Colorectal Cancer Screening

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

The Plan follows the colorectal cancer screening guidelines from the U.S. Preventive Services Task Force and the U.S. Multi-Society Task Force of Colorectal Cancer (MSTF), which represents the American College of Gastroenterology, the American Gastroenterological Association, and The American Society for Gastrointestinal Endoscopy. Colorectal cancer screening is a medically necessary preventive service for men and women aged 45 years and older, and for even younger men and women 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 or a colonoscope that is not inserted all the way
- "Double Contrast Barium Enema" is a form of contrast radiography in which x-rays of the colon and rectum are taken using barium and air contrast to visualize the internal structures more easily.
- "CT Colonography" or "Virtual Colonoscopy" is a procedure that uses specialized CT scan 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 disposable capsule has small cameras which take video as it moves through the digestive system to visualize the colon for detection of polyps.The video signal is recorded by an external box, then downloaded to a computer so your doctor can 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, a very twisty colon anatomy, 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 be able to detect for other signs of cancer such as blood or cell debris 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.This detects bleeding from any part of the gut.
- "Fecal Immunochemical Test (FIT)" is a non-invasive screening tool that targets human red blood cell components in stool. This detects bleeding predominantly originating in the colon.
- "Stool DNA Test (sDNA)" is a non-invasive screening tool that targets both human red blood cell components and specific genetic alterations in stool.
- "Serum-based testing" is a non-invasive blood-based screening tool that looks for evidence of existing colon cancer.

Clinical Indications

General Criteria: *Average Risk*

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

1. ONE of the following age groups:
    a. Ages 45 to 75, for which regular screening indicated; *or*
    b. Ages 76 to 85, for which screening is indicated based on individual's prior screening history and overall health status; *and*
2. No personal or family history of adenomatous polyps, colorectal cancer, familial adenomatous, polyposis (FAP), hereditary nonpolyposis colorectal cancer (HNPCC), or other genetic syndromes that predispose members to an increased risk of colorectal cancer; *and*
3. No personal history of inflammatory bowel disease such as Crohn's Disease or Ulcerative Colitis.

General Criteria: *High Risk*

People at increased or high risk of colorectal cancer may begin colorectal cancer screening before age 45 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:

1. A personal history of colorectal cancer or adenomatous polyps. This may include individuals up to age 85, for which re-screening is indicated based on individual's prior screening history and overall health status; *or*
2. 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 the time of initial colonoscopy.
3. A family history of colorectal cancer or polyps; *or*
    - Persons with a first-degree relative in whom colorectal cancer developed any age should undergo a colonoscopy at 40 years of age or an age 10 years younger than the relative's age when cancer developed, whichever is earlier.
4. A known family history of hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP), hereditary non-polyposis colon cancer (HNPCC), or other genetic syndromes that predispose members to an increased risk of colorectal cancer.
    - 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.

Services & Criteria

The Plan considers the following tests medically necessary for either average *or* high risk patients for the detection of polyps (precancerous lesions) *and* cancer when the following criteria are met:

1. A preventive screening that results in a therapeutic service done at the same encounter and as an integral part of the preventive service (e.g., polyp removal during a preventive colonoscopy), the therapeutic service would still be considered a preventive service upon screening.
2. A Colonoscopy may be indicated as a preventive measure when ALL of the following are present:
    a. General criteria (above) for average risk is met and no colonoscopy within the past 10 years; *or*
    b. General criteria (above) for high risk is met OR MCG Colonoscopy (A-0129) criteria are met for abnormal results of screening, high-risk family history, or high-risk personal history; *and*
    c. Testing frequency is ordered for 1 of the following:
        i. For high risk members, a screening interval appropriate for the individual's underlying high risk indication and associated degree of risk; *or*

ii. Accelerated rescreening with optimal preparation is warranted when examination is performed in the setting of limited visualization due to patient factors or occluding colonic contents.

3. A Flexible Sigmoidoscopy may be indicated as a preventive measure when ALL of the following are present:
    a. General criteria (above) for average is met; *or*
    b. General criteria (above) for high risk is met OR MCG Sigmoidoscopy, Flexible (A-0128) colorectal cancer screening criteria are met for family history or surveillance for local recurrence (excludes MCG average-risk adult criteria); *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.
4. A Double Contrast Barium Enema may be indicated as a preventive measure when ALL of the following are present:
    a. General criteria (above) for average risk is met; *and*
    b. Colonoscopy or CT colonography are not available or desired by the member; *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 Plan considers the following tests medically necessary for average risk patients for the detection of cancer when the following criteria are met:

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 criteria (above) for average risk is met; *and*
    b. MCG Colonography, CT (Virtual Colonoscopy) (A-0030) colorectal cancer screening 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 adequately screen for precancerous polyps but may be indicated as a preventive measure when ALL of the following are present:
    a. General 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 adequately screen for precancerous polyps but may be indicated as a preventive measure when ALL of the following are present:
    a. General 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 (e.g., 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 adequately screen for precancerous polyps but may be indicated as a preventive measure when ALL of the following are present:
    a. The stool DNA test is the Cologuard® test; *and*
    b. General criteria (above) for average risk is met; *and*
    c. No stool DNA test within 1 year; *and*
    d. No positive result from another colorectal cancer screening test in last 6 months; *and*
    e. No signs or symptoms of active colorectal disease (e.g., no lower GI pain, no blood in stool, no positive guaiac fecal blood test or FIT test); *and*
    f. Testing is ordered once every one to three years and in lieu of colonoscopy, unless test results warrant further colonic investigation.

