Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MP089

Section: Medical Benefit Policy

Subject: Evaluation of Breast Ductal Fluid

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
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit 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 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.

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 ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

19499 Unlisted procedure, breast

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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.

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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

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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)

Reviewed: 6/10, 6/11, 6/13, 6/14, 6/15, 6/16, 5/17,