ONCOLOGY: CANCER SCREENING (PREAUTHORIZATION REQUIRED)

V.57

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DESCRIPTION

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 computed tomography (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 convenient samples as they are relatively easy and inexpensive to collect.

It is important to note that 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.

evidence is needed to support and guide the implementation of these tests.

Dates

Original Effective
06-01-2020
Last Review
08-07-2024
Next Review
08-11-2025

RELATED POLICIES

Related Policies:

V.60 Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies for criteria related to DNA testing of a solid tumor or a blood cancer.

V.59 Genetic Testing: Hereditary Cancer Susceptibility Syndromes for criteria related to genetic testing to determine if an individual has an inherited cancer susceptibility syndrome.

V.58 Oncology: Algorithmic Testing for criteria related to gene expression profiling and tumor multianalyte assays with algorithmic analyses.

V.61 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.

V.74 Genetic Testing: General Approach to Genetic and Molecular Testing for coverage criteria related to cancer screening that is not specifically discussed in this or another non-general policy.

REFERENCE TABLE

The tests, associated laboratories, CPT codes, and ICD codes contained within this document serve only as examples to help users navigate claims and corresponding coverage criteria; as such, they are not comprehensive

Sections	Example Tests (Labs)	CPT Codes	Codes	Ref
Colorectal Cancer Screening Tests				
FIT-DNA Testing (Stool DNA Testing)	Cologuard (Exact Sciences Corporation, LLC) Cologuard Plus	81528 0464U	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-CRC (Beacon Biomedical)	0163U	Z12.10-Z12.13	4
	FirstSight (CellMax Life)	0091U		
	ColonSentry (StageZero Life Sciences)	81599		
	Epi proColon (Epigenomics)	81327, G0327		
	ColoVantage (Quest Diagnostics)			
	ColoScape Colorectal Cancer Detection (DiaCarta Clinical Lab)	0368U		
	Guardant Shield (Guardant Health) Shield (Guardant Health)	81479 0537U		
Lung Cancer Screening Tests				
Blood-based Biomarker Lung Cancer Screening Tests	FirstLook (Delfi Diagnostics)	81479, 81599	Z12.2	3

POLICY

COLORECTAL CANCER SCREENING TESTS

FIT-DNA Testing (Stool DNA Testing) ***** This test does not require a preauthorization*****

I. The use of FIT-DNA Testing (stool DNA testing) (81528) to screen for colorectal cancer may be considered **medically**

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.

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)

COLOGUARD PLUS TESTING

I. The use of Cologuard Plus testing (0464U) is considered i**nvestigational** as this is not FDA approved and clinical efficacy has not been established.

Urinary Biomarker Tests for Pre-cancerous Polyps

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

Blood-based Biomarker Colorectal Cancer Screening Tests

I. The use of blood-based biomarkers to screen for colorectal cancer (0091U, 0163U, 0368U, 0537U 81327, 81479, 81599, G0327) is considered **investigational**.

LUNG CANCER SCREENING TESTS

Blood-based Biomarker Lung Cancer Screening Tests

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

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 test:** 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. **Low-dose computed tomography (LDCT):** 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)**: Tissue specific, small, non-coding RNAs regulating gene expression which may identify candidates for early detection of lung cancer.

BACKGROUND

COLON CANCER SCREENING TESTS

FIT-DNA Testing (Stool DNA Testing)

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Colorectal Cancer Screening (1.2024) support the use of FIT-DNA for colorectal cancer screening in average-risk individuals aged 45-75 with a life expectancy greater than or equal to 10 years, and notes that the decision to screen individuals aged 76-85 should be individualized. (p. CSCR-1A). The choice of screening modality should be based on patient preference and availability after discussion. (p. CSCR-1).

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

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.

Urinary Biomarker Tests for Pre-cancerous Colon Polyps

National Comprehensive Cancer Network (NCCN)

Current NCCN guidelines on Colon Cancer Screening (1.2024) do not include a recommendation for colorectal cancer screening via urine-based screening.
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.

Blood-based Biomarker Colorectal Cancer Screening Tests

Concert Evidence Review for Coverage Determination (Published 12/21/2023)

Multiple studies have been published on BeScreened, FirstSight CRC, ColonSentry, Epi proColon, 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. Most of 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 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 United States Preventive Services Task Force (USPSTF) and the National Comprehensive Cancer Network (NCCN) address blood-based tests for colon cancer screening in their most recent recommendations, neither recommend the testing.

At the present time, blood-based biomarker tests such as BeScreened, FirstSight CRC, ColonSentry, Epi proColon, Colovantage, ColoScape Colorectal Cancer Detection and Guardant Shield have INSUFFICIENT EVIDENCE 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 (2.2024) do not include a recommendation for lung cancer screening via blood-based or micro-RNA

BlueCross BlueShield Nebraska

recommendations for or against this testing within standard professional society guidelines covering this area of testing were identified.

Quick Code Search

Use this feature to find out if a procedure and diagnosis code pair will be approved, denied or held for review. Simply put in the procedure code, then the diagnosis code, then click "Add Code Pair". If the codes are listed in this policy, we will help you by showing a dropdown to help you.

Procedure

Please type a procedure code

Enter at least the first 3 characters of the code

Diagnosis

Please type a diagnosis code

Enter at least the first 3 characters of the code

Add

CODES

+ **CPT-PLA**
+ **CPT4**
+ **HCPCS**

REFERENCES

https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

2024

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.

2024

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf

2023

Concert. Evidence Review for Coverage Determination for ColoRectal Cancer Blood Based Biomarker Tests. Published 12/21/2023.

REVISIONS

12-10-2024
Updated new version for 01/01/2025

09-26-2024
Added new codes for 10/01/2024: 0498U 0501U

07-02-2024
Adding new 07/01/2024 PLA code: 0464U as investigational as not yet FDA approved.

01-01-2024
Updated Background and References.

09-27-2023
Changed "may be considered medically necessary" to "may be considered scientifically validated"

Added: "investigational when the above criteria is not met and for all other indications"

06-13-2023
Refomatted and updated references for 07/01/2023

03-06-2023
Added new code for 04/01/2023: 0368U

11-02-2022
01012023 - minor revisions - updated references

06-15-2022
No criteria changes, added 1 new reference. New verison effective 07/01/2022

06-25-2021
Added new code for 07/01/2021: G0327