



MASSACHUSETTS

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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 (For Plan internal use only)

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**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

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into the natural nipple opening of the individual mammary ducts, saline solution is infused, and ductal fluid is withdrawn.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

Date	Action
9/2022	Annual policy review. Policy updated with literature review through September 2022. References added. Policy statements unchanged.
2/2020	Policy updated with literature review through February 1, 2020, no references added. Policy statements unchanged.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.

10/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
12/2009	Annual policy review. No changes to policy statements.
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
7/2009	Annual policy review. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
9/2008	Annual policy review. No changes to policy statements.
10/2007	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
9/2007	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.

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

1. Dooley WC, Ljung BM, Veronesi U et al. Ductal lavage for detection of cellular atypia in women at high risk for breast cancer. *J Natl Cancer Inst* 2001; 93(21):1624-32.
2. Wrensch MR, Petrakis NL, King EB et al. Breast cancer incidence in women with abnormal cytology in nipple aspirates of breast fluid. *Am J Epidemiol* 1992; 135(2):130-41.
3. Wrensch MR, Petrakis NL, Miike R et al. Breast cancer risk in women with abnormal cytology in nipple aspirates of breast fluid. *J Natl Cancer Inst* 2001; 93(23):1791-8.
4. Fabian CJ, Kimler BF, Zalles CM et al. Short-term breast cancer prediction by random periareolar fine-needle aspiration cytology and the Gail risk model. *J Natl Cancer Inst* 2000; 92(15):1217-21.
5. Dupont WD, Page DL. Risk factors for breast cancer in women with proliferative breast disease. *N Engl J Med* 1985; 312(3):146-51.
6. Port ER, Montgomery LL, Heerdt AS et al. Patient reluctance toward tamoxifen use for breast cancer primary prevention. *Ann Surg Oncol* 2001; 8(7):580-5.
7. Fisher B, Costantino JP, Wickerham DL et al. Tamoxifen for prevention of breast cancer: report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Natl Cancer Inst* 1998; 90(18):1371-88.
8. Cytoc Corporation FirstCyte Web site. www.producthealth.com
9. Morrow M, Vogel V, Ljung BM et al. Evaluation and management of the woman with an abnormal ductal lavage. *J Am Coll Surg* 2002; 194(5):648-56.
10. 2002 TEC Assessments; Tab 1.
11. Khan SA, Wiley EL, Rodriguez N et al. Ductal lavage findings in women with known breast cancer undergoing mastectomy. *J Natl Cancer Inst* 2004; 96(20):1510-7.
12. Khan SA, Wolfman JA, Segal L et al. Ductal lavage findings in women with mammographic microcalcifications undergoing biopsy. *Ann Surg Oncol* 2005;12(9):689-96.
13. Brogi E, Robson M, Panageas KS et al. Ductal lavage in patients undergoing mastectomy for mammary carcinoma: a correlative study. *Cancer* 2003; 98(10):2170-6.
14. Johnson-Maddux A, Ashfaq R, Cler L et al. Reproducibility of cytologic atypia in repeat nipple duct lavage. *Cancer* 2005; 103(6):1129-36.

15. O'Shaughnessy JA. Ductal lavage: clinical utility and future promise. *Surg Clin North Am* 2003; 83(4):753-69.
16. Newman LA. Ductal lavage: what we know and what we don't. *Oncology* 2004; 18(2):179-85.
17. Fabian CJ, Kimler BF, Mayo MS. Ductal lavage for early detection – what doesn't come out in the wash. *J Natl Cancer Inst* 2004; 96(2):1488-9.
18. The American Society of Breast Surgeons. Official statement. Ductal lavage and cell-based risk assessment. Available at: http://www.breastsurgeons.org/statements/Ductal_Cell.pdf. Last viewed May 2009.
19. Visvanathan K, Santor D, Ali SZ et al. The importance of cytologic intrarater and interrater reproducibility: the case of ductal lavage. *Cancer Epidemiol Biomarkers Prev* 2006; 15(12):2553-6.
20. Patil DB, Lankes HA, Nayar R et al. Reproducibility of ductal lavage cytology and cellularity over a six month interval in high risk women. *Breast Cancer Res Treat* 2007 Dec 21. [Epub ahead of print]
21. Arun B, Valero V, Logan C et al. Comparison of ductal lavage and random periareolar fine needle aspiration as tissue acquisition methods in early breast cancer prevention trials. *Clin Cancer Res* 2007; 13(16):4943-8.
22. Bushnaq ZI, Ashfaq R, Leitch AM et al. Patient variables that predict atypical cytology by nipple duct lavage. *Cancer* 2007; 109(7):1247-54.
23. Visvanathan K, Santor D, Ali SZ et al. The reliability of nipple aspirate and ductal lavage in women at increased risk for breast cancer--a potential tool for breast cancer risk assessment and biomarker evaluation. *Cancer Epidemiol Biomarkers Prev* 2007; 16(5):950-5.
24. Khan SA, Lankes HA, Patil DB et al. Ductal lavage is an inefficient method of biomarker measurement in high-risk women. *Cancer Prev Res (Phila Pa)* 2009; 2(3):265-73.
25. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology™, Breast cancer screening and diagnosis guidelines v.1.2009. Available at: http://www.nccn.org/professional/physician_gls?PDF/breast-screening.pdf. Last accessed May 2009.
26. National Cancer Institute. Breast cancer screening (PDQ®). Available at: <http://www.cancer.gov/cancertopics/pdq/screening/breast/HealthProfessional/page4>.
27. Chen K, et al. Ductal Lavage for Patients with Nonlactational Mastitis: A Single-Arm, Proof-of-Concept Trial. *J Surg Res* 2019 - Clinical Trial. PMID 30691827
28. Kai Chen et al. Ductal Lavage for Patients with Nonlactational Mastitis: A Single-Arm, Proof-of-Concept Trial. *J Surg Res*. 2019 Mar;235:440-446.