02-10000-19

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Reviewed: 03/27/25

Revised: 04/15/25

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.

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

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, 2024) 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 (2024) 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:

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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:

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	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	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.			