Subject: Ductal Lavage for Breast Cancer Screening

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.”

Policy and Coverage Criteria:

Ductal lavage for breast cancer screening is NOT a covered service. It is considered investigational/experimental and unproven.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: Ductal lavage is a diagnostic procedure intended to identify cancerous and precancerous cells from the milk ducts of the breasts. During the procedure, the physician uses a breast pump or aspirator to draw out nipple fluid from the milk ducts of the breast. Ducts that have released fluid are then infused with saline through a microcatheter. Cells from the duct are suspended in the saline and sent for laboratory analysis.

2. Literature Review: Currently, evidence supporting the utility of ductal lavage is not strong enough to be on par with current breast cancer diagnostic and surgical methods. There is very little literature evaluating the impact of ductal lavage accurately determining a patient’s breast cancer risk, treatment course, or long-term outcomes. No Federal public health agencies or leading professional medical organizations have recommended ductal lavage as a screening test for women at high-risk for breast cancer.

While ductal lavage is intended to help screen women at higher risk for breast cancer, there is limited evidence in peer-reviewed literature on the sensitivity, specificity and positive predictive value of the fluid obtained. Studies have shown ranges in sensitivity and specificity from 17-83.8% and 64-100%, respectively (Lang et al., 2007; Dua et al., 2006; Khan et al., 2004).

Carruthers et al. (2007) performed 223 ductal lavages on 116 patients at high-risk for breast cancer. 62% of the procedures yielded enough sample for evaluation. 11% of the lavages had atypical or papillary-type cells. 15 women underwent further evaluation for atypia and no evidence of cancerous or precancerous lesions were found. Follow up ranged from 1 to 4 years. 2 women with previous normal lavage results developed breast cancer. No patients with abnormal lavage results developed cancer during follow-up. Based on these results, Carruthers et al. concluded ductal lavage to be of limited value and abnormal lavage results did not correlate with an increased risk of developing breast cancer.

A 2009 study from Wood et al. found the procedure to have low sensitivity when performed on malignant breasts. They noted their study added to the growing body of evidence that ductal lavage is not an effective tool in identifying abnormal cells.

3. Professional/Governmental Agencies:

CMS: No NCD
American Society of Breast Surgeons: 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.
http://www.breastsurgeons.org/statements/PDF_Statements/Ductal_Cell.pdf

Codes:
19499 - Unlisted procedure, breast

References:
   Diagnosis and Screening. Hayes Inc.: Lansdale, PA; August 2004.
2. Lang, J E., Kuerer, HM. Breast ductal secretions: clinical features, potential uses, and possible applications.
   2006; 24(7): 1209-16.
5. Curruthers CD, Chapleskie LA, Flynn MB, Frazier TG. The use of ductal lavage as a screening tool in women
7. Wood, ME., Stanley, MA., Crocker, AM., Kingsley, FS., Leiman, G. Ductal lavage of cancerous and unaffected

Summary of Changes

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<td>Removed Benchmarks</td>
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