



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date ..... 2/15/2011  
Next Review Date..... 2/15/2012  
Coverage Policy Number ..... 0057

## Subject Mammary Ductoscopy

### Table of Contents

Coverage Policy .....	1
General Background .....	1
Coding/Billing Information .....	5
References .....	5
Policy History.....	9

### Hyperlink to Related Coverage Policies

- Breast Biopsy Procedures including Sentinel Node Biopsy
- Electrical Impedance Scanning (EIS) and Optical Imaging of the Breast
- Genetic Testing for Susceptibility to Breast and Ovarian Cancer (e.g., BRCA1 & BRCA2)
- Magnetic Resonance Imaging (MRI) of the Breast
- Mammary Duct Aspiration and Lavage
- Mammography
- Nuclear Imaging including Single-Photon Emission Computed Tomography (SPECT)
- Prophylactic Mastectomy

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

**CIGNA does not cover mammary ductoscopy (MD) for any indication because it is considered experimental, investigational or unproven.**

## General Background

Mammary ductoscopy (MD) also referred to as fiberoptic ductoscopy (FDS) or breast duct endoscopy (BDE), involves the direct visualization of the mammary ducts and the use of a rigid camera or ductoscope.

MD has been proposed as a diagnostic tool for screening individuals at high-risk of breast cancer. 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). However, the capacity of mammary ductoscopy (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 (Periera, 2005). 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 (Al Sarakbi, 2006). However, 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 (Hung, 2009; Kapenhaus-Valdes, 2008).

Standard methods that are commonly used by health care providers to screen for breast cancer include mammography, clinical breast examination (CBE), and breast self-exam (BSE) (American Cancer Society [ACS], 2010; National Cancer Institute [NCI], 2010; National Comprehensive Cancer Network [NCCN], 2010; NCI, 2008;). For mammography, the NCI (2010) reports that the relative breast cancer-specific mortality is decreased by 15% for follow-up analysis and 20% for evaluation analysis. The absolute benefit is approximately 1% overall but depends on inherent breast cancer risk, which rises with age (NCI, 2010). Overall sensitivity of mammography is 75%, with a range of 54%–58% in women younger than 40 years to 81% to 94% in those older than 65 years; specificity is >90%. The positive predictive value (PPV) of a screening mammogram ranges between 6.3%–8%, depending upon age. In women ages 50–59 years, specificity for clinical breast exam ranges from 88%–96%, while the PPV is 3%–4% (NCI, 2010). The sensitivity, specificity and predictive values of ductoscopy as a screening tool are unknown.

If breast abnormalities are found on screening or are present on physical exam, standard methods used for further testing include additional diagnostic mammography films, ultrasound, magnetic resonance imaging (MRI), fine-needle aspiration (FNA), core-needle, or incisional breast biopsy (ACS, 2008; Gemignani, 2004; NCCN, 2010). The use of MRI in combination with mammography provides a highly sensitive screening strategy (i.e. sensitivity 93%–100%) (Lord, 2007). 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, 2008; Morrogh, 2007). Ductoscopy has also been proposed for the investigation of pathologic nipple discharge. In a prospective case series by Sauter, et al. (2009) involving 84 samples from 75 women comparing nipple aspirate fluid and MD demonstrated a sensitivity and specificity of MD of 13% and 88%, respectively, for cytology in breasts with pathological nipple discharge (PND). In breasts without PND, sensitivity and specificity were 14% and 100%, respectively. Although the specificity of MD is relatively high in this series, there are scarce data in the form of well-designed controlled trials comparing outcomes of this technology and standard therapies. The use of MD for this indication is not considered a standard diagnostic tool

Prospective randomized controlled studies are required to determine the benefits of MD over conventional diagnostic and surgical methods. While MD appears to be technically feasible, issues that have yet to be determined concerning the use of MD include:

- how the use of MD 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
- how findings from MD may be used to modify ongoing chemotherapeutic regimens
- whether validation by MD that no atypia exists in a known high-risk patient warrants additional studies, other than repeat mammography, CBE, ultrasound or MRI (Newman, 2004)

Clinical trials are in progress to determine the diagnostic utility of using nipple aspirate fluid, ductal lavage and MD as potential screening tools for women at moderate-to-high risk of developing breast cancer. Studies will also analyze the extent to which nipple aspiration, ductal lavage, and duct endoscopy may assess cancer cells in women who are undergoing surgery for breast cancer.

