I. POLICY

Breast Duct Endoscopy

Breast duct endoscopy is considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Epithelial Cell Cytology in Breast Cancer Risk assessment and High-Risk Patient Management (Ductal Lavage and Suction Collection Systems)

Cytologic analysis of epithelial cells from nipple aspirations as a technique to assess breast cancer risk and manage patients at high risk of breast cancer is considered **investigational**. Techniques of collecting nipple aspiration fluid include, but are not limited to, ductal lavage and suction. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids  
[N] PPO  
[N] HMO  
[N] SeniorBlue HMO  
[N] SeniorBlue PPO

[N] SpecialCare  
[N] POS  
[Y] FEP PPO*  
[N] Indemnity

* The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.
III. DESCRIPTION/BACKGROUND

Breast Duct Endoscopy
Breast duct endoscopy is a technique that provides for direct visual examination of the breast ducts through nipple orifice cannulation and exploration. The technique has been investigated in the following clinical situations:

- As a follow-up test for women with atypical cytology as detected by ductal lavage;
- Delineation of intraductal disease to define margins of surgical resection;
- Diagnostic technique in women with spontaneous nipple discharge, where endoscopy might function as an alternative to surgical excision;
- Technique to obtain cellular material to stratify women for risk of breast cancer;
- The direct delivery of therapeutic agents, including photodynamic therapy, laser ablation, topical biological agents, etc.

Of related interest, three-dimensional reconstruction techniques of computed tomography scans are now being studied in another approach referred to as virtual ductoscopy.

Epithelial Cell Cytology in Breast Cancer Risk assessment and High-Risk Patient Management (Ductal Lavage and Suction Collection Systems)

Ductal lavage involves several steps. First, fluid yielding mammary ducts are identified using nipple aspiration. Next, a microcatheter is inserted into the natural nipple opening of the individual mammary ducts, saline solution is infused, and ductal fluid is withdrawn. The fluid is analyzed microscopically for cytologic abnormalities. The FirstCyte Breast Test (Cytyc) is a device used for ductal lavage that has been cleared for marketing by the U.S. Food and Drug Administration (FDA).

A suction collection system, the HALO NAF Collection system (Neomatrix) has also received FDA clearance as a technique to collect ductal epithelial cells. In this system, small breast cups are placed on the woman’s breast and adjusted to fit. The system is then engaged and automatically warms the breast and applies light suction to bring nipple aspirate fluid to the surface. Similar to ductal lavage, the fluid is then analyzed microscopically for cytologic abnormalities.

IV. DEFINITIONS
CANNULATION is the act of introducing a cannula through a passageway.
DUCTAL LAVAGE is a technique for collecting epithelial cells from individual mammary ducts for subsequent cytologic analysis.

ENDOSCOPY refers to inspection of body organs or cavities by use of an endoscope.

EPITHELIAL refers to the layer of cells forming the epidermis of the skin and the surface layer of mucous and serous membrane.

INTRADUCTAL refers to within a duct.

LAVAGE refers to washing out of a cavity.

MAMMARY pertains to the breast.

PHOTODYNAMIC refers to the effects of light on biological, chemical, or physical systems.

V. BENEFIT VARIATIONS
The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VI. DISCLAIMER
Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES
American Cancer Society Mammograms and other breast imaging tests 10/26/2010.


VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational and therefore not covered when used to report breast duct endoscopy or breast epithelial cell cytology:

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<th>CPT Codes®</th>
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[Note: Final page is signature page and is kept on file, but not issued with Policy.]
## IX. Policy History

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