

CONCERT GENETIC TESTING ONCOLOGY: CANCER SCREENING AND SURVEILLANCE

Rev Date: 02/26

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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](#) section.

POLICY REFERENCE TABLE

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<p>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. CRITERIA SECTIONS</p>	<p>EXAMPLE TESTS (LABS)</p>	<p>COMMON BILLING CODES</p>	<p>REF</p>
<p>Colorectal Cancer Screening Tests</p>			
<p>FIT-DNA Testing (Stool DNA Testing)</p>	<p>ColoGuard - 81528 (Exact Sciences)</p>	<p>81528, Z12.10-Z12.13</p>	<p>1, 2</p>
	<p>ColoGuardPlus- 0464U (Exact Sciences)</p>	<p>0464U, Z12.10-Z12.13</p>	
<p>Urinary Biomarker Tests for Precancerous Colon Polyps</p>	<p>PolypDx - 0002U (Metabolomic Technologies)</p>	<p>0002U, Z12.10-Z12.13</p>	<p>1</p>
<p>Blood-based Biomarker Colorectal Cancer Screening Tests</p>	<p>BeScreened-CRC - 0163U (Beacon Biomedical)</p>	<p>81327, 81479, 81599, 0091U, 0163U, 0368U, 0453U, G0327, Z12.10-Z12.13</p>	<p>4</p>
	<p>FirstSight - 0091U (CellMax Life)</p>		
	<p>ColonSentry (StageZero Life Sciences)</p>		
	<p>Epi proColon (Epigenomics)</p>		
	<p>ColoVantage (Quest Diagnostics)</p>		

<p>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. CRITERIA SECTIONS</p>	<p>EXAMPLE TESTS (LABS)</p>	<p>COMMON BILLING CODES</p>	<p>REF</p>
	<p>ColoScape Colorectal Cancer Detection - 0368U (DiaCarta Clinical Lab)</p> <p>ColonAiQ - 0453U (Breakthrough Genomics)</p> <p>Guardant Shield (Guardant Health)</p>		
<p>Lung Cancer Screening Tests</p>			
<p>Blood-based Biomarker Lung Cancer Screening Tests</p>	<p>FirstLook (Delfi Diagnostics)</p>	<p>81479, Z12.2</p>	<p>3</p>
<p>Multi-Cancer Early Detection Screening Tests</p>			
<p>Multi-Cancer Early Detection Screening Tests</p>	<p>Galleri (Grail)</p>	<p>81479, C00-C96</p>	<p>26</p>

RELATED POLICIES

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

- Oncology Testing: Hematologic Malignancy Molecular Diagnostics*** for 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 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 criteria related to genetic testing for hereditary cancer predisposition syndromes.
- ***Oncology Testing: Algorithmic Assays*** for criteria related to gene expression profiling and tumor biomarker tests with algorithmic analyses.
- ***General Approach to Laboratory Testing*** for criteria related to tumor and hematologic malignancy testing that is not specifically discussed in this or another non-general policy.

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CRITERIA

It is the policy of health plans affiliated with Centene Corporation[®] that the specific genetic testing noted below is **medically necessary** when meeting the related 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/enrollee is 45 years of age or older, **AND**
 - B. The member/enrollee is an individual who is at average risk for colorectal cancer, because the member/enrollee 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. Current evidence does not support the use of [FIT-DNA Testing](#) (stool DNA testing) to screen for colorectal cancer 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. Current evidence does not support the use of urinary biomarker tests for precancerous colon polyps for all indications.

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Blood-based Biomarker Colorectal Cancer Screening Tests

- I. Current evidence does not support the use of blood-based biomarkers to screen for colorectal cancer for all indications.

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LUNG CANCER SCREENING TESTS

Blood-based Biomarker Lung Cancer Screening Tests

- I. Current evidence does not support the use of blood-based biomarker tests for lung cancer screening for all indications.

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(1)

b) Is under 70 years of age, **AND**

(1) Is being assessed for testosterone therapy for hypogonadism, **AND**

(a) Has not yet initiated treatment, **OR**

(b) Initiated treatment in the last 3 to 12 months, **OR**

B. The member/enrollee is between the ages of 45 and 75 years, **AND**

1. Has not received PSA testing in the past 2 years, **OR**

C. The member/enrollee is between the ages of 55 and 70 years, **AND**

MULTI-CANCER EARLY DETECTION SCREENING TESTS

Multi-Cancer Early Detection Screening Tests

- I. Current evidence does not support multi-cancer early detection screening tests for all indications.

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RATIONALE

FIT-DNA Testing (Stool DNA Testing)

National Comprehensive Cancer Network (NCCN)

The NCCN guidelines on Colorectal Cancer Screening (1.2024) recommend 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).

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.

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Urinary Biomarker Tests for Precancerous Polyps

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Colon Cancer Screening (1.2024) do not include a recommendation for colorectal cancer (CRC) screening via urine-based screening methods for individuals of average risk for CRC (p. CSCR-2).

Concert Note

There is insufficient evidence to support the use of this test. No recommendations for or against this testing within standard professional society guidelines covering this area of testing were identified.

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Blood-based Biomarker Colorectal Cancer Screening Tests

Concert Evidence Review for Coverage Determination (Published 1/1/2025)

At the present time, blood-based biomarker tests such as BeScreened, FirstSight CRC, ColonSentry, Colovantage, ColoScape Colorectal Cancer Detection and have INSUFFICIENT EVIDENCE in peer-reviewed publications to effectively result in improved health outcomes compared to the current standard of care.

Consistent with Arkansas legislation, Epi Pro Colon and Guardant Shield are covered as FDA approved testing. The plan highly recommends providers follow CMS national coverage determination guidelines for testing, which only covers Guardant Shield.

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Blood-based Biomarker Lung Cancer Screening Tests

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Lung Cancer Screening (1.2025) do not include a recommendation for lung cancer screening via blood-based or micro-RNA based screening.

Concert Note

There is insufficient evidence to support the use of this test. No recommendations for or against this testing within professional society guidelines covering this area of testing were identified.

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The NCCN guidelines for Peritoneal Mesothelioma (2.2024) recommends consideration of CA-125 testing when the patient has signs or symptoms of peritoneal mesothelioma, such as recurrent ascites and/or peritoneal thickening or masses (p. PEM-1).

The NCCN guidelines for Uterine Neoplasms (3.2024) recommends consideration of CA-125 testing during the initial evaluation of uterine neoplasms (p. UN-1) as well as suspected extrauterine disease of endometrial carcinoma (p. ENDO-3).

The NCCN guidelines for Colon Cancer (5.2024) recommends consideration of CA-125 testing for individuals with appendiceal adenocarcinoma, especially if CEA and CA-19-9 are normal (p. COL-I 1 of 3).

The NCCN guidelines for Occult Primary tumors (2.2025) recommend CA-125 testing for adenocarcinoma or carcinoma not otherwise specified in those with a uterus and/or ovaries in the setting of a peritoneal presentation or ascites (p. OCC-4) or inguinal nodes (p. OCC-5).

American College of Obstetrics and Gynecology (ACOG)

The ACOG committee opinion number 716 (published 2017; reaffirmed in 2024) states that “the use of transvaginal ultrasonography and tumor markers (such as CA-125), alone or in combination, for early detection of ovarian cancer in average-risk women have not been proved to reduce mortality, and harms exist from invasive diagnostic testing (eg, surgery) resulting from false-positive test results” (p. 1).

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American College of Obstetricians and Gynecologists (ACOG)

In ACOG Practice Bulletin No. 215: Vaginitis in Nonpregnant Patients, the authors state: "Pap tests are not reliable for the diagnosis of vaginitis" (p. e10).

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Multi-Cancer Early Detection Screening Tests

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.

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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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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	03/23	03/23
Semi-annual review. Updated title to reflect V1.2024 version. Overview, coding, reference-table, background and references updated. Throughout policy: replaced “coverage criteria” with “criteria. For Policy Reference Table; Cancer Screening Tests: added G0328. For Other Related Policies: added “and Molecular”. For Criteria; Blood-based Biomarker Colorectal Cancer Screening Tests: added G0327 and G0328. For Background and Rationale; Colon Cancer Screening Tests- Blood-based Biomarker Colorectal Cancer Screening Tests: removed “Technical Assessment 2021”; removed “October 2021...”; added “May 2023.”	10/23	10/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Semi-annual review. Updated title to reflect V2.2024 version. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	04/24	04/24
Semi-annual review. Updated title to reflect V1.2025 version. Urinary Biomarker Tests for Pre-cancerous Colon Polyps: Reformatted Background and Rationale; Updated NCCN version. Blood-based Biomarker Colorectal Cancer Screening Tests: Streamlined portions of Background and Rationale section for brevity; Updated NCCN version. Blood-based Biomarker Lung Cancer Screening Tests: Updated example test in Policy Reference Table; Streamlined and clarified portions of Background and Rationale section. FIT-DNA Testing (Stool DNA Testing): Updated NCCN version in Background and Rationale and references.	11/24	11/24
Annual review. Minor rewording without clinical significance. FIT-DNA Testing (Stool DNA Testing): added requirement that member does not have "Symptoms suspicious for an undiagnosed colorectal cancer (e.g., rectal bleeding, iron deficiency anemia, abdominal pain, weight loss)." Name of criteria set updated from "Urinary Biomarker Tests for Pre-cancerous Polyps" to "Urinary Biomarker Tests for Precancerous Polyps." Added the following new criteria section: Multi-Cancer Early Detection Screening Tests. Coding table and rationale updated.	02/2026	02/26

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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