

# Concert Genetics Oncology: Cancer Screening –and Surveillance

Reference Number: LA.CP.CG.16

[Coding implications](#)

Date of Last Revision ~~4/25~~03/26

[Revision Log](#)

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

## OVERVIEW

This policy ~~relates to~~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 ~~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. of developing a specific cancer.~~

~~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.~~

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 [2023/2024](#), 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 and may not support medical necessity. 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.

The tests, ~~associated laboratories~~, CPT codes, and ICD codes ~~contained within~~ referenced in this document ~~serve only as examples to help users navigate claims and corresponding criteria; as such, the policy~~ are not comprehensive, and ~~are~~ their inclusion does not represent a guarantee of coverage or non-coverage. Please see the [Concert Platform](#) ~~Platform~~ for ~~a comprehensive list of~~ additional registered tests.

**NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (\*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.**

<u>Criteria Sections</u> CRITERIA SECTIONS			<u>Example Tests</u> (Labs) <u>EXA</u> <u>MPL</u> <u>TESTS</u> (LABS)	<u>Common CPT Codes</u> <u>COMMON</u> <u>BILLING</u> <u>CODES</u>	<u>Common ICD Codes</u> <u>REF</u>
<u>Colorectal Cancer Screening Tests</u> Colorectal Cancer Screening Tests					
<u>FIT-DNA Testing (Stool DNA Testing)</u> <u>FIT-DNA Testing (Stool DNA Testing)</u>	<u>ColoGuard</u> ColoGuard - <u>81528</u> (Exact Sciences Corporation, LLC)	81528	<u>81528</u> , <u>Z12.10-</u> <u>Z12.13</u>	1, 2	
	<u>ColoGuardPlus</u> - <u>0464U*</u> (Exact Sciences)		<u>0464U*</u> , <u>Z12.10-</u> <u>Z12.13</u>		

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	<u>Criteria Sections</u> CRITERIA SECTIONS		<u>Example Tests</u> (Labs) <u>EXA</u> <u>MPL</u> <u>TESTS</u> (LABS)	<u>Common-CPT Codes</u> COMMON <u>BILLING</u> CODES	<u>Common ICD Codes</u> REF	<u>Ref</u>
<u>Urinary Biomarker Tests for Precancerous Colon Polyps</u> <u>Urinary Biomarker Tests for Precancerous Colon Polyps</u>	PolypDx - <u>0002U*</u> (Metabolomic Technologies)	<u>0002U*</u>	<u>0002U*</u> , Z12.10- Z12.13	1		
<u>Blood-based Biomarker Colorectal Cancer Screening Tests</u> <u>Blood-based Biomarker Colorectal Cancer Screening Tests</u>	BeScreened-CRC - <u>0163U*</u> (Beacon Biomedical)	<u>0163U*</u>	<u>81327*</u> , <u>8147</u> , <u>9</u> , <u>8159</u> , <u>9*</u> , <u>0091</u> , <u>U*</u> , <u>0163</u> , <u>U*</u> , <u>0368</u> , <u>U*</u> , <u>0453</u> , <u>U*</u> , <u>G032</u> , <u>7*</u> , Z12. 10- Z12. 13	4		

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<u>Criteria Sections</u> CRITERIA SECTIONS		<u>Example Tests</u> (Labs) <u>EXA</u> <u>MPL</u> <u>TESTS</u> (LABS)	<u>Common-CPT</u> <u>Codes</u> <u>COMMON</u> <u>BILLING</u> <u>CODES</u>	<u>Co</u> <u>mm</u> <u>on</u> <u>ICD</u> <u>Cod</u> <u>es</u> <u>R</u> <u>EF</u>	<u>Ref</u>
	FirstSight - <u>0091U*</u> (CellMax Life)	<u>0091U*</u>			
	ColonSentry (StageZero Life Sciences)				
	Epi proColon (Epigenomics)				
	ColoVantage (Quest Diagnostics)				
	ColoScape Colorectal Cancer Detection - <u>0368U*</u> (DiaCarta Clinical Lab)	<u>0368U*</u>			
	<u>ColonAiQ - 0453U* (Breakthrough Genomics)</u>				
	Guardant Shield (Guardant Health)				
<u>Lung Cancer Screening Tests</u> Lung Cancer Screening Tests					
<u>Blood-based Biomarker Lung Cancer Screening Tests</u> <u>Blood-based Biomarker Lung Cancer Screening Tests</u>	FirstLook (Delfi Diagnostics)		<u>81479, Z12.2</u> 3		

