MASSACHUSETTS

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Medical Policy

Multicancer Early Detection Testing

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Policy Number: 124

BCBSA Reference Number: 2.04.158 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

Analysis of Human DNA in Stool Samples as a Technique for Colorectal Cancer Screening, #557

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

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

Policy guidelines

The review will focus on MCED tests that are available in the US. The Galleri test is the only commercially available MCED test in the US at this time. This review will not include tests that screen for only 1 cancer (e.g., colon).

While advocates of the test might claim the simplicity of a blood test will improve compliance over existing cancer screening tests and offer screening for cancers that currently do not have recognized screening tests available, no evidence exists to support these claims or to estimate the potential harms of false positives.

Plans may need to alter local coverage medical policy to conform to state law regarding coverage of biomarker testing.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There are not any specific codes for this service.

Description

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.[2] 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.

Summary

Description

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.

Summary of Evidence

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.

Policy History

Date	Action
11/2023	New medical policy describing investigational indications. Effective 11/1/2023.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

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