

Reimbursement Policy

Epithelial Cell Cytology in Breast Cancer Risk Assessment

[POLICY DESCRIPTION](#) | [INDICATIONS AND/OR LIMITATIONS OF COVERAGE](#) | [APPLICABLE STATE AND FEDERAL REGULATIONS](#) | [APPLICABLE CPT/HCPCS PROCEDURE CODES](#) | [EVIDENCE-BASED SCIENTIFIC REFERENCES](#) | [REVISION HISTORY](#)

I. Policy Description

Nipple aspiration and/or ductal lavage are non-invasive techniques to obtain epithelial cells for cytological examination to aid in the evaluation of nipple discharge for breast cancer risk.¹ Fine needle aspiration (FNA) is another approach that can be used in the initial diagnosis of a suspicious breast mass, although core biopsy is superior in sensitivity, specificity, and correct histological grading.²

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

- 1) Cytologic analysis of epithelial cells to assess breast cancer risk and manage patients at high risk of breast cancer **DOES NOT MEET COVERAGE CRITERIA.**

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Reimbursement Policy

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
88108	Cytopathology, concentration technique, smears and interpretation (eg, Saccomanno technique)
88112	Cytopathology, selective cellular enhancement technique with interpretation (eg, liquid based slide preparation method), except cervical or vaginal
88172	Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site
88173	Cytopathology, evaluation of fine needle aspirate; interpretation and report
88177	Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)

Current Procedural Terminology© American Medical Association. All Rights reserved.

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

1. Golshan M. Nipple discharge. Updated February 12, 2024.
<https://www.uptodate.com/contents/nipple-discharge>
2. Moy L, Heller SL, Bailey L, et al. ACR Appropriateness Criteria(®) Palpable Breast Masses. *J Am Coll Radiol*. May 2017;14(5s):S203-s224. doi:10.1016/j.jacr.2017.02.033
3. Shaheed SU, Tait C, Kyriacou K, Linforth R, Salhab M, Sutton C. Evaluation of nipple aspirate fluid as a diagnostic tool for early detection of breast cancer. *Clin Proteomics*. 2018;15:3. doi:10.1186/s12014-017-9179-4
4. Moelans CB, Patuleia SIS, van Gils CH, van der Wall E, van Diest PJ. Application of Nipple Aspirate Fluid miRNA Profiles for Early Breast Cancer Detection and Management. *Int J Mol Sci*. Nov 19 2019;20(22)doi:10.3390/ijms20225814
5. Joe BN, Esserman LJ. Breast biopsy. Updated May 3, 2023.
<https://www.uptodate.com/contents/breast-biopsy>
6. Kooistra BW, Wauters C, van de Ven S, Strobbe L. The diagnostic value of nipple discharge cytology in 618 consecutive patients. *European journal of surgical oncology : the journal of*

Reimbursement Policy

- the European Society of Surgical Oncology and the British Association of Surgical Oncology*. Jun 2009;35(6):573-7. doi:10.1016/j.ejso.2008.09.009
7. Hornberger J, Chen SC, Li Q, Kakad P, Quay SC. Proliferative epithelial disease identified in nipple aspirate fluid and risk of developing breast cancer: a systematic review. *Current medical research and opinion*. Feb 2015;31(2):253-62. doi:10.1185/03007995.2014.988209
 8. Chatterton RT, Heinz RE, Fought AJ, et al. Nipple Aspirate Fluid Hormone Concentrations and Breast Cancer Risk. *Horm Cancer*. Apr 2016;7(2):127-36. doi:10.1007/s12672-016-0252-7
 9. Kamali GH, Kamali S. The Role of Ductal Lavage Cytology in the Diagnosis of Breast Cancer. *Archives of Iranian Medicine (AIM)*. 2022;25(11)doi:10.34172/aim.2022.118
 10. Zhu J, Cong H, Zhang X, et al. New method for cytological evaluation using direct nipple discharge without aspiration. *Scientific Reports*. 2025/02/04 2025;15(1):4175. doi:10.1038/s41598-025-88456-9
 11. ASBS. Screening Mammography. 2019. <https://www.breastsurgeons.org/docs/statements/Position-Statement-on-Screening-Mammography.pdf>
 12. ASBS. Consensus Guideline on Concordance Assessment of Image-Guided Breast Biopsies and Management of Borderline or High-Risk Lesions. <https://www.breastsurgeons.org/docs/statements/Consensus-Guideline-on-Concordance-Assessment-of-Image-Guided-Breast-Biopsies.pdf>
 13. NCCN. NCCN Clinical Practice Guidelines in Oncology; Breast Cancer Screening and Diagnosis V2.2025. National Comprehensive Cancer Network. Updated March 28, 2025. https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf
 14. Williams A, Omnigraphics Inc. *Breast cancer sourcebook : basic consumer health information about the prevalence, risk factors, and symptoms of breast cancer, including ductal and lobular carcinoma in situ, invasive carcinoma, inflammatory breast cancer, and breast cancer in men and pregnant women; along with facts about benign breast changes, breast cancer screening and diagnostic tests, treatments such as surgery, radiation therapy, chemotherapy, and hormonal and biologic therapies, tips on managing treatment side effects and complications, a glossary of terms, and a directory of resources for additional help and information*. Sixth edition. ed. Omnigraphics,; 2019:1 online resource.
 15. FDA. Mammography: What You Need to Know. Updated October 26, 2023. <https://www.fda.gov/consumers/consumer-updates/mammography-what-you-need-know>
 16. Sanford MF, Slanetz PJ, Lewin AA, et al. ACR Appropriateness Criteria® Evaluation of Nipple Discharge: 2022 Update. *J Am Coll Radiol*. Nov 2022;19(11s):S304-s318. doi:10.1016/j.jacr.2022.09.020
 17. NCI. Breast Cancer Screening (PDQ®)—Health Professional Version. Updated April 10, 2025. <https://www.cancer.gov/types/breast/hp/breast-screening-pdq>

Reimbursement Policy

VI. Revision History

Revision Date	Summary of Changes
09/04/2025	Reviewed and Updated: Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review did not necessitate any modifications to coverage criteria.