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		<b>Example Tests</b> (Labs) <u>EXA</u> <u>MPL</u> <u>TESTS</u> (LABS)	<b>Common CPT Codes</b> <u>COMMON</u> <u>BILLING</u> <u>CODES</u>	<b>Common ICD Codes</b> <u>ICD</u> <u>Codes</u> <u>REF</u>	<b>Ref</b>
<b><u>Criteria Sections</u>CRITERIA SECTIONS</b>					
<b><u>Multi-Cancer Early Detection Screening Tests</u></b>					
<u>Multi-Cancer Early Detection Screening Tests</u>	<u>Galleri (Grail)</u>	<u>81479, C00-C96</u>	<u>26</u>		

## ~~OTHER~~ RELATED POLICIES

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

- ~~**Oncology: Molecular Analysis of Solid Tumors and Testing: Hematologic Malignancies**~~**Malignancy Molecular Diagnostics** for criteria related to ~~DNA~~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 solid tumor or a blood cancer known or suspected cancer (e.g., broad molecular profiling, including Minimal Residual Disease (MRD) Testing, Tumor Mutational Burden (TMB), and cytogenetic / fusion testing).
- ~~**Genetic Oncology Testing: Hereditary Cancer Susceptibility Syndromes**~~ for criteria related to genetic testing ~~to determine if an individual has an inherited cancer susceptibility syndrome~~ for hereditary cancer predisposition syndromes.
- ~~**Oncology Testing: Algorithmic Testing Assays**~~ for criteria related to gene expression profiling and tumor ~~multianalyte assays~~biomarker tests 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.

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- ***Genetic Testing: General Approach to ~~Genetic and Molecular Laboratory~~ Testing*** for criteria related to ~~cancer screening~~ 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 Louisiana Healthcare Connections 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~~ 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~~, 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. The Symptoms suspicious for an undiagnosed colorectal cancer (e.g., rectal bleeding, iron deficiency anemia, abdominal pain, weight loss).

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- II. Current evidence does not support the use of ~~FIT-DNA Testing~~ 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~~ **Precancerous Colon Polyps**

- I. The ~~Current evidence does not support the~~ use of urinary biomarker tests for ~~pre-cancerous~~ **precancerous colon** polyps (0002U) ~~is considered~~ **investigational** for all indications.

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## Blood-based Biomarker Colorectal Cancer Screening Tests

- I. The ~~Current evidence does not support the~~ use of blood-based biomarkers to screen for colorectal cancer (0091U, 0163U, 0368U, 81327, 81479, 81599, G0327) ~~is considered~~ **investigational** for all indications.

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## LUNG CANCER SCREENING TESTS

### Blood-based Biomarker Lung Cancer Screening Tests

- I. The ~~Current evidence does not support the~~ use of blood-based biomarker tests for lung cancer screening ~~are considered~~ **investigational** for all indications.

## ~~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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(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

### ~~COLON CANCER SCREENING TESTS~~

#### **FIT-DNA Testing (Stool DNA Testing)**

*National Comprehensive Cancer Network (NCCN)*

~~Current~~The NCCN guidelines on Colorectal Cancer Screening (1.2024) ~~support~~recommend the ~~use~~ of Fecal immunochemical test (FIT-DNA) 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)., ~~and~~ notes

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 ~~decision to screen~~ preferred screening method for individuals aged 76-85 should be individualized. (p. at increased risk. CSCR-1A). 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

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the presence of CRC or advanced adenoma and should be followed by diagnostic colonoscopy (p. 17).

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 ~~Pre-cancerous Colon~~ 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 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~~

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~~Comprehensive Cancer Network (NCCN) address blood-based tests for colon cancer screening in their most recent recommendations, neither recommend the testing. 1/1/2025)~~

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~~

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## Blood-based Biomarker Lung Cancer Screening Tests

*National Comprehensive Cancer Network (NCCN)*

Current NCCN guidelines on Lung Cancer Screening (~~2.2024~~1.2025) 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.~~

### 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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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).

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### 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

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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	Effective Date
Converted corporate to local policy.	09/23	11/27/23	
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.”	12/23	2/27/24	
Semi-annual review. Updated title to reflect V2.2024 version. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	06/24	8/19/24	9/19/24
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.	1/25	3/31/25	5/1/25

<u>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)."</u> <u>Name of criteria set updated from "Urinary Biomarker Tests for Pre-cancerous Polyps" to "Urinary Biomarker Tests for Precancerous Polyps."</u>	<u>03/26</u>		
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<a href="#">Added the following new criteria section: Multi-Cancer Early Detection Screening Tests. Coding table and rationale updated.</a>			
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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. LHCC 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. 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 LHCC administrative policies and procedures.

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