Medica Central Coverage Policy

Policy Name:	**Genetic Testing – Oncology Testing - Cancer Screening and Surveillance MP9606**
Effective Date:	**01/01/2026**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

OVERVIEW

This policy addresses the use of genetic and biomarker tests that aim to screen for specific cancers in individuals who are at risk to develop them. These genetic and biomarker screening tests can be designed for asymptomatic individuals that are at an average risk level for cancer, or for individuals that are known to be at a higher risk of developing a specific cancer.

For additional information see the Rationale and References section.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage. Please see the Concert Platform for additional registered tests.

POLICY REFERENCE TABLE

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Colorectal Cancer Screening Tests			
FIT-DNA Testing (Stool DNA Testing)	ColoGuard - 81528 (Exact Sciences)	81528, 0464U, Z12.10-Z12.13	Rationale/ References

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
	ColoGuardPlus- 0464U (Exact Sciences)		
Urinary Biomarker Tests for Precancerous Colon Polyps	PolypDx - 0002U (Metabolomic Technologies)	0002U, Z12.10-Z12.13	Rationale/ References
Blood-based Biomarker Colorectal Cancer Screening Tests	BeScreened-CRC - 0163U (Beacon Biomedical)	81327, 81479, 81599, 0091U, 0163U, 0368U, 0453U, 0537U, 0562U, G0327, Z12.10-Z12.13	Rationale/ References
	FirstSightCRC - 0091U (CellMax Life)		
	ColonSentry (StageZero Life Sciences)		
	Epi proColon (Epigenomics)		
	ColoVantage (Methylated Septin 9) (Quest Diagnostics)		
	ColoScape Colorectal Cancer Detection - 0368U (DiaCarta Clinical Lab)		
	ColonAiQ - 0453U (Breakthrough Genomics)		
	Shield - 0537U (Guardant Health)		
	PGDx elio plasma focus - 0562U (Personal Genome Diagnostics)		
Lung Cancer Screening Tests			
Blood-based Biomarker Lung Cancer Screening Tests	FirstLook (Delfi Diagnostics)	81479, Z12.2	Rationale/ References
Multi-Cancer Early Detection Screening Tests			

COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	SUPPORT
Multi-Cancer Early Detection Screening Tests	Galleri (Grail)	81479, 0566U, C00-C96	Rationale/ References
	EPISEEK MPE (Malignant Pleural Effusion Detection Test) - 0566U (Precision Epigenomics, Inc)		

RELATED POLICIES

This policy document provides coverage criteria for cancer screening and surveillance. Please refer to:

- ***Oncology Testing: Hematologic Malignancy Molecular Diagnostics*** for coverage criteria related to molecular profiling of a known or suspected blood cancer (e.g., broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic / fusion testing).
- ***Oncology Testing: Solid Tumor Molecular Diagnostics*** for coverage criteria related to molecular profiling of a known or suspected cancer (e.g., broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic / fusion testing).
- ***Oncology Testing: Hereditary Cancer*** for coverage criteria related to genetic testing for hereditary cancer predisposition syndromes.
- ***Oncology Testing: Algorithmic Assays*** for coverage criteria related to gene expression profiling and tumor biomarker tests with algorithmic analyses.
- ***General Approach to Laboratory Testing*** for coverage criteria related to tumor and hematologic malignancy testing that is not specifically discussed in this or another non-general policy.

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COVERAGE CRITERIA

COLORECTAL CANCER SCREENING TESTS

FIT-DNA Testing (Stool DNA Testing)

I. The use of FIT-DNA Testing (stool DNA testing) to screen for colorectal cancer may be considered **medically necessary** when:

   A. The member is 45 years of age or older, **AND**

   B. The member is an individual who is at average risk for colorectal cancer, because the member does not have any of the following:

1. A personal history of colorectal cancer or adenoma or sessile serrated polyp, **OR**
2. A family history of colorectal cancer in close relatives, **OR**
3. A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease), **OR**
4. A personal history of cystic fibrosis, **OR**
5. A confirmed or suspected hereditary colorectal cancer syndrome, such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC), **OR**
6. A personal history of receiving radiation to the abdomen (belly) or pelvic area to treat a prior cancer, **OR**
7. Symptoms suspicious for an undiagnosed colorectal cancer (e.g., rectal bleeding, iron deficiency anemia, abdominal pain, weight loss).

II. The use of FIT-DNA Testing (stool DNA testing) to screen for colorectal cancer is considered **investigational** for all other indications.

NOTE: Fecal immunochemical testing (FIT) alone is not in the scope of this policy (see definitions)

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Urinary Biomarker Tests for Precancerous Colon Polyps

I. The use of urinary biomarker tests for precancerous colon polyps is considered **investigational** for all indications.

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Blood-based Biomarker Colorectal Cancer Screening Tests

I. The use of blood-based biomarkers to screen for colorectal cancer is considered **investigational** for all indications.

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LUNG CANCER SCREENING TESTS

Blood-based Biomarker Lung Cancer Screening Tests

I. The use of blood-based biomarker tests for lung cancer screening is considered **investigational** for all indications.

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MULTI-CANCER EARLY DETECTION SCREENING TESTS

Multi-Cancer Early Detection Screening Tests

I. Multi-cancer early detection screening tests are considered **investigational** for all indications.

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PRIOR AUTHORIZATION

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

RATIONALE AND REFERENCES

FIT-DNA Testing (Stool DNA Testing)

National Comprehensive Cancer Network (NCCN): Colorectal Cancer Screening (2.2025)

This guideline recommends the Fecal immunochemical test (FIT) for colorectal cancer (CRC) screening in average-risk individuals aged 45-75 with no personal history of pre-cancerous polyps, irritable bowel disease (IBD), high-risk germline condition, cystic fibrosis, childhood cancer, and no family history of advanced precancerous polyps in a first-degree relative or close relatives with CRC (CSCR-1). The individual must also have a life expectancy greater than or equal to 10 years (p. CSCR-1A).

NCCN states that symptoms associated with CRC may include rectal bleeding, iron deficiency anemia, abdominal pain or weight loss, and that a rectal exam and colonoscopy should be considered for all patients with these symptoms (regardless of age). Colonoscopy is the preferred screening method for individuals at increased risk. The choice of screening modality should be based on patient preference and availability after discussion (p. CSCR-1 and CSCR-2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening 2.2025
https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf

Food and Drug Administration (FDA)

Cologuard (Exact Sciences):

On August 12, 2014, Cologuard (Exact Sciences) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process as an automated fecal DNA testing product (P130017). Cologuard is intended for the qualitative detection of colorectal neoplasia associated with DNA markers and occult hemoglobin in human stool. A positive result may indicate

the presence of CRC or advanced adenoma and should be followed by diagnostic colonoscopy (p. 1).

On September 20, 2019, the FDA approved the expansion of the Cologuard label to include adults ages 45 years or older. Cologuard was previously indicated for those aged 50 years or older. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

U.S Food and Drug Administration.Summary of Safety and Effectiveness Data for Cologuard (PMA No. P130017). FDA website. Approved August 11, 2014. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p130017

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Urinary Biomarker Tests for Precancerous Colon Polyps

National Comprehensive Cancer Network (NCCN): Colorectal Cancer Screening (2.2025)

This guideline does not include a recommendation for colorectal cancer (CRC) screening via urine-based screening methods for individuals of average risk for CRC (p. CSCR-2).

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening 2.2025 https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf

Concert Note

There is insufficient evidence of clinical utility to support the routine use of these tests in clinical care. A search for guidelines, position statements, systematic reviews, and consensus statements regarding the use of urinary biomarker tests for precancerous colon polyps was performed in April 2025, and no conclusive, objective support was identified. The following guideline bodies were assessed for relevant guidance: National Comprehensive Cancer Network.

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Blood-based Biomarker Colorectal Cancer Screening Tests

Concert Evidence Review for Coverage Determination (Published 08/15/2025)

This review focused on a search for evidence-based guidelines and peer-reviewed, published evidence of the clinical validity and clinical utility of blood-based biomarker colorectal cancer screening from 11/14/2025 to 7/22/2025. A total of 121 abstracts were identified and 26 references were fully reviewed, 1 of which met the inclusion criteria. This prospective, multicenter, cross-sectional observational study (PREEMPT CRC study) performed by Shaukat et al evaluated the clinical performance of a blood-based circulating tumor DNA test (Freenome) intended to screen for colorectal cancer in an average risk population. A cohort of 27,010 eligible participants were included in the analysis. The blood test demonstrated 79.2% sensitivity for colorectal cancer, and 91.5% specificity or advanced colorectal neoplasia. All participants underwent a colonoscopy. The study concluded that this blood-based test provides acceptable accuracy in detecting colorectal cancer, but the sensitivity at detecting advanced precancerous neoplasms was low at 12.5%.

Multiple previous studies have been published on BeScreened, FirstSight CRC, ColonSentry, Colovantage, ColoScape Colorectal Cancer Detection, and Guardant Shield and their ability to

screen for increased risk of colorectal cancer, including several meta-analyses and validation studies. These studies include a measure of clinical validity measured by sensitivity and specificity, and several studies compared these measures to those of colonoscopy, FIT or FOBT testing. The evidence for clinical validity does not consistently demonstrate superior sensitivity or specificity for these tests across studies. This lack of consistency highlights the importance of understanding the mechanism of these biomarkers in colorectal cancer in order to explain the observed variability.

Further, there is limited short or long term evidence to demonstrate that these tests promote a safe and effective alternative to colonoscopy or useful screening test to prioritize patients who should get colonoscopies. While the National Comprehensive Cancer Network (NCCN) addresses blood-based tests for colon cancer screening in their most recent recommendations (2.2025), they do so in moderate terms with very specific stipulations about the appropriateness of the use of these tests.

There is **INSUFFICIENT EVIDENCE** in published guidelines and peer-reviewed literature to definitively demonstrate improved health outcomes from the use of blood-based biomarker colorectal cancer screening, such as Shield (Guardant Health), FirstSight (CellMax Life), and ColoVantage (Quest Diagnostics), as compared to the current standard of care. At this time, the available evidence does not support health plan coverage of these tests, in part due to lack of strong support, or absence of support, present in current existing professional society guidelines (USPSTF).

Concert. Evidence Review for Coverage Determination for ColoRectal Cancer Blood Based Biomarker Tests. Published 08/15/2025.

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Blood-based Biomarker Lung Cancer Screening Tests

National Comprehensive Cancer Network (NCCN): Lung Cancer Screening (1.2025)

This guideline does not include a recommendation for lung cancer screening via blood-based or micro-RNA based screening.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening 1.2025
https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

Concert Note

There is insufficient evidence of clinical utility to support the routine use of these tests in clinical care. A search for guidelines, position statements, systematic reviews, and consensus statements regarding the use of blood-based biomarker lung cancer screening tests was performed in April 2025 and no conclusive, objective support was identified.

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Multi-Cancer Early Detection Screening Tests

Wade, et al.

A 2025 systematic literature review examined 36 studies of the use of multi-cancer early detection tests which met inclusion criteria, including studies performed in US-based populations. The review concluded that the decision regarding whether or not to implement multi-cancer early detection tests on asymptomatic populations should be supported by robust evidence such as a randomized controlled trial, with an appropriate length of time for proper follow-up to ensure evidence-based evaluation. None of the tests evaluated by this systematic review were supported by this level of evidence, and therefore widespread use of multi-cancer early detection tests cannot be recommended at this time (p. 41).

Wade R, Nevitt S, Liu Y, et al. Multi-cancer early detection tests for general population screening: a systematic literature review. Health Technology Assessment. 2025 Jan;29(2):1–105. doi:10.3310/dlmt1294

National Cancer Institute (NCI)

According to the NCI, there are no large clinical trials showing that the use of any MCD (multi-cancer detection) test for cancer screening reduces the number of individuals who die from cancer. To date, there are no professional medical societies, including the U.S. Preventive Services Task Force (USPSTF), that have issued recommendations on the use of MCD tests for cancer screening.

Multi-Cancer Detection (MCD) research. Division of Cancer Prevention. Accessed April 9, 2025. https://prevention.cancer.gov/major-programs/multi-cancer-detection-mcd-research.

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DEFINITIONS

1. **Fecal immunohistochemical testing (FIT):** Screening test for colon cancer that detects human blood in the lower intestines. (FIT testing alone does not involve any genetic test and is outside of the scope of this policy).
2. **FIT-DNA testing:** Combination of the fecal immunochemical (FIT), which uses antibodies to detect blood in the stool, with a test that detects abnormal DNA from cancer or polyp cells in the stool.
3. **Close relatives** include first, second, and third degree blood relatives:
    a. **First-degree relatives** are parents, siblings, and children
    b. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings
    c. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins

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Note: The Health Plan uses the genetic testing clinical criteria developed by Concert Genetics, an industry-leader in genetic testing technology assessment and policy development.

	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Health Services Division	December 21, 2022
Revised:	Medical Policy Committee/Health Services Division	March 15, 2023
	Medical Policy Committee/Health Services Division	September 20, 2023
	Medical Policy Committee/Health Services Division	March 20, 2024
Reviewed:	Medical Policy Committee/Health Services Division	March 15, 2023
	Medical Policy Committee/Health Services Division	September 20, 2023
	Medical Policy Committee/Health Services Division	March 20, 2024

Original Effective Date: 01/01/2023

Re-Review Date(s): 12/19/2024- Concert Genetics Effective Date: January 01, 2025 (V.1.2025)

06/18/2025 - Concert Genetics Effective Date: July 01, 2025 (V.2.2025)

12/16/2025 - Concert Genetics Effective Date: January 01, 2026 (V.1.2026)

Administrative Update:

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