

MEDICAL POLICY STATEMENT OHIO MEDICARE

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Policy Name		Policy Number
Screening and Surveillance for Colorectal Cancer		MM-0039
Policy Type		
MEDICAL	Administrative	Pharmacy
		Reimbursement

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A. SUBJECT

Screening and Surveillance for Colorectal Cancer

B. 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.

The evidence is convincing that appropriate screening reduces colorectal cancer mortality in adults 50-75 years of age. The benefit of early detection of and intervention for colorectal cancer declines after 75 years of age. African Americans have been shown to have higher CRC rates of incidence and it is recommended by both the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy that CRC screening begin at 45 years of age.

Screening strategies have centered on the use of endoscopic exams (colonoscopy and flexible sigmoidoscopy), radiologic imaging scanning (double contrast barium enema (DCBE), and computed tomography (CT Colonography) 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 are followed by colonoscopy.

Over the past decade the relative utility of screening techniques has demonstrated a trend toward declining rates of flexible sigmoidoscopy and double contrast barium enema. Rates of colonoscopy have increased during this time frame while the use of stool blood tests have remained relatively constant.

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. While clinical evidence demonstrates the effectiveness of multiple screening tests, it does not establish the superiority of one screening modality over another as illustrated in the information provided below.

American College of Physicians

The American College of Physicians (ACP) recommends that clinicians screen for colorectal cancer in average-risk adults starting at the age of 50 years and in high-risk adults starting at the age of 40 years or 10 years younger than the age at which the youngest affected relative was diagnosed with colorectal cancer.

ACP recommends using a stool-based test, flexible sigmoidoscopy, or optical colonoscopy as a screening test in patients who are at average risk. ACP recommends using optical colonoscopy as a screening test in patients who are at high risk. Clinicians should select the test based on the benefits and harms of the screening test, availability of the screening test, and patient preferences.

American College of Gastroenterology (ACG)

The American College of Gastroenterology (ACG) recommends a colonoscopy be performed every 10 years beginning at age 50 in average risk individuals, (beginning at 45 years of age for African Americans) colonoscopy remains the preferred colorectal carcinoma screening strategy.



For patients that are either unwilling to undergo a colonoscopy or do not have the financial means to do so, alternative prevention tests are recommended, including: flexible sigmoidoscopy every 5-10 years, or a computed tomography (CT) Colonography every 5 years or a cancer detection test (fecal immunochemical test for blood, FIT).

The recommendation for screening when family history is positive for single first-degree relative with CRC or advanced adenoma diagnosed at age greater than 60 years of age is consistent with individuals at average risk. Individuals with single first-degree with CRC or advanced adenoma diagnosed less than 60 years of age should begin screening colonoscopy every 5 years at age 40 or 10 years younger than age at diagnosis of the youngest affected relative.

American Cancer Society (ACS)

The American Cancer Society (ACS) recommends men and women be screened for colorectal cancer beginning at age 50 with one of the following tests:

- Colonoscopy every 10 years
- CT Colonography every 5 years
- Flexible sigmoidoscopy every 5 years
- Double-contrast barium enema every 5 years

The ACS recommends men and women at an increased or high risk for colorectal cancer start screening before the age of 50. The ACS recognizes the following conditions as high risk factors:

- A personal history of colorectal cancer or adenomatous polyps
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)
- A strong family history of colorectal cancer or polyps
- A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or Lynch syndrome (hereditary non-polyposis colon cancer or HNPCC)

United States Preventive Services Task Force (USPSTF)

Importantly the US Preventive Services Task Force (USPSTF) has been tasked with determining the effectiveness and value for preventative and screening tests made available through the Affordable Care Act (effective September 2010). Recommendations of the USPSTF with an "A" or "B" rating must be covered. Currently the USPSTF recommends screening for colorectal cancer (CRC) beginning at age 50 years and continuing until age 75 years. They note further that risks and benefits of different screening methods vary.

A screening colonoscopy is generally recommended every 10 years for asymptomatic patients having no history of colon cancer, polyps, or other gastrointestinal disease. Based on the recommendation of the USPSTF when screening tests 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."

C. 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
- **Colon Polyp:** a neoplastic (e.g. adenoma) or non-neoplastic (e.g. inflammatory or hyperplastic) protuberance rising above the mucosa into the lumen of the colon
- **CT Colonography:** also known as "virtual colonoscopy" utilizing advanced computed tomography (CT) to produce 2 and 3 dimensional images of the colon and rectum
- **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 medicines that utilizes 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 CRC
- **Multi-Targeted 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
- **Screening Colonoscopy:** the evaluation for CRC in individuals without symptom
- **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)

