MEDICAL POLICY

POLICY TITLE	**GERMLINE GENETIC TESTING FOR PANCREATIC CANCER SUSCEPTIBILITY GENES (ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, AND TP53)**
POLICY NUMBER	**MP 2.392**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**RETIRED 7/1/2026**

I. POLICY

Genetic testing for *BRCA1, BRCA2, and PALB2* variants to guide selection for treatment with platinum-based chemotherapy in previously untreated individuals with locally advanced or metastatic pancreatic cancer may be considered **medically necessary**.

Genetic testing for *BRCA1* and *BRCA2* variants to guide selection for treatment with olaparib (Lynparza) in individuals with pancreatic cancer may be considered **medically necessary.**

Genetic testing for *ATM, CDK2NA, EPCAM, MMR* genes (*MLH1, MSH2, MSH6, PMS2*), *STK11*, and *TP53* in individuals with pancreatic cancer is considered **investigational** unless the individual meets criteria for testing as specified in another policy (see policy guidelines). The evidence is insufficient to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Genetic testing for *ATM, BRCA1, BRCA2, CDK2NA, EPCAM, MMR* genes (*MLH1, MSH2, MSH6, PMS2*), *PALB2, STK11*, and *TP53* in asymptomatic individuals at high risk for hereditary pancreatic cancer is considered **investigational** unless the individual meets criteria for testing as specified in another policy (see policy guidelines). The evidence is insufficient to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Related Policies on Hereditary Cancer Syndromes

- Genetic testing for *BRCA1, BRCA2, and PALB2* variants
    - **MP 2.211 Germline Genetic Testing for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers *(BRCA1, BRCA2, PALB2)***

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POLICY NUMBER	MP 2.392

- Genetic testing for *ATM, CHEK2, and BARD1* gene variants
    - **MP 2.279 Germline Genetic Testing for Gene Variants Associated with Breast Cancer in Individuals at High Breast Cancer Risk (*CHEK2, ATM, and BARD1*)**
- Genetic testing for *EPCAM*, *MMR* (*MLH1*, *MSH2*, *MSH6, PMS2),* and *STK11* gene variants
    - **MP 5.013 Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes**
- Genetic testing for *CDKN2A* gene variants
    - **MP 2.246 Genetic Testing for Familial Cutaneous Malignant Melanoma**
- Genetic testing for *TP53* gene variants
    - **MP 2.274 Genetic Testing for Li-Fraumeni Syndrome**
- Genetic cancer susceptibility panel testing
    - **MP 2.325 Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing**

Testing At-Risk Relatives

Individuals are considered at high risk for hereditary pancreatic cancer if they have:

- 2 close relatives with pancreatic adenocarcinoma where 1 is a first-degree relative, OR
- have 3 or more close relatives with pancreatic cancer, OR
- have a history of hereditary pancreatitis.

For familial assessment, 1st-, 2nd-, and 3rd-degree relatives are blood relatives on the same side of the family (maternal or paternal).

- 1st-degree relatives are parents, siblings, and children.
- 2nd-degree relatives are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half-siblings.
- 3rd-degree relatives are great-grandparents, great-aunts, great-uncles, great-grandchildren, and first cousins.

At-risk relatives primarily refer to first-degree relatives. However, some judgment must be permitted, e.g., in the case of a small family pedigree, when extended family members may need to be included in the testing strategy.

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Targeted Variant Testing

It is recommended that, when possible, initial genetic testing for variants associated with hereditary pancreatic cancer be performed in an affected family member so that testing in unaffected family members can focus on the pathogenic variant found in the affected family member. In unaffected family members of potential hereditary pancreatic cancer families, most test results will be negative and uninformative. Therefore, it is strongly recommended that an affected family member be tested first whenever possible to adequately interpret the test. Should a variant be found in an affected family member(s), DNA from an unaffected family member can be tested specifically for the same variant of the affected family member without having to sequence the entire gene.

Genetic Counseling

Experts recommend formal genetic counseling for individuals who are at risk for inherited disorders and who wish to undergo genetic testing. Interpreting the results of genetic tests and understanding risk factors can be difficult for some individuals; genetic counseling helps individuals understand the impact of genetic testing, including the possible effects the test results could have on the individual or their family members. It should be noted that genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing; further, genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods.

