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Clinical Guideline

Guideline Number: CG024, Ver. 2

Colorectal Cancer Screening

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Oscar endorses colorectal cancer screening guidelines from the U.S. Preventive Services Task Force and the American Cancer Society. Colorectal cancer screening is a medically necessary preventive service for men and women aged 50 years and older, and for men and women under the age of 50 with specific risk factors. Depending on individual risk factors, the treating provider may recommend the appropriate screening regimen and intervals. Screening options may be chosen based on individual risk and also by personal preference.

Definitions

"Polyps" are abnormal tissue growths that most often look like small, flat bumps or tiny mushroom-like stalks.

"Endoscopic and Radiologic Screening Examinations" include colonoscopy, flexible sigmoidoscopy, double-contrast barium enema, capsule endoscopy and CT colonography and are based on direct or radiographic visualization of the polyp or cancer. Procedures that fall within this definition include:

- **"Colonoscopy"** is a procedure that allows a provider to examine the inner lining of the large intestine (rectum and colon) by using a thin, flexible tube called a colonoscope.
- **"Flexible Sigmoidoscopy"** is a procedure that allows the provider to examine the rectum and lower sigmoid colon using a flexible sigmoidoscope.

- **“Double Contrast Barium Enema”** is a form of contrast radiography in which x-rays of the colon and rectum are taken using barium contrast to visualize the internal structures more easily.
- **“CT Colonography**” or **“Virtual Colonoscopy”** is a procedure that uses special x-ray equipment to examine the large intestine for cancer or polyps.
- **“Capsule Endoscopy”** is a procedure where a small ingestible capsule is swallowed. This capsule has small cameras which take video as it moves through the digestive system to visualize the colon for detection of polyps.

“Incomplete Colonoscopy” refers to a situation when the colon cannot be fully evaluated for a number of reasons, such as patient discomfort, prior surgery, or suboptimal bowel preparation.

“Stool-Based Screening Tests” include the guaiac-based fecal occult blood test (gFOBT), fecal immunochemical test (FIT), and stool DNA testing (sDNA). While these tests typically cannot detect precancerous polyps, they may detect for other signs of cancer such as blood or cell debri in the stool. Tests that fall within this definition include:

- **“Guaiac-Based Fecal Occult Blood Test (gFOBT)”** is a non-invasive screening tool that targets human red blood cell components in stool.
- **“Fecal Immunochemical Test (FIT)”** is a non-invasive screening tool that targets human red blood cell components in stool.
- **“Stool DNA Test (sDNA)”** is a non-invasive screening tool that targets both human red blood cell components and specific genetic alterations in stool.

Clinical Indications and Coverage

General Coverage Criteria: Average Risk

Average risk includes persons who meet **ALL** of the following criteria:

- **ONE** of the following age groups:
  - Ages 50 to 75, for which regular screening indicated; ***or***
  - Ages 76 to 85, for which screening is indicated based on individual’s prior screening history and overall health status.
- No personal or family history of adenomatous polyps, colorectal cancer, familial adenomatous polyposis (FAP), or hereditary nonpolyposis colorectal cancer (HNPCC); ***and***
- No personal history of inflammatory bowel disease such as Crohn’s Disease or Ulcerative Colitis.

General Coverage Criteria: High Risk

People at increased or high risk of colorectal cancer should begin colorectal cancer screening before age 50 and be screened at more frequent intervals. For individuals defined as high risk, increased

surveillance generally means a specific recommendation for colonoscopy. High risk includes persons who meet **ONE** of the following criteria:

- A personal history of colorectal cancer or adenomatous polyps; ***or***
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease); ***or***
  - Guidelines recommend screening colonoscopy for these patients 8-10 years after diagnosis, with the interval for further surveillance guided by risk factors and findings at time of initial colonoscopy
- A family history of colorectal cancer or polyps; ***or***
  - Persons with a first-degree relative in whom colorectal cancer developed before 60 years of age should undergo colonoscopy at 40 years of age or an age 10 years younger than the relative's age when cancer developed, whichever is earlier
- A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC); ***or***
  - Persons with a family history of FAP should undergo their first colonoscopy at the age of 10 to 12 years of age followed by a yearly flexible sigmoidoscopy thereafter
  - Persons with a family history of HNPCC should undergo their first colonoscopy at the age of 20 to 25 years, or 10 years before the youngest case in their immediate family followed by a colonoscopy every 1-2 years thereafter
- African-Americans should begin their screening at age 45 due to a higher risk for colorectal cancer than other populations.

