

**Policy: MP089**

**Section: Medical Benefit Policy**

**Subject: Evaluation of Breast Ductal Fluid**

### Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

### I. Policy: Evaluation of Breast Ductal Fluid

#### II. Purpose/Objective:

To provide a policy of coverage regarding Evaluation of Breast Ductal Fluid

#### III. Responsibility:

- A. Medical Directors
- B. Medical Management

#### IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

#### V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

#### Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

Gail Risk Model – a risk calculation model utilizing five factors (age, age at menarche, age at first live birth, previous breast biopsies, and family history of breast cancer in first-degree relatives) to determine the risk of developing an invasive breast cancer over the next five years as well as a lifetime probability of developing an invasive breast cancer.

#### **DESCRIPTION:**

Ductal lavage of the breast is a method of collecting epithelial cells from the mammary ducts of the breast for cytological analysis. The fluid sample is analyzed for the presence of benign, atypical or malignant cells. The results are used to provide additional risk stratification information to a member considering the use of Tamoxifen therapy for the purpose of risk reduction.

Fiberoptic Ductoscopy (also known as microendoscopic intraductal mammary visualization) is a technique that provides for direct visual examination of the breast ducts through nipple orifice cannulation and exploration. The procedure is performed with a fiberoptic microendoscope equipped with an outer sheath through which aspiration can be performed in order to retrieve epithelial cells for cytological analysis.

Nipple Aspirate Fluid Suction Technique (i.e. Halo NAF system) is a noninvasive suction collection system used to collect ductal epithelial cells. The system utilizes an adjustable breast cup which warms the breast and applies suction to draw nipple aspirate fluid to the surface which is then analyzed for cytologic analysis.

#### **EXCLUSIONS:**

The Plan does **NOT** provide coverage for Breast Ductal lavage which includes Fiberoptic Ductoscopy and Nipple Aspirate Fluid Suction Technique (i.e. Halo NAF System) as a means of screening or as a diagnostic tool because the current evidence does not support its use as a screening or diagnostic test for breast cancer screening.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

#### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**CODING ASSOCIATED WITH:** Evaluation of Breast Ductal Fluid

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

19499 Unlisted procedure, breast

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

#### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

#### **REFERENCES:**

Geisinger Clinic Technology Assessment Committee, "Breast Ductal Lavage for Breast Cancer Detection", July 9, 2002.

ECRI, Health Technology Assessment Information Service, Windows on Medical Technology, "Ductal Lavage and Nipple Aspiration for Identifying Women at High Risk of Breast Cancer", 80:1-27, July 2002.

TEC Assessment Program, "Use of Epithelial Cell Cytology in Breast Cancer Risk Assessment and High-Risk Patient Management", 17(1):1-34, June 2002.

Hayes Alert, "Breast Ductal Lavage for Cytological Examination", 4(4):1-3, April 2001.

"Breast Cancer Risk Assessment Guidelines Outlined", *Oncology News International*, 11(5), May 2002.

Dooley W, Veronesi U, et.al., "Detection of Pre-Malignant and Malignant Cells by Ductal Lavage: Results From a Multicenter Trial", <http://www.ductallavage.com/professionals/multiClinRes.cf>, accessed 8/23/2002.

Dooley WC, Ljung BM, et.al., "Ductal Lavage for Detection of Cellular Atypia in Women at High Risk for Breast Cancer", *Journal of the National Cancer Institute*, 93(21):1624-1632. Nov 7, 2001.

O'Shaughnessy JA, Ljung BM, et.al., "Ductal Lavage and the Clinical Management of Women at High Risk of Breast Carcinoma", *Cancer*, 94(2):292-298. Jan 15, 2002.

Geisinger Technology Assessment Committee, "Breast Ductal Lavage – Review of Additional Tech Data", July 9, 2003.

Proctor KA, et al. Cytologic features of nipple aspirate fluid using an automated non-invasive collection device: a prospective observational study. *BMC Women's Health* 2005 Aug 3;5:10.

Winifred S. Hayes INC., HAYES Directory "Breast Ductal Lavage and Fiberoptic Ductoscopy for Breast Cancer Diagnosis and Screening. August 23, 2004 Updated November 19, 2005.

Sauter ER, Ehya H, Klein-Szanto AJ, Wagner-Mann C, Macgibbon B. Fiberoptic Ductoscopy findings in women with and without spontaneous nipple discharge. *Cancer* 2005;103:914-21.

Hunnerbein M, Raubach M, Gebauer B, Schneider W, Schlag PM. Ductoscopy and intraductal vacuum assisted biopsy in women with pathologic nipple discharge. *Breast Cancer Res Treat*. 2006 Jun 3;[Epub ahead of print].

Shen KW, WU J, Lu JS, Han QX, Shen ZZ, Nguyen M, Barsky SH, Shao ZM. Fiberoptic Ductoscopy for breast cancer patients with nipple discharge. *Surg Endosc* 2001;15:1340-1345.

Moncrief RM, Nayar R, Diaz LK, Staradub VL, Morrow M, Khan S. A comparison of Ductoscopy-guided and conventional surgical excision in women with spontaneous nipple discharge. *Ann Surg* 2005;241:575-581.

American Cancer Society (ACS). Other breast imaging tests. 2011. Available at: <http://www.cancer.org/Treatment/UnderstandingYourDiagnosis/ExamsandTestDescriptions/MammogramsandOtherBreastImagingProcedures/mammograms-and-other-breast-imaging-procedures-other-br-imaging-tests>

National Cancer Institute (NCI). Breast Cancer Screening Modalities. Available at: [http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/Page4#Section\\_256](http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/Page4#Section_256)

The American Society of Breast Surgeons (ASBS). Ductal Cell-Based Risk Assessment Statement. 2007. Available at: [http://www.breastsurgeons.org/statements/PDF\\_Statements/Ductal\\_Cell.pdf](http://www.breastsurgeons.org/statements/PDF_Statements/Ductal_Cell.pdf)

National Comprehensive Cancer Network. (NCCN) Practice Guidelines in Oncology. Breast Cancer Screening and Diagnosis V1.2022

ECRI, Health Technology Assessment Information Service. Ductal Lavage and Nipple Aspiration for Identifying Women at High Risk of Breast Cancer. July 8 2011

Do Canto LM, Marian C, Willey S, et al. MicroRNA analysis of breast ductal fluid in breast cancer patients. *Int J Oncol*. 2016;48(5):2071-2078

Waaiker L, Simons JM, Borel Rinkes IH, 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.

Chen K, Zhu L, Hu T, et al. Ductal lavage for patients with nonlactational mastitis: A single-arm, proof-of-concept trial. *J Surg Res*. 2019;235:440-446.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 9/02

**Revised:** 7/03; 7/04; 7/05; 7/06 (Description/Exclusions); 7/07, 7/08, 6/09 (coding), 6/12 (change current position to investigational); 5/18 (clarified exclusion), 5/20 (grammatical change)

**Reviewed:** 6/10, 6/11, 6/13, 6/14, 6/15, 6/16, 5/17, 5/19, 5/21, 5/22, 5/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.