



Subject: Breast Ductal Lavage and Fiberoptic Breast Ductoscopy*

Effective Date: December 10, 2002

Department(s): Utilization Management

Policy: Noninvasive retrieval of epithelial cells from the breast by ductal lavage is not reimbursable under Plans administered by QualCare, Inc.

Fiberoptic breast ductoscopy is not reimbursable under Plans administered by QualCare, Inc.

Mammary duct aspiration by non-invasive collection devices (HALO Breat Pap Test, Mammary Aspirate Specimen Cytology Test System) is not reimbursable under Plans Administered by QualCare, Inc.

Objective: To insure proper and consistent reimbursement for medically necessary services, and to exclude coverage of a service that is still investigational.

Procedure:

- A. Requests for coverage of ductal lavage for breast cytology shall be denied as investigational because the efficacy of this procedure is not adequately supported by peer-reviewed literature.
- B. Requests for coverage of fiberoptic breast ductoscopy shall be denied as investigational because the efficacy of this procedure is not adequately supported by peer-reviewed literature.

C. As there is not a specific **CPT code** for either of these procedures, the most likely code to be submitted is **19499**, an unlisted breast procedure.

References:

National Comprehensive Cancer Network(NCCN) guidelines Version 2.2018-Breast Cancer Screening and Diagnosis accessed at nccn.org

National Comprehensive Cancer Network(NCCN) guidelines Version1.2016-Breast Cancer Screening and Diagnosis accessed at nccn.org

Waaiker L, Simons JM, Borel Rinkes IH, van Diest PJ, Verkooijen HM, Witkamp AJ. Systematic review and meta-analysis of the diagnostic accuracy of ductoscopy in patients with pathological nipple discharge. *Br J Surg*. 2016 Mar 23. doi: 10.1002/bjs.10125. [Epub ahead of print]

Bevers TB, Bonnaccio E, Buys SS, Calhoun KE, et al. NCCN Guidelines Version 2.2013 Breast Cancer Screening and Diagnosis. Accessed online 5/21/14 www.NCCN.org

Cyr AE, Margenthaler JA, Conway J, Rastelli AL. Correlation of Ductal Lavage Cytology with Ductoscopy-Directed Duct Excision Histology in Women at High Risk for Developing Breast cancer: A Prospective, Single Institution Study. *Ann Surg oncol*. 2011;18(11):3192-97(Oct)

Bevers TB, Bonnaccio E, Buys SS, Calhoun KE, et al. NCCN Guidelines Version 1.2011 Breast Cancer Screening and Diagnosis. Accessed online 3/08/12 www.NCCN.org

Dooley WC. Breast ductoscopy and the evolution of the intra-ductal approach to breast cancer. [*Breast J*](#). 2009;15 Suppl 1:S90-4 (Sep-Oct)

Wood ME, Stanley Ma, Crocker Am, *et al*. Ductal Lavage of cancerous and unaffected breasts: Procedure success rate and cancer detection. *Acta Cytol* 2009;53(4):410-415 (Jul-Aug)

Vaughan A, Crowe JP, Brainard J, *et al*. Mammary ductoscopy and ductal washings for the evaluation of patients with pathologic nipple discharge. *Breast J* 2009;15(3):254-260 (May-Jun)

Loud JT, Thiébaud AC, Abati AD, *et al*. Ductal lavage in women from BRCA 1 / 2 families : Is there a future for ductal lavage in women at increased genetic risk of breast cancer ? *Cancer Epidemiol Biomarkers Prev*. 2009;18(4):1243-1251 (Apr)

Denewer A, El-etribi K, Nada N, *et al*. The role and limitations of mammary ductoscope in management of pathologic nipple discharge. *Breast J* 2008;14(5):442-449 (Sep-Oct)

National Cancer Institute. Breast Cancer Screening Modalities. Tissue Sampling (Fine-Needle Aspiration, Nipple Aspirate, Ductal Lavage) Available at: http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/256.cdr#Section_256 Accessed 02/21/2010.