## Literature Review

**Breast Cancer Screening:** As part of an ongoing long-term research project aimed at exploring the potential clinical applications of MD, Sarakbi and colleagues (2006) conducted a prospective study to assess its technical

feasibility, its role in guiding ductal excisional surgery, and its use in the identification of malignancy. Twenty-six patients were subdivided into two study groups: Group A (n=13) undergoing mastectomy or lumpectomy for ductal carcinoma, and Group B (n=13) presenting with pathological nipple discharge (PND). Mammary ductoscopy (MD) using the Mastascope™ was successful in 11 patients in Group A. Intraductal pathology was visualized in eight (80%) of ten patients, but ductal cytology was positive for malignancy in only two cases (sensitivity, 16%; specificity, 100%). In Group B, MD was successful in nine patients. Seven of these 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.

Badve et al. (2003) conducted a retrospective analysis evaluating the efficacy of fiberoptic ductoscopy (FDS) as a screening tool for detecting cancer. Investigators examined the frequency of involvement of the nipple and central duct area in mastectomy specimens as surrogate markers to estimate the utility of ductoscopy in breast cancer patients. The review of 801 mastectomy specimens showed nipple and central duct involvement in only 22% of the cases. The authors noted that these findings suggest FDS is not a good method for detecting most forms of breast cancer, as ductoscopy yielded a low diagnostic accuracy. This study is limited by the lack of statistical analysis including the comparison between FDS and standard screening tools, and the lack of specific clinical outcomes data.

**Evaluation of Nipple Discharge:** Liu et al. (2008) reported the findings on 1048 women (1093 breasts) for spontaneous nipple discharge who underwent FDS between 1997 and 2005. FDS visualized intraductal abnormalities in 594 (54.3%) mammary ducts of this cohort. Four hundred thirty-seven patients (73.6%) received standard surgical assessment and final tissue diagnosis which revealed 49 cases (11.2%) of breast cancer. Thirty-six of these abnormalities (69.2%) were nonpalpable by clinical exam. Sensitivity for FDS for breast cancer associated with nipple discharge is 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 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 PPV of FDS.

Dietz et al. (2002) conducted a cross-sectional study to assess the intraoperative localization rate of MD by correlating visual findings to pathologic diagnosis. During duct excision, the researchers dissected along the shaft of the ductoscope, excising the abnormal duct. The pathologic diagnosis was then compared to the observations made during MD. Eighty-eight percent of proliferative lesions were identified in the patients. Investigators suggested that randomized controlled trials with long-term follow-up may show whether ductoscopy-directed duct excision for patients with pathologic nipple discharge can reduce the occurrence of ipsilateral breast cancer development.

Yamamoto et al. (2001) conducted a diagnostic study comparing ductography and MD and their relative diagnostic value. Sixty-five women with abnormal nipple discharge were evaluated by ductography and ductoscopy. Forty women were found to have positive screening results and subsequently underwent biopsy and histopathologic analysis. MD exhibited higher positive predictive values for identifying intraductal abnormal lesions than ductography (97.4% versus 89.2%, respectively). However, two patients with negative MD but abnormal ductographic findings in the fifth and sixth branches of the segmental duct had evidence of small papillomas in the small ducts. A true false-negative rate cannot be calculated, as the subjects who had negative screenings did not undergo definitive diagnosis with biopsy. The researchers concluded that due to the lack of the negative predictive value, the accuracy of this diagnostic test remains questionable.

A diagnostic study conducted by Shen et al. (2000) evaluated fiberoptic ductoscopy (FDS) in 259 women who had nipple discharge and analyzed the visual findings, cytological washings, and subsequent histopathology. In 92 women (36%), FDS was successful in detecting an intraductal papillary lesion. The overall positive predictive value of FDS screening was 83%. Sensitivity, specificity, or the negative predictive value of the test was not reported. This study fails to demonstrate the diagnostic accuracy of this technology.

**Guided Duct Incision/Breast Conserving Surgery:** Researchers have investigated mammary ductoscopy (MD) 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 (Khan, 2006; Kappenhuis-Valdes, 2008).

