I. Policy: Genetic Susceptibility Cancer Panels

II. Purpose/Objective:
   To provide a policy of coverage regarding Genetic Testing Hereditary Cancer Panels

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
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: For members presenting with clinical features and/or has a family history consistent with a hereditary cancer syndrome related to BRCA, please refer to MP097 Genetic Testing for BRCA1 or BRCA2 for Breast or Ovarian Cancer

For members presenting with clinical features and/or has a family history consistent with a hereditary cancer syndrome related to Lynch syndrome and Familial Adenomatous Polyposis, please refer to MP098 Genetic Testing Related to Colorectal Cancer

Genetic testing with a multi-gene cancer panel is considered medically necessary in members who have previously tested negative or indeterminate for the high penetrance genes that are most likely to explain the personal or family history of 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; **and**
- The member’s personal and family history is suggestive of an inherited susceptibility that can be diagnosed by testing of one or more genes included in the specific hereditary cancer panel including **at least one of the following:**
  - A personal history of at least two different cancers
  - A personal history of cancer diagnosed at age 40 or younger
  - A personal history of cancer and at least one first, second- or third-degree blood relative with a cancer associated with Lynch Syndrome (i.e., brain, colorectal, endometrial, gastric, ovarian, pancreatic, renal, small intestine, or ureter cancers, sebaceous adenomas, or sebaceous carcinomas)
  - At least one first, second, or third-degree blood relative diagnosed with breast, ovarian, prostate or pancreatic cancer at age 40 or younger
  - At least three first, second, or third-degree blood relative on the same side of the family diagnosed with any cancer

EXCLUSIONS: Multi-gene hereditary cancer panels are unproven and not medically necessary for general population screening, and all other indications not meeting the criteria outlined in this policy.

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 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 adenomatosis 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], EPCAM [deletion/duplication only]) [OvaNext®, Ambry Genetics®, Ambry Genetics]

0104U Hereditary pan cancer (e.g., hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal 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 (32 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only]) [CancerNext®, Ambry Genetics®, Ambry Genetics]

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


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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


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

Devised: 8/19

Revised:

Reviewed: