Breast Duct Endoscopy
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00140
Original Effective Date: 06/28/2004
Current Effective Date: 08/15/2012

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers breast duct endoscopy to be investigational.*

Background/Overview
Breast duct endoscopy is a technique that provides for direct visual examination of the breast ducts through nipple orifice cannulation and exploration. The technique has been investigated in the following clinical situations:

- As a diagnostic technique in women with spontaneous nipple discharge, where endoscopy might function as an alternative to surgical excision
- As a technique to obtain cellular material to stratify women for risk of breast cancer
- As a follow-up test for women with atypical cytology as detected by ductal lavage (DL)
- As a technique to delineate intraductal disease to define margins of surgical resection
- As a technique for the direct delivery of therapeutic agents, including photodynamic therapy, laser ablation, topical biological agents, etc.

Of related interest, three-dimensional reconstruction techniques of computed tomography (CT)-scans are now being studied in another approach referred to as virtual ductoscopy.

FDA or Other Governmental Regulatory Approval
Centers for Medicare and Medicaid Services (CMS)
No national coverage.

Rationale/Source
While published data suggest that breast duct endoscopy is feasible, there is minimal published information about how this procedure would be used in the management of the patient, i.e., either in determining the need for other diagnostic tests, such as mammography or ductography, determining the need for biopsy or excision or determining the extent of surgical excision. Love and Barsky published a feasibility study in 1996, in which nine patients scheduled to undergo mastectomy first underwent breast duct endoscopy. The authors concluded that the intraductal approach is feasible for the study of the early changes of breast cancer. Shen and colleagues studied the role of breast duct endoscopy in 259 women with nipple discharge. In 36% of patients, ductoscopy successfully identified an intraductal papillary lesion.
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Although the authors conclude that ductoscopy is a safe alternative to ductography in guiding subsequent breast surgery, there was no direct comparison between these two techniques. The same group of authors subsequently published a larger case series of 415 women with nipple discharge; presumably, this study overlaps with the previous study. An intraductal lesion was detected in 40% of these 166 patients; 11 were shown to have ductal carcinoma in situ (DCIS). While the authors concluded that ductoscopy may be a useful technique for diagnosing DCIS prior to surgery, there are no data reporting on how the results of ductoscopy influence either the decision to undergo biopsy or excision or the extent of the excision.

Dooley reported on a case series of 201 patients who underwent breast endoscopy during a lumpectomy procedure. The author concluded that ductoscopy could locate additional intraductal lesions outside the lumpectomy site, thus decreasing the incidence of a positive margin of resection. In a subsequent study, Dooley reported on a case series of 88 patients who underwent ductoscopy for nipple discharge or as a follow-up to a DL; many of the patients also had mammographic abnormalities. The authors concluded that office ductoscopy with biopsy is both feasible and does identify suspicious or malignant atypia in patients with expressed or spontaneous nipple fluid. Sauter and Matsunaga and colleagues have also documented the technical feasibility of ductoscopy in large case series of patients with nipple discharge.

In summary, the available published data consist of uncontrolled case series. The data are insufficient to permit scientific conclusion regarding the role of breast duct endoscopy in the evaluation and management of patients with known or suspected breast cancer.

Literature between 2004 through October 2005 remained dominated by uncontrolled case series. Improvements in the size of the endoscope, image quality and method of sample collection for cytology are being reported. Given the rapid technological advances, most clinical studies are outdated by the time of publication. With this caveat in mind, two small prospective case series from Europe indicate that, in patients with nipple discharge, ductoscopy can effectively identify the location of a lesion but it is not sufficiently sensitive for the diagnosis of malignancy. A retrospective review suggests that compared with major duct excision (140 patients), microductectomy (95 patients) detects a lower percentage of occult carcinoma; this may be related to the larger sample size of the resection specimen. The National Comprehensive Cancer Network does not currently include ductoscopy in its recommendations for diagnostic follow-up of pathological nipple discharge. Newer methods may more effectively distinguish between benign and malignant lesions, potentially eliminating the need for unnecessary duct excision. This and other indications for breast duct endoscopy will need to be evaluated in larger trials.

Louie conducted a retrospective study of patients with nipple discharge who underwent ductoscopy and had a diagnosis of cancer. In this small series of cancer patients, duct wall irregularities or intraluminal growths were noted during ductoscopy in 57% of breast cancer patients. The authors concluded that no clear morphologic changes noted during ductoscopy definitively indicated malignancy. In a study from Europe, Hunerbein reported results using a new, rigid ductoscope during the evaluation of 66 patients with breast cancer and 45 patients with nipple discharge. This new instrument is said to have improved optics as well
as an approach for vacuum-assisted biopsy. In this case series, intraductal lesions were noted in 41% of patients with breast cancer. In addition, 16% of “normal” ducts had extensive intraductal lesions. Grunwald and colleagues compared various diagnostic tests in patients with breast disease. In this study, ductoscopy was compared to mammography, galactography, sonography, magnetic resonance imaging (MRI), nipple smear, fine-needle aspiration cytology (FNAC), and high-speed core biopsy. However, not all patients received all evaluations; for example, only 19 patients had galactography. There were 71 ductoscopies that were followed up by open biopsies. Here, three invasive and eight ductal carcinomas in situ were found, as well as 3 atypical ductal hyperplasias, 44 papillomas/papillomatosis (all considered to be disease); and 13 benign findings. Feasibility of ductoscopy was 100% in this series. Duct sonography showed the highest sensitivity (67.3%), followed by MRI (65.2%), galactography (56.3%), ductoscopy (55.2%) and FNAC (51.9%). The highest specificity was shown by FNAC, core biopsy and galactography (each 100.0%), followed by mammography (92.8%), nipple smear (77.8%), ductoscopy and duct sonography (each 61.5%); the lowest specificity was displayed by MRI (25.0%). The authors believe that these results are promising and indicate that a multicenter European study is underway to further evaluate ductoscopy. Results are expected near the end of 2008. In contrast to these results, in a study from China involving 1,048 women evaluated between 1997 and 2005, Liu identified 49 of 52 (94%) cancers among women presenting with spontaneous nipple discharge. However, evaluation and follow-up was limited among the 489 cases that had normal ductoscopy and cytology. The authors do note that 77 of these cases underwent tissue diagnosis within a median follow-up time of 19 months during which one malignancy (DCIS) was diagnosed. The 2008 NCCN guidelines for evaluation of those with nipple discharge again do not recommend breast ductendoscopy. In another paper from a European center, Jacobs describes ongoing research and development in an attempt to have breast ductoscopy become a potential therapeutic as well as a diagnostic approach. The authors comment that these instruments, which require an additional working channel, are not presently available in the United States. Results for use of this technology are viewed as preliminary. Further studies are needed to better define both the clinical validity and clinical utility of this technique in appropriate populations. This procedure is considered investigational because its impact on health outcomes is uncertain.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. reference to federal regulations.

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