Cross-References:

MP 2.211 Germline Genetic Testing for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers (BRCA1, BRCA2, PALB2)
MP 2.246 Genetic Testing for Familial Cutaneous Malignant Melanoma
MP 2.274 Genetic Testing for Li-Fraumeni Syndrome
MP 2.279 Germline Genetic Testing for Gene Variants Associated with Breast Cancer in Individuals at High Breast Cancer Risk (CHEK2, ATM, BARD1)
MP 2.325 Genetic Cancer Susceptibility Panels Using Next-Generation Sequencing
MP 2.377 Molecular Testing for Germline Variants Associated with Ovarian Cancer (BRIP1, RAD51C, RAD51D, NBN)
MP 2.393 Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Breast Cancer (BRCA1, BRCA2, PIK3CA, Ki-67, RET, BRAF, ESR1, NTRK)
MP 2.394 Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Prostate Cancer (BRCA1/2, Homologous Recombination Repair Gene Alterations, NTRK Gene Fusion)

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POLICY NUMBER	MP 2.392

MP 2.395 Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency, NTRK)
MP 5.013 Genetic Testing for Lynch Syndrome and Other Inherited Colon Cancer Syndromes

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.

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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Pancreatic Cancer Epidemiology

Pancreatic cancer is the fourth leading cause of cancer death in the U.S., accounting for 8.3% of all cancer deaths in 2023. The disease has a poor prognosis, with only 12.5% of patients surviving to 5 years. Five-year survival for localized pancreatic cancer is 41.6% but most symptomatic patients have advanced, incurable disease at diagnosis.

Genetics and Pancreatic Cancer

Approximately 10% to 15% of patients with pancreatic cancer are thought to have a hereditary susceptibility to the disease. Multiple genetic syndromes, including hereditary breast and ovarian cancer syndrome, are associated with an increased risk for pancreatic cancer. Five percent to 9% of pancreatic ductal adenocarcinomas (PDACs) develop in patients with a germline *BRCA* or *PALB2* variant, with higher rates observed in those with a family or personal history of pancreatic cancer or other *BRCA*-related malignancies. The incidence of germline *PALB2* variants in persons with PDAC is estimated to be between 0.6% and 2.1%.

Having a first-degree relative with pancreatic cancer increases an individual's risk of developing pancreatic cancer, and the degree of risk increases depending on the number of affected relatives (Table 1). Individuals are considered at high-risk for hereditary pancreatic cancer if they have 2 relatives with pancreatic cancer where 1 is a first-degree relative, have 3 or more relatives with pancreatic cancer, or have a history of hereditary pancreatitis. In 80% of pancreatic cancer patients with a family history of pancreatic cancer, the genetic basis of the inherited predisposition is unknown.

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Table 1. Family History and Pancreatic Cancer Risk

Number of FDR with Pancreatic Cancer	Increased Risk
1 affected FDR	4.6-fold
2 affected FDR	6.4-fold
3 affected FDR	32-fold

Sources: American Society of Clinical Oncology; American College of Gastroenterology

FDR: first-degree relative.

Germline genetic testing for pancreatic cancer susceptibility genes has several proposed purposes. In patients with pancreatic cancer, the purpose of genetic testing would be to guide treatment decisions (e.g., selection of platinum-based chemotherapy for first-line treatment, targeted treatment with a poly *ADP* ribose polymerase [PARP] inhibitor). In asymptomatic patients at high risk of pancreatic cancer (e.g., due to family history or other clinical factors), the purpose of genetic testing would be to inform decisions about surveillance for early detection of pancreatic cancer. Because the incidence of pancreatic cancer in the general population is low, with a lifetime risk of approximately 1.6%, screening is not recommended for patients who are not at high-risk, but patients with a family history of pancreatic cancer or a syndrome associated with increased risk of pancreatic cancer are potential targets for surveillance.

Regulatory Status

Testing for variants associated with pancreatic cancer is typically done by direct sequence analysis or next-generation sequencing. A number of laboratories offer to test for the relevant genes, either individually or as panels.

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). 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 (FDA) has chosen not to require any regulatory review of this test.

In December 2019, the FDA approved olaparib (Lynparza, AstraZeneca Pharmaceuticals LP) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma, as detected by an FDA approved test, whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Also in 2019, BRACAnalysis CDx received expanded FDA approval for use as a companion diagnostic for Lynparza (olaparib) in pancreatic cancer patients.

