MEDICAL POLICY

POLICY TITLE	GENETIC TESTING FOR FAMILIAL CUTANEOUS MALIGNANT MELANOMA
POLICY NUMBER	2.246

Effective Date:	9/1/2023

I. POLICY

Genetic testing for the CDKN2A variant is considered **medically necessary** for either of the following:

- For members with 3 or more invasive cutaneous melanomas; or
- For members with invasive cutaneous melanoma who have a first-degree relative diagnosed with pancreatic cancer.

Other than those indications listed above, genetic testing for genes associated with familial cutaneous malignant melanoma or associated with susceptibility to cutaneous malignant melanoma is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

The National Comprehensive Cancer Network (NCCN) is a nonprofit alliance of cancer centers throughout the United States. NCCN develops the Clinical Practice Guidelines in Oncology which are recommendations aimed to help health care professionals diagnose, treat and manage patients with cancer. Guidelines evolve continuously as new treatments and diagnostics emerge and may be used by Capital Blue Cross when determining medical necessity according to this policy.

Policy Guidelines

A first-degree relative is defined as parents, siblings, and children.

Genetics Nomenclature Update

Human Genome Variation Society (HGVS) nomenclature is used to report information on variants found in DNA and serves as an international standard in DNA diagnostics. It is being implemented for genetic testing medical evidence review updates starting in 2017 (see Table PG1). HGVS nomenclature is recommended by HGVS, the Human Variome Project, and the Human Genome Organization (HUGO).

The American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) standards and guidelines for interpretation of sequence variants represent expert opinion from ACMG, AMP, and the College of American Pathologists. These recommendations primarily apply to genetic tests used in clinical laboratories, including genotyping, single genes, panels, exomes, and genomes. Table PG2 shows the recommended

standard terminology—"pathogenic," "likely pathogenic," "uncertain significance," "likely benign," and "benign"—to describe variants identified that cause Mendelian disorders.

Table PG1. Nomenclature to Report on Variants Found in DNA

Previous	Updated	Definition
Mutation	Disease-associated variant	Disease-associated change in the DNA sequence
	Variant	Change in the DNA sequence
	Familial variant	Disease-associated variant identified in a proband for use in subsequent targeted genetic testing in first-degree relatives

Table PG2. ACMG-AMP Standards and Guidelines for Variant Classification

Variant Classification	Definition
Pathogenic	Disease-causing change in the DNA sequence
Likely pathogenic	Likely disease-causing change in the DNA sequence
Variant of uncertain significance	Change in DNA sequence with uncertain effects on disease
Likely benign	Likely benign change in the DNA sequence
Benign	Benign change in the DNA sequence

ACMG: American College of Medical Genetics and Genomics; AMP: Association for Molecular Pathology.

Genetic Counseling

Genetic counseling is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be very difficult and complex. Therefore, genetic counseling will assist individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the individual's family. Genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

Cross-reference:

MP 2.259 Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies
MP 2.360 Gene Expression Profiling for Melanoma

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

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FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Genetics of Cutaneous Malignant Melanoma

A genetic predisposition to cutaneous malignant melanoma is suspected in specific clinical situations: (1) melanoma has been diagnosed in multiple family members; (2) multiple primary melanomas have been identified in a single patient; and (3) early age of onset. A positive family history of melanoma is the most significant risk factor; it is estimated that approximately 10% of melanoma cases report a first- or second-degree relative with melanoma. Although some of the familial risk may be related to shared environmental factors, 3 principal genes involved in cutaneous malignant melanoma susceptibility have been identified. Cyclin-dependent kinase inhibitor 2A (*CDKN2A*), located on chromosome 9p21, encodes proteins that act as tumor suppressors. Variants in this gene can alter the tumor suppressor function. The second gene, cyclin-dependent kinase 4 (*CDK4*), is an oncogene located on chromosome 12q13 and has been identified in about 6 families worldwide. A third gene, not fully characterized, maps to chromosome 1p22.

Some common allele(s) are associated with increased susceptibility to cutaneous malignant melanoma but have low-to-moderate penetrance. One gene of moderate penetrance is the melanocortin 1 receptor gene (*MC1R*). Variants in this gene are relatively common and have low penetrance for cutaneous malignant melanoma. This gene is associated with fair complexion, freckles, and red hair, all risk factors for cutaneous malignant melanoma. Variants in *MC1R* also modify the cutaneous malignant melanoma risk in families with *CDKN2*A variants.

