

02-10000-19

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## Subject: Breast Ductoscopy

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.

<a href="#">Position Statement</a>	<a href="#">Billing/Coding</a>	<a href="#">Reimbursement</a>	<a href="#">Program Exceptions</a>	<a href="#">Definitions</a>	<a href="#">Related Guidelines</a>
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### DESCRIPTION:

Breast ductoscopy (also known as fiberoptic ductoscopy, breast endoscopy, or mammary ductoscopy) is a technique that provides for direct visual examination of the breast ducts. The procedure is performed under sedation and involves inserting a fiberoptic, flexible scope through the nipple and threading the scope through the network of ducts deep in the breast. Fluid may be collected through the scope for examination or a thin wire probe may be passed into the breast to visualize the ductal system to detect abnormalities. The use of ductoscopy has been proposed to aid in the detection and management of early stage breast cancer and other forms of intraductal breast disease. Several ductoscopes have been approved for use by the U.S. Food and Drug Administration (FDA).

Summary and Analysis of Evidence: An UpToDate review on “Nipple Discharge” (Golshan, 2022) states that “ In a small trial of women undergoing microductectomy or major duct excision, half were randomly assigned to undergo ductoscopy before surgery. Ductoscopy demonstrated a sensitivity of 80 percent and specificity of 71 percent in identifying any lesion but did not influence the pathological yield or the volume of the surgical specimen compared with control patients.” Yuan et al (2022) concluded that “high-frequency ultrasound of breast is a preferred evaluation method for patients with nipple discharge.” The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology- Breast Cancer (2024) and Breast Cancer Screening and Diagnosis (2023) do not mention the use of ductoscopy. The available published data is limited and the procedure is currently being studied in clinical trials. There is also minimal information on how the procedure would be used in patient management such as determining the need for other tests, biopsy, or excision. The evidence is insufficient to determine the role of ductoscopy in the evaluation and management of patients with known or suspected breast cancer.

## POSITION STATEMENT:

Breast ductoscopy is considered **experimental or investigational** for all indications. 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 ductoscopy; unlisted code 19499 may be used.

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](#)

## 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:

No guideline specific definitions apply.

## RELATED GUIDELINES:

[Ductal Lavage and Suction Collection Systems, 02-10000-14](#)

## OTHER:

None applicable.

## REFERENCES:

1. Chang YK, Chen CT, et al. Could ductoscopy alleviate the need of microdochectomy in pathological nipple discharge? *Breast Cancer*. 2020 Jul;27(4):607-612. PMID:32008216.
2. ClinicalTrials.gov. Feasibility and Therapeutic Efficacy of Ductoscopic Papilloma Extraction in Patients With Pathologic Nipple Discharge; accessed February 2024.
3. De Boorder T, Waaijer L, et al. Ex vivo feasibility study of endoscopic intraductal laser ablation of the breast. *Lasers Surg Med*. 2018 Feb;50(2):137-142. Doi: 10.1002/lsm.22745. Epub 2017 Oct 9. PMID: 28990682.
4. Denewer A, El-Etribi K, Nada N, El-Metwally M, The Role and Limitations of Mammary ductoscope in Management of Pathologic Nipple Discharge, *Breast J*. 2008 Sep-Oct; 14(5): 442-9.

