Cigna healthcare

Medical Coverage Policy

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Mammary Ductoscopy, Aspiration and Lavage

Table of Contents

Related Coverage Resources

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Overview

This Coverage Policy addresses mammary ductoscopy, ductal lavage of the mammary ducts and mammary duct aspiration using a non-invasive device for the screening and early detection of breast cancer.

Coverage Policy

The following are considered experimental, investigational or unproven for any indication:

- mammary ductoscopy (MD)
- ductal lavage of the mammary ducts
- mammary duct aspiration by a non-invasive collection device (e.g., HALO™ Breast Pap Test, Mammary Aspirate Specimen Cytology Test [MASCT] System)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Experimental/Investigational/Unproven when used to report mammary ductoscopy, lavage or aspiration by a non-invasive collection device:

CPT®* Codes	Description
19499	Unlisted procedure, breast

General Background

The goal of breast screening exams is to find cancers before they start to cause symptoms and at an early stage when it can be treated and may be cured. Standard methods of early breast cancer detection are screening mammography, clinical breast examination (CBE), and monthly self-breast exam. Overall sensitivity of mammography has been reported at 70%–90%; with a specificity of 75% to 90% or greater. Overall sensitivity of clinical breast exam is 40%–69%. In women ages 50–59 years, specificity for clinical breast exam ranges from 88%–99%, while the positive predictive value (PPV) is 3%–4% (National Cancer Institute [NCI], 2025; National Comprehensive Cancer Network® [NCCN], 2025; Elmore and Lee, 2024; Liu et al., 2015).

If breast abnormalities are found on screening or are present on physical exam, standard methods used for further testing may include diagnostic mammography films, ultrasound, magnetic resonance imaging (MRI), fine needle aspiration (FNA), core-needle and/or incisional breast biopsy (NCCN, 2025). The use of MRI in combination with mammography provides a highly sensitive screening strategy (i.e. sensitivity 93%–100%). In select cases, ductography (i.e., sensitivity 19%, negative predictive value [NPV] 63%) also known as galactography may be used to evaluate spontaneous nipple discharge (Inglehart, 2007; Lord, 2007; Morrogh, 2007).

Mammary ductoscopy (MD) has been proposed as a diagnostic tool for screening individuals at high-risk of breast cancer, investigation of pathologic nipple discharge, and intraoperative use to guide duct excision in breast conserving surgery. The role of mammary ductoscopy in breast cancer screening and breast conservation surgery has yet to be fully defined.

Ductal lavage has been proposed as a means of extracting nipple aspirate fluid to screen for breast cancer, and for use in risk assessment and stratification. The lavage is recommended as an adjunctive test to mammography and it is not recommended for women with a low risk of breast cancer. Mammary duct aspiration by a non-invasive collection device (e.g., HALO™ Breast Pap Test, Mammary Aspirate Specimen Cytology Test [MASCT] System) has also been proposed as a screening tool for the breast cancer. However, there is insufficient evidence in the peer reviewed literature to support the clinical effectiveness of these procedures.

Mammary Ductoscopy

Mammary ductoscopy (MD), also referred to as fiberoptic ductoscopy or breast duct endoscopy, involves the direct visualization of the mammary ducts and the use of a rigid camera or ductoscope. Researchers have proposed the use of direct visualization of the mammary ducts through rigid and fiberoptic scopes in an attempt to increase the sensitivity of early recognition of cellular changes in the mammary duct lining. The rationale is that direct visualization may assist in confirming the presence of cancer when a diagnosis cannot be confirmed using standard imaging techniques such as mammography, ultrasound or magnetic resonance imaging (MRI). Successful ductoscopy depends on the presence of a consistent nipple discharge and the capability to access and expand the affected duct for examination (Golshan, 2024). However, the capacity of MD for the direct observation of lesions in smaller caliber peripheral ducts and the terminal duct-lobular units where premalignant and malignant lesions often originate is limited by the outer diameter of the scope and the complex branching pattern of the mammary ducts. Ductoscopy is a highly performer dependent device, and there is a learning curve to acquire the skills to operate it. Surgeons also require more knowledge to comment on the images recorded during the procedure. The use of MD allows the visualization of only a few of the ducts that open to the nipple, leaving the other 13–18 ducts that open at or just below the nipple surface unexamined. As technologies have evolved, the addition of fiberoptics has expanded the visual fields that may be examined during this procedure. Currently available ductoscopes have limited ability to biopsy lesions. At this time its limited biopsy facility and inability to visualize all of the ductal system limit its usefulness in the screening of breast cancer. Specific data about the endoscopic imaging of the ductal system is lacking and there is a need for a special image reporting system for ductoscopy, which may help to improve the diagnostic ability of the procedure (Liu, et al., 2015; Hung, et al., 2009; Kapenhaus-Valdes, et al., 2008; Al Sarakbi, et al., 2006; Pereira and Mokbel, 2005).

