Highmark Delaware Health Options

CLINICAL MEDICAL POLICY	
Policy Name:	Colorectal Cancer Screening
Policy Number:	MP-059-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	04/01/2019; 07/15/2018; 10/01/2017
Issue Date:	05/06/2019; 08/15/2018
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Annual Approval Date:	03/12/2020
Revision Date:	03/12/2019; 06/19/2018
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 8

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 procedures.

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

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 non-polyposis colorectal cancer; family history of MYH-associated polyposis in siblings; and diagnosis of Cowden syndrome.

PROCEDURES

Highmark Health Options considers preventive colorectal cancer screening tests medically necessary for average-risk patients aged 40 years and continuing until age 85* when recommended by a physician.

1. The following preventive routine colon cancer screening tests are covered:
   - A. Fecal Occult Blood Test (FOBT) using guaiac-based FOBT (gFOBT)or immunochemical-based FOBT (iFOBT) – annually
   - B. Double contrast barium enema (DCBE) - every 5 years
   - C. Anal PAP Smear - annually
   - D. Flexible sigmoidoscopy – one every 5 years
   - E. *Colonoscopy – one every 10 years
   - F. Computed tomography colonography (CTC) – every 5 years
   - G. 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:
     1) Age 50-75; AND
     2) 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
     3) No prior history of abnormal fecal DNA testing
     4) Specific for patients who are at average risk for developing colorectal cancer:
        - a. No personal history of adenomatous polyps colorectal cancer or inflammatory bowel disease (Ulcerative Colitis and Crohn's disease)
        - b. 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 to 85 years should be advised with consideration of the patient's overall health and prior screening history.

2. Contraindications
   Relative contraindications for colon cancer screening by colonoscopy may include:
   - Suspected peritonitis or intestinal perforation or intestinal adhesions

- Toxic megacolon
- 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 patients 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

3. Non-covered colorectal cancer screening tests
   A. Magnetic resonance imaging (MRI) colonography
   B. Wireless capsule endoscopy (see medical policy MP-038-MD-DE)

   These services are considered not medically necessary.

4. 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.

5. Place of Service

   The place of service for all colorectal cancer screening methods is 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

Procedure Codes

CPT Codes	Description
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s)by brushing or washing, when performed (separate procedure)

44389	Colonoscopy through stoma; diagnostic, including collection of specimen(s) with biopsy, single or multiple, when performed (separate procedure)
44392	Colonoscopy through stoma; diagnostic, with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
44394	Colonoscopy through stoma; diagnostic, with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45330	Sigmoidoscopy, flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyps(s), or other lesion(s) by hot biopsy forceps or bipolar cautery
45334	Sigmoidoscopy, flexible; with control of bleeding (e.g., injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)
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, proximal to splenic flexure; diagnostic, with or without collection of specimen(s) by brushing or washing, with or without colon decompression (separate procedure)
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple
45381	Colonoscopy, flexible, with directed submucosal injection(s), any substance
45382	Colonoscopy, flexible, proximal to splenic flexure; with control of bleeding (e.g., injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)
45384	Colonoscopy, flexible, proximal to splenic flexure; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery
45385	Colonoscopy, flexible, proximal to splenic flexure; 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 post processing (virtual colonoscopy)
81528	Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 NA 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 (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
82274	Blood, occult, by fecal hemoglobin determination by immunoassay, qualitative, feces, 1-3 simultaneous determinations
HCPCS Codes	**Description**
G0104	Colorectal cancer screening; flexible sigmoidoscopy
G0105	Colorectal cancer screening; colonoscopy on individual at 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, 1-3 simultaneous determinations

Diagnosis Codes

ICD-10 Codes	Description
Z00.00	Encounter for general adult medical examination without abnormal findings
Z00.01	Encounter for general adult medical examination with abnormal findings
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
Z80.0	Family history of malignant neoplasm of digestive organs
Z83.71	Family history of colonic polyps
Z85.00	Personal history of malignant neoplasm of unspecified digestive organs
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.020	Personal history of malignant carcinoid tumor of stomach
Z85.028	Personal history of other malignant neoplasm of stomach
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
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx
Z85.819	Personal history of malignant neoplasm of unspecified site of lip, oral cavity, and pharynx
Z86.010	Personal history of colonic polyps

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 source 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 a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or Lynch 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

POLICY SOURCE(S)

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS # 11 2011-017, Date 11/18/2011. Option #3. Accessed on May 5, 2017.

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: Cologuard test Technology Assessment Group meeting; Option #2. Accessed on January 18, 2019.

American Cancer Society. About colorectal cancer. Research and Statistics. Accessed on May 8, 2017.

United States Preventive Services Task Force (USPSTF). Screening for colorectal cancer: U.S. preventive services task force recommendation statement. Agency for Healthcare Research and Quality. NGC: 011005; 2016, June 21. Accessed on May 8, 2017.

United States Preventive Services Task Force (USPSTF). Draft research plan for colorectal cancer: screening. The draft plan has not been finalized at the time of the policy development. Public comment time frame expires on January 30, 2019. Accessed on January 18, 2019.

Stein DE, Geibel J. Colonoscopy. Medscape: Drugs & Disease, Clinical Procedures. Updated March 13, 2016. Accessed on May 9, 2017.

Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM, et al. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. Am J Gastroenterol. 2009 March. 104(3): 739-50. Accessed on May 9, 2017.

Agency for Healthcare Research and Quality (AHRQ): Appropriateness Criteria® colorectal cancer screening. Guideline Summary. NGC: 010144 1998 (Revised 2013). Accessed on May 9, 2017.

Exact Sciences Corporation. Cologuard. Accessed on May 9, 2017.

Agrawal S, Bhupinderjit A, Bhutani MS, et al. Colorectal cancer in African Americans Colorectal Cancer. Am J Gastroenterol. 2005'100(3): 515-523. Accessed on May 9, 2017.

American Cancer Society (ACS). Guideline for colorectal cancer screening: for people at average risk. Last reviewed May 30, 2018. Accessed on January 17, 2019.

National Comprehensive Cancer Network (NCCN). Colorectal cancer screening, Version 1.2018.

Policy History

Date	Activity
07/03/2017	Initial policy developed
09/27/2017	QI/UM Committee approval
10/09/2017	Correction of ICD-10 code typo: A85.819 corrected to Z85.819 & corrected description
10/20/2017	Under Operational Guidelines the policy has been revised from preservice to postservice application.
11/01/2017	Provider effective date
06/19/2018	Revision: Removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C; The medical policy has been revised changing the application of the policy from prepayment to post-payment.
06/19/2018	QI/UM Committee Review Approval
08/15/2018	New Provider Effective Date
03/12/2019	Annual Review: added for average risk individuals, colorectal cancer screening is covered starting at age 40 instead of age 50 and removed the African American notation indicating age 45; two notes added at the end of the Procedure section to provide specific direction; deleted typographical error under Procedure 1.G; Updated Operational Guidelines regarding eligible ages; revised procedures with the addition of 44388, 44389, 44392, 44394, G0122; corrected code description for G0106; updated the Summary of Literature; updated Reference section and removed hyperlinks.
03/12/2019	QI/UM Committee Review Approval
03/06/2019	Provider effective date