BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Intraductal Biopsy/Breast Duct Endoscopy

Policy #: 120
Latest Review Date: August 2024
Category: Surgical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **intraductal biopsy** as a **covered benefit** for coverage for individuals with **nipple discharge and normal mammography**.

Blue Advantage will treat **intraductal biopsy** when performed as **routine screening, to evaluate breast lesions without nipple discharge, or for nipple discharge with abnormal mammography,** as a **non-covered benefit** and as **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Intraductal biopsy is a minimally invasive, non-radiological microendoscopic procedure conducted on an outpatient basis. The technique, also called ductoscopy-directed duct excision, involves a tiny endoscope being passed through the nipple and deep into a duct, enabling the duct epithelium to be visualized.

Once the ductoscope is in place and the lesion has been identified, a biopsy system is introduced into the working channel of the scope. Using ductoscopic-viewing techniques, the biopsy system is directed through the nipple and guided through the maze-like ductal systems to arrive at the lesion site. The physician uses recorded visuals to help negotiate the way back to the lesion site. It is essential that the physician place the biopsy system in such a way as to optimize the attempt to capture an adequate tissue specimen. The procedure is repeated multiple times to assure a high probability of success.

Depending on the anatomic variability and the nature of the lesion, the physician tries different combinations of biopsy tools. These lesions may be peduncular, obstructive, thread-like, adherent, or have other characteristics. Also the lesions maybe located at distant, terminal lobules, at lobules perpendicular to the main duct, or in the duct. Because the ducts are fragile, thin-walled structures that have many branches, orientation within the ductal system is problematic and requires experience and a visual documentation system.

Intraductal biopsy is different from ductal lavage. Intraductal biopsy or ductoscopy is more invasive that ductal lavage. Ductal lavage is a method of sampling breast epithelium that involves the elicitation of nipple fluid by breast massage and suction aspiration of the nipple. Fluid yielding ducts are cannulated and cytology examinations are performed.

KEY POINTS:

The most recent literature update was performed through August 2024.

Summary of Evidence

Breast carcinoma and precancer are thought to start in the lining of the milk duct or lobule. Although the incidence of breast cancers presenting as nipple discharge is decreasing as earlier detection and screening techniques are emphasized, cancer is still the etiology of pathologic nipple discharge (PND) in 2% to 10% of cases. The majority of patient with PND have normal mammograms, however, the presence of a radiographic abnormality is associated with an increased cancer risk. It is also important to note that patients with PND and a normal mammogram can have cancer. Clinical symptoms are unreliable in assessing the malignant potential of discharge. Bloody discharge does increase the cancer risk, but malignancies can also be present in patients with milky or green discharge. Common causes of nipple discharge are intraductal papilloma or papillomatosis, which are observed in 35% to 48% of cases based on surgical pathology analysis of excised tissues.

Until recently, physicians have not had a means of direct access to the lining of the milk duct other than blindly removing tissue by core biopsy or fine-needle aspiration. Studies have shown that the overall positive predictive value of intraductal biopsy screening is 83%.
The role of intraductal biopsy is to inspect and diagnose intraductal alterations and growths. Knowledge of the extent of intraductal changes can be of assistance in planning if surgery is needed and the extent of surgery.

Sauter et al published the results of fiberoptic ductoscopy (FD) findings in women with and without spontaneous nipple discharge. One hundred fiberoptic ductoscopy specimens were taken, 60 were from breasts without spontaneous nipple discharge (SND) and 40 with WND. A model using cytology and SND was 92% sensitive and 60% specific in predicting which women had breast carcinoma. Their conclusions were pronounced differences in FD samples from those with and without SND. FD biologic parameters can be chosen to optimize breast carcinoma predictive sensitivity and specificity. SND cytology can present a diagnostic problem, suggesting the need for histologic confirmation before the initiation of therapy.

Sarakbi et al discussed the technical feasibility of mammary ductoscopy (MD) and its role in guiding ductal surgery and in the early diagnosis of malignancy. Twenty-six patients underwent mammary ductoscopy and were performed under either local or general anesthesia. The authors concluded that MD is technically feasible in most patients and has a potential in the early detection of breast cancer. The procedure can be performed safely in the office setting and should be considered in all patients presenting with a single duct pathological nipple discharge (PND). MD has the potential to reduce the number of duct excision procedures and minimize the extent of surgical resection. Ductoscopic cytology is not sufficiently sensitive for the diagnosis of malignancy and the development of a biopsy tool that obtains tissue under direct visualization is required.

