Medical Coverage Policy | Multicancer Early Detection Testing

EFFECTIVE DATE: 01|01|2024
POLICY LAST REVIEWED: 06|17|2026

OVERVIEW
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 individuals through screening. 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
No applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of multicancer early detection (MCED) tests (e.g., Galleri) is not covered for cancer screening as the evidence is insufficient to determine that the technology results in an improvement in net health outcome.

Commercial Products
The use of multicancer early detection (MCED) tests (e.g., Galleri) is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in net health outcome.

Some genetic testing services are not covered and a contract exclusion for any self-funded group that has excluded the expanded coverage of biomarker testing related to the state mandate, R.I.G.L**. §27-19-81** described in the Biomarker Testing Mandate policy. For these groups, a list of which genetic testing services are covered with prior authorization, are not medically necessary or are not covered because they are a contract exclusion can be found in the Coding section of the Genetic Testing Services or Proprietary Laboratory Analyses policies. Please refer to the appropriate Benefit Booklet to determine whether the member's plan has customized benefit coverage. Please refer to the list of Related Policies for more information.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
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. 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. MCED tests are distinct from traditional cancer screening tests due to two main factors. Firstly, they employ a single blood test rather than x-rays, imaging tests like mammography, or procedures like colonoscopy. Secondly, they simultaneously screen for multiple types of cancer from various organs, including those not checked by existing methods. MCED tests predict the presence of cancer, rather than diagnose it. Depending on the biological signals measured, they may screen for multiple cancer types. Current development focuses on measuring signals in blood plasma, such as changes in DNA/RNA sequences, DNA methylation patterns, DNA fragmentation patterns, protein biomarker levels, and antibodies against cancer cell components. Researchers are continually developing new technological approaches to expand the range of measurable biological signals, such as those identified by immune cells.

No MCED tests have been approved or cleared by the U.S. Food and Drug Administration (FDA). Several tests, including Galleri® (GRAIL), CanScan™ (Genesseeq), OverC™ Multi-Cancer Detection Blood Test (Burning Rock) have 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.

For individuals who are being screened for cancer who receive multicancer early detection (MCED) testing, the relevant published evidence includes a systematic review, and one US-based prospective study. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, quality of life, treatment-related mortality, and treatment-related morbidity. A systematic review of 36 studies on MCED tests highlighted variability in diagnostic accuracy. Evidence was limited, with no completed RCTs. While the tests exhibited high specificity, sensitivity varied depending on study design, population, reference tests, and follow-up duration. Insufficient follow-up for negative results led to high risk of bias across studies. Currently, the Galleri test is the only commercially available MCED test in the United States. One prospective study of the Galleri test reported a positive predictive value of 38% (95% CI, 29 to 48) and specificity and negative predictive value of approximately 99%. The specifics regarding the practical application of the test, including the appropriate at-risk target populations, frequency of testing, and follow-up for positive and negative results, have not been fully described. There is a need for performance characteristics for both the prediction of overall cancer likelihood and the tissue of origin. No clinical utility studies have been published to date, and estimates of changes in cancer-specific mortality, quality of life, functional outcomes, and rates of overdiagnosis and overtreatment remain unknown. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

CPT codes have not been assigned to the test(s) addressed in this policy. Therefore, an Unlisted code(s) should be used.

RELATED POLICIES

Biomarker Testing Mandate
Unlisted Procedures

PUBLISHED

Provider Update, August 2026
Provider Update, November 2025

Provider Update, September 2024
Provider Update, November 2023

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