U.S. Food and Drug Administration (FDA): Mammary ductoscopes have been approved for use by the FDA through the 510(k) process and are considered unclassified by the FDA. Unclassified medical devices are a unique subset within the regulatory framework and still require 510(k) clearance before they can be marketed. According to the FDA, a ductoscope is a device intended for use in viewing an interior cavity of the human body through either a natural opening or an incision.

Device or Product	Identifier	Manufacturer
ViaDuct™ Miniscope and Accessories	K040949	Acueity Inc.

*FDA product code: GCT

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review - Breast Cancer Screening: Randomized controlled clinical trial data evaluating the effectiveness of mammary ductoscopy for breast cancer screening are lacking.

As part of an ongoing long-term research project aimed at exploring the potential clinical applications of mammary ductoscopy, Al Sarakbi and colleagues (2006) conducted a prospective study of 26 women to assess its technical feasibility, its role in guiding ductal excisional surgery, and its use in the identification of malignancy. Study participants were divided into two groups with Group A (n=13) undergoing mastectomy or lumpectomy for ductal carcinoma, and Group B (n=13) presenting with pathological nipple discharge (PND). MD was performed using the Mastascope™ (Lifeline Biotechnologies, Pompano Beach, FL). Intraductal pathology was visualized in 80% of patients, but ductal cytology was positive for malignancy in only two cases with sensitivity of 16% and specificity of 100%. In Group B, seven patients underwent ductoscopy-guided duct excision, which revealed ductal carcinoma in situ (DCIS) in one, papilloma in four, and benign disease in two patients. The authors concluded that, although MD is feasible, its cytological yield is not sufficient for the diagnosis of malignancy, and the development of a biopsy tool that obtains tissue under direct visualization is required.

Literature Review - Evaluation of Nipple Discharge: Randomized controlled clinical trials evaluating the effectiveness of mammary ductoscopy for evaluation of nipple discharge are lacking. Evidence consists primarily of uncontrolled case series and retrospective reviews (Motoda, et. al., 2020; Waaijer, et al., 2016; Waaijer, et al., 2015; Liu, et al., 2015; Ohlinger et al., 2014; Sauter, et al., 2010; Simpson, et al., 2009).

Gui et al. (2018) conducted a randomized control trial to see if using duct endoscopy to target a lesion causing pathological nipple discharge would result in more accurate surgery with fewer complications. A total of 68 breasts in 66 patients were included. Prior to surgery, patients requiring microdochectomy and/or major duct excision were randomized to duct endoscopy (n=31) or no duct endoscopy (n=37). Primary outcomes were successful visualization of the pathological lesion in patients randomized to duct endoscopy, and a comparison of the causative pathology between the two groups. The secondary outcome was to compare the specimen size between groups. Follow-up was 5.4 (mid-range 3.3-8.9) years in the duct endoscopy group and 5.7 (mid-range 3.1-9.0) years in no-endoscopy group. Duct endoscopy had a sensitivity of 80%, specificity of 71%, positive predictive value of 71%, and negative predictive value of 80%. No differences were found in the causative pathology between the groups or in the median volume of the surgical resection specimen. No wound infections, toxicities or serious adverse events were reported. A hematoma in the no-endoscopy group requiring surgical excision was reported. A limitation of the study was the small patient population. Duct endoscopy did not influence the pathological yield of benign or malignant diagnoses nor surgical resection volumes.