Moncrief and colleagues (2005) performed a retrospective review of the records of 117 consecutive women who underwent ductoscopy to guide ductal excision or received conventional terminal duct excision without ductoscopy. These investigators stated that

ductoscopy identifies intra-ductal lesions in a high proportion of women with spontaneous nipple discharge and it may contribute to more accurate resection of these. However, a prospective study is needed to obtain an unbiased assessment of these possible advantages.

Hunerbein et al published results for a study that included 38 women with nipple discharge using a microendoscope and a special needle for intraductal vacuum assisted biopsy. Cannulation was successful in 37 or 38 women and intraductal lesions were found in 29 women. Diagnostic biopsies were obtained in 26 or 28 patients. Histological analysis of the biopsy specimens showed 22 papilloma, two in situ carcinoma and two invasive carcinoma. The authors concluded that using the ductoscopic vacuum assisted biopsy is a new technique for tissue sampling of intraductal breast lesions may improve preoperative evaluation of pathologic nipple discharge in selected patients, but it should not be considered as a method for screening of early breast cancer.

Liu et al (2008) reported the outcomes of fiberoptic ductoscopy (FD) combined with cytology testing for diagnosing spontaneous nipple discharge. A total of 1,048 women (1,093 breasts total) underwent successful diagnostic FD. Discharge was unilateral (86.8 %), single ductal (93.4 %), and serous (57.9 %) or bloody (36.0 %). Among 437 (40.0 %) of the FD-positive breasts, breast carcinomas was revealed in 49 cases (11.2 %), central papillomas in 228 cases (52.2 %), and atypical ductal hyperplasia in 5 cases (1.1%). Ten patients with positive cytology testing received microdochectomy in spite of having a negative FD, which revealed 2 additional ductal carcinomas in situ (DCIS), and 4 papillomas. About 489 breasts were negative for both FD and cytology testing and were subjected to follow-up. Approximately 77 (15.7 %) of the breasts underwent tissue diagnosis within a median follow-up time span of 19 months, and 1 DCIS was detected. The sensitivity of FD for detection of malignant lesions was 94.2 % and increased to 98.1 % when combined with cytology testing. Nevertheless, it was less sensitive ($p < 0.01$) if these researchers used only cytology testing (58.3 %), mammography (48.6 %), high-frequency sonography (36.4 %), or combination of mammography and sonography (56.8 %) to detect these malignant lesions. The authors stated that these findings confirmed the value of FD combined with cytology testing as a diagnostic procedure in women with nipple discharge.

Kapenhas-Valdes et al published the results of a prospective review of 93 patients that underwent ductoscopy for evaluation of nipple discharge. Of these, 67 had abnormal findings and therefore underwent ductoscopy with guided duct excision. The remaining 26 had normal ductoscopic examinations. Forty-two patients were diagnosed with papilloma/papillomatosis, six had atypical papilloma/atypical ductal hyperplasia/atypical lobular hyperplasia, and six were diagnosed with cancer. The authors found the mammary ductoscopy as a useful tool in evaluation of patients with nipple discharge. Mammary ductoscopy allowed for accurate visualization, analysis and excision of intraductal abnormalities.

Tekin et al investigated the reliability of intra-operative breast ductoscopy in patients with pathologic nipple discharge that was not identified on radiologic tests. Thirty-four patients had breast ductoscopy under general anesthesia. Twenty patients had intraductal lesions. In two cases, invasive breast carcinoma was identified. These authors determined that breast ductoscopy is a reliable and easy-to-use method to demonstrate the source of pathologic nipple discharge in cases with bleeding and other intraductal lesions.

KEY WORDS:
Intraductal biopsy, Fiberoptic ductoscopy, Fiber-ductoscopy, FDS, Mammoscopy, ViaDuct™ MicroEndoscope, ductoscope, ductoscopy, breast duct endoscopy, duct endoscopy, fiberoptic ductoscopy, mammary ductoscopy

APPROVED BY GOVERNING BODIES:
The ViaDuct™ MicroEndoscope and accessories were FDA approved April 18, 2001.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT codes:

19499	Unlisted procedure, breast
88172	Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode each site
88177	Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (List separately in addition to code for primary procedure)

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, June 2007
Medical Policy Group, June 2009
Medical Policy Group, December 2010; 2011 coding updates
Medical Policy Group, December 2011

Medical Policy Group, July 2019
Medical Policy Group, August 2021
Medical Policy Group, August 2022: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, August 2023: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, August 2024
UM Committee, August 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