National Cancer Institute. Clinical Trials PDQ[®] Phase II Study of Nipple Aspiration, Ductal Lavage, and Duct Endoscopy For Diagnostic Assessment in Women Undergoing Surgery For Breast Cancer Available at: <http://www.cancer.gov/clinicaltrials/RMNHS-2283> Accessed 02/21/2010

Carruthers CD, Chapleskie LA, Flynn MB, *et al.* The use of ductal lavage as a screening tool in women at high risk for developing breast carcinoma. *Am J Surg* 2007;194(4):463-466 (Oct)

Ghanouni P, Kurian AW, Margolis D, *et al.* Ductal pattern enhancement on magnetic resonance imaging of the breast due to ductal lavage. *Breast J* 2007;13(3):281-286 (May)

Danforth DN Jr, Abati A, Filie A, *et al.* Combined breast ductal lavage and ductal endoscopy for the evaluation of the high-risk breast : A feasibility study. *J Surg Oncol* 2006;94(7):555-564 (Dec)

Zhang W, Yang YC, Zhang BN *et al.* Biomarker analysis on breast ductal lavage cells in women with and without breast cancer. *Int J Cancer* 2006;119(2):359-364 (Jul 15)

Antill YC, Mitchell G, Johnson SA, *et al.* Loss of heterozygosity analysis in ductal lavage samples from BRCA1 and BRCA2 carriers: A cautionary tale. *Cancer Epidemiol Biomarkers Prev* 2006;15(7):1396-1398 (Jul)

West KE, Wojcik EM, Dougherty TA *et al.* Correlation of nipple aspiration and ductal lavage cytology with histopathologic findings for patients before scheduled breast biopsy examination. *Am J Surg* 2006;191(1):57-60 (Jan)

Hurria A, Joyce RM, Come SE. Follow-up for breast cancer survivors: Recommendations for surveillance after therapy. *UpToDateOnline* 13.2, 2005. www.uptodate.com accessed 10/25/05

Rivers A, Newman LA. Ductal lavage for breast cancer risk assessment. *Surg Oncol Clin N Am* 2005;14(1):45-68 (Jan)

Maddux AJ, Ashfaq R, Naftalis E, *et al.* Patient and duct selection for nipple duct lavage. *Am J Surg.* 2004;188(4): 390-394 (Oct)

Abeloff MD, Wofll AC, Wood WC, *et al.* Cancer of the Breast. Ch 94 in Abeloff MD, Armitage JO, Niederhuber JE, *et al.* *Clinical Oncology* 3rd ed. Philadelphia. Elsevier/Churchill Livingstone. 2004

Domchek SM. The utility of ductal lavage in breast cancer detection and risk assessment. *Breast Cancer Res* 2002;4(2):51-53 (Jan)

Dooley WC, Ljung BM, Veronesi U, *et al.* Ductal lavage for detection of cellular atypia in women at high risk for breast cancer. *J Natl Cancer Inst* 2001;93(21):1624-1632 (Nov 7)

Drafted By: BFisher, MD 10/31/02
Approved By/Date: QM Committee 12/10/02
Reviewed without Revision By/Date: BFisher, MD 10/25/05
Approved By/Date: QM Committee 12/12/05
Revised By/Date: BFisher, MD 03/02/08
Approved By/Date: QM Committee 03/25/08
Revised by/Date: BFisher, MD 02/21/10
Approved By/Date: QM Committee 03/23/10
Reviewed without Revision By/Date: MMcNeil, MD 03/08/12
Approved By/Date: QM Committee 3/27/12
Revised By/Date: MMcNeil, MD 05/21/14
Approved By/Date: QM Committee: 06/10/14
Reviewed w/o Revision By/Date: MMcNeil, MD 01/04/17
Approved By/Date: QM Committee 2/21/17
Reviewed w/o Revision By/Date: MMcNeil, MD 07/31/18
Approved By/Date: QM Committee 08/21/18

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.