Grunwald et al. (2007) performed a retrospective analysis of 71 MDs on 64 patients that were preoperatively undertaken in patients in which an open biopsy with targeted excision was indicated. Indications for open biopsy were based on results obtained from cytological, histological or image findings from mammography, galactography or sonography of the breast. Additionally, magnetic resonance imaging (MRI), nipple smear, fine needle aspiration cytology, and high-speed core biopsy were performed in some patients according to indications and to examine the performance of the individual diagnostic methods. In 71 mammary ductoscopies, this procedure showed a sensitivity and specificity of 55.2% and 61.5%, respectively, compared to nipple smear (n=58, 36.7%, 92.3%); mammography (n=71, 37.9%, 92.3%); galactoscopy (n=19, 56.3%, 100%); duct sonography (n=71, 67.3%, 61.5%); MRI (n=27, 65.2%, 25.0%); FNAC (n=34, 51.9%, 100%); and core biopsy (n=11, 42.9%, 100%), respectively. Positive predictive value (PPV) was 100% for all procedures. The authors noted that a prospective, multicenter trial has been initiated in order to make conclusive statements about ductoscopy, especially to precisely define the indications for this method.

Kapenhuis-Valdes et al. (2008) reviewed outcomes of the use of MD in 110 ducts of 93 women with nipple discharge. A subset of patients (n=67) underwent ductoscopically-guided duct incision of 77 ducts. Brush biopsy samples and lavage fluid was sent for cytologic analysis. Six patients were found to have breast cancer on biopsy. Of these six patients, all had spontaneous nipple discharge (four with bloody discharge) and two of six had fullness and nodular density on physical exam prior to ductoscopy. 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.

Louie and colleagues (2006) retrospectively reviewed the characteristics of 188 patients with nipple discharge who underwent ductoscopy-assisted excisional biopsy and had a confirmed diagnosis of carcinoma. Fourteen specimens had confirmed carcinoma (i.e., 12 had ductal carcinoma-in-situ [DCIS]; two had invasive carcinoma with or without DCIS). Surgical margins were positive in seven of the ten samples, and two were positive within one millimeter (mm) of the specimen edge. The authors noted that MD did not offer additional information to the clinician when performed prior to surgical resection, as there were no clear landmarks that could be identified. Additional prospective studies are needed to determine the value of using MD in patients with cancer.

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. In those cases where the tip of the ductoscope was either proximal to, or adjacent to the standard mastectomy cavity, an additional ductoscopy-directed margin of tissue was taken for histologic analysis. 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 intratumoral or adjacent to the standard partial mastectomy resection field and histology was negative for carcinoma. Of five patients who had ductal abnormalities that were proximal to the resection cavity only one ductoscopy-directed margin demonstrated infiltrating 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.

The role of MD in breast cancer screening and breast conservation surgery has yet to be fully defined (Tang, 2010). Randomized controlled clinical trials published in the peer-reviewed scientific literature evaluating the use of mammary ductoscopy in the screening of breast cancer, for the evaluation and management of nipple

discharge, and for its role in breast-conserving surgery are lacking; studies are limited to uncontrolled case series and case reports. There is also a lack of comparison of long-term clinical outcomes of MD compared with conventional technologies or used as an adjunct to conventional technologies. At this time mammary ductoscopy (MD) is not considered a standard diagnostic tool for any indication.

### U.S. Food and Drug Administration (FDA)

Several ductoscopes have been approved for use by the FDA. Although they were originally classified as 510(k) devices, they are now considered unclassified by the FDA. 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. Examples of these devices include the ViaDuct™ Miniscope (Acueity Inc., Palo Alto, CA) which received 510(k) approval in May 2004, and the Mastascope™ (Lifeline Biotechnologies, Pompano Beach, FL), approved in June 2004.

### Professional Societies/Organizations

The American Cancer Society, American College of Obstetricians and Gynecologists, American Society of Breast Surgeons, National Cancer Institute, and National Comprehensive Cancer Network do not address the use of mammary ductoscopy for the screening, diagnosis, or treatment of breast cancer.

### Summary

Data are lacking in the published peer-reviewed scientific literature regarding the diagnostic utility of mammary ductoscopy (MD) for any indication. Published studies are limited by a lack of randomized controlled trials evaluating the safety and effectiveness of this technology. Additionally, long-term clinical outcomes regarding MD compared with conventional technologies such as mammography, ultrasound, or magnetic resonance imaging are lacking. The role of mammary ductoscopy has not yet been established for any indication.