In 2012, Ward et al reviewed the literature on germline melanoma susceptibility and concluded that in addition to the 2 rare, high-penetrance variants (*CDKN2A* and *CDK4*), there are potentially many single nucleotide polymorphisms which have small effects and low penetrance.

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Melaris® (Myriad Genetics) and other *CDKN2A* tests are available under the auspices of the CLIA. Laboratories that offer laboratory-developed tests must be licensed by the CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

IV. RATIONALE

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Summary of Evidence

For individuals who have CMM and a family history of this disease who receive genetic testing for genes associated with familial CMM, the evidence includes genetic association studies correlating variants in certain genes and the risk of developing cutaneous melanoma. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Limitations with clinical validity include difficulties with variant interpretations, variable penetrance of a given variant, and residual risk with a benign variant. Currently, management of melanoma patients does not change based on genetic variants identified in genes associated with familial CMM, therefore, clinical utility is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Input from NCCN Clinical Practice Guidelines in Oncology gives recommendations for genetic testing for CDKN2A in persons diagnosed with invasive cutaneous melanoma. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are asymptomatic and in a family at high-risk of developing CMM who receive genetic testing for genes associated with familial CMM, the evidence includes genetic association studies correlating variants in certain genes and the risk of developing CMM. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Limitations with clinical validity include difficulties with variant interpretations, variable penetrance of a given variant, and residual risk with a benign variant. Currently, management of patients considered high risk for CMM focuses on the reduction of sun exposure, use of sunscreens, vigilant cutaneous surveillance of pigmented lesions, and prompt biopsy of suspicious lesions. It is unclear how genetic testing for variants associated with increased risk of CMM would alter these management recommendations; therefore, clinical utility is lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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ALLELE(S) refers to one of two or more different genes containing specific inheritable characteristics that occupy corresponding positions (loci) on paired chromosomes.

GENETIC MARKERS is a gene which has an easily identifiable phenotype so that one can tell apart cells or individuals which have the gene and those which do not have it. Such a gene can also be used as a probe to mark cell nuclei or chromosomes so that they can easily be isolated or identified from other nuclei or chromosomes later.

PREDISPOSITION is a latent susceptibility to disease which may be activated under certain conditions, as by stress.

PHENOTYPES are the total characteristics displayed by an organism under a particular set of environmental factors, regardless of the actual genotype of the organism. Results from interaction between the genotype and the environment

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational, therefore not covered, when used for testing CDK4 or any other variant other than CDKN2A:

Procedure Codes							
81479							

Covered when medically necessary for CDKN2A testing:

Procedure Codes							
81404							

ICD-10-CM Diagnosis Code	Description
C43 code range	Malignant melanoma of skin

IX. REFERENCES

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X. POLICY HISTORY

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MP-2.246	**CAC 6/26/12** - New policy. Adopting BCBSA, CBC previously silent on this testing. Now considered investigational. FEP variation references FEP Medical Policy Manual MP-2.04.44 Genetic Testing for Cutaneous Malignant Melanoma
	7/30/13 Admin coding review complete
	CAC 9/24/13 Consensus review. References updated, but no changes to the policy statements. Rationale added.
	CAC 7/22/14 Consensus review. References and rationale updated, but no changes to the policy statement.
	CAC 7/21/15 Consensus review. No change to the policy statement. Rationale and reference update. Medicare variation added. No coding changes.
	11/2/15 Administrative change. LCD number changed from L34796 to L35396 due to Novitas update to ICD-10.

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	CAC 7/26/16 Consensus review. No changes to the policy statements Rationale and references updated. Appendix added. Coding reviewed.
	Admin update 1/1/17: Product variation section reformatted.
	CAC 9/26/17 Consensus. No change to policy statements. Background, rationale, and references updated**.** Coding reviewed**.**
	5/25/18 Consensus review. No change to the policy statement. Rationale revised. Background and references updated. Appendix removed.
	3/28/19 Consensus review. Policy statement unchanged. References updated.
	3/13/20 Consensus review. Policy statement unchanged. FEP variation unavailable, policy updated to reflect. References updated.
	6/8/21 Minor review. Added that CDKN2A testing is MN for 3 or more invasive cutaneous melanomas or for invasive cutaneous melanoma with first-degree relative diagnosed with pancreatic cancer. Added NCCN language and cross-references. Updated FEP, background, rationale, and references. Updated coding so that 81404 is now MN.
	4/6/2022 Consensus review. Policy statement unchanged. FEP references updated. No coding changes.
	6/2/2023 Consensus review. Updated background and references. Updated coding table. No changes to procedure codes.

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