

02-10000-14

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Subject: Ductal Lavage and Suction Collection Systems

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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.

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.

DEFINITIONS:

None

RELATED GUIDELINES:

[Breast Ductoscopy, 02-10000-19](#)

OTHER:

None applicable.

REFERENCES:

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7. ClinicalTrials.gov, Evaluation Of The Role Of Nipple Aspiration, Ductal Lavage And Duct Endoscopy At The Time Of Surgery In Patients With Breast Cancer, sponsored by Royal Marsden NHS Foundation Trust; accessed 03/25/19.

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13. 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.
14. 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 & Coverage Committee on 03/25/21.

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.