---

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Experimental, investigational, unproven, and not covered when used to report mammary ductoscopy (MD):**

CPT* Codes	Description
19499	Unlisted procedure, breast

ICD-9-CM Diagnosis Codes	Description
V16.3	Family history of malignant neoplasm; breast
V84.01	Genetic susceptibility to malignant neoplasm of breast
	All codes

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

---

## References

1. Al Sarakbi W, Salhab M, Mokbel K. Does mammary ductoscopy have a role in clinical practice? Int Semin Surg Oncol. 2006 Jun 30;3:16.
2. American Cancer Society (ACS). How is breast cancer diagnosed? Revised 2010 Dec 16. Accessed January 6, 2011. Available at URL address: [http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_3X\\_How\\_is\\_breast\\_cancer\\_diagnosed\\_5.asp?sitearea=CRI](http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_How_is_breast_cancer_diagnosed_5.asp?sitearea=CRI)

3. American Cancer Society (ACS). New breast scope technology may help patients, surgeons. Revised October 2000. Accessed January 6, 2011. Available at URL address: [http://www.cancer.org/docroot/NWS/content/NWS\\_1\\_1x\\_New\\_Breast\\_Scope\\_Technology\\_May\\_Help\\_Patients\\_\\_Surgeons.asp](http://www.cancer.org/docroot/NWS/content/NWS_1_1x_New_Breast_Scope_Technology_May_Help_Patients__Surgeons.asp)
4. American Society of Breast Surgeons (ASBS). Official statement: ductal lavage and cell-based risk assessment. Revised 2007 May 6. Accessed January 6, 2011. Available at URL address: [http://www.breastsurgeons.org/statements/PDF\\_Statements/Ductal\\_Cell.pdf](http://www.breastsurgeons.org/statements/PDF_Statements/Ductal_Cell.pdf)
5. Badve S, Wiley E, Rodriquez N. Assessment of utility of ductal lavage and ductoscopy in breast cancer—a retrospective analysis of mastectomy specimens. *Mod Pathol*. 2003 Mar;16(3):206-9.
6. Beechey-Newman N, Kulkarni D, Kothari A, D'Arrigo C, Culora G, Hamed H, et al. Breast duct microendoscopy in nipple discharge. *Surg Endosc*. 2005;19:1648-51.
7. Burstein HJ, Harris RJ. Malignant tumors of the breast. In: DeVita VT, Hellman S, Rosenberg SA (editors). *Cancer: Principles and Practice of Oncology*. 8<sup>th</sup> ed. Lippincott, Williams & Wilkins; 2008.
8. Danforth DN, Abati A, Filie A, Prindiville SA, Palmieri D, Simon R, et al. Combined breast ductal lavage and ductal endoscopy for the evaluation of the high-risk breast: a feasibility study. *J Surg Oncol*. 2006;94:555-64.
9. Dooley WC. Ductal lavage, nipple aspiration, and ductoscopy for breast cancer diagnosis. *Curr Oncol Rep*. 2003 Jan;5(1):63-5.
10. Dua RS, Isacke CM, Gui GPH. The intraductal approach to breast cancer biomarker discovery. *J Clin Oncol*. 2006;24(7):1209-16.
11. Escobar PF, Crowe JP, Matsunaga T, Mokbel K. The clinical applications of mammary ductoscopy. *Am J Surg*. 2006;191:211-5.
12. Fralinger JA, Kurtzman SH. Combined ductal lavage and ductoscopy: what is the future for the intraductal approach? *J Surg Oncol*. 2006;94:553-4.
13. Gray RJ, Pockaj BA, Karstaedt PJ. Navigating murky waters: a modern treatment algorithm for nipple discharge. *Am J Surgery*. 2007;194:850-55.
14. Grunwald S, Bojhar B, Schessinger G, Schimming A, Kohler G, Schultz K, et al. Mammary ductoscopy for the evaluation of nipple discharge and comparison with standard diagnostic techniques. *J Minim Invasive Gynecol*. 2006 Sep-Oct;13(5):418-23.
15. Grunwald S, Heyer H, Paepke S, Schwesinger G, Schimming A, Hahn M, et al. Diagnostic value of ductoscopy in the diagnosis of nipple discharge and intraductal proliferations in comparison to standard methods. *Onkologie*. 2007 May;30(5):243-8. Epub 2007 Apr 24.
16. Hunerbein M, Dubowy A, Raubach M, Gebauer B, Topalidis T, Schlag P. Gradient index ductoscopy and intraductal biopsy of intraductal breast lesions. *Am J Surg*. 2007 Oct;194(4):511-4.
17. Hung WK, Yng M, Chan CM, Lam HS, Mak KL. Minimally invasive technology in the management of breast disease. *Breast Cancer*. 2009;16(1): 23-9. Epub 2008 Sep 26.
18. Inglehart JD, Smith BL. Diseases of the breast. In: Townsend CM, Beauchamp RD, Evers BM, Mattox KL, editors. *Sabiston's textbook of surgery*. 18<sup>th</sup> ed. Philadelphia, PA: Saunders Elsevier; 2007.
19. Kapenhas-Valdes E, Feldman SM, Cohen JM, Boolbol SK. Mammary ductoscopy for evaluation of nipple discharge. *Ann Surg Oncol*. 2008 Oct;15(10):2720-7. Epub 2008 Aug 7.