D. POLICY

- I. CareSource will cover, as medically necessary, screening tests for members considered at average risk for CRC, which is defined as:
 - A. Members 50-75 years of age (screening for African Americans will begin at age 45)
 - B. Members that are asymptomatic and without any of the following:
 1. A family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer (such as Lynch syndrome or familial adenomatous polyposis)
 2. A personal history of inflammatory bowel disease
 3. A previous adenomatous polyp, or
 4. A previous history of colorectal cancer
- II. The following preventive screening tests will be covered:
 - A. Screening Colonoscopy every 10 years
 - B. Flexible sigmoidoscopy every 5 years in combination with FOBT or FIT every 3 years
 - C. DCBE every 5 years
 - D. FOBT or FIT yearly
 - E. CT Colonography every 5 years (CT Colonography is not recommended for high risk patients)
 - F. Multi-targeted Stool DNA (Cologuard) every 3 years
- III. CareSource will cover, as medically necessary, screening tests for members considered at high risk for CRC, which is defined as members with:
 - A. A personal history of CRC or adenomatous polyp
 - B. A predisposition to CRC caused by a genetic syndrome (ie, hereditary nonpolyposis colorectal cancer [HNPCC], familial adenomatous polyposis [FAP])
 - C. One first-degree relative with CRC or advanced adenoma diagnosed at age <60 years
 - D. Two or more first-degree relatives with CRC or advanced adenoma at any age
 - E. A personal history of Inflammatory bowel disease resulting in pancolitis or long-established (>8 to 10 years) active disease
 - F. A personal history of childhood cancer requiring abdominal radiation therapy
 - G. First degree relative (sibling, parent, child) who has had colorectal ca or adenomatous polyps (screening is considered medically necessary beginning at age 40 years, or 10 years younger than the earliest diagnosis in their family --whichever is first)



IV. The following screening tests will be covered for high risk members as frequently as every 2 years:

- A. DCBE
- B. Sigmoidoscopy
- C. Colonoscopy

V. Surveillance

Individuals with adenomatous polyps or CRC require surveillance following removal and/or resection. The USPSTF does not address evidence for the effectiveness of any particular regimen and professional societies continue to vary considerably on surveillance guidelines. The risk and prognosis following resection for CRC is individualized and depends on a variety of factors, including, but not limited to: histology and stage of malignancy. The preferred method and frequency of surveillance should be guided by the risk of reoccurrence and the status of the patient. More frequent testing is advised for patients at higher risk for reoccurrence of CRC.

E. CONDITIONS OF COVERAGE

HCPCS
CPT

AUTHORIZATION PERIOD

F. RELATED POLICIES/RULES

Screening and Surveillance for Colorectal Cancer, PY-0064 (Medicare)

G. REVIEW/REVISION HISTORY

DATES		ACTION
Date Issued	10/4/2016	New Policy.
Date Revised	11/01/2017	Separate policy by State/market.
Date Effective	03/01/2018	

H. REFERENCES

1. Center for Disease Control and Prevention: <http://www.cdc.gov/cancer/colorectal/statistics/>
2. American Cancer Society: Colorectal Cancer Prevention and Early Detection <http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancer/earlydetection/colorectal-cancer-early-detection-ac-s-recommendations>
3. Meissner HI, Breen N, Klabunde CN, Vernon SW. Patterns of colorectal cancer screening uptake among men and women in the United States. *Cancer Epidemiol Biomarkers Prev* 2006;15:389–394.
4. Hayes GTE Report: Cologuard; Published 10/16/2014.
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
6. *Final Recommendation Statement: Colorectal Cancer: Screening*. U.S. Preventive Services Task Force. June 2017. <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/colorectal-cancer-screening2>
7. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010)
8. National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3). (n.d.). Retrieved October 03, 2017, from <https://www.cms.gov/medicare-coverage->



- [database/\(S\(v0cxhe45alguxjupvix24zai\)\)/details/ncd-io-details.aspx?NCDId=281&ncdver=5&CALId=97&ver=5&CalName=Prothrombin%2BTime%2BAnd%2BFecal%2BOccult%2BBlood%2B%28Revision%2Bof%2BICD-9-CM%2BCodes%2Bfor%2BInjury%2Bto%2BGastrointestinal%2BTract%29&bc=gAgAAAAAgAIAAA%3D%3D&](https://www.cms.gov/medicare-coverage-database/details/ncd-io-details.aspx?NCDId=281&ncdver=5&CALId=97&ver=5&CalName=Prothrombin%2BTime%2BAnd%2BFecal%2BOccult%2BBlood%2B%28Revision%2Bof%2BICD-9-CM%2BCodes%2Bfor%2BInjury%2Bto%2BGastrointestinal%2BTract%29&bc=gAgAAAAAgAIAAA%3D%3D&)
9. Qaseem, A., Denberg, T. D., Hopkins, R. H., Humphrey, L. L., Levine, J., Sweet, D. E., & Shekelle, P. (2012, March 06). Screening for Colorectal Cancer: A Guidance Statement From the American College of Physicians. Retrieved October 06, 2017, from <http://annals.org/aim/article/1090701/screening-colorectal-cancer-guidance-statement-from-american-college-physicians>
 10. Colorectal Cancer Screening. (n.d.). Retrieved October 06, 2017, from <https://gi.org/guideline/colorectal-cancer-screening/>
 11. (n.d.). Retrieved October 10, 2017, from [https://www.uptodate.com/contents/screening-for-colorectal-cancer-strategies-in-patients-at-average-risk?source=search_result&search=colorectal screening&selectedTitle=1~150#H27](https://www.uptodate.com/contents/screening-for-colorectal-cancer-strategies-in-patients-at-average-risk?source=search_result&search=colorectal%20screening&selectedTitle=1~150#H27)
 12. (n.d.). Retrieved October 10, 2017, from https://www.uptodate.com/contents/colorectal-cancer-epidemiology-risk-factors-and-protective-factors?source=see_link
 13. (n.d.). Retrieved October 16, 2017, from [https://www.uptodate.com/contents/overview-of-computed-tomographic-colonography?source=search_result&search=overview of computed tomographic colonography&selectedTitle=1~150](https://www.uptodate.com/contents/overview-of-computed-tomographic-colonography?source=search_result&search=overview%20of%20computed%20tomographic%20colonography&selectedTitle=1~150)
 14. (n.d.). Retrieved October 16, 2