Name of Policy: Intraductal Biopsy/Breast Duct Endoscopy

Policy #: 120
Category: Surgical

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**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 than 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.

**Policy:**

*Intraductal biopsy meets* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for patients with nipple discharge and normal mammography.

*Intraductal biopsy* when performed as routine screening, to evaluate breast lesions without nipple discharge, or for nipple discharge with abnormal mammography does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered 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.*
Key Points:
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 patients 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. 100 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. 26 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.

June 2009 Update
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, 2 in situ carcinoma and 2 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.

Kapenas-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, 6 had atypical papilloma/atypical ductal hyperplasia/atypical lobular hyperplasia, and 6 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 2 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.

Based on this information, the policy statement will remain unchanged.

**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.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity. Pre-certification requirements: Not applicable
CURRENT Coding:
CPT codes: 19499 Unlisted procedure, breast

Effective for dates of service on or after January 1, 2011:

88172 Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode each site
88177 (list separately in addition to code for primary procedure).

References:

Policy History:
Medical Policy Group, January 2003
Medical Policy Group, March 2003 (2)
Medical Policy Administration Committee, June 2003
Available for comment July 1-August 14, 2003
Medical Policy Group, June 2005 (1)
Medical Policy Group, June 2007 (1)
Medical Policy Group, June 2009 (1)
Medical Policy Group, June 29, 2011: Active Policy but no longer scheduled for regular literature reviews and updates.
This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.