Revision log

CONCERT GENETICS ONCOLOGY: CANCER SCREENING

See Important Reminder at the end of this policy for important regulatory and legal information.

OVERVIEW

This policy relates to genetic and biomarker tests that aim to screen for specific cancers in individuals who are at risk to develop them. These 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 to develop a specific cancer. Genetic and biomarker cancer screening tests aim to identify the presence of cancer before symptoms appear and when treatment is often most effective. These tests are not currently diagnostic for cancer, but typically determine if an individual has an increased chance that cancer is present.

Screening tests for colorectal cancer may be performed by analyzing specific DNA present in fecal matter or peripheral blood. Cancer screening tests may also be performed on urine samples to screen for bladder cancer and colon polyps. These methods offer a noninvasive alternative to currently available screening approaches such as colonoscopy.

Screening tests for lung cancer are potentially useful adjuncts to the low-dose CT (LDCT), a recommended lung cancer screening tool in high-risk populations. Biomarkers such as autoantibodies, metabolites, proteins, and microRNA may be sampled from many different bodily sources, including whole blood, serum, plasma, bronchial brushings, and sputum. Circulating blood-based and serum based biomarkers are a convenient compartment to sample as they are relatively easy and inexpensive to collect.

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

Please see the Concert Genetics Platform for a comprehensive list of registered tests.

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Colorectal Cancer Screening Tests				
FIT-DNA Testing (Stool DNA Testing)	Cologuard (Exact Sciences Corporation)	81528	Z12.10-Z12.13	1, 2
Urinary Biomarker Tests for Pre-cancerous Colon Polyps	PolypDx (Metabolomic Technologies)	0002U	Z12.10-Z12.13	1
Blood-based Biomarker Colorectal Cancer Screening Tests	BeScreened (Beacon Biomedical)	0163U	Z12.10-Z12.13	4
	FirstSightCRC (CellMax Life)	0091U		
	ColonSentry (StageZero Life Sciences)	81599		
	Epi proColon (Epigenomics)	81327, G0327, G0328		
	ColoVantage (Quest Diagnostics)			
	ColoScape Colorectal Cancer Detection (DiaCarta Clinical Lab)	0368U		
Lung Cancer Screening Tests				
Blood-based Biomarker Lung Cancer Screening Tests	EarlyCDT-Lung (Oncimmune)	83520	Z12.2	3

OTHER RELATED POLICIES

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

- ***Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies*** for criteria related to DNA testing of a solid tumor or a blood cancer.
- ***Genetic Testing: Hereditary Cancer Susceptibility Syndromes*** for criteria related to genetic testing to determine if an individual has an inherited cancer susceptibility syndrome.
- **Oncology: *Algorithmic Testing*** for criteria related to gene expression profiling and tumor multianalyte assays with algorithmic analyses.
- **Oncology: *Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)*** for criteria related to circulating tumor DNA (ctDNA) or circulating tumor cell testing performed on peripheral blood for cancer diagnosis, management and surveillance.
- ***Genetic Testing: General Approach to Genetic and Molecular Testing*** for criteria related to cancer screening that is not specifically discussed in this or another non-general policy.

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) (81528) 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.

II. The use of FIT-DNA Testing (stool DNA testing) (81528) 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 Pre-cancerous Polyps

I. The use of urinary biomarker tests for pre-cancerous polyps (0002U) is considered **investigational**.

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Blood-based Biomarker Colorectal Cancer Screening Tests

I. The use of blood-based biomarkers to screen for colorectal cancer (0091U, 0163U, 0368U, 81327, 81599, G0327, G0328) is considered **investigational**.

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LUNG CANCER SCREENING TESTS

Blood-based Biomarker Lung Cancer Screening Tests

I. The use of blood-based biomarker tests (83520) for lung cancer screening are considered **investigational**.

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NOTES AND DEFINITIONS

1. **Fecal immunohistochemical testing (FIT)** is a 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 test** combines 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. **Low-dose computed tomography (LDCT)** has been proposed as a method of screening asymptomatic, high risk individuals for lung cancer; it refers to a non contrast study with a multi-detector CT scanner during a single maximal inspiratory breath-hold with a scanning time of under 25 seconds. It has been suggested that LDCT may be an improved early lung cancer detection tool based on the advantages it appears to have over CXR and sputum cytology to detect lung cancer at an earlier stage.

4. **MicroRNAs (miRNAs)** are tissue specific, small, non-coding RNAs regulating gene expression which may identify candidates for early detection of lung cancer.

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CLINICAL CONSIDERATIONS

Screening tests are not diagnostic tests. The results from a screening test put an individual into a lower risk or higher risk status. For an individual that is put into the higher risk status, following up with an appropriate diagnostic test would be necessary to make a definitive diagnosis of cancer.

For lung cancer, approaches where a biomarker based initial screen is followed by low-dose computed tomography (LDCT) or in which a biomarker test is combined with LDCT show promise for use in early detection. However, more high quality evidence is needed to support and guide the implementation of these tests.

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BACKGROUND AND RATIONALE

Colon Cancer Screening Tests - FIT-DNA Testing (Stool DNA Testing)

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Colorectal Cancer Screening (1.2023) support the use of FIT-DNA in average-risk individuals aged 45-75 who might have a life expectancy greater than or equal to 10 years, and notes that the decision to screen individuals aged 76-85 should be individualized.

Current NCCN guidelines (1.2023) do not include a recommendation for colorectal cancer screening via blood-based or urine-based screening.

US 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.

Colorectal Cancer Screening Tests - Urinary Biomarker Tests for Pre-cancerous Colon Polyps

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Colon Cancer Screening (1.2023) do not include a recommendation for colorectal cancer screening via blood-based or urine-based screening.

Colorectal Cancer Screening Tests - Blood-based Biomarker Colorectal Cancer Screening Tests

Concert Genetics

This review focused on peer-reviewed, published evidence of the clinical utility of BeScreened, FirstSight CRC, ColonSentry, Epi ProColon, and Colovantage through May 2023. A PubMed search was performed. Search terms included BeScreened, FirstSight CRC, ColonSentry, Epi ProColon, Colovantage, colon cancer screen, circulating tumor cells, Cripto, ANXA3, CLEC4D, LMNB1, PRRG4, TNFAIP6, VNN1, SEPT9. References were also identified from the performing laboratory's website. At the time of the initial evidence review, a total of 60 abstracts from these sources were reviewed, and 17 full text publications were evaluated. An updated evidence review was performed, which yielded no additional peer-reviewed full text articles for review. At the present time, BeScreened, FirstSight CRC, ColonSentry, Epi ProColon, and Colovantage have not been adequately shown in peer-reviewed publications to effectively result in improved health outcomes compared to the current standard of care.

Lung Cancer Screening Tests - Blood-based Biomarker Lung Cancer Screening Tests

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Lung Cancer Screening (1.2024) do not include a recommendation for lung cancer screening via blood-based or micro-RNA based screening. Current NCCN guidelines support lung cancer screening using LDCT for individuals with high risk factors.

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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

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening. Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf
2. Summary of Safety and Effectiveness Data (SSED): Cologuard™. U.S. Food & Drug Administration website. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017B.pdf.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology for Lung Cancer Screening. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf
4. Concert Genetics. Technology Assessment Summary of Blood Based Biomarkers for Colorectal Cancer. Version 2023.1

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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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, 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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