



Geisinger Health Plan Policies and Procedure Manual

Policy: MP248

Section: Medical Benefit Policy

Subject: Single Nucleotide Polymorphisms (SNPs) to Predict Risk of Non-Familial Breast Cancer

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Single Nucleotide Polymorphisms (SNPs) to Predict Risk of Non-Familial Breast Cancer

II. Purpose/Objective:

To provide a policy of coverage regarding Single Nucleotide Polymorphisms (SNPs) to Predict Risk of Non-Familial Breast Cancer

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.

Commercial

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.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children’s Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

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

DESCRIPTION:

Single nucleotide polymorphisms, usually referred to as SNPs, are small genetic changes among single base nucleotides. Tests called "Polygenic Risk Scores" or PRS tests, combine the risk from Single nucleotide polymorphisms (SNPs) associated with breast cancer in Genome Wide Association Studies (GWAS). GWAS have identified over 300 SNPs among people of European origin, associated with risk for breast cancer. Some tests include combinations of SNPs and biomarkers to predict risk.

Researchers suggest that SNPs in functional regions of genes involved in sex hormone synthesis, signaling and metabolism may differentially impact breast cancer risk, depending on the person's age or menopausal status. The available assays are designed to test for several SNPs, which are thought to predict an individual's risk of breast cancer relative to the general population in order to identify those at increased risk who might benefit from more intensive surveillance. There are several SNP-based or PRS tests available which include but are not limited to BREVAgen, OncoVue, deCODEBrestCancer, 23andMe, and Navigenics.

EXCLUSIONS:

The Plan does **NOT** provide coverage for the testing for one or more single nucleotide polymorphisms (SNPs) to predict an individual's risk of breast cancer because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

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.

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: Single Nucleotide Polymorphisms (SNPs) to Predict Risk of Non-Familial Breast Cancer

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
81599 Unlisted multianalyte assay with algorithmic analysis

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 Technology Assessment Triage Committee. Single Nucleotide Polymorphisms (SNPs) for Breast Cancer Prediction November 2010.

National Comprehensive Cancer Network[®] (NCCN) a. NCCN GUIDELINES[™] Clinical Guidelines in Oncology[™]. Breast cancer screening and diagnosis guidelines. Version. v1.2022

Gail MH. Value of adding single-nucleotide polymorphism genotypes to a breast cancer risk model. J Natl Cancer Inst. 2009;101(13):959-963.

Intergenetics, Inc [website]. What is OncoVue? Intergenetics, Inc. Oklahoma City, OK; 2009. Available at: <http://www.intergenetics.com/intergenetics/oncovue.html>.

Reeves GK, Travis RC, Green J et al. Incidence of breast cancer and its subtypes in relation to individual and multiple low-penetrance genetic susceptibility loci. JAMA 2010; 304(4):426-34.

Ralph DA, Zhao LP, Aston CE, Manjeshwar S, Pugh TW, DeFreese DC, Gramling BA, Shimasaki CD, Jupe ER. Age-specific association of steroid hormone pathway gene polymorphisms with breast cancer risk. Cancer. 2007 May 15;109(10):1940-8.

Silva SN, Guerreiro D, Gomes M, Azevedo AP, Bezerra De Castro G, Rueff J, Gaspar JF. SNPs/pools: a methodology for the identification of relevant SNPs in breast cancer epidemiology. Oncol Rep. 2012 Feb;27(2):511-6.

Hayes Inc. Single Nucleotide Polymorphism (SNP) Testing for Breast Cancer Risk Assessment. GTE Synopsis April 14, 2014, Archived. Apr. 2015

Hayes Inc. deCODE BreastCancer (deCODE diagnostics). GTE Synopsis January 3, 2009, Archived Dec.2013

National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic v1.2023

Cuzick J, Brentnall AR, Segal C, et al. Impact of a panel of 88 single nucleotide polymorphisms on the risk of breast cancer in high-risk women: results from two randomized tamoxifen prevention trials. J Clin Oncol. Mar 2017;35(7):743-750.

Curtit, E, Pivot, X, Henriques, J, et al. Assessment of the prognostic role of a 94-single nucleotide polymorphisms risk score in early breast cancer in the SIGNAL/PHARE prospective cohort: no correlation with clinico-pathological characteristics and outcomes. Breast Cancer Res. 2017 Aug 22;19(1):98.

Schuetz, J. M., Grundy, A., Lee, et al. Genetic variants in genes related to inflammation, apoptosis and autophagy in breast cancer risk. PLoS One ,2019; 14(1), e0209010

Zeinomar N, Chung WK. Cases in Precision Medicine: The Role of Polygenic Risk Scores in Breast Cancer Risk Assessment. Ann Intern Med. 2021 Mar;174(3):408-412. doi: 10.7326/M20-5874. Epub 2020 Dec 1. PMID: 33253037; PMCID: PMC7965355.

Roberts E, Howell S, Evans DG. Polygenic risk scores and breast cancer risk prediction. Breast. 2023 Feb;67:71-77. doi: 10.1016/j.breast.2023.01.003. Epub 2023 Jan 10. PMID: 36646003; PMCID: PMC9982311

Sherman ME, Winham SJ, Vierkant RA, et al. Polygenic risk scores stratify breast cancer risk among women with benign breast disease. J Natl Cancer Inst. 2024 Oct 16:djae255. PMID: 39412492

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

Devised: 1/17/11

Revised: 1/24 (expand description)

Reviewed: 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 1/18, 1/19, 1/20, 1/21, 1/22, 1/23, 1/25

CMS UM Oversight Committee Approval: 12/23, 5/24, 2/25

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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.