Medica Coverage Policy

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<th>Policy Name:</th>
<th>Single Nucleotide Polymorphism (SNP) Genetic Testing for Assessment of Cancer Risk</th>
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<td>Effective Date:</td>
<td>10/21/2019</td>
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**Important Information - Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

Single nucleotide polymorphism (SNP) genetic testing for assessment of cancer risk is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Note:** See also related Medica coverage policies; *Laboratory Tests* and *Genetic and Pharmacogenetic Testing*

**Note:** This policy is no longer scheduled for routine review of the scientific literature.

**Description**

OA single nucleotide polymorphism (SNP) is a genetic variation in a DNA sequence that occurs when a single nucleotide (adenine, cytosine, guanine, thiamine) is replaced by another within the sequence of a DNA molecule. They are considered evolutionary point mutations that have persisted over time and recur in a significant proportion of the population. They are the most common type of genetic variation found. Most often, SNPs occur in locations along a DNA strand that do not affect the overall health or development of an individual. However, when occurring within or near a gene, SNPs may affect the gene’s function and therefore play a more direct role in disease. SNPs have been isolated that are purported to help predict an individual’s response to certain drugs, susceptibility to environmental factors such as toxins, and risk of developing particular diseases (e.g., cancer). SNPs can also be used to track the inheritance of disease-related genes within families.

Many SNP cancer risk assessments (i.e., SNP genotyping) have been developed or are currently under development. Some are commercially available, while many others are being marketed by direct-to-consumer (DTC) testing companies.
Two assessments commercially available in the United States are suggested to predict breast cancer risk:

1. **OncoVue® (InterGenetics®, Inc):**
   According to the manufacturer, the OncoVue Breast assay was developed following study of the effects of 117 common SNPs on breast cancer risk in a population of more than 5000 women. The assay examines 22 SNPs in 19 genes. This data, combined with personal history information and menopausal status, is purported to identify women at high risk for developing breast cancer. Use of InterGenetics’ proprietary CombiSNP platform and computer algorithms, a person’s risk is categorized as standard, moderate, or high. The test is intended for women between the ages of 30 and 69 and is available through a participating center in the Breast Cancer Risk Testing Network (BCRTN).

   Examples of additional Intergenetics cancer risk assessments currently under study include:
   1. OncoVue Colon
   2. OncoVue Lung
   3. OncoVue Ovarian
   4. OncoVue Prostate

2. **BREVAGen™ (Phenogen Sciences):**
   BREVAGen combines testing for 7 SNPs which were selected from related literature containing Gail risk estimates, a commonly used risk estimate model for sporadic breast cancer. Gail risk estimated incorporate risk factors such as age, family history of breast cancer in first-degree relatives, personal reproductive history including age at first menarche and first live birth, and personal history of breast biopsies. Phenogen Sciences purports that the risk score calculated from the combined SNPs and Gail risk is more discriminating than the Gail risk score alone. Following testing, a personalized test report is provided which describes the individual’s risk of developing breast cancer within the next five years and over the individual’s lifetime. The BREVAGen website states that the test does not take into account other breast cancer risk factors such as extensive family history of breast and ovarian cancer. BREVAGen is offered through a network of participating doctors accessible through the BREVAGen website.

   Other SNP cancer risk assessments are also available. Genetic testing labs offering SNP genotyping accompanied by a physician order include, but are not limited to, Navigenics (subsidiary of Life Technologies) and City of Hope laboratory. Many genetic testing laboratories are offering SNP genotyping through DTC marketing not requiring a physician order. Examples include, but are not limited to: i. 23andMe, ii. deCODE Genetics, iii. Matrix Genomics.

**FDA Approval**
Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and does not market the test for distribution. Neither OncuVue Breast nor BREVAGen are marketed for general clinical use, and are not subject to FDA premarket approval. OncoVue Breast is available through one of the participating centers in the Breast Cancer Risk Testing Network, while BREVAGen is available from within a network of participating doctors posted on the BREVAGen website.

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.
CPT Code:
81599 - Unlisted multi-analyte assay with algorithmic analysis
88299 – Unlisted cytogenetic study

Original Policy Effective Date:  10/1/2010
Re-Review Date(s):  6/17/2013
7/20/2016
7/17/2019
2/28/2020 – administrative update; format