Waaijer et al. (2016) conducted a systematic review and meta-analysis to evaluate the diagnostic accuracy of ductoscopy for the evaluation of pathological nipple discharge (PND). Studies reporting ductoscopic findings in patients presenting with PND were included. Twenty studies met inclusion criteria (n=3144) including ten prospective case series, six retrospective reviews and four studies for which the study designs were not mentioned. Twelve studies (n=1944) were included in meta-analysis that classified any intraductal lesion visualized by ductoscopy as a positive finding and resulted in a pooled sensitivity of 94% and specificity of 47%. A meta-analysis including eight studies (n=933) was performed to find the optimal cut-off point for the classification in which suspicious ductoscopic findings were classified as positive. This analysis resulted in a pooled sensitivity of 50% and specificity of 83%. The cut-off point assessed in the suspicious classification resulted in increased specificity at the cost of an unacceptably low sensitivity. These results implied that, to exclude malignancy in patients with PND and positive ductoscopy, histological diagnosis remains necessary. Owing to the high sensitivity and low incidence of malignancy in patients with PND, the negative predictive value ranged from 98%–100%. The malignancy rate of the 20 included studies ranged from 0%–27%, but only two studies demonstrated malignancy rates above 11%. Limitations of the studies included: heterogeneity in the interpretation of the ductoscopy; high risk of bias; variation in the morphological category scales that were used which were likely subjective and observer-dependent; arbitrary cut-off values of positive ductoscopy; and poorly reported information on inclusion methods, previous diagnostic investigations and patient characteristics. Also, studies including diagnoses of atypical ductal hyperplasia, atypical lobular neoplasia and papilloma (with or without atypia) were left out of the analysis. Data on the clinical usefulness of ductoscopy is limited. According to the authors most clinicians are unfamiliar with the use of ductoscopy and ductoscopy does not permit reliable discrimination between malignant and benign findings.

Waaijer et al. 2015 conducted a prospective study (n=82) to evaluate the outcomes of ductoscopy in patients with pathological nipple discharge (PND) without a suspected malignancy. PND was defined as spontaneous, single-duct nipple discharge during a non-lactational period for more than three months. Cannulation was successful in 71 patients and failed in 11 patients due to narrow duct orifice, unidentifiable orifice or due to nipple retraction. Ductoscopy was positive in 53 patients. Abnormalities included polypoid lesions (n=29), epithelial lesions (n=16) and other miscellaneous findings (n=8). False routes (duct perforation) occurred in 12 patients (15%) and prevented cannulation in three patients. Due to the type or size of lesions, ductoscopic extraction was not attempted in 19/52 (36%) patients. Only the 34 patients in whom ductoscopic extraction was attempted were included in the subsequent analyses of the interventional procedure. Of the 34 remaining patients lesion removal was completed in 21, partial lesion removal in six and seven attempts failed. A sufficient amount of tissue for adequate histological assessment was collected in 13/34 patients and diagnosed as intraductal papilloma. Failure of histological assessment was due to insufficient tissue quantity and intraductal loss of removed tissue. Follow-ups ranged from 3–45 months following ductoscopy. Forty patients no longer had PDN without having surgery, 36 had persistent PND, four had immediate surgery after ductoscopy and two were lost to follow-up. A total of 19/27 patients who had a lesion removed had symptom resolution. After a median follow-up of three months (range 0–8), surgery was performed in 26 (32%) of 82 patients, Thirteen patients had a diagnosis based on tissue sample from ductoscopy. A total of 23 papillomas were diagnosed histologically and 20 of these had been visualized as a polypoid lesion by ductoscopy. The complication rate of 15% included areola scar, necrosis of the nipple, postoperative mastitis and wound infection. Limitations of the study include the small patient population; small number of patient in whom ductoscopic lesion extraction was performed; and lack of histology for 56% of patients.

Liu et al. (2015) conducted a prospective review (n=238) to evaluate the efficacy of ductoscopy and follow-up for the diagnoses of intraductal lesions and the concomitant advantages of avoiding surgery for patients with pathologic nipple discharge (PND). A total of 177 patients underwent ductoscopy. A total of 266 ductoscopic exams were performed and of these 168 (63.2%) breasts were found to have positive images, including 124 solitary papillomas (SP), 41 multiple papillomas

(MP), and 3 abnormal surfaces. Of the 73 patients with negative ductoscopy, 63 were followed for 6–84 months. Twelve patients experienced recurrent PND and final pathologies revealed ten patients had intraductal papilloma and two patients had intraductal papillomatosis. The remaining 51 patients did not have recurrence of PND. Limitations of the study include the small patient population and lack of a comparator. The author's noted that because of the risks associated with ductoscopy, selection of patients without intraductal lesions prior to biopsy is critical for avoiding unnecessary ductal resection in patients with PND.

Ohlinger et al. (2014) conducted a multicenter, prospective, study (n=214) to compare the sensitivity, specificity and efficiency of ductoscopy with standard diagnostic studies for intraductal anomalies in women with nipple discharge (ND). Patients with spontaneous or elicited uni- or bilateral ND were included. Other preoperative diagnostic tests included: breast sonography, mammography, magnetic resonance imaging (MRI), galactography, cytologic nipple swab, and ductal lavage cytology. All patients received a ductal excision after ductoscopy to compare the results of preoperative diagnostics and ductoscopy with the histological findings. Patient age ranged from 19–86 years and the mean number of ductoscopy visualizations was 2.3 (range 1–12). Histology was benign in 89 patients. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were as follows:

Diagnostic Study	**Sensitivity %**	**Specificity %**	**PPV %**	**NPV %**	**Efficiency %**
Galactography (n=120)	81.3	44.4	70.9	58.8	67.5
Ductal lavage cytology (n=72)	57.8	85.2	86.7	54.8	68.1
Ductoscopy (n=214)	71.2	49.4	66.4	55.0	62.1
Breast MRI (n=88)	82.5	11.8	61.0	36.4	57.9
Breast ultrasonography (n=212)	82.9	17.9	58.3	43.2	55.7
Nipple swab (n=134)	22.8	85.5	69.2	43.5	48.5
Mammography (n=191)	57.1	33.3	58.6	32.0	48.2

A false passage was created in seven patients and one patient had no identifiable duct, otherwise no complications were reported due to ductoscopy. Limitations of the study include: small patient population; lack of randomization; women's refusal of some of the diagnostic methods resulting in variable number of cases for each diagnostic method; and inability to evaluate efficiency of combined diagnostic methods due to the variations in number of tests conducted.

In a prospective case series by Sauter et al. (2010) (n=75), the sensitivity and specificity of MD were reported to be 13% and 18%, respectively, for cytology in breasts with pathological nipple discharge (PND). In breasts without PND, sensitivity and specificity were 14% and 100%, respectively. Study limitations include uncontrolled design and lack of comparison with standard therapies.

Simpson et al. (2009) reported experience with mammary ductoscopy as the first center in Canada to apply this technology to surgical practice. Between 2004 and 2008, 65 women with pathologic nipple discharge received ductoscopy prior to surgical duct excision under general anesthesia. Data regarding cannulation and complication rates, procedure length and lesion visualization rate compared to preoperative ductography (if performed) were prospectively collected. Cannulation was achieved in 63 of 66 breast ducts (95%) and a lesion was visualized in 52 of 63 breast ducts (83%). The mean procedure length was 5.1 minutes, and there were no complications. Lesions seen during ductography were seen endoscopically (i.e., during ductoscopy) 30 of 33 times (91%). All three malignancies were seen during ductoscopy; invasive carcinoma in one patient, and in situ disease in two. Ductoscopy was helpful in defining the extent of duct excision. There was poor correlation, however, between endoscopic classification and final pathology. The authors concluded that ductoscopy is feasible, safe and practical, routinely to identify the location and extent of the excision without ordering preoperative ductography. However, identifying pathology based on the endoscopic appearance is unreliable unless the lesion is solitary and polypoid.

Liu et al. (2008) reported findings on 1048 women (1093 breasts) with spontaneous nipple discharge who underwent fiberoptic ductoscopy. Intraductal abnormalities were visualized in 54.3% of this cohort. Sensitivity for breast cancer associated with nipple discharge was 94.2% in this cohort and 94.4% for nonpalpable disease. Mammography, high-frequency sonography, and mammography plus sonography were also performed as preoperative assessment and to guide subsequent biopsy. Sensitivity for these tools was reported as 56.8%, 48.6%, and 36.4%, respectively ($p<0.001$) for breast cancer associated with nipple disease and 42.3%, 38.5%, and 10.3% for nonpalpable disease. Limitations include uncontrolled study design and lack of data regarding specificity and the positive and negative predictive value of fiberoptic ductoscopy.

