Colorectal Cancer Screening and Surveillance



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Medicare Advantage Medical Coverage Policy

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Disclaimer

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT° codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Capsule Endoscopy
Genetic Testing for Hereditary Colorectal and Uterine Cancer
Liquid Biopsy

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/Transmittals.

Туре	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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Internet- Only Manuals (IOMs)	Pub. 100-04, Medicare Claims Processing Manual, Chapter 16 – Laboratory Services	§ 80 - Issues Related to Specific Tests		
NCD	Colorectal Cancer Screening Tests	210.3		
NCD	Fecal Occult Blood Test	190.34		
LCD LCA	Colonoscopy and Sigmoidoscopy- Diagnostic	<u>L34614</u> <u>A56394</u>	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE
LCD LCA	Computed Tomographic (CT) Colonography for Diagnostic Uses	<u>L33562</u> <u>A57026</u>	J6 - National Government Services, Inc. (Part A/B MAC) JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCD LCA	Colonoscopy/Sigmoidoscopy/ Proctosigmoidoscopy	L34005 A56456	J15 - CGS Administrators , LLC (Part A/B MAC)	кү, он
LCD LCA	Virtual Colonoscopy (CT Colonography)	<u>L34055</u> <u>A56800</u>	J15 - CGS Administrators , LLC (Part A/B MAC)	кү, он
LCD LCA	Diagnostic and Therapeutic Colonoscopy	<u>L34213</u> <u>A57342</u>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands

LCD LCA	Diagnostic and Therapeutic Colonoscopy	<u>L36868</u> <u>A57343</u>	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Diagnostic Colonoscopy	L38812 A58428	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
			JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, D.C., MD, NJ, PA
LCD LCA	Colonoscopy/Sigmoidoscopy/ Proctosigmoidoscopy	<u>L34454</u> <u>A56632</u>	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
			JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD	Virtual Colonoscopy (CT Colonography)	<u>L33452</u> <u>A56772</u>	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCA			JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCA	Billing and Coding: Incomplete Colonoscopy/Failed Colonoscopy	A55227	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
		ASSEZT	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCA	Billing and Coding: Screening Colonoscopy Converted to a Diagnostic and/or Therapeutic Colonoscopy	<u>A55069</u>	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
			JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD LCA	Diagnostic Colonoscopy	<u>L33671</u> <u>A55937</u>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

Colorectal cancer (CRC) screening evaluates the asymptomatic individual to detect cancer that develops in the colon or rectum. Screening tests may identify cancers at an early and potentially more treatable stage. Some methods such as colonoscopy may detect polyps (precancerous abnormal growths) that can be removed before becoming malignant. Screening differs from diagnostic tests which are used to evaluate an individual who exhibits signs and symptoms of disease.

Laboratory methods for CRC screening include, but may not be limited to:

- Blood-based biomarker panels are laboratory tests that assess the expression of genes or other biomarkers purportedly associated with increased risk of CRC. Examples include, but may not be limited to:
 - BeScreened CRC is a multianalyte assay with algorithmic analysis (MAAA) using 3 blood-based biomarkers (carcinoembryonic antigen [CEA], extracellular matrix (ECM) protein and teratocarcinomaderived growth factor-1 [TGDF-1, Cripto-1]).
- **Stool-based tests** are noninvasive laboratory methods to detect blood in stool which may be an early (and sometimes only) symptom of CRC. Examples include, but may not be limited to:
 - Fecal immunochemical test (FIT) identifies intact human hemoglobin in stool collected by an
 individual at home then submitted to a laboratory. Multitarget stool DNA testing (FIT-DNA) (eg,
 Cologuard) combines FIT with additional testing for altered DNA biomarkers in the stool. An individual
 with an abnormal (positive) FIT or FIT-DNA test must undergo a definitive test for colon cancer, such
 as a colonoscopy.
 - Fecal occult blood test (FOBT) detects occult (hidden) blood in the stool. Blood may come from anywhere along the digestive tract and for that reason, additional types of tests may be ordered.
 Colonoscopy is performed following an abnormal (positive) FOBT result.
 - o **Multitarget stool RNA test (RNA-FIT)** (eg, Geneoscopy) analyzes ribonucleic acid (RNA) biomarkers in the stool and has been proposed as a means for early cancer detection.
- **Urine-based testing** is a laboratory method that assesses an individual's urine for biomarkers purportedly associated with CRC. An example includes PolypDx, which is proposed to detect adenomatous polyps (CRC precursor). The assay analyzes urine to detect three metabolites: ascorbic acid, succinic acid and carnitine. It is suggested for those at average to moderate risk for CRC

Endoscopic visualization includes methodologies used to view the inside of the large intestine and may be utilized for CRC screening. Examples include, but may not be limited to:

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- **Colonoscopy** is a technique that allows a physician to examine the lining of the entire large intestine by using a colonoscope (flexible, fiberoptic instrument) that is inserted through the anus. This test may reveal inflamed tissue, abnormal growths, ulcers, or early signs of cancer in the colon or rectum. If needed, special instruments can be passed through the colonoscope to remove polyps.
- **Sigmoidoscopy** uses a short, flexible fiberoptic tube that provides visualization of the sigmoid (descending) colon and rectum. The tube is inserted through the anus allowing a physician to see abnormal growths, bleeding, inflammation, and ulcers. If polyps or cancer are found, then a colonoscopy is performed to screen for polyps or cancer in the remainder of the colon. This procedure may be performed in conjunction with FIT

