the extent of surgical excision. Although ductoscopy may be a useful technique for diagnosing ductal carcinoma in situ (DCIS) prior to surgery, there is no data reporting on how the results of ductoscopy influences either the decision to undergo biopsy or excision or the extent of the excision. The data is insufficient to permit scientific conclusion regarding the role of breast duct endoscopy in the evaluation and management of patients with known or suspected breast cancer.

CODING

BlueCHiP for Medicare and Commercial Products

There is no specific CPT code for Breast Ductal Lavage or Fiberoptic Ductoscopy. Follow the unlisted process:

19499 Unlisted procedure, breast

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, April 2016
Provider Update, June 2015
Provider Update, November 2014
Provider Update, January 2013
Provider Update, February 2012
Provider Update, November 2010
Provider Update, October 2009
Provider Update, October 2008

Policy Update, July 2006

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3. National Cancer Institute (NCI). Breast Cancer Screening PDQ®. Last modified April 2013. Available at: http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/AllPages. Accessed May 29, 2013.
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