Literature Review - Guided Duct Incision/Breast Conserving Surgery: There is insufficient data from randomized controlled trials evaluating the effectiveness of mammary ductoscopy (MD) to guide duct incision during breast conserving surgery and for resection of breast lesions. Studies are primarily in the form of uncontrolled case series with small patient populations and a lack of long-term outcomes. MD has been investigated as a surgical guide to assist the clinician in minimizing the extent of breast tissue excised during breast conserving surgery while ensuring clear histopathological margins. Although MD may identify intraductal abnormalities they may be benign or within the standard field of resection therefore adding no benefit to the patient (Yuan, et al., 2017; Kapenhaus-Valdes, et al., 2008).

Tekin et al. (2009) conducted a case series to investigate the reliability of intra-operative breast ductoscopy n patients with pathologic nipple discharge that could not be identified using mammography or ultrasound (n=34). Discharge was considered pathologic if it was spontaneous, bloody, serous, and persisting more than two months. The ductoscope was successfully introduced into the external orifice of the ducts at the nipple and proximal breast ducts were successfully visualized in 30 of 34 patients (88%). Ductoscopy revealed intraductal lesions in 20 patients (66%), including papilloma (9), signs of either acute inflammation (bleeding, erythema) or previous inflammation with healing (adhesions and blocked ducts.). Invasive breast carcinoma was identified in two patients, one with ductal carcinoma in situ with minimal invasion, and one with invasive breast carcinoma. The authors concluded that breast ductoscopy is a useful diagnostic modality in patients with pathologic nipple discharge, and that there is an obvious need to design prospective clinical trials that evaluate the potential role in breast cancer screening, guiding risk reducing strategies, and addressing this technique as an adjunct to breast conservation surgery.

Kapenhaus-Valdes et al. (2008) prospectively reviewed outcomes of the use of mammary ductoscopy (MD) in 110 ducts of 93 women with nipple discharge. A subset of patients (n=67) underwent ductoscopically-guided duct incision of 77 ducts. No statistical comparison of outcomes between the use of MD and other technologies was reported. This review also lacks data regarding the PPV, sensitivity and specificity of this technology. No conclusion regarding how this technology compares to standard diagnostic methods in the diagnosis of nipple discharge can be made.

Kim et al. (2004) performed a case series study (n=30) reporting the results of 19 patients with a preoperative histologic diagnosis of in situ or invasive breast cancer who underwent intraoperative MD immediately preceding therapeutic partial mastectomy. Only 19 of 30 patients were able to produce nipple aspirate fluid. An intraductal abnormality was visualized in 15 of 19 patients; however, 10 of these intraductal abnormalities were intramural or adjacent to the standard partial mastectomy resection field and histology was negative for carcinoma. The authors noted that MD did not add value to patient care or alter the surgical intervention that the patients were undergoing. This study was also limited by lack of randomization, small patient numbers, and lack of statistical analysis of the PPV, sensitivity, or specificity of this technology as well as a lack of statistical comparison between this technology and partial mastectomy outcomes.

Dooley (2003) prospectively studied the use of operative breast endoscopy to assist the surgeon in the determination of intraoperative margin assessment, and to define the ductal anatomy in order to best position the lumpectomy to achieve clear margins at first excision of abnormal or malignant breast tissue. The surgeon was able to successfully perform mammary ductoscopy (MD) on 150 of 201 patients. Notably, the positive margin rate of the 150 patients was 5.0%. Additionally, MD identified 83 cases that showed additional intraluminal lesions outside the margin anticipated based on clinical and preoperative imaging. This study is limited by the lack of statistical analysis, randomization, or long-term patient outcomes.

Professional Societies/Organizations: Neither the National Comprehensive Cancer Network® (2025) nor the National Cancer Institute (2025) guidelines on screening for breast cancer discuss mammary ductoscopy as an option for evaluating patients with nipple discharge or any other symptoms.

Mammary Duct Lavage and Aspiration

Nipple aspirate fluid (NAF) has been investigated as a risk assessment tool for patients who produce discharge. Uncontrolled studies have demonstrated an increased relative risk (RR=1.9–5) of breast cancer in women with abnormal cytology or epithelial cells in NAF when compared to women from whom NAF was attempted but not obtained (Baltzell, et al., 2008; Buehring, et al., 2006; West, et al., 2006).

