Colorectal Cancer Screening

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary colorectal cancer screening.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Average-Risk Population – Patient population defined as having no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease (Crohn's disease and Ulcerative Colitis); no family history of colorectal cancer or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer.

High-Risk Population – Patient population defined as having a first-degree relative (sibling, parent, or child) who has had colorectal cancer or adenomatous polyps; family history of familial adenomatous polyposis; family history of hereditary nonpolyposis colorectal cancer; family history of MYH-associated polyposis in siblings; and diagnosis of Cowden syndrome.

PROCEDURES

A prior authorization may be required.

Highmark Health Options considers preventive colorectal cancer screening tests medically necessary for average-risk patients aged 45 years and continuing until age 85* when recommended by a physician.

The following preventive routine colon cancer screening tests are covered:

- Fecal Occult Blood Test (FOBT) using guaiac-based FOBT (gFOBT)or immunochemical-based FOBT (iFOBT) – annually
- Double contrast barium enema (DCBE) - every 5 years
- Anal PAP Smear - annually
- Flexible sigmoidoscopy – one every 5 years
- *Colonoscopy – one every 10 years
- Computed tomography colonography (CTC) – every 5 years
- Fecal DNA (Cologuard) (FIT-DNA)

  Fecal DNA testing using Cologuard is a covered service once every three years for patients who meet all the following criteria:

  - Age 50-75; AND
  - Patients who show no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive fecal occult blood test (FOBT) or fecal immunochemical testing (iFOBT); AND
  - No prior history of abnormal fecal DNA testing
  - Specific for patients who are at average risk for developing colorectal cancer:
    - No personal history of adenomatous polyps colorectal cancer or inflammatory bowel disease (Ulcerative Colitis and Crohn's disease)
    - No family history of colorectal cancer or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer

Note: when a screening test results in the diagnosis of colorectal adenomas or cancer, screening guidelines are no longer applicable.

* Screening and surveillance for colon cancer in adults aged 76–85 years should be advised with consideration of the patient's overall health and prior screening history.

Contraindications

Relative contraindications for colon cancer screening by colonoscopy may include:

- Toxic megacolon
- Suspected peritonitis or intestinal perforation or intestinal adhesions
- Severe cardiovascular disease
- Pregnancy
- Severe psychiatric disorders
- Known or suspected colonic perforation
- Fulminant colitis or severe inflammatory bowel disease with ulceration
- Patients on chronic anticoagulation
- Severe chronic lung disease patient who are at risk for undergoing sedation

Contraindications for Cologuard per the website include:

- Patients with a history of colorectal cancer, adenomas, or other related cancers
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months
- Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome such as Hereditary Non-polyposis Colorectal Cancer syndrome, Peutz-Jeghers syndrome, MYH-Associated Polyposis, Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, Familial Hyperplastic Polyposis
- Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
  - Inflammatory bowel Disease (IBD) Chronic Ulcerative Colitis (CUC)
  - Crohn's disease
  - Familial adenomatous polyposis (FAP)
  - Family history of colorectal cancer

Noncovered colorectal cancer screening tests

- Magnetic resonance imaging (MRI) colonography
- Wireless capsule endoscopy

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service: Outpatient

GOVERNING BODIES APPROVAL

On August 24, 2014, Exact Sciences received FDA premarket approval for its latest automated fecal DNA product, Cologuard (P130017).

CODING REQUIREMENTS

Screening codes

CPT code	Description
45378 (E)	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).
74263 (F)	Computed tomographic (CT) colonography, screening, including image post-processing.
74280 (B)	Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high density barium and air) study, including glucagon, when administered.
81528 (G)	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 (A)	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided 3 cards or single triple card for consecutive collection).
82272 (A)	Blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces, 1-3 simultaneous determinations, performed for other than colorectal neoplasm screening.
82274 (A)	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations.
88160 (C)	Cytopathology, smears, any other source; screening and interpretation.
G0104 (D)	Colorectal cancer screening; flexible sigmoidoscopy.
G0105 (E)	Colorectal cancer screening; colonoscopy on individual at high risk.
G0106 (B)	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema.
G0120 (B)	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema.
G0121 (E)	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.
G0122 (B)	Colorectal cancer screening; barium enema.
G0328 (A)	Colorectal cancer screening; fecal occult blood test, immunoassay, one to three simultaneous determinations.

Modifiers

Modifier	Description
-PT	Colorectal cancer screening test; converted to diagnostic test or other procedure.
-33	When the primary purpose of the service is the delivery of an evidence-based service in accordance with a US Preventive Services Task Force A or B rating in effect and other preventive services identified in preventive services mandates (legislative or regulatory), the service may be identified by adding 33 to the procedure. For separately reported services specifically identified as preventive, the modifier should not be used.