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IV. RATIONALE

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For individuals who have pancreatic cancer who receive testing for a *BRCA1, BRCA2, or PALB2* variant to guide selection for first-line treatment, the evidence includes observational studies. Multiple observational studies have demonstrated that testing patients with pancreatic cancer can identify individuals with *BRCA1, BRCA2, and PALB2* variants, including among those who do not have a family history of pancreatic cancer. Observational studies have reported a survival advantage when patients with a *BRCA or PALB2* variant were treated with platinum-based chemotherapy regimens compared to non-platinum-based regimens. Although these studies are limited by their small sample sizes and retrospective designs, the consistency and magnitude of benefit across studies suggests that genetic testing for these variants to aid in treatments decisions is a reasonable approach. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pancreatic cancer who receive testing for a *BRCA1 or BRCA2* variant to guide selection for targeted treatment, the evidence includes observational studies and 1 randomized controlled trial. Multiple observational studies have demonstrated that testing patients with pancreatic cancer can identify individuals with *BRCA1 or BRCA2* variants, including among those who do not have a family history of pancreatic cancer. A placebo-controlled trial of olaparib as maintenance therapy in patients with germline *BRCA1 or BRCA2* variants and metastatic pancreatic cancer found longer progression-free survival with olaparib (7.4 months vs. 3.8 months; hazard ratio, 0.53; 95% confidence interval 0.35 to 0.82; p=.04). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with pancreatic cancer who receive genetic testing for *ATM, CDK2NA, EPCAM, MMR genes (MLH1, MSH2, MSH6, PMS2), STK11, and TP53* to guide treatment, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Multiple observational studies have demonstrated that testing patients with pancreatic cancer can identify individuals with disease-associated variants, including among those who do not have a family history of the disease. However, there is no direct evidence comparing health outcomes in patients tested or not tested for a variant. Additionally, there are no targeted treatments for pancreatic cancer based on these genes, and management changes that would result from testing these genes are unclear. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are asymptomatic and at high risk for hereditary pancreatic cancer who receive testing for genes associated with hereditary pancreatic cancer, the evidence includes observational studies. There is no direct evidence comparing health outcomes in patients tested or not tested for a variant. There is indirect evidence from 2 comparative observational studies of high-risk individuals under surveillance that the risk of progression to pancreatic cancer is higher among individuals with a known pathogenic variant than in individuals identified as at-risk based on family history alone. There is also evidence from prospective observational studies

that surveillance of high-risk individuals can identify pancreatic cancer and precursor lesions. In 1 analysis of 76 high-risk individuals under surveillance, survival was better in those who had surgery due to detection of either low- or high-risk neoplastic precursor lesions (n=71) compared to those who had advanced to unresectable disease (n=5). Although observational studies have demonstrated that surveillance can identify pancreatic cancer and precursor lesions in asymptomatic individuals, it is not possible to conclude from this body of evidence that surveillance improves survival. Longer survival time observed in individuals undergoing surveillance could be due to earlier identification of the disease (downstaging) and not the effects of early intervention and treatment. Additionally, evidence is too limited to determine if selecting patients for surveillance based on genetic testing leads to better outcomes than using criteria such as family history alone. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS/BACKGROUND

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N/A

VI. DISCLAIMER

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Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

VII. 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. The codes need to be in numerical order.

Investigational; therefore, not covered:

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Procedure Codes							
0129U	81288	81292	81293	81294	81295	81296	81297
81298	81299	81300	81317	81318	81319	81403	81404
81405	81408	81432	81435	81479*			

*Code can be used for TP53 or any other variant without its own code

Covered when medically necessary:

Procedure Codes							
81162	81163	81164	81165	81166	81167	81212	81215
81216	81217	81307	81308	81479**			

**Code can be used for BRCA1 or PALB2 common duplication/deletion analysis

ICD-10-CM Diagnosis Code	Description
C25.0-C25.9	Malignant neoplasm of the pancreas code range
D01.7	Carcinoma in situ of other specified digestive organs (pancreas)
Z12.89	Encounter for screening for malignant neoplasm of other sites
Z15.06	Genetic susceptibility to other malignant neoplasm of digestive system
Z15.068	Genetic susceptibility to malignant neoplasm of digestive system
Z15.09	Genetic susceptibility to other malignant neoplasm
Z80.0	Family history of malignant neoplasm of digestive organs
Z85.07	Personal history of malignant neoplasm of pancreas

VIII. REFERENCES

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IX. POLICY HISTORY

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MP 2.392	**01/14/2025 Major Review.** New Policy Adoption
	06/24/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	09/03/2025 Administrative Update. New ICD10 codes added as part of new code process for 10/01/2025

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	03/03/2026 Retirement Review. Services to be managed by vendor Evicore

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