Several methods of mammary duct aspiration have been proposed as means of extracting nipple aspirate fluid. These include invasive (e.g., ductal lavage) and non-invasive methods (e.g., automated mammary aspiration collection devices). Prospective randomized studies are required to determine the benefits of these methods over conventional diagnostic and surgical methods.

Ductal Lavage (DL)

DL has been investigated as a method to improve the sensitivity of standard screening mammography. For its use in the identification of intraductal abnormalities, published data on the sensitivity and specificity of DL reflect ranges of 17%–83.8% and 64%–100%, respectively (Lang and Kuerer, 2007; Dua, et al., 2006; Khan, 2004). DL has also been suggested as a way to improve the stratification of women with clinical evidence of increased breast cancer risk by the detection of atypia within the cells of the mammary ducts. It is proposed that analysis of ductal lavage fluid containing atypical cells may indicate that a patient is at increased risk of developing breast cancer. Scarce data are available regarding the sensitivity, specificity, and positive predictive value (PPV) of aspirate fluid obtained by DL.

While DL may be feasible for retrieving epithelial cells, the relationship between the various degrees of cellular atypia and the underlying process of tumorigenesis is unknown. DL allows duct-specific sampling but is more invasive than standard imaging techniques recommended for breast cancer screening. Additionally, the use of saline irrigation may dilute the nipple aspirate fluid and complicate quantitative analysis of biomarkers (Locke, 2004). Comparison of sensitivity, specificity and positive predictive value of cytologic interpretation of DL nipple aspiration samples to mammography results are unknown. Data are limited and do not suggest that DL is an effective screening tool for breast cancer.

There are several concerns regarding the diagnostic utility of ductal lavage (DL). These include how the use of DL findings will translate into possible increased surveillance of at-risk patients of all ages; whether unwarranted chemotherapeutic or surgical prophylactic treatment may be initiated because of false-positive results; and how findings from DL may modify ongoing chemotherapeutic regimens. Additionally, it is unknown whether validation by DL that no atypia exists in a known high-risk patient warrants additional studies, other than repeat mammography, clinical breast exam, ultrasound or magnetic resonance imaging (MRI) (Masood, 2005; Newman, 2004).

Literature Review for Ductal Lavage: There is insufficient evidence that ductal lavage (DL) has clinical utility compared with established methods of detecting and diagnosing breast cancer or that this diagnostic technique improves health outcomes. No definitive patient selection criteria for ductal lavage of the breast have been established. Additional limitations in the peer-reviewed, published literature include significant methodological and study design problems, as well as lack of standardization of risk assessment protocols. The role of ductal lavage has not yet been established.

Data regarding the sensitivity and specificity of DL in detecting breast cancer, its usefulness in risk stratification, and the significance of mild atypia as detected by DL are limited. Well-designed systematic evaluation of the impact of DL on risk assessment, treatment determination and long-term outcomes is lacking. The published peer-reviewed scientific literature consists of uncontrolled case series and case reports.

Literature Review - Breast Cancer Screening: Loud et al. (2009) evaluated patient characteristics of a cohort of women from BRCA families (n=171) by obtaining NAF and adequate cell counts of DL specimens. The authors concluded that DL is unlikely to be useful in breast cancer screening among BRCA1/2 mutation carriers because the procedure fails to yield adequate specimens sufficient for reliable cytologic diagnosis or to support translational research activities.

To determine if ductal lavage (DL) could predict the occurrence of breast cancer as well as stratify patients at high risk of developing breast cancer, Carruthers et al. (2007) performed 223 DL procedures in 116 high-risk patients. Sixty-two percent had sufficient cells for evaluation. In 15 patients who underwent further evaluation for atypia, no evidence of cancerous or precancerous lesions was found. All patients received follow-up ranging from one to four years; two patients with previous normal lavage developed breast cancer. No patient with abnormal lavage developed cancer during follow-up. The authors noted that DL was of limited value in the screening of high-risk patients and removed it from their treatment algorithm. Data suggest that abnormal lavage did not correlate with premalignant or malignant pathology in the breast at the time of lavage and did not correlate with an increased risk of development of breast carcinoma during the study period.