5. Escobar, P. F., Crowe, J. P., Matsunaga, T. & Mokbel, K. (2006). The Clinical Applications of Mammary Ductoscopy. *American Journal of Surgery*, 191, 211-215.
6. Fei X, Yong W, et al. Advances in fiberoptic ductoscopy for the diagnosis and treatment of pathologic papillary overflow. *Heliyon*. 2023 Dec 2;10(1):e23211.
7. Filipe MD, Waaijer L, et al. Interventional Ductoscopy as an Alternative for Major Duct Excision or Microdochectomy in Women Suffering Pathologic Nipple Discharge: A Singlecenter Experience. *Clin Breast Cancer*. 2020 Jun;20(3):e334-e343.PMID:32081573.
8. Golshan M. Nipple Discharge. In: UpToDate, Chagpar AB &Chen W (Eds), UpToDate, Waltham, MA; accessed February 2024 at uptodate.com.
9. Han Y, Li J, et al. Diagnostic value of endoscopic appearance during ductoscopy in patients with pathological nipple discharge. *BMC Cancer*. 2017 May 2;17(1):300.
10. 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.
11. Hunerbein M, Schwarz L, Schneider U, Schlag P. Evaluation of pathologic nipple discharge with ductoscopy (let). *Journal of the American College of Surgeons*. Oct 2003; 197(4).
12. Jikuzono T, Manabe E, et al. RNA recovery from specimens of duct-washing cytology performed contemporaneously with mammary ductoscopy. *BMC Res Notes*. 2022 Feb 10;15(1):34.
13. Kapenhas-Valdes E, Feldman SM, Boolbol SK, The Role of Mammary Ductoscopy in Brest Cancer: A Review of the Literature, *Annals of Surgical Oncology*, 15(12):3350-3360, 10/08.
14. Liu GY, Lu JS, Shen KW, 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.
15. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology-Breast Cancer; accessed at nccn.org.
16. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology-Breast Cancer Screening and Diagnosis; accessed at nccn.org.
17. Sauter ER, Klein-Szanto A, Macgibbon B, Ehya H, Nipple Aspirate Fluid and Ductoscopy to Detect Breast Cancer, *Diagn Cytopathol*. 2009 Sep 30.
18. Smith, R., Saslow, D., Sawyer, K. A., Burke, W., Costanza, M. E., Evans, W. P., Foster, R. S., Hendrick, E., Eyre, H. J. & Sener, S. (2003). American Cancer Society Guidelines for Breast Cancer Screening: Update 2003. *CA Cancer J. Clin* 2003, 53, 141-169.
19. Uchida K, Fukushima H, Toriumi Y, et al, Mammary Ductoscopy: Current Issues and Perspectives, *Breast Cancer*, 2009; 16(2): 93-6.
20. U.S. Food and Drug Administration (FDA); accessed at fda.gov.
21. Vaughan A, Crowe JP, Brainard J, Dawson A, et al, Mammary Ductoscopy and Ductal Washings for the Evaluation of Patients with Pathologic Nipple Discharge, Vol 15, Issue 3, pages 254-260, 05/09.
22. Waaijer L, Simons JM, et al. Systematic review and meta-analysis of the diagnostic accuracy of ductoscopy in patients with pathological nipple discharge. *Br J Surg*. 2016 May;103(6):632-643. Doi: 10.1002/bjs.10125. Epub 2016 Mar 23. PMID: 27004588.
23. Wu W, Li XR, Yang KY, Dong BN, Chen DJ, Breast Intraductal Lesion Resection Under Breast Fiberoptic Ductoscopy, *Zhong Nan Da Xue Xue Bao Yi Xue Ban*, 2008 Jan; 33(1): 81-4.
24. Xu F, Zhu C, et al. Deep learning for real-time detection of breast cancer presenting pathological nipple discharge by ductoscopy. *Front Oncol*. 2023 Mar 22;13:1103145.
25. Ye Han, Jianyi Li, et al, Diagnostic value of endoscopic appearance during ductoscopy in patients with pathological nipple discharge. *BMC Cancer*. 2017 May 2;17(1):300. Doi: 10.1186/s12885-017-3288-3.

26. Yilmaz R, Bender O, et al. Diagnosis of Nipple Discharge: Value of Magnetic Resonance Imaging and Ultrasonography in Comparison with Ductoscopy. *Balkan Med J.* 2017 Apr 5;34(2):119-126.
27. Yuan H, Tang X, et al. A comparative analysis of diagnostic values of high-frequency ultrasound and fiberoptic ductoscopy for pathologic nipple discharge. *BMC Med Imaging.* 2022 Sep 2;22(1):155.

### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 03/28/24.

### GUIDELINE UPDATE INFORMATION:

12/15/03	New Medical Coverage Guideline – investigational.
12/15/04	Scheduled review and revision of guideline; consisting of updated references and maintaining investigational status.
01/01/06	Annual review – maintain investigational.
11/15/06	Annual review – maintain investigational.
07/15/07	Annual review, investigational status maintained, guideline reformatted, references updated.
10/15/08	Annual review: position statement maintained, references updated.
07/15/09	Annual review: position statement maintained, title revision, and references updated.
04/15/10	Annual review: position statement maintained and references updated.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
09/15/17	Review; Investigational position maintained; title, description and references updated.
05/15/19	Review; Position statement maintained and references updated.
05/15/21	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.