

Policy: MP365

Section: Medical Policy

Subject: Multi-Cancer Early Detection Testing

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Multi-Cancer Early Detection Testing

II. Purpose/Objective: To provide a policy of coverage regarding Multi-Cancer Early Detection Testing

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Multi-Cancer Early Detection (MCED) tests are intended for use as cancer screening test in symptom-free individuals. MCED tests attempt to look for biological signals, or biomarkers, in blood that are released by cancer cells or induced by their presence to determine whether there is a strong likelihood that a person has cancer and identify where in the body that tumor is located. To date, these tests have evolving but limited data to show that they can detect multiple types of cancer. However, their sensitivity to find cancer when it is present varies by test and for each cancer type.

EXCLUSIONS:

The Plan does **NOT** provide coverage for Multi-Cancer Early Detection (MCED) Testing, including, but not limited to GRAIL Galleri, OneTest™, Cancerguard™, because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

81479 Unlisted molecular pathology procedure

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Cohen JD, Li L, Wang Y et al. Detection and localization of surgically resectable cancers with a multi-analyte blood test. *Science* 2020;359(6378), 926–930.

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.* 2021;32(9), 1167–117

Liu MC, Oxnard GR, Klein EA, Swanton C, Seiden MV. Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA. *Ann Oncol.* 2020;31(6), 745–759

Beer TM, McDonnell CH, Nadauld L et al. Interim results of PATHFINDER, a clinical use study using a methylation-based multi-cancer early detection test. *J. Clin. Oncol.* 2021;39(Suppl. 15), S3010

Chen X, Dong Z, Hubbell E et al. Prognostic significance of blood-based multi-cancer detection in plasma cell-free DNA. *Clin. Cancer Res.* 2021;27(15), 4221–4229

Raouf S, Lee RJ, Jajoo K, Mancias JD, Rebbeck TR, Skates SJ. Multicancer early detection technologies: a review informed by past cancer screening studies. *Cancer Epidemiol. Biomarkers Prev.* 2022;31(6), 1139–1145

Owens L, Gulati R, Etzioni R. Stage shift as an endpoint in cancer screening trials: implications for evaluating multi-cancer early detection tests. *Cancer Epidemiol. Biomarkers Prev.* 2022;31(7), 1298–1304

Multicancer Early Detection Consortium Initiative. Establishing the foundation for a multicancer early detection consortium 2021. www.tapestrynetworks.com/sites/default/files/publication_pdf/MCED%20-%20Summary%20of%20Themes%20Final_0_0.pdf Google Scholar

Braunstein GD, Ofman JJ. Criteria for Evaluating Multi-cancer Early Detection Tests. *touchREVIEWS in Oncology & Haematology*. 2021;17(1):3-6

Loomans-Kropp HA, Umar A, et al. Multi-Cancer Early Detection Tests: Current Progress and Future Perspectives. *Cancer Epidemiol Biomarkers Prev* 2022;31(3):512–514.

Etzioni R, Gukati R, Weiss NS. Multicancer Early Detection: Learning From the Past to Meet the Future. *JNCI: Journal of the National Cancer Institute*, 2022;114(3):349–352.

Lennon AM, Buchanan AH, Kinde I, et al. Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention. *Science*.2020;369(6499).

Tafazzoli, A et al. EE5 Assessment of Value Based Price (VBP) for a Multi-Cancer Early Detection (MCED) Test in a Medicare Population. *Value in Health*, 2023; 25(7): S335-S336. <https://doi.org/10.1016/j.jval.2022.04.257>

Schrag D, Beer, TM, McDonnell CH, et al. Blood-based tests for multicancer early detection (PATHFINDER): a prospective cohort study. *The Lancet*, 2023; 402(10409): 1251-1260.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/22

Revised: 11/23 (added test name exclusions)

Reviewed:

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.