02-10000-14

Original Effective Date: 05/15/02

Reviewed: 03/27/25

Revised: 04/15/25

Subject: Ductal Lavage and Suction Collection Systems

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Since most breast cancer begins in the epithelial cells that line the ducts, analysis of epithelial cells found in breast ductal fluid has been studied as an early indicator of breast cancer. If atypical, these cells may indicate the possibility of future breast cancer. Breast ductal fluid can be obtained by fine needle aspiration, nipple aspiration via suction, or ductal lavage. Ductal lavage is a technique for collecting epithelial cells from the breast ducts for cytological analysis for identification of atypical cells. Ductal lavage enables the retrieval of these cells using a microcatheter inserted into the milk ducts through the nipple orifices. A saline solution is flushed through the catheter into the ducts to wash out cells for cytological examination. The technique is directed at patients identified as being at high risk for breast cancer. The procedure has been dubbed "breast pap smear" because like the test for cervical cancer, it is a nonsurgical approach to identifying abnormal cells prior to their development into cancer.Several devices have been approved by the U.S. Food & Drug Administration (FDA) including suction collection systems. In these systems, small breast cups are adjusted on the patient's breast. 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 for cytological abnormalities.

Summary and Analysis of Evidence: The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology- Breast Cancer Screening and Diagnosis (2024) states, "Thermography and ductal lavage are not recommended by the NCCN Panel for breast cancer screening or diagnosis. The FDA has issued a safety alert stating that ductal lavage should not be a replacement for mammograms." An UpToDate review on "Nipple Discharge" (Golshan, 2024) states that "Cytology of the discharge or of a ductal lavage specimen is not recommended, because the result does not impact management. Technically, it would be difficult to distinguish crenated or apoptotic cells from atypical cells, and abnormal cytologic findings cannot be easily localized to a specific lesion." The available published data is limited and the evidence is insufficient to determine the effects of the technology on health outcomes.

POSITION STATEMENT:

Breast ductal aspiration and cytology is considered **experimental or investigational** for all indications including breast cancer screening and breast cancer risk assessment. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

There is no specific CPT or HCPCS code for breast ductal lavage or suction; unlisted code 19499 may be used.

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

None

RELATED GUIDELINES:

Breast Ductoscopy, 02-10000-19

OTHER:

None applicable.

REFERENCES:

1. American Society of Breast Surgeons Consensus Statement on Screening Mammography, 10/29/15; accessed at breastsurgeons.org.
2. American Society of Breast Surgeons Official statement: Ductal Lavage and Cell-Based Risk Assessment; accessed at breastsurgeons.org.
3. Blue Cross Blue Shield Association Technology Evaluation Center. "Use of Epithelial Cell Cytology in Breast Cancer Risk Assessment and High-Risk Patient Management", 06/02.

4. Chen K, Zhu L, et al. Ductal Lavage for Patients With Nonlactational Mastitis: A Single-Arm, Proof-of-Concept Trial. J Surg Res. 2019 Mar;235:440-446. doi: 10.1016/j.jss.2018.10.023. Epub 2018 Nov 19. PMID: 30691827.
5. Danforth DN, Warner AC, et al, An Improved Breast Epithelial Sampling Method for Molecular Profiling and Biomarker Analysis in Women at Risk for Breast Cancer. Breast Cancer (Auckl). 2015 Jun 8;9:31-40.
6. Golshan M. Nipple discharge, 2024. In UpToDate, CHagpar AB, Chen W (Eds); UpToDate, Waltham, MA; accessed at uptodate.com.
7. Matos Do Canto L, Marian C, et al. Metabolomic profiling of breast tumors using ductal fluid. Int J Oncol. 2016 Dec;49(6):2245-2254.
8. National Cancer Institute (NCI), Breast Cancer Screening (PDQ®)–Health Professional Version: accessed at cancer.gov.
9. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology-Breast Cancer Screening and Diagnosis; accessed at nccn.org.
10. 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.
11. U.S. Food & Drug Administration (FDA), Nipple Aspirate Test Is No Substitute for Mammogram; accessed at fda.gov.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 03/27/25.

GUIDELINE UPDATE INFORMATION:

05/15/02	New Medical Coverage Guideline.
07/01/03	Annual review. 07/01/03 HCPCS Update, added code 0046T and 0047T.
06/15/04	Scheduled review and revision to guideline; consisting of updated references. Maintain investigational status.
05/15/05	Scheduled review and revision to guideline; consisting of updated references.
06/15/06	Annual review; maintain investigational.
06/15/07	Annual review; maintained investigational status; reformatted guideline; references updated.
07/15/08	Annual review: position statement maintained, references updated.
01/01/09	Annual HCPCS coding update: deleted codes 0046T and 0047T.
05/15/09	Annual review: position statement maintained and references updated.
05/11/14	Revision: Program Exceptions section updated.
07/15/17	Revision; Position statement, description section, and references updated.
05/15/19	Review; Position statement maintained and references updated.
04/15/21	Review; Position statement maintained; references updated.
05/15/23	Review: Position statement maintained and references updated.
05/23/23	Update to Program Exceptions section.
04/15/24	Review: Position statement maintained; description and references updated.
04/15/25	Review: Position statement maintained and references updated.