Radiologic visualization is a medical imaging technique to view internal structures in the body and may also be used for CRC screening. This includes, but may not be limited to:

- Computed tomographic colonography (CTC), also known as virtual colonoscopy, is a minimally invasive method to examine the colon and rectum for abnormalities (e.g., CRC and polyps). Helical computed tomography (CT) and computer-generated images are used to produce high-resolution two- and three-dimensional (3D) images. If suspicious lesions are detected, the individual generally must undergo further testing via conventional colonoscopy.
- **Double-contrast barium enema (DCBE)**, also called a lower gastrointestinal (GI) exam, is an x-ray of the large intestine (colon and rectum). During the procedure, the colon is filled with barium, which enhances the visualization of the outline of the colon. The barium is removed, and the colon is then filled with air. This provides a more detailed view of the inner surface of the colon, making it easier to detect colon polyps and/or other abnormalities (eg, inflammation, strictures). If the test is abnormal (positive), a colonoscopy is needed for further evaluation.
- Magnetic resonance (MR) colonography is a type of magnetic resonance imaging (MRI) that evaluates the entire colon by producing two- and three-dimensional images to detect polyps and cancer without radiation exposure. Studies indicate the test might detect polyps and cancer with high specificity; however, MR colonography is less sensitive than conventional colonoscopy.

Adjunctive methods for endoscopic and radiologic visualization are add-on techniques used in conjunction with real-time endoscopy to purportedly enhance detection and classification of polyps. These include, but may not be limited to:

- Artificial intelligence (AI) software is a type of computer program added to existing colonoscopy systems that has been suggested to improve adenoma detection. Examples include, but may not be limited to, EndoScreener and GI Genius Intelligent Endoscopy Module.
- Computer-aided detection (CAD) is an automated add-on to real-time endoscopy that purportedly enhances detection and classification of colorectal polyps. It is used as an aid for radiologists to assist in the interpretation and identification of suspicious findings. CAD is not intended to be used in place of a radiologist but rather as a second examination of the images. SKOUT is a US Food & Drug Administration (FDA)-approved system for computer-aided polyp detection.

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- **G-EYE** is a type of colonoscope that uses an integrated balloon purported to improve visibility during the colonoscopy procedure.
- In vivo analysis is performed as an adjunct to endoscopic procedures, providing real-time additional imaging to purportedly improve examination of in vivo methods including, but may not be limited to:
 - Chromoendoscopy
 - Confocal laser microscopy
 - Confocal miniprobe (eg, Cellvizio)
 - Fiberoptic analysis
 - Magnification endoscopy
 - Narrow band imaging
 - Optical coherence tomography (OCT)
- Retrograde imaging/illumination uses additional small cameras with endoscopy to purportedly enhance evaluation of the colon through illumination and continuous retrograde views. Examples of these devices include, but may not be limited to:
 - Third Eye Panoramic can be attached to the distal end of the colonoscope with a flexible clip and provides continuous left- and right-side views of the colon that are displayed simultaneously on monitors.
 - Third Eye Retroscope is a disposable, single-use imaging device that is inserted into the endoscopic working channel and is purported to provide an additional retrograde (backward) view of areas behind folds and colonic flexures.
- **Colonic lavage** uses 35 or more liters of warmed, gravity-fed water and is purported to prepare and cleanse the bowel prior to colonoscopy or other endoscopy procedures. HygiPrep is an example of a colonic lavage system that is FDA approved.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for colorectal screening and surveillance

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria.

Colorectal Cancer Screening and Surveillance

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The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
44799	Unlisted procedure, small intestine	
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance	
45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)	
45380	Colonoscopy, flexible; with biopsy, single or multiple	
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance	
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps	
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	

45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)	
45999	Unlisted procedure, rectum	
74263	Computed tomographic (CT) colonography, screening, including image postprocessing	
74270	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; single-contrast (eg, barium) study	
74280	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (eg, high density barium and air) study, including glucagon, when administered	
76498	Unlisted magnetic resonance procedure (eg, diagnostic, interventional)	
81401	MOLECULAR PATHOLOGY PROCEDURE LEVEL 2	
81479	Unlisted molecular pathology procedure	
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result	
82270	Blood, occult, by peroxidase activity (eg, guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided 3 cards or single triple card for consecutive collection)	
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations	
84999	Unlisted chemistry procedure	
0002U	Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps	

0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	
CPT®		
Category III Code(s)	Description	Comments
0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter	
HCPCS Code(s)	Description	Comments
C1749	Endoscope, retrograde imaging/illumination colonoscope device (implantable)	
G0104	Colorectal cancer screening; flexible sigmoidoscopy	
G0105	Colorectal cancer screening; colonoscopy on individual at high risk	
G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema	
G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema	
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk	
G0122	Colorectal cancer screening; barium enema	
G0327	Colorectal cancer screening; blood-based biomarker	
G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, one to three simultaneous determinations	

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Change Summary

- 01/01/2024 New Policy.

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