In order to determine if a five-year Gail risk ≥ 1.7% or the presence of nipple aspirate fluid (NAF) predicts atypia, Bushnaq et al. (2007) reported the results of 150 women who were unselected for breast cancer risk and who underwent nipple ductal lavage (DL) with cannulation of all NAF-producing ducts, producing 516 lavage samples. Of these, 33% were classified as insufficient cellular material for diagnosis (ICMD). Samples were adequate for cytologic diagnosis in 89.9% of patients. Neither NAF by ductal lavage nor Gail risk predicted lavage atypia.

To assess the reproducibility of cannulation, cell yield and cytologic diagnosis from DL from the same duct at two time points, Patil et al. (2008) conducted a phase II clinical trial of women at high risk of breast cancer. One hundred eighty-two women were recruited to the study; 161 received a successful baseline DL. Sixty-three patients with 162 ducts underwent successful DL on follow-up at three months; matched ducts yielding ≥ 100 total epithelial cells was 49%. Reproducible atypia was seen in 42% women and 20% of matched ducts with atypical cytology at baseline. The authors noted that trials that require assessments of duct cannulation-related biomarkers at two time points need to build a significant attrition of the study population into the design. In this study cytologic diagnosis of cells obtained by ductal lavage (DL) was not reproducible over time, even in the absence of a risk-reducing intervention, and does not appear to be a useful biomarker.

Literature Review - Risk Assessment and Stratification: According to Cyr (2011) a prospective trial of 102 women who underwent DL demonstrated poor concordance with histology and the addition of ductoscopy added little to the evaluation in asymptomatic, high-risk patients. Ductal lavage and ductoscopy identified histologic atypia or malignancy in only 5% high-risk women although cytologic atypia was identified in 26%. There was no apparent difference in the risk of future breast cancer development between those with atypia on ductal lavage and those without at six years of follow-up. Cytologic evaluation of ductal lavage and ductoscopy specimens appears to be of limited utility for stratifying or monitoring women at high risk of developing breast cancer.

Khan et al. (2009) reported results of a study evaluating the effectiveness of DL for biomarker assessment. One hundred fifteen women received an initial DL with repeat DL at six months. The authors noted although expected changes in tamoxifen-related biomarkers were noted, "poor reproducibility of biomarkers in the observation group, the 53% attrition rate of subjects from recruitment to biomarker analyses, and the expense of DL are significant barriers to the use of this procedure for biomarker assessment over time."

Arun et al. (2007) compared random periareolar fine needle aspiration (RPFNA) and DL as breast tissue acquisition methods by evaluating sample adequacy and tolerability in participants in two prospective Phase II breast cancer prevention trials. Eighty-six women considered high risk for breast cancer underwent these procedures on the same day to establish a baseline. Retrieval rate for RPFNA was 100%; 96% of these were adequate samples (i.e., ≥ 10 epithelial cells). Breast fluid samples were retrieved via DL in 73% of the patients; 71% were also considered adequate samples. When the entire cohort was considered, adequate samples via DL were retrieved in only 31% of patients. The authors noted that the cytology of the DL and RPFNA slides from the same subject were not different. In the DL samples, identification of atypical hyperplasia (AH) and hyperplasia was 3.7% and 11.1%, respectively, compared with 12.9% and 24.7%, respectively for RPFNA.

Visvanathan et al. (2007) evaluated the reliability of nipple aspirate fluid (NAF) and DL at two time points six months apart in 69 women with increased risk of breast cancer. Of the 47 women returning for a second visit, 24 produced NAF and 18 were successfully recannulated. Cellular yield between the two time points was inconsistent, and only fair cytologic agreement was reached. The use of ductal lavage is limited by technical challenges in cannulation, inconsistent NAF production, a high rate of inadequate cellular material for analysis, fair cytologic reproducibility, and low participant return rates.

To determine the accurate correlation of nipple aspirate, ductal lavage cytology and histopathological findings, West et al. (2006) conducted a prospective correlative study of 22 patients scheduled to undergo core needle or surgical breast biopsy. Overall specificity of cytology versus histopathological findings was 83.4%; however, cytologic-histologic correlation was discordant in 50% of the findings. West and colleagues noted that the use of ductal lavage (DL) in screening for intraepithelial neoplasias or early invasive cancers requires further investigation with perhaps a larger multicenter trial and that currently the procedure should not be recommended outside of the context of a scientific study.

