MEDICAL POLICY

POLICY TITLE	MULTICANCER EARLY DETECTION TESTING
POLICY NUMBER	MP 2.387

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:	**3/1/2024**

I. POLICY

The use of multicancer early detection (MCED) tests (e.g., Galleri) is considered **investigational** for cancer screening.

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with the above procedures.

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 BlueCross when determining medical necessity according to this policy.

POLICY GUIDELINES

The Galleri test is the only commercially available MCED test in the US at this time.

II. PRODUCT VARIATIONS TOP

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 TOP

Cancer is the second leading cause of death in the US following heart disease. Cancer is the cause of death in 1 of every 5 deaths in the US. In the US, more than 1.7 million new cases of cancer were reported in 2019, and almost 600,000 people died of cancer.[1]

Many cancers appear to have a better prognosis if diagnosed early in their natural history. This has led to efforts to detect preclinical cancers in asymptomatic persons through screening. However, screening tests have associated benefits and harms that must be considered when evaluating whether a test should be used in a population.

Early detection of cancer has 2 components: early diagnosis and screening. Early diagnosis is the early identification of cancer in *symptomatic* individuals with the aim of reducing the proportion of individuals diagnosed at a late stage. Screening is the identification of preclinical cancer or precursor lesions in apparently healthy, *asymptomatic* populations by tests that can be applied rapidly and widely in the target population. This review focuses on tests for screening indications.

Cancer screening tests such as 'liquid biopsies' that are minimally invasive and can simultaneously detect multiple types of cancer have been called multicancer early detection (MCED) tests.

Regulatory Status

No MCED tests have been approved or cleared by the U.S. Food and Drug Administration (FDA). GRAIL, Inc. announced in 2019 that its MCED test (Galleri®) had been granted breakthrough device designation by the FDA.

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. Galleri is available under the auspices of the Clinical Laboratory Improvement Amendments.

Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the FDA has chosen not to require any regulatory review of this test.

IV. RATIONALE

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For individuals who are being screened for cancer who receive multicancer early detection (MCED) testing with Galleri, the published evidence includes case-control studies. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, quality of life, treatment-related mortality, and treatment-related morbidity. Specifics of how the test should be used in practice, including the appropriate at-risk target populations, frequency of testing, and follow-up of positive and negative test results, have not been fully described. Performance characteristics for both the prediction of overall likelihood of cancer and the tissue of origin are needed. Published clinical validity studies have used populations consisting of patients with an established diagnosis of cancer and control populations of healthy individuals and as such, do not reflect the intended-use population. Therefore, estimates of sensitivity, specificity, false-positives, false-negatives and predictive values are not available for the intended-use population. No clinical utility studies have been published;

estimates of changes in cancer-specific mortality, quality of life, functional outcomes and rates of overdiagnosis and overtreatment are unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

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 TOP

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 TOP

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:

Procedure Codes							
81479							

IX. REFERENCES

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15. *Klein EA, Richards D, Cohn A, et al. Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. Ann Oncol. Sep 2021; 32(9): 1167-1177. PMID 34176681*
16. *Tang WHW, Yimer H, Tummala M, et al. Performance of a targeted methylation-based multi-cancer early detection test by race and ethnicity. Prev Med. Feb 2023; 167: 107384. PMID 36495927*
17. *Shao SH, Allen B, Clement J, et al. Multi-cancer early detection test sensitivity for cancers with and without current population-level screening options. Tumori. Oct 31 2022: 3008916221133136. PMID 36316952*
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20. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.04.158, Multicancer Early Detection Testing. July 2023.*

X. POLICY HISTORY

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MP 2.387	**6/9/2023 New Policy adoption.**
	1/19/2024 Administrative update. Clinical benefit added.

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