Medical Policy

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

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Policy Number: 492
BCBSA Reference Number: 2.01.45A
NCD/LCD: NA

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare Members: Managed Care HMO BlueSM and Medicare PPO BlueSM

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 INVESTIGATIONAL. Techniques of collecting nipple aspiration fluid include, but are not limited to, ductal lavage and suction.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Product</th>
<th>Coverage Status</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**

There is no specific CPT code for this service.

**Description**

Various collection systems have been investigated as techniques to obtain epithelial cells for cytological examination. These techniques have been evaluated as a diagnostic and risk assessment tool in patients at high risk of breast cancer.

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 then analyzed microscopically for cytologic abnormalities.

Examples of ductal lavage devices for nipple discharge aspiration include the FirstCyte Breast Test from Cytyc. All ductal lavage devices for nipple discharge aspiration are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

A suction collection system is 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.

Examples of suction collection systems for ductal epithelial cells collection include the HALO NAF collection system from Neomatrix. All suction collection systems for ductal epithelial cells collection are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

**Summary**

In summary, the available literature regarding ductal lavage and suction collection systems for breast cancer risk assessment are inadequate to draw clinical conclusions. The policy statement remains unchanged. These procedures are investigational for the assessment of breast cancer risk given the insufficient evidence to evaluate the impact on net health outcome.

**Policy History**

<table>
<thead>
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<th>Date</th>
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<tr>
<td>2/2020</td>
<td>Policy updated with literature review through February 1, 2020, no references added. Policy statements unchanged.</td>
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</table>
Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References
10. 2002 TEC Assessments; Tab 1.