

Policy: MP170

Section: Medical Benefit Policy

Subject: Gene Expression Profiling for Breast Cancer Treatment

I. Policy: Gene Expression Profiling for Breast Cancer Treatment

II. Purpose/Objective:

To provide a policy of coverage regarding Gene Expression Profiling for Breast Cancer Treatment

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.

DESCRIPTION:

Conventionally, the prognosis of breast cancer patients is determined by age, tumor size, histology, status of axillary lymph nodes, histologic type and hormone receptor status. More recently, investigation has focused on examining the gene expression in tumor tissue as a prognostic factor to predict a patient's chance of recurrence. Examples of this type of testing include Oncotype Dx®, Prosigna® Breast Cancer Assay, EndoPredict®, MammaPrint®, and a 76-gene signature.

CRITERIA FOR COVERAGE:

Oncotype DX™ Breast Assay; EndoPredict:

The Plan considers Oncotype DX™ Breast Cancer Assay gene expression profiling for breast cancer treatment as medically necessary to assess the need for adjuvant chemotherapy in newly diagnosed breast cancer when **ALL** of the following are met:

- A clinical diagnosis of Stage I or Stage II is made; **and**
- The tumor is estrogen receptor (ER) and/or progesterone receptor (PR) positive; **and**
- HER2 receptor status is negative; **and**
- Tumor size is 0.5 to 1.0 cm with moderate/poor differentiation or unfavorable features; or tumor size > 1 cm **and**
- The member is node negative, or staged at pN1mi (micrometastasis of 0.2-2.0mm)*, or with no more than three positive nodes ; **and**
- The member is a candidate for possible adjuvant chemotherapy (i.e. chemotherapy is not precluded due to other factors), and testing is being done specifically to guide the decision as to whether or not adjuvant chemotherapy will be used; **and**
- Less than six months have elapsed since the initial diagnosis

* Members with micrometastases (isolated tumor cells in the lymph node) are considered to be node negative

Prosigna® Breast Cancer Assay:

The Plan considers Prosigna® Breast Cancer Assay gene expression profiling for breast cancer treatment as medically necessary to assess the need for adjuvant chemotherapy in newly diagnosed breast cancer when **ALL** of the following are met:

- Diagnosed with Stage I or II breast cancer within the previous 6 months; **and**
- Node negative* or Stage II with 1-3 positive nodes; **and**
- Estrogen receptor (ER) positive or progesterone-receptor (PR) positive tumor; **and**
- Her2 negative tumor; **and**
- Tumor size 0.6 to 1.0 cm with moderate/poor differentiation or unfavorable features; or tumor size > 1 cm
- The member would be a candidate for adjuvant chemotherapy (i.e., chemotherapy is not contraindicated due to other factors); **and**
- The result of the test will guide the decision whether or not to use chemotherapy; **and**
- The member would choose to receive chemotherapy if offered.

* Members with micrometastases (isolated tumor cells in the lymph node) are considered to be node negative

MammaPrint® 70-Gene Breast Cancer Recurrence Assay

The Plan considers MammaPrint® Breast Cancer Assay gene expression profiling for breast cancer treatment as medically necessary to assess the need for adjuvant chemotherapy in newly diagnosed breast cancer when **ALL** of the following are met:

- A clinical diagnosis of Stage I or Stage II is made; **and**
- fresh or fresh frozen tissue is available; **and**
- tumor is estrogen receptor positive or progesterone receptor positive; **and**
- tumor is HER2 (human epidermal growth factor receptor 2) negative; **and**
- tumor size ≤ 5.0 centimeters; **and**
- the member is node negative or with 1-3 positive ipsilateral axillary lymph nodes; **and**
- the member would be a candidate for adjuvant chemotherapy (i.e., chemotherapy is not contraindicated due to other factors); **and**
- the result of the test will guide the decision whether or not to use chemotherapy; **and**
- the member would choose to receive chemotherapy if offered.

Breast Cancer Index™ (BCI)

The Plan considers Breast Cancer Index (BCI) as medically necessary for prediction of benefit from extended endocrine therapy when considering adjuvant systemic therapy for postmenopausal women with invasive breast cancer when **ALL** of the following criteria are met:

- Pathology reveals invasive carcinoma of the breast that is ER+ and/or PR+ and HER2-; and
- Member has early-stage disease (T1-3, pN0, M0); and
- member is lymph node negative; and
- member has no evidence of distant breast cancer metastasis (i.e., non-relapsed); and
- Test results will be used in determining treatment management of the member for chemotherapy and/or extension of endocrine therapy.

LIMITATIONS:

The test(s) are covered once per primary tumor, per individual.

FOR MEDICARE SEGMENTS: – CMS directives allow MammaPrint® 70 gene assay to be considered for coverage when used to predict recurrence risk in members with ER-positive or ER-negative, lymph node-negative breast cancer. Palmetto GBA established a formal coverage policy for all Medicare patients. This local carrier determination is applicable nationally.

