Dean Health Plan Coverage Policy

Policy Name:	**Oncology: Cancer Screening MP9606**
Effective Date:	**January 01, 2025**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by Dean Health Plan. 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 Dean Health Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this medical policy see Provider Communications for additional information. https://deancare.com/Providers/Provider-communications

Dean Health Plan medical policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

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 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.

For lung cancer, approaches where a biomarker based initial screen is followed by 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.

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 and are not a guarantee of coverage or non-coverage. Please see the Concert Platform for a comprehensive list of registered tests.

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

Coverage 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, LLC)	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-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		

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Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
	Guardant Shield (Guardant Health)	81479		
Lung Cancer Screening Tests				
Blood-based Biomarker Lung Cancer Screening Tests	FirstLook (Delfi Diagnostics)		Z12.2	3

OTHER RELATED POLICIES

This policy document provides coverage 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 coverage criteria related to cancer screening 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) (81528) 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.

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, 81479, 81599, G0327) 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 for lung cancer screening are considered **investigational**.

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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 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.

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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.

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 (1.2024) 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 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.

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 based screening. Current NCCN guidelines support lung cancer screening using LDCT for individuals with high risk factors. 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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REFERENCES

1. 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
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 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf
4. Concert. Evidence Review for Coverage Determination for ColoRectal Cancer Blood Based Biomarker Tests. Published 12/21/2023.

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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.

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