Diagnostic Codes

44388-44408 (E)
45330-45350 (D)
45378-45398 (E)
Z12.11
Z12.12
Z80.0
Z83.71
Z86.010
Z85.030
Z85.038
Z85.040
Z85.048

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Colorectal cancer (CRC) is the term used to describe cancer that develops in the colon or rectum. Colorectal cancer is the third most common cancer diagnosed in both men and women in the United States. The American Cancer Society estimates the number of colorectal cancer cases in the United States in 2017 will be:

- 95,520 new cases of colon cancer
- 39,910 new cases of rectal cancer

The five-year survival rate of CRC when detected in the early stages is 92%, however, the five-year survival rate is decreased to 11% in patients diagnosed after the cancer has metastasized. Nearly 90% of CRC cases are found in persons aged 50 and older.

Colorectal cancer screening can detect cancer, precancerous polyps, and other colon abnormalities. Polyps are believed to develop into cancer over an extended period of time. With colorectal cancer screening, these polyps can be removed before the polyps can develop into cancer.

There are multiple sources such as the U.S. Preventive Services Task Force (USPSTF), American Cancer Society, American College of Physicians, American College of Gastroenterology, and the National Comprehensive Cancer Network that recommend colorectal cancer screening at age 50 for men and women at average risk for colorectal cancer because this age group can have a higher incidence of colon cancer. However, these organizations may differ with regard to frequency of screening and age at which to discontinue screening, as well as the preferred method of screening. In October 2008, the USPSTF revised colorectal cancer screening recommendations to be performed at 50 years of age and continuing until age 75.

The USPSTF (2016) stated that multi-targeted stool DNA testing (FIT-DNA) is an emerging screening strategy that combines FIT (fecal immunochemical test) with testing for altered DNA biomarkers in cells shed into the stool. This test has increased single-test sensitivity for detecting colorectal cancer compared to FIT alone. The harms of stool-based testing result from adverse events associated with follow-up colonoscopy of positive findings. The specificity of FIT-DNA is lower than FIT alone, which may result in a higher number of false-positives and higher likelihood of follow-up colonoscopy.

The USPSTF (2019) is currently seeking public comment on the draft research plan for colorectal cancer screening. A review of the draft plan indicates that the proposed age for screening for adults has been lower to age 40 and older. Screening methods include:

- Direct visualization tests consisting of colonoscopy, flexible sigmoidoscopy, computed tomography colonography, and capsule endoscopy.
- Stool-based tests: guaiac-based fecal occult blood test, fecal immunochemical test, fecal immunochemical test plus stool DNA test.
- Blood-based test: methylated septin 9 gene DNA test (mSEPT9).

The American College of Gastroenterology (ACG) has recommended specific guidelines for colorectal cancer screening as follow:

- Tests that prevent cancer are preferred over those that only detect cancer;
- The preferred colorectal cancer prevention test is colonoscopy every 10 years beginning at age 50 but at age 45 in African Americans;

- For patients who decline colonoscopy or another cancer prevention test, the preferred cancer test is FIT to be conducted annually;
- Alternative cancer detection tests include annual Hemoccult Sensa® and fecal DNA testing every 3 years.

At this time there is no change in the criteria listed above. The ACG is currently reviewing the existing colorectal cancer screening guidelines.

The American Cancer Society (2018) recommends that people at increased or high risk of colorectal cancer might need to start colorectal cancer screening before age 45, be screened more often, and/or get specific tests. This includes people with:

- A strong family history of colorectal cancer or certain types of polyps (see Colorectal Cancer Risk Factors)
- A personal history of colorectal cancer or certain types of polyps
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A known family history of hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or Lunch syndrome (also known as hereditary non-polyposis colon cancer or HNPCC)
- A personal history of radiation to the abdomen (belly) or pelvic area to treat a prior cancer

The National Comprehensive Cancer Network Version 1.2018 (2018) colorectal cancer screening recommendations for the average risk individual are as follows:

- Age ≥ 50
- The decision to screen between the ages of 76-85 years of age should be individualized and include a discussion of the risks and benefits based on comorbidity status and estimated life expectancy.
- No history of adenoma or sessile serrated polyp or colorectal cancer
- No history of inflammatory bowel disease
- Negative family history for colorectal cancer or confirmed advanced adenoma (i.e., high-grade dysplasia, ≥ 1 cm, villous or tubulovillous histology)

The screening modalities for colorectal cancer include:

- Colonoscopy every 10 years: OR
- Stool based testing (high-sensitivity guaiac-based or immunochemical-based testing and fecal immunochemical-DNA based testing). The interval for screening is uncertain, however, every 3 years is suggested: OR
- Flexible sigmoidoscopy every 5-10 years: OR
- CT colonography every 5 years

References

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POLICY UPDATE HISTORY

08/19/2021	Approved in Medical Policy Committee.
01/24/2022	Annual review.