Palmetto GBA, the designated national contractor for its Oncotype DX® breast cancer test, has expanded its coverage policy for all qualified Medicare patients to include patients with ductal carcinoma in situ (DCIS).

CMS directives allow Breast Cancer Index (BCI) Gene Expression Test to be considered for coverage when used to predict 10yr distant recurrence risk in members breast cancer. Palmetto GBA established a formal coverage policy for all Medicare patients. This local carrier determination is applicable nationally.

EXCLUSIONS:

Unless coverage is mandated, the Plan does NOT provide coverage for any other assays of genetic expression in breast tumor tissue (e.g. Blueprint™, TargetPrint®, Mammostrat® Breast Cancer Test, BreastOncPx™, NexCourse® Breast IHC4, PreciseDx™ Breast Cancer Test, BreastPRS™, and the Rotterdam Signature 76-Panel) because they are considered experimental, investigational or unproven.

FOR MEDICAID BUSINESS SEGMENT:

EndoPredict 12-gene molecular score is considered to be Experimental/Investigational and therefore **NOT COVERED**.

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, will be evaluated on a case by case basis.

CODING ASSOCIATED WITH: *Gene Expression Profiling for Breast Cancer Treatment*

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.

- 81479 Unlisted molecular pathology procedure (may be used to represent Mammostrat, Breast Cancer Index (BCI), Blueprint, TargetPrint)
- 84999 Unlisted Chemistry Procedure (may be used to represent Mammostrat, Breast Cancer Index (BCI), Blueprint, TargetPrint)
- 81599 Unlisted multianalyte assay with algorithmic analysis (may be used to represent Mammostrat, Breast Cancer Index (BCI), Blueprint, TargetPrint)
- 81518 Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy {Breast Cancer Index (BCI)}

- 81519 Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score {e.g., Oncotype DX(Genomic Health)}
- 81520 Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score {e.g., Prosigna} (Prosigna Breast Cancer Prognostic Gene Signature Assay)
- 81521 Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis {MammaPrint}
- 81522 Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
- 81523 Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis {MammaPrint® NGS}
- S3854 Gene profiling for the use in the management of breast cancer treatment
- 0045U Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score {EndoPredict, OncoTypeDX Breast DCIS Score Test }
- 0153U Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
- 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, "Gene Expression Profiling for Breast Cancer Treatment", January 11, 2006.

National Cancer Institute: Probability of Breast Cancer in American Women, reviewed 03/04/05. Accessed October 13, 2005 <http://cis.nci.nih/gov>

Genomic Health: About Oncotype DX. Genomic Health Inc. 2005 Accessed on October 3, 2005 at <http://www.genomichealth.com/oncotype/about/hcp.aspx?Layout=Print>

Paik S et al. A Multigene Assay to Predict Recurrence of Tamoxifen-Treated, Node Negative Breast Cancer. N Engl J Med 30 December 2004; 351:2817-26.

Espinosa E, Fresno Vara JA, Redondo A, Sanchez JJ, Hardisson D, Zamora P, Gomez Pastrana F, Cejas P, Martinez B, Sudrez A, Calero F, Gonzalez Baroin M. Breast Cancer Prognosis Determined by Gene Expression Profiling: A Quantitative Reverse Transcriptase Polymerase Chain Reaction Study. J Clin Oncol October 2005;23(29):7278-7285.

Esteva FJ et al. Prognostic Role of a Multigene Reverse Transcriptase-PCR Assay in Patients with Node-Negative Breast Cancer not Receiving Adjuvant Systemic Therapy. Clinical Cancer Research. May 2005; 11:3315-3319.

Molecular Profiling Inc. MammaPrint. Accessed on October 5, 2005 at <http://www.molecularprofiling.com/products/mammaprint.cfm>

Gianni L et al. Gene Expression Profiles in Paraffin-Embedded Core Biopsy Tissue Predict Response to Chemotherapy in Women with Locally Advanced Breast Cancer. J Clin Oncol. October 2005; 23(29): 7265-7277.

Van't Veer LJ, Paik S, Hayes DF. Gene Expression Profiling of Breast Cancer: A New Tumor Marker. J Clin Oncol March 2005; 23:1631-1635.

Ayers M et al. Gene Expression Profiles Predict Complete Pathologic Response to Neoadjuvant Paclitaxel and Fluorouracil, Doxorubicin and Cyclophosphamide Chemotherapy in Breast Cancer. J Clin Oncol. June 2004; 22(12): 2284-2293.

Chang J, Powless TJ, Allred DC, Ashley SE, Clark GM, Assersohn ML, Gregory RK, Osborne CK, and Dowsett M. Biologic Markers as Predictors of Clinical Outcome From Systemic Therapy for Primary Operable Breast Cancer. *J Clin Oncol*. October 1999; 17(10): 3058-3063.