20. Kapenhas-Valdes E, Feldman SM, Boolbol SK. The role of mammary ductoscopy in breast cancer: a review of the literature. *Ann Surg Oncol*. 2008 Dec;15(12):3350-60. Epub 2008 Oct 8.
21. Kim JA, Crowe JP, Woletz J, Dinunizio A, Kelly T, Dietz JR. Prospective study of intraoperative mammary ductoscopy in patients undergoing partial mastectomy for breast cancer. *Am J Surg*. 2004 Oct;188(4):411-4.
22. Kim JA. Mammary ductoscopy: current and future applications (breast cancer and benign disease). Revised 2004. Accessed January 6, 2011. Available at URL address: <http://www.cancernews.com/printer.asp?aid=236>
23. King BL, Love SM. The fourth international symposium on the intraductal approach to breast cancer, Santa Barbara, California, 10-3 March 2005. *Breast Cancer Res*. 2005;7(5):198-204.
24. Liu GY, Lu JS, Shen KW, Wu J, Chen CM, Hu Z, et al. Fiberoptic ductoscopy combined with cytology testing in the patients of spontaneous nipple discharge. *Breast Cancer Res Treat*. 2008 Mar;108(2):271-7. Epub 2007 May 2.
25. Lord SJ, Lei W, Craft P, Cawson JN, Morris I, Walleser S, et al. A systematic review of the effectiveness of magnetic resonance imaging (MRI) as an addition to mammography and ultrasound in screening young women at high risk of breast cancer. *Eur J Cancer*. 2007 Sep;43(13):1905-17.
26. Louie LD, Crowe JP, Dawson AE, Lee KB, Baynes DL, Dowdy T, Kim JA. Identification of breast cancer in patients with pathologic nipple discharge: does ductoscopy predict malignancy? *Am J Surg*. 2006;192:530-3.
27. Moncreif RM, Nayar R, Diaz LK, Staradub VL, Morrow M, Khan SA. A comparison of ductoscopy-guided and conventional surgical excision in women with spontaneous nipple discharge. *Ann Surg*. Apr; 241(4):575-81.
28. Morrogh M, Morris EA, Liberman L, Borgen PI, King TA. The predictive value of ductography and magnetic resonance imaging in the management of nipple discharge. *Ann Surg Oncol*. 2007 Dec;14(12):3369-77.
29. National Cancer Institute (NCI). Breast cancer (PDQ<sup>®</sup>) screening: Breast cancer screening modalities. Updated 3 Dec 2010. Accessed January 6, 2011. Available at URL address: <http://www.cancer.gov/cancertopics/pdq/screening/breast/HealthProfessional/page4>
30. National Cancer Institute (NCI). Breast Cancer Risk Assessment Tool. Updated Apr 28, 2008. Accessed January 10, 2010. Available at URL address: <http://www.cancer.gov/bcrisktool/Default.aspx>
31. National Cancer Institute (NCI). Phase II Study of Nipple Aspiration, Ductal Lavage, and Duct Endoscopy for Diagnostic Assessment in Women Undergoing Surgery for Breast Cancer. Updated 2010 Sep 10. Accessed Jan 6, 2011. Available at URL address: <http://www.clinicaltrial.gov/ct2/show/NCT00083018>
32. National Cancer Institute (NCI). Study of Breast Duct Lavage, Breast Duct Endoscopy, and DNA Gene Expression Profiling in Women with Ipsilateral Breast Cancer Versus Healthy Women Who Are and Are Not at High Risk for Breast Cancer. Revised 2010 Feb 3. Accessed Jan 6, 2011. Available at URL address: <http://www.cancer.gov/search/ViewClinicalTrials.aspx?cdrid=334479&version=HealthProfessional&protocolsearchid=4022695>
33. National Comprehensive Cancer Network<sup>®</sup> (NCCN). NCCN GUIDELINES<sup>™</sup> Clinical Guidelines in Oncology<sup>™</sup>. Breast cancer. V2.2011. © National Comprehensive Cancer Network, Inc. 2010, All Rights Reserved. Accessed Jan 6, 2011. Available at URL address: [http://www.nccn.org/professionals/physician\\_gls/PDF/breast.pdf](http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf)