Experimental or Investigational / Not Medically Necessary

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:

- 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 the Plan. Furthermore, serum-based genetic testing or biomarker testing for the purposes of colorectal cancer routine screening is considered experimental. (However, testing and monitoring related to the diagnosis of colon cancer may be considered medically necessary as per MCG or NCCN, but is considered outside the scope of this Colorectal Cancer Screening guideline).
Experimental routine *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

- ColoSense™ (multitarget stool RNA (mt-sRNA) test)
- Guardant Health's Shield™ Blood Test
- Methylated Septin 9 (ColoVantage, EpiproColon)
- MicroRNA Detection in serum or stool
- Screening Upper Endoscopy
- Chromoendoscopy or Narrow-Band Imaging Optical Colonoscopy
- Other Stool DNA Tests (PreGen-26, PreGen-Plus, ColoSure)
- Serum-based screening test

Applicable Billing Codes (HCPCS & CPT Codes)

CPT Codes considered medically necessary if clinical criteria are met:

Table 1
CPT/HCPCS Codes considered medically necessary if criteria are met (*a screening colonoscopy or sigmoidoscopy may turn into a diagnostic or therapeutic procedure due to findings during the procedure and should be billed with the appropriate diagnosis codes or modifiers*):

Code	*Description*
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
44389	Colonoscopy through stoma; with biopsy, single or multiple
44390	Colonoscopy through stoma; with removal of foreign body(s)
44391	Colonoscopy through stoma; with control of bleeding, any method
44392	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre-and post-dilation and guide wire passage, when performed)
44403	Colonoscopy through stoma; with endoscopic mucosal resection
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance

45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple
45332	Sigmoidoscopy, flexible; with removal of foreign body(s)
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
45334	Sigmoidoscopy, flexible; with control of bleeding, any method
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
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s)
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)
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45379	Colonoscopy, flexible; with removal of foreign body(s)
45380	Colonoscopy, flexible; with biopsy, single or multiple
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance
45382	Colonoscopy, flexible; with control of bleeding, any method
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)
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
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)
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
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
G0328	Colorectal cancer screening; fecal occult blood test, immunoassay, one to three simultaneous determinations
S0285	Colonoscopy consultation performed prior to a screening colonoscopy procedure
ICD-10 codes considered medically necessary if criteria are met:	
C18.0-C18.9	Malignant neoplasm of colon
C19	Malignant neoplasm of rectosigmoid junction

C20	Malignant neoplasm of rectum
C21.0 - C21.8	Malignant neoplasm of 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 - K51.919	Ulcerative colitis
K52.0 - K52.9	Other and unspecified noninfective gastroenteritis and colitis
K55.011 - K55.9	Vascular disorders of intestine
K57.20 - K57.21	Diverticular disease of large intestine with perforation and abscess
K57.30 - K57.33	Diverticular disease of large intestine without perforation or abscess
K57.40 - K57.41	Diverticulitis of both small and large intestine with perforation and abscess
K57.50 - K57.53	Diverticulitis of both small and large intestine without perforation or abscess
K57.80 - K57.81	Diverticulitis of intestine, part unspecified, with perforation and abscess
K57.90 - K57.93	Diverticulitis of intestine, part unspecified, without perforation or abscess
K63.5	Polyp of colon
Z12.10	Encounter for screening for malignant neoplasm of intestinal tract, unspecified
Z12.11	Encounter for screening for malignant neoplasm of colon
Z12.12	Encounter for screening for malignant neoplasm of 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
Z83.79	Family history of other diseases of the digestive system
Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum

Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus
Z86.010	Personal history of colonic polyps

Table 2 CPT/HCPCS codes considered experimental or investigational:	
Code	*Description*
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
0229U	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis (Colvera®, Clinical Genomics Pathology Inc)
0368U	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer [Includes ColoScape™ Colorectal Cancer Detection, DiaCarta Clinical Lab, DiaCarta, Inc]
0421U	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk
0651T	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report.

44799	Unlisted procedure, small intestine ● Due to the broad nature of this code, specific exclusions are indicated: ● When this code is billed for chromoendoscopy or narrow-band imaging optical colonoscopy, it is considered experimental or investigational
45399	Unlisted procedure, colon ● Due to the broad nature of this code, specific exclusions are indicated: ● When this code is billed for chromoendoscopy or narrow-band imaging optical colonoscopy, it is considered experimental or investigational
45999	Unlisted procedure, rectum ● Due to the broad nature of this code, specific exclusions are indicated: ● When this code is billed for chromoendoscopy or narrow-band imaging optical colonoscopy, it is considered experimental or investigational
81327	SEPT9 (Septin9) (eg, colorectal cancer) promoter 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
88271	Molecular cytogenetics; DNA probe, each (e.g., 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
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

G0327	Colorectal cancer screening; blood-based biomarker

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