

**Policy: MP328**

**Section: Medical Benefit Policy**

**Subject: Genetic Susceptibility Cancer Panels (Multi-Gene Panel Testing)**

### Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

**I. Policy:** Genetic Susceptibility Cancer Panels (Multi-Gene Panel Testing)

**II. Purpose/Objective:**

To provide a policy of coverage regarding Genetic Susceptibility Cancer Panels (Multi-Gene Panel Testing)

**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

**DESCRIPTION:**

Hereditary cancer syndromes are a group of disorders in which the presence of one or a combination of gene variants have been shown to increase the risk for the development of specific cancers. genetic cancer susceptibility panel testing using next generation sequencing will be considered to be medically necessary when the medical criteria outlined in this policy are met.

**INDICATIONS: REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE**

For members presenting with a personal or family history of cancer suggestive of hereditary breast and ovarian cancer syndrome please refer to **MP097 Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer**

- HBOC related cancers include: breast, ovary, pancreas, and prostate

For members presenting with a personal or family history of cancer suggestive of Lynch syndrome (LS), Familial Adenomatous Polyposis (FAP), MUTYH-associated polyposis (MAP), and rare polyposis syndrome such as Peutz-Jeghers or Juvenile Polyposis please refer to **MP098 Genetic Testing Related to Colorectal Cancer**.

- LS-related cancers include: brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal, small intestine, prostate, or ureter cancers, sebaceous adenomas, and sebaceous carcinomas.
- FAP, MAP, and rare polyposis syndromes are described in the above policy.

Genetic evaluation using a multi-gene cancer panel is considered medically necessary in members who have:

1. A personal or family history that is consistent with Hereditary Breast & Ovarian Cancer Syndrome (HBOC) *or* Lynch syndrome (LS), **AND**
  - a) prior testing was limited (e.g. BRCA1 and BRCA2 sequencing only), or included high-penetrance genes only (e.g. *BRCA1*, *BRCA2*, *MLH1*, *MSH2*, *MSH6*, *PMS2*, *EPCAM*, *PTEN*, *STK11*, *TP53*), and the result was negative or indeterminate; **AND**
  - b) update testing is available with genes that have medical management recommendations per NCCN.

**OR**
2. A personal history of *any* solid tumor type, where more than one gene may be associated with an inherited cancer syndrome **AND** may be suggestive of more than one hereditary cancer syndromes where limited or targeted testing may miss actionable variant(s) (eg. Cowden Syndrome, Lynch syndrome, Hereditary Leukemia and Hematologic Malignancies Syndromes, Li-Fraumeni Syndrome, Von Hippel-Lindau disease, Multiple endocrine neoplasias, etc.) **OR**
3. When **ALL of the following** criteria are met:
  - The suspected hereditary cancer syndrome(s) can be diagnosed by one or more of the genes included in the requested hereditary cancer panel; **and**
  - The results of testing will directly impact the member's clinical management options; **and**
  - The member's personal and family history has been evaluated by a non-lab employed genetic counselor or a non-lab employed adequately trained health care professional, and the pedigree analysis is suggestive of an inherited susceptibility including **at least one of the following**:
    - A personal history of, or at least one first-degree blood relative with a history of, at least two different primary solid tumors at any age, or
    - A personal history of a solid tumor with at least one somatic finding reported at an allele frequency suggestive of potential germline etiology, or
    - A personal history of an HBOC- or LS related cancer, or at least one first- or second-degree blood relative with a history of, an HBOC- or LS related cancer at any age, or
    - A personal history of a malignancy meeting NCCN criteria for evaluation of inherited cancer risk; or
    - At least three people on the same side of the family with the same type of malignancy.
      - The member does not need to be affected, but a first-degree relative must have a combination of first, second, or third-degree blood relatives, on the same side of the family, diagnosed with any solid tumor or a hematologic malignancy of the same origin (e.g. myeloid vs lymphoid).

**Genetic testing is appropriate only when offered in a setting where a licensed or certified genetic counselor\* or adequately trained health care professional is able to provide appropriate pre or post-test genetic counseling, and medical necessity is supported by ALL of the following criteria:**

1. The information is needed to adequately assess risk in the member; **and**
2. The information will be used in the immediate care plan of the member; **and**
3. Pedigree analysis establishes that the insured individual is in a high-risk group for the disease; **or**
4. Clinical presentation of symptomology is evident and diagnosis cannot be established with conventional evaluation testing.

\*A genetic counselor is considered by the Plan to be qualified if the following are met:

- M.S. or Ph.D. degree from a genetic counseling program approved/ certified by the American Board of Genetic Counseling or the American Board of Medical Genetics
- or**
- Board certified or board qualified/eligible in the orderly process of obtaining board certification by the American Board of Genetic Counseling or American Board of Medical Genetics
- and**
- Proof of current competence and demonstrated ability (minimum of two years recent and continual experience within the past three years).

#### **EXCLUSIONS:**

Multi-gene hereditary cancer panels (including, but not limited to MI CancerSeek, etc) are unproven and not medically necessary for general population screening, and all other indications not meeting the criteria outlined in this policy.

#### **Medicare Business Segment:**

Germline testing for inherited cancer syndromes are covered per MolDx L38972

#### **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: Genetic Susceptibility Cancer Panel**

***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.***

- 0101U Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatous polyposis), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only]) [hereditary@, Ambry Genetics@, Ambry Genetics]
- 0102U Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication]) [BreastNext@, Ambry Genetics@, Ambry Genetics]
- 0103U Hereditary ovarian cancer (e.g., hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with mRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], <i>EPCAM</i> [deletion/duplication only]) [OvaNext@, Ambry Genetics@, Ambry Genetics]
- 0129U hereditary breast cancer related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer) genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN and TP53)

- 0130U Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53)
- 0131U Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes)
- 0132U Hereditary ovarian cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes)
- 0133U Hereditary prostate cancer-related disorders, targeted mRNA sequence analysis panel (11 genes)
- 0134U Hereditary pan cancer (e.g., hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes)
- 0135U Hereditary gynecological cancer (e.g., hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes)
- 0160U MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis
- 0161U PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis
- 0162U Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2)
- 0171U Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence MyMRD® NGS Panel RNAinsight™ for GYNPlus®, Ambry Genetics
- 0211U Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association (CARIS MI CancerSeek)
- 81432 Hereditary Breast Cancer-related disorders (e.g., hereditary Breast Cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53
- 81433 Hereditary Breast Cancer-related disorders (e.g., hereditary Breast Cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
- 81435 Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11
- 81436 Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
- 81437 Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL
- 81438 Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL

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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.**

#### REFERENCES:

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

**Devised:** 8/19

**Revised:** 8/20, 1/21 (add PA and genetic counselor requirement); 1/23 (update criteria and Medicare coverage) 2/24 (revise criteria)

**Reviewed:** 1/22

**CMS UM Oversight Committee Approval:** 12/23

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>

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