Goldhirsch A et al. Meeting Highlights: international Consensus Panel on the Treatment of Primary Breast Cancer. Proceedings from the Seventh International Conference on Adjuvant Therapy of Primary Breast Cancer. St. Gallen Switzerland. February 2001. *J Clin Oncol*. September 2001; 19(18): 3817-3827.

Van't Veer LJ, Dai H, Van de Vijver et al. Gene Expression Profiling Predicts Clinical Outcome of Breast Cancer. *Nature* 2002 Jan 31; 415(6871): 530-6.

Van de Vijver MJ et al. A Gene Expression Signature as a Predictor of Survival in Breast Cancer. *N Engl J Med* December 2002; 347(25): 1999-2009.

Veridex LLC. Gene Search Breast Sentinel Lymph Node assay. Accessed on October 5, 2005 at: <http://www.veridex.com/systems/systems.aspx?id=2>

Wang et al. Gene-Expression Profiles to predict distant metastasis of Lymph-Node-negative primary Breast Cancer. *The Lancet*. February 2005; 365: 671-679.

Hayes Inc. GTE Comparison of Breast Cancer Index, EndoPredict, Oncotype DX Breast Cancer Assay, and Prosigna Tests Jan.19, 2017

Hayes Inc. GTE Report. EndoPredict July 20, 2017

Hayes Inc. GTE Report. MammaPrint 70-Gene Breast Cancer Recurrence Assay. March 16, 2018

ECRI Target Database. Gene Expression assay for predicting recurrence of breast cancer. September 2005.

ECRI Target Database. Gene expression profiling of breast cancer to predict the likelihood of recurrence. March 2007.

NCCN Clinical Practice Guidelines in Oncology, Breast Cancer, v2.2022 National Comprehensive Cancer Network

Paik S, Tang G, Shak S, Kim C, et al. N. Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. *J Clin Oncol* 24:3726-3734.

Cardoso F, Van't Veer L, Rutgers E, et al. Clinical application of the 70-gene profile: The MINDACT Trial. *J Clin Onc*. Feb. 2008;26(5):729-735.

Sparano JA, Paik S. Development of the 21-gene assay and its application in clinical practice and clinical trials. *J Clin Onc*. Feb. 2008;26(5):721-728.

BlueCross BlueShield Association. Technology Evaluation Center (TEC). Gene expression profiling of breast cancer to select women for adjuvant chemotherapy. BlueCross BlueShield Association. Technology Evaluation Center (online) April 2008;22(15).

Harris LN, Ismaila N, McShane LM, et al. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early-Stage Invasive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline. *J Clin Oncol*. 2016.

Recommendations from the EGAPP Working Group: can tumor gene expression profiling improve outcomes in patients with breast cancer? EGAPP Recommendation Statement. *Genetics in Medicine* 2009;11(1):66-73.

Blue Cross Blue Shield Association, Technology Evaluation Center (TEC). Gene expression profiling in women with lymph-node-positive breast cancer to select adjuvant chemotherapy treatment. Nov. 2010;25(1).

California Technology Assessment Forum. Gene expression profiling as a guide for the management of early stage breast cancer. Oct. 18, 2006. <http://ctaf.org/content/assessment/detail/621>

Albain KS, Barlow WE, Shak S, et al. Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: a retrospective analysis of a randomised trial. *Lancet Oncol* 2010;11:55-65.

Dowsett M, Cuzick J, Wale C, et al. Prediction of risk of distant recurrence using the 21-gene recurrence score in node-negative and node-positive postmenopausal patients with breast cancer treated with anastrozole or tamoxifen: a TransATAC study. *J Clin Oncol* 2010;28:1829-34.

Liebermann N, Baehner FL, Soussan-Gutman L, Klang S, Yoshizawa C, Shak S. Evaluation of Recurrence Score, nodal status and traditional clinicopathologic metrics in a large ER positive patient cohort. European Society for Medical Oncology. Providence, RI; May 16-19, 2011

Nguyen B, Cusmano PG, et al. Comparison of molecular subtyping with Blueprint, MammaPrint, and TargetPrint to local subtyping in breast cancer patients. *Ann Surg Onc.* 2012;19:3257-3263.

Deck KB, Sinha R, et al. Comparison of MammaPrint and TargetPrint with clinical parameters in patients with breast cancer: Findings from a prospective U.S. cohort. *J Clin Onc.* 2011;29(15)suppl May 20.

