

MEDICARE: MEDICAL POLICY STATEMENT			
Original Effective Date	Next Annual Review Date		Last Review / Revision Date
02/23/2016	02/23/2017		02/23/2016
Policy Name		Policy Number	
Screening and Surveillance for Colorectal Cancer		MM-0039	
Policy Type			
	☐ Administrative		☐ Payment

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A. SUBJECT

Screening and Surveillance for Colorectal Cancer

B. DEFINITIONS

- **Colonoscopy:** an endoscopic procedure allowing direct inspection of the lining of the entire colon with biopsy sampling and/or removal of polyps or early stage cancers
- CT Colonography: also known as "virtual colonoscopy" is a minimally invasive imaging technique utilizing advanced computed tomography (CT) to produce 2 and 3 dimensional images of the colon and rectum to identify early cancerous and precancerous lesions..
- **Double Contrast Barium Enema (DCBE):** also called "air contrast barium enema" during which air and liquid contrast are inserted into the colon and x-rays are taken.
- **Fecal DNA Testing:** a stool test that measures abnormal sections of DNA (mutations) from cancer or polyp cells.
- Fecal Immunochemical Testing: (FIT or iFOBT): a home screening test, unaffected by food or medicine that utilize a chemical reaction with hemoglobin to detect human blood from the lower intestine.
- Fecal Occult Blood Testing (FOBT): a home screening test that detects hidden blood arising from anywhere in the digestive tract in the stool through a chemical reaction
- Flexible Sigmoidoscopy; an endoscopic examination of the lower half of the colon
- Monitoring Colonoscopy: the evaluation of individuals after diagnosis or treatment for CTC.
- Screening Colonoscopy: the evaluation for CRC in individuals without symptoms.



- Stool DNA (Cologuard): a home screening test utilizing an algorithmic analysis of stool DNA amplified by polymerase chain reaction (PCR) in combination with a fecal immunochemical test (FIT) test.
- **Surveillance Colonoscopy**: periodic colonoscopy on an individual with a prior history of adenoma(s) or CRC to remove polyps (missed previously or which have developed since prior examination)

C. Background

Of malignancies affecting both men and women in the US colorectal carcinoma (CRC) is the 3rd most common resulting in over 50,000 deaths annually and rising to the 2nd leading cause of cancer deaths overall.

Uncommon before the age of 40 the incidence rises successively especially after the age of 50. Over the past two decades there has been a gradual decline in the incidence of CRC likely as a result of increased screening promoting identification and removal of early-stage cancer and adenomatous polyps.

There evidence is convincing that appropriate screening reduces colorectal cancer mortality in adults 50-75 years of age. Screening strategies have centered on the use of endoscopic exams (colonoscopy and flexible sigmoidoscopy), radiologic imaging (double contrast barium enema (DCBE), and computed tomography (CT Colonography) scanning and stool tests (fecal occult blood testing (FOBT) and Fecal Immunochemical Testing (FIT)); or abnormal DNA constituents (Fecal DNA). Positive screening by stool testing, radiographic tests and sigmoidoscopy is following by colonoscopy.

Various expert medical and scientific panels have established clinical guidelines which support screening colonoscopy based on patient age and risk stratification, separating individuals of "average" risk from those at "increased or high" risk. The USPSF has specifically been tasked with determining the effectiveness and value for preventative and screening tests made available through the Affordable Care Act (effective September 2010).

A screening colonoscopy is generally recommended every 10 years for asymptomatic patients between the age of 50-75 having no history of colon cancer, polyps, or other gastrointestinal disease. Based on the recommendation of the USPSTF when screening test result in the diagnosis of clinically significant colorectal adenomas or cancer, the patient should be "followed by a surveillance regimen and recommendations for screening are no longer applicable."

D. POLICY:

 CareSource will cover as medically necessary preventive the following (A-D) screening tests for members at average risk for CRC between 50-75 years of age (ending at 76th birthday).

A. Screening Colonoscopy:

- 1. Once every 120 months OR
- 2. 48 months after a previous flexible sigmoidoscopy

B. Flexible sigmoidoscopy:

- Once every 48 months after the last flexible sigmoidoscopy or barium enema;
 OR
- 2. 120 months after a previous screening colonoscopy

C. ACBE:

Once every 48 months when used instead of sigmoidoscopy or colonoscopy



D. FOBT or FIT:

1. Once every 12 months

II. Multi-targeted stool DNA test (Cologuard):

- A. CareSource will cover as medically necessary once every 3 years for members meeting **ALL** of the following:
 - 1. Age 50-85
 - 2. Average risk for developing colorectal cancer (i.e.no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis)
 - 3. Absence of positive family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer
 - Absence of signs or symptoms of colorectal disease including, but not limited to, lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test, or fecal immunochemical test

III. Screening for CRC in members at high risk defined as ONE of the following:

- A. A first degree relative (sibling, parent or child) who has had colorectal cancer or an adenomatous polyp
- B. A family history of familial adenomatous polyposis
- C. Inherited risk through a family history of hereditary nonpolyposis colorectal cancer (HNPCC) or familial adenomatous polyposis (FAP)
- D. A personal history of adenomatous polyps
- E. A personal history of colorectal cancer
- F. A personal history of inflammatory bowel disease including Crohn's disease or ulcerative colitis
 - 1. CareSource will cover as medically necessary preventative:
 - a. Screening Colonoscopy every 24 months
 - b. Screening ACBE every 24 months (as an alternative to sigmoidoscopy or colonoscopy).

IV. CT Colonography:

A. CareSource considers the use of CT Colonography for screening purpose of CRC to be unproven for improving health outcomes and not medically necessary.

V. Other Stool DNA Tests:

A. CareSource considers **ALL** other screening stool DNA tests other than Cologuard as unproven for improving health outcomes and not medically necessary.

No prior authorization is required for participating providers.

For Medicare Plan members, reference the Applicable National Coverage Determinations (NCD) and Local Coverage Determinations (LCD). Compliance with NCDs and LCDs is required where applicable.

CONDITIONS OF COVERAGE HCPCS CPT

AUTHORIZATION PERIOD



E. RELATED POLICIES/RULES

F. REVIEW/REVISION HISTORY

Date Issued: 02/23/2016 Date Reviewed: 02/23/2016

Date Revised:

G. REFERENCES

- 1. Center for Disease Control and Prevention: http://www.cdc.gov/cancer/colorectal/statistics/
- 2. US Preventative Services Task Force: http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFi nal/colorectal-cancer-screening
- 3. American Cancer Society: Colorectal Cancer Prevention and Early Detection:

 http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancer-early-detection-acs-recommendations
- 4. OAC 5160-4-34, Preventive Medicine Services: https://www.medicare.gov/publications/pubs/pdf/10110.pdf
- 5. 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; CA Cancer J Clin 2008:58:130–160
- U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Stool DNA-based colorectal cancer screening test. Cologuard (Exact Sciences Corp., Madison, WI). Summary of Safety and Effectiveness. No. P130017. 2014b. http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017b.pdf.
- 7. Hayes Technology Report: Computed Tomography Colonography (Virtual Colonoscopy); Published 3/13/2008

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent Medical Review - 2/2016 AllMed