Covered Services & Criteria

The following tests can detect polyps (precancerous lesions) and cancer and are therefore indicated for **average risk OR high risk** patients:

1. A **Colonoscopy** may be indicated as a preventive measure when **ALL** of the following are present:
   a. General coverage criteria (above) for average or high risk is met; ***and***
   b. MCG Colonoscopy (A-0129) criteria are met; ***and***
   c. Testing frequency is ordered for 1 of the following:
      i. Once every 10 years for average risk patients; ***or***
      ii. For high risk members, a screening interval appropriate for the individual's underlying high risk indication and associated degree of risk.
2. A **Sigmoidoscopy** may be indicated as a preventive measure when **ALL** of the following are present:
   a. General coverage criteria (above) for average or high risk is met; ***and***
   b. MCG Sigmoidoscopy, Flexible (A-0128) criteria are met; ***and***

    c. Testing frequency is ordered for 1 of the following:
        i. Once every 5 years for average risk patients; ***or***
        ii. For high risk members, a screening interval appropriate for the individual's underlying high risk indication and associated degree of risk.
3. A **Double Contrast Barium Enema** may be indicated as a preventive measure when **ALL** of the following are present:
    a. General coverage criteria (above) for average risk is met; ***and***
    b. MCG Barium Enema: Double-Contrast or Therapeutic (A-0011) criteria are met; ***and***
    c. Testing frequency is ordered for 1 of the following:
        i. Once every 5 years for average risk patients; ***or***
        ii. For high risk members, a screening interval appropriate for the individual's underlying high risk indication and associated degree of risk.

The following tests detect cancer and are primarily indicated for **average risk** patients:

1. A **CT Colonography** can detect but not remove polyps and may be indicated as a preventive measure when **ALL** of the following are present:
    a. General coverage criteria (above) for average is met; ***and***
    b. MCG Colonography, CT (Virtual Colonoscopy) (A-0030) criteria is met; ***and***
    c. Testing is ordered once every 5 years.

    **The patient may also qualify if unable to tolerate a colonoscopy with sedation or has medical conditions, e.g., recent myocardial infarction, recent colonic surgery, bleeding disorders, severe lung and/or heart disease
2. A **Guaiac-Based Fecal Occult Blood Test (gFOBT)** cannot detect polyps but may be indicated as a preventive measure when **ALL** of the following are present:
    a. General coverage criteria (above) for average risk is met; ***and***
    b. No gFOBT within 1 year; ***and***
    c. gFOBT is ordered for 3 separate bowel movements yearly; ***and***
    d. gFOBT is ordered alone or in conjunction with a sigmoidoscopy; ***and***
    e. No positive result from another colorectal cancer screening test in last 6 months; ***and***
    f. No signs or symptoms of active colorectal disease (e.g., no lower GI pain, no blood in stool, no positive stool DNA test or fecal immunochemical test); ***and***
    g. Testing is ordered once annually.
3. A **Fecal Immunochemical Test (FIT)** cannot detect polyps but may be indicated as a preventive measure when **ALL** of the following are present:
    a. General coverage criteria (above) for average risk is met; ***and***
    b. No FIT testing within 1 year; ***and***

    c. No positive result from another colorectal cancer screening test in last 6 months; ***and***
    d. No signs or symptoms of active colorectal disease (eg, no lower GI pain, no blood in stool, no positive guaiac fecal blood test or stool DNA test); ***and***
    e. Testing is ordered once annually.
4. A **Stool DNA Test (sDNA)** cannot detect polyps but may be indicated as a preventive measure when **ALL** of the following are present:
    a. General coverage criteria (above) for average risk is met; ***and***
    b. MCG Fecal DNA Testing (A-0388) criteria are met; ***and***
    c. The stool DNA test is the Cologuard® test; ***and***
    d. No stool DNA test within 3 years; ***and***
    e. No positive result from another colorectal cancer screening test in last 6 months; ***and***
    f. No signs or symptoms of active colorectal disease (eg, no lower GI pain, no blood in stool, no positive guaiac fecal blood test or FIT test); ***and***
    g. Testing is ordered once every three years.