Khan et al. (2004) conducted a consecutive case study of 39 women to determine the association between histopathological mastectomy findings versus the cytologic findings from ductal lavage; to establish the sensitivity and specificity of ductal lavage in the presence of known breast cancer; and to estimate the frequency with which cancer was found in breast ducts that failed to yield fluid. Ductal lavage (DL) was performed on 44 cancerous breasts and eight noncancerous breasts. When the lavage samples were analyzed for marked atypia or malignant cytology, only five ductal samples confirmed the diagnosis of breast cancer (sensitivity, 43%; specificity, 96%; accuracy, 77%). Sensitivity, specificity and accuracy decreased when the lavage samples were analyzed for mild, marked atypia or malignant cells (sensitivity, 79%; specificity, 64%; accuracy, 69%). Total study sensitivity, specificity, and accuracy were 17%, 100%, and 19%, respectively. It could not be determined if these findings resulted from cancer-containing ducts failing to yield fluid or if they had benign or mildly atypical cytology. This study failed to show that DL could be used as a reliable screening or diagnostic tool for breast cancer patients or patients with known high risk for breast cancer.

Professional Societies/Organizations: The National Cancer Institute (NCI, 2025) PDQ on breast cancer screening stated that various methods, including ductal lavage, have been proposed for breast cancer screening but none have been shown to be associated with mortality reduction.

The National Comprehensive Cancer Network™ (NCCN™) Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis (2025) states that NCCN does not recommend the use of ductal lavage as a screening procedure or for diagnosis.

Non-Invasive Mammary Duct Aspiration Collection Devices

The use of a collection device to perform mammary duct aspiration has been proposed to obtain nipple aspirate fluid for cytological analysis.

U.S. Food and Drug Administration (FDA): Non-Invasive Mammary Duct Aspiration Collection Devices are considered Class II medical devices and are regulated by the FDA via the 510(k) pathway. A noninvasive, office-based test collects nipple aspirate fluid from breast ducts for cytologic evaluation to assess breast cancer risk. This procedure is intended for the determination and differentiation of normal, premalignant, and malignant cells using laboratory cytological testing.

Device or Product	Identifier	Manufacturer
Halo™ Breast Pap Test system (NAFD 100)	K020848	Halo Healthcare, Inc
Mammary Aspiration Specimen Cytology Test (MASCT) System	K030443	Atossa Genetics, Inc

*FDA product codes: KNW

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review: Data is scarce in the published peer-reviewed scientific literature regarding the effectiveness of collection devices for the screening of breast cancer. There is a lack of well-designed controlled studies, and long-term outcomes. Randomized controlled studies are required to determine the clinical utility of these devices compared with standard methods of breast cancer screening.

Proctor et al. (2005) reported results of a prospective, multi-center, observational clinical study sponsored by the device manufacturer involving 500 asymptomatic, nonpregnant, non-lactating women with no history of breast cancer, breast surgery (e.g. breast augmentation or breast reduction), or nipple piercing. Fluid production, adequacy, safety and patient acceptance of the Halo NAF Collection System were assessed. Thirty-eight percent of patients produced fluid; 187 were available for cytologic analysis. Cytologic classification of fluid producers showed 50% with insufficient cellular material, 38% with benign nonhyperplastic ductal epithelial cells, 10% with benign hyperplastic ductal epithelial cells, 3% with atypical ductal epithelial cells, none were unequivocal malignancy. Overall, 19% of the subjects produced NAF with adequate cellularity and 1% were found to have cytologic atypia. Gail five-year risk profiles were obtained for the participants over the age of 35. Overall, no statistical difference was seen with regards to fluid production and calculated Gail profile result ($p = 0.2$). Comparison of Gail risk (>1.7% versus <1.7%) and cytology category results, for the 190 women assessed, showed no significant difference ($p = 0.68$). The study is limited by study design, and long-term follow-up is needed to determine the clinical significance of study outcomes.

Professional Societies/Organizations: Professional society statements addressing the use of non-invasive mammary duct aspiration collection devices for the screening, diagnosis or treatment of breast cancer are lacking.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No National Determination found	
LCD		No Local Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• No clinical policy statement changes	1/15/2026
Annual review	• Revised policy statement for readability	1/15/2025
Annual review	• No clinical policy statement changes	1/15/2024