MEDICAL POLICY

<table>
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<th>SUBJECT: BREAST EPITHELIAL CELL COLLECTION FOR CYTOLOGIC ANALYSIS</th>
<th>EFFECTIVE DATE: 09/19/01</th>
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<tr>
<td>POLICY NUMBER: 7.01.50</td>
<td>REVISED DATE: 10/16/02, 09/18/03, 08/19/04, 07/21/05, 08/17/06, 08/16/07, 08/21/08</td>
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<tr>
<td>CATEGORY: Technology Assessment</td>
<td>ARCHIVED DATE: 07/16/09</td>
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<td>EDITED DATE: 07/15/09, 07/21/11, 07/19/12, 07/18/13, 05/22/14</td>
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- If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
- Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
- Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:
Based upon our criteria and the lack of published peer-reviewed literature, breast duct lavage and collection of epithelial cells via suction have not been medically proven to be effective and are considered investigational in the risk stratification of patients at high risk for breast cancer and in the diagnosis of breast cancer as the influence on patient management and effect on treatment outcomes has not yet been determined.

Refer to Corporate Medical Policy# 11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:
The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:
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. Various techniques for collecting epithelial cells for cytologic analysis have been investigated.

Breast duct lavage, or ductal lavage, is a technique described for use in diagnosing and assessing risk in patients at high risk for developing breast cancer. Breast duct lavage involves identification of the nipple aspirate fluid (NAF) obtained from mammary ducts via nipple aspiration. Using a microcatheter, inserted into the natural nipple opening of the individual mammary ducts, saline is infused and the ductal fluid is withdrawn. The fluid is then analyzed microscopically for cytologic abnormalities. Breast duct lavage is performed using the FirstCyte Breast Test.

The HALO™ Breast Pap Test, by Neomatrix, is a suction system that collects ductal epithelial cells by placing a cup on the breast, warming the breast, and applying suction to bring NAF to the surface. The NAF can then be analyzed for cytologic abnormalities.

Both breast duct lavage and NAF collection may be referred to as a “breast pap smear”.

RATIONALE:
Ductal lavage: The components of the system used for breast duct lavage, the FirstCyte Aspirator™, FirstCyte E-Z® MicroCatheter, and MicroDilator have received FDA approval for marketing. There are no prospective data evaluating risk when sampling for cytologic hyperplasia is performed by ductal lavage. The effect of greater prevalence of atypia from ductal lavage on risk estimates is unknown. No studies have used ductal lavage to influence patient management for those whose management was determined by the results of routine surveillance versus surveillance plus epithelial cell cytology analysis. Whether cytologic atypia, or the lack thereof, influences patient management and improves patient outcomes has not been demonstrated in the investigational setting and is unknown.
Nipple aspirate fluid suction techniques: The Halo™ Breast Pap Test was approved by the FDA in October 2005 for collection of nipple aspirate fluid for cytological evaluation. One study has been identified that addresses the Halo system (Proctor 2005). This study is a prospective, observational study of 500 healthy, asymptomatic women designed to assess fluid production, adequacy, safety and patient acceptance of the system. 38% of the patients produced NAF with the overall results of 19% of the patients producing NAF with adequate cellularity and 1% were found to have cytologic atypia. The authors concluded the Halo system is a simple, safe, and rapid automated method for collecting NAF and is acceptable to patients; however, further prospective studies with long-term clinical follow-up are needed to determine the clinical significance of NAF non-producers versus producers, insufficient samples and other cytologic categories found on NAF samples collected with the Halo system.

**CODES:**

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<th>Number</th>
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<td>Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.</td>
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CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

**CPT:** No specific code(s)

**HCPCS:** No specific code(s)

**ICD9:**

- 174.0–174.9 Malignant neoplasm of the female breast (code range)
- 198.81 Secondary malignant neoplasm of the breast
- 233.0 Carcinoma in situ of breast
- 238.3 Neoplasm of uncertain behavior of breast
- 239.3 Neoplasm of unspecified nature of breast
- 451.89 Thrombophlebitis of breast
- 611.0 Inflammatory disease of breast
- 611.1 Hypertrophy of breast
- 611.2 Fissure of nipple
- 611.3 Fat necrosis of breast
- 611.4 Atrophy of breast
- 611.5 Galactocele
- 611.6 Galactorrhea not associated with childbirth
- 611.71 Mastodynia
- 611.72 Lump or mass in breast
- 611.79 Other signs and symptoms in breast (nipple discharge)
- 793.80-793.89 Nonspecific abnormal finding on radiological and other examination of body structure, abnormal mammogram, breast (code range)
- V10.3 Personal history of malignant neoplasm of breast

*Proprietary Information of Excellus Health Plan, Inc.*
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V16.3 Family history of malignant neoplasm of breast
V76.10-V76.19 Special screening for malignant neoplasms, breast (code range)

ICD10:
C50.011-C50.019 Malignant neoplasm of nipple and areola, female breast (code range)
C50.111-C50.119 Malignant neoplasm of central portion of female breast (code range)
C50.211-C50.219 Malignant neoplasm of upper-inner quadrant of female breast (code range)
C50.311-C50.319 Malignant neoplasm of lower-inner quadrant of female breast (code range)
C50.411-C50.419 Malignant neoplasm of upper-outer quadrant of female breast (code range)
C50.511-C50.519 Malignant neoplasm of lower-outer quadrant of female breast (code range)
C50.611-C50.619 Malignant neoplasm of axillary tail of female breast (code range)
C50.811-C50.819 Malignant neoplasm of overlapping sites of female breast (code range)
C50.911-C50.919 Malignant neoplasm of unspecified site of female breast (code range)
C79.81 Secondary malignant neoplasm of breast
D50.00-D50.92 Carcinoma in situ of unspecified breast (code range)
D48.60-D48.62 Neoplasm of uncertain behavior of unspecified breast (code range)
D49.3 Neoplasm of unspecified behavior of breast
I80.8 Phlebitis and thrombophlebitis of other sites
N61-N64.89 Other disorders of breast (code range)
R92.0-R92.8 Abnormal and inconclusive findings on diagnostic imaging of breast (code range)
Z12.31-Z12.39 Encounter for screening for malignant neoplasm of breast (code range)
Z80.3 Family history of malignant neoplasm of breast
Z85.3 Personal history of malignant neoplasm of breast

REFERENCES:


*BlueCross BlueShield Association Technology Evaluation Center (TEC). Use of epithelial cell cytology in breast cancer risk assessment and high-risk patient management. 2002 Jun;17(1).


Proprietary Information of Excellus Health Plan, Inc.


**KEY WORDS:**
Breast duct lavage, Breast Pap smear, Ductal lavage, Halo™ Breast Pap Test.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, breast duct lavage and collection of epithelial cells by suction is not addressed in National or Local Medicare coverage determinations or policies.