Coverage Exclusions

Colorectal cancer screening is currently **NOT** recommended for average risk patients age 85 or older.

The application and clinical utility of the **Capsule Endoscopies** are considered experimental or investigational and are therefore not covered:

- Colon capsule endoscopy (e.g., PillCam COLON 2)
- Patency capsule (e.g., PillCam Patency System)

Any colorectal cancer screening tests for which safety and efficacy has not been established and proven is considered experimental, investigational, or unproven, and is therefore not covered by Oscar. Non-covered screening tests include, but are not limited to, the following:

- Colon Cancer Gene Expression Assay Oncotype DX
- Colon Cancer Gene Expression Assay GeneFx Colon
- Colon Cancer Gene Expression Assay ColoPrint
- Colorectal Cancer (Hereditary) Gene Panel
- Methylated Septin 9 (ColoVantage, EpiproColon)
- MicroRNA Detection
- Screening Upper Endoscopy
- Chromoendoscopy or Narrow-Band Imaging Optical Colonoscopy
- Other Stool DNA Tests (PreGen-26, PreGen-Plus, ColoSure)

Applicable Billing Codes (HCPCS & CPT Codes)

CPT Codes covered if clinical criteria are met:

CPT/HCPCS Codes covered if criteria are met:	
Code	*Description*
44388 - 44408	Colonoscopy through stoma
45330 - 45350	Sigmoidoscopy, flexible
45378 - 45398	Colonoscopy, flexible
74261	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material
74262	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s) including non-contrast images, if performed
74263	Computed tomographic (CT) colonography, screening, including image postprocessing
74270	Radiologic examination, colon; contrast (eg, barium) enema, with or without KUB
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600 variant(s)
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)
82272	Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening

82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report
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
S0285	Colonoscopy consultation performed prior to a screening colonoscopy procedure
ICD-10 codes covered if criteria are met:	
C18.0 - C21.8	Malignant neoplasm of colon, rectosigmoid junction, rectum, anus and anal canal
C7a.020 - C7a.029	Malignant carcinoid tumors of the appendix, large intestine, and rectum
D12.0 - D12.9	Benign neoplasm of colon, rectum, anus and anal canal
D3a.020 - D3a.029	Benign carcinoid tumors of the appendix, large intestine, and rectum
K50.00 - K50.919	Crohn's disease [regional enteritis]
K51.00 - K55.9	Noninfective enteritis and colitis
K57.20 - K57.93	Diverticular disease of intestine
K63.5	Polyp of colon
Z12.10 - Z12.12	Encounter for screening for malignant neoplasm of intestinal tract, colon and rectum
Z15.09	Genetic susceptibility to other malignant neoplasm

Z80.0	Family history of malignant neoplasm of digestive organs
Z83.71	Family history of colonic polyps
Z85.038, Z85.048	Personal history of other malignant neoplasm of large intestine, rectum, rectosigmoid junction, and anus
Z86.010	Personal history of colonic polyps

CPT/HCPCS codes *not* covered:	
Code	*Description*
43200	Esophagoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed **[separate procedure]**
44799	Unlisted procedure, small intestine **[may include chromoendoscopy or narrow-band imaging optical colonoscopy]**
81327	SEPT9 (Septin9) (eg, colorectal cancer) methylation analysis
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11
81436	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score
88271	Molecular cytogenetics; DNA probe, each (eg, FISH)
88272	Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (eg,

	for derivatives and markers)
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (eg, for microdeletions)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells
88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells

References

1. Bailey, et al. Colorectal Cancer Screening: Stool DNA and Other Noninvasive Modalities. Gut and Liver, 2016; 10(2), 204.
2. Chapman CG, Pekow J. The emerging role of miRNAs in inflammatory bowel disease: a review. Therapeutic Advances in Gastroenterology 2015;8(1):4-22.
3. Chung SJ, Kim D, Song JH, et al. Comparison of detection and miss rates of narrow band imaging, flexible spectral imaging chromoendoscopy and white light at screening colonoscopy: A randomised controlled back-to-back study. Gut. 2014;63(5):785-791.
4. Davila RE, Rajan E, Baron TH, et al; Standards of Practice Committee, American Society for Gastrointestinal Endoscopy. ASGE guideline: Colorectal cancer screening and surveillance. Gastrointest Endosc. 2006;63(4):546-557.
5. De Iudicibus S, Lucafo M, Martelossi S, Pierobon C, Ventura A, Decorti G. MicroRNAs as tools to predict glucocorticoid response in inflammatory bowel diseases. World Journal of Gastroenterology 2013;19(44):7947-54.
6. Fornaro, et al. Colorectal Cancer in Patients with Inflammatory Bowel Disease: The Need for a Real Surveillance Program. Clinical Colorectal Cancer. 2016; 15(3), 204-212.
7. Imperiale TF, et al. Multitarget stool DNA testing for colorectal-cancer screening. New England Journal of Medicine 2014;370(14):1287-97.
8. Inadomi, et al. Screening for Colorectal Neoplasia. The New England Journal of Medicine. 2017; 376:149-56.
9. Jensen MD, Andersen RF, Christensen H, Nathan T, Kjeldsen J, Madsen JS. Circulating microRNAs as biomarkers of adult Crohn's disease. European Journal of Gastroenterology & Hepatology 2015;27(9):1038-44.
10. LaDuca H, et al. Utilization of multigene panels in hereditary cancer predisposition testing: analysis of more than 2,000 patients. Genetics in Medicine 2014; 16(11):830-7.
11. Lieberman, et al. Guidelines for Colonoscopy Surveillance After Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2012;143:844–857.

12. Levin, et al. Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology, Revised. CA Cancer J Clin 2008;58(3):130-160.
13. MacFarland, et al. Revised Colorectal Screening Guidelines: Joint Effort of the American Cancer Society, U.S. Multisociety Task Force on Colorectal Cancer, and American College of Radiology. Radiology. 2008; 248(3): 717-720.
14. Molnar B, Toth K, Bartak BK, Tulassay Z. Plasma methylated septin 9: A colorectal cancer screening marker. Expert Rev Mol Diagn. 2015;15(2):171-184.
15. Peacock O, Lee AC, Larvin M, et al. MicroRNAs: Relevant tools for a colorectal surgeon? World J Surg. 2012;36(8):1881-1892.
16. Qaseem A, Denberg TD, Hopkins RH; for the Clinical Guidelines Committee of the American College of Physicians. Screening for colorectal cancer: A guidance statement from the American College of Physicians. Ann Intern Med. 2012;156(5):378-386.
17. Recommendations for Colorectal Cancer Early Detection. The American Cancer Society. Accessed at http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations on March 20, 2017.
18. Rex DK, et al. Colorectal Cancer Screening. Am J Gastroenterol 2009;104:739–750.
19. "Risk Factors for Colorectal Cancer." The American Cancer Society. Accessed at http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-risk-factors-for-crc on March 20, 2017.
20. Smith, et al. Cancer Screening in the United states, 2016: A Review of Current American Cancer Society Guidelines and Current Issues in Cancer Screening. CA: A Cancer Journal for Clinicians. 2016; 66(2), 95-114.
21. Syngal S, et al. ACG Clinical Guideline: Genetic Testing and Management of Hereditary Gastrointestinal Cancer Syndromes. Am J Gastroenterol. 2015; 110: 223–262.
22. Whiteoak SR, Felwick R, Sanchez-Elsner T, Fraser Cummings JR. MicroRNAs in inflammatory bowel diseases: paradoxes and possibilities. Inflammatory Bowel Diseases 2015;21(5):1160-5.
23. Williams, et al.Use of NCCN Guidelines, Other Guidelines, and Biomarkers for Colorectal Cancer Screening. Journal of the National Comprehensive Cancer Network. 2016; 14 (11). 1479-1485.
24. US Preventive Services Task Force. Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement. *JAMA.* 2016;315(23):2564-2575.
25. Zoghbi, et al. New era of colorectal cancer screening. World Journal of Gastrointestinal Endoscopy. 2016; 8(5), 252.

26. American Society for Gastrointestinal Endoscopy (ASGE). Guideline. Technology Status Evaluation Report. Wireless capsule endoscopy. Available at https://www.asge.org/docs/default-source/importfiles/assets/0/73730/c4d44578-c3d0-4583-9949-b15f3e8537e0.pdf?sfvrsn=4. 2013. January 8, 2018.

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