34. National Comprehensive Cancer Network® (NCCN). NCCN GUIDELINES™ Clinical Guidelines in Oncology™. Breast cancer screening and diagnosis. V1.2011. © National Comprehensive Cancer Network, Inc. 2010, All Rights Reserved. Accessed Jan 6, 2011. Available at URL address: [http://www.nccn.org/professionals/physician\\_gls/PDF/breast-screening.pdf](http://www.nccn.org/professionals/physician_gls/PDF/breast-screening.pdf)
35. Newman LA. Ductal lavage: what we know and what we don't. *Oncology*. 2004 Feb;179-86.
36. Pereira B, Mokbel K. Mammary ductoscopy: past, present, and future. *Int J Clin Oncol*. 2005;10:112-6.
37. Sarakbi WA, Salhab M, Mokbel K. Does mammary ductoscopy have a role in clinical practice? *Int Semin Surg Oncol*. 2006; 3: 16. Accessed Jan 60, 2011. Available at URL address: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1524964>
38. Sauter ER, Klein-Szanto A, Ehya H, Macgibbon B. Ductoscopic cytology and image analysis to detect breast carcinoma. *Cancer*. 2004 Sep;101(6):1283-92.
39. Sauter ER, Klein-Szanto A, Macgibbon B, Ehya H. Nipple aspirate fluid and ductoscopy to detect breast cancer. *Diagn Cytopathol*. 2009 Sep 30.
40. Sharma R, Dietz J, Wright H, Crowe J, DiNunzio A, Woletz J, et al. Comparative analysis of minimally invasive microductectomy versus major duct excision in patients with pathologic nipple discharge. *Surgery*. 2005 Oct;138(4):591-7.
41. Simpson JS, Connolly EM, Leong WM, Escallon J, McCready D, Reedijk M, et al. Mammary ductoscopy in the evaluation and treatment of pathologic nipple discharge: a Canadian experience. *Ca, J Surg*. 2009 Dec;52(6):E245-8.
42. Smith RA, Cokkinides V, Eyre HJ. Cancer screening in the United States, 2007: a review of current guidelines, practices, and prospects. *CA Cancer J Clin*. 2007 Mar-Apr;57(2):90-104.
43. Tang SS, Twelves DJ, Isacke CM, Gui GP. Mammary ductoscopy in the current management of breast disease. *Surg Endosc*. 2010 Dec 18. [Epub ahead of print]
44. Uchida K, Fukushima H, Toriumi Y, Kawase K, Tabei I, Yamashita A, et al. Mammary ductoscopy: current issues and perspectives. *Breast Cancer*. 2008 Nov 19. Epub ahead of print.
45. Uchida K, Toriumi Y, Kawase K, Tabei I, Yamashita A, Nogi H. Percutaneous endoscopy-guided biopsy of an intracystic tumor with a mammary ductoscopy. *Breast Cancer*. 2007;14(2):215-8.
46. US Food and Drug Administration (FDA). Centers for Devices and Radiologic Health (CDRH). Breast Ductoscope. Updated Jun 2006. Accessed January 6, 2011. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=3272>
47. Valdes EK, Boolbol SK, Cohen J-M, Balassanian R, Feldman SM. Clinical experience with mammary ductoscopy. *Ann Surg Oncol*. 2006 Jul 29; [Epub ahead of print]

---

## Policy History

---

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	2/15/2008	0057	Mammary Ductoscopy (DL)

“CIGNA”, “CIGNA HealthCare” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.