Hayes Inc. GTE Overview. Blueprint Molecular subtyping profile for breast cancer. Dec. 7, 2016 Palmetto GBA. MoIDX. Oncotype DX Breast Cancer Assay Coding and Billing Guidelines (M00003): <http://www.palmettogba.com/palmetto/MoIDX.nsf/DocsCat/MoIDX%20Website~MoIDX~Browse%20By%20Topic~Covered%20Tests~8SLME78317?open&navmenu=%7C%7C>

Bastien RRL, Vaughn C, et al. Clinical validation of the Prosigna breast cancer prognostic gene signature assay on formalin-fixed paraffin embedded breast cancer tumors with comparison to standard molecular markers. *J Clin Oncol* 32, 2014 (suppl; abstr e11518)

Sparano JA, Gray RJ, et al. prospective Validation of a 21-Gene expression Assay in Breast Cancer. *NEJM* 2015;373(13) e-pub ahead of print

Dubsky P, Brase JC, Jakesz R, et al. The EndoPredict score provides prognostic information on late distant metastases in ER+/HER2- breast cancer patients. *British J Cancer* (2013), 1–6.

Martin M, Brase JC, et al. Prognostic ability of EndoPredict compared to research-based versions of the PAM50 risk of recurrence (ROR) scores in node-positive, estrogen receptor-positive, and HER2-negative breast cancer. A GEICAM/9906 sub-study. *Breast Cancer Res Treat.* 2016 Feb;156(1):81-9

Buus R, Sestak I, Kronenwett R, et al. Comparison of EndoPredict and EPclin With Oncotype DX Recurrence Score for Prediction of Risk of Distant Recurrence After Endocrine Therapy. *J Natl Cancer Inst.* 2016; 108(11)

Müller BM, Brase JC, Haufe F, et al. Comparison of the RNA-based EndoPredict multigene test between core biopsies and corresponding surgical breast cancer sections. *Journal of Clinical Pathology* 2012;65:660-662.

Filipits M, Dubsky C, et al. Impact of the EndoPredict-clin score on risk stratification in ER-positive, HER2-negative breast cancer after considering clinical guidelines. *Journal of Clinical Oncology* 2012;30(15 suppl.):542

Roberts MC, Miller DP, Shak S, et al. Breast cancer-specific survival in patients with lymph node-positive hormone receptor-positive invasive breast cancer and Oncotype DX Recurrence Score results in the SEER database. *Breast Cancer Res Treat.* Jun 2017;163(2):303-310

Jasem J, Fisher CM, Amini A, et al. The 21-Gene Recurrence Score assay for node-positive, early-stage breast cancer and impact of RxPONDER Trial on chemotherapy decision-making: have clinicians already decided? *J Natl Compr Canc Netw.* Apr 2017;15(4):494-503.

PA Dept. of Human Services Managed Care Operations Memorandum, General Operations OPS # 08/2018-014

Sparano JA, Gray RJ, Makower DF, et al. Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer. *N Engl J Med.* 2018; 12:379(2):111-121

Blok, E.J., Bastiaannet, E., van den Hout, W.B., Liefers, G.J., Smit, V.T., Kroep, J.,R., & van de Velde, C.J.H. Systematic review of the clinical and economic value of gene expression profiles for invasive early breast cancer available in Europe. *Cancer Treatment Reviews*, 2018;62, 74-90.

Woodward WA, Barlow WE, Jagsi R et al. Association between 21-gene assay recurrence score locoregional recurrence rates in patients with node-positive breast cancer. *JAMA Oncol.* 2020 Jan

Andre F, Ismaila N, et al. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer: ASCO Clinical Practice Guideline Update – Integration of Results From TAILORx. *J Clin Oncol* 2019; 37:1956-1964.

Liefers GJ, Noordhoek I. et al. Breast cancer index (BCI) predicts benefit of two-and-a-half versus five years of extended endocrine therapy in HR+ breast cancer patients treated in the ideal trial. ASCO Meeting Library. <https://meetinglibrary.asco.org/record/184899/abstract>

Noordhoek I, Treuner K, Putter H, et al. Breast Cancer Index predicts extended endocrine benefit to individualize selection of HR+ early stage breast cancer patients for 10 years of endocrine therapy. Clin Cancer Res October 27, 2020. <http://clincancerres.aacrjournals.org/content/early/2020/10/27/1078-0432.CCR-20-2737>

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

Devised: 01/12/06

Revised: 02/07, 7/07, 6/09(wording); 3/11 (criteria revision); 3/12 add Medicare mandate, revise criteria; 6/12 revise criteria; 11/14 (add DCIS coverage for Medicare); 9/15 (added Prosigna), 7/16 (Gender Language), 11/16 (Exclusions); 11/17 (add EndoPredict); 9/18 (expand MammaPrint indication, add Medicaid exclusion); 9/19 (update criteria, remove P/A); 9/20 (add Medicare coverage; exclusions); 3/21 (add BCI coverage)

Reviewed: 7/08, 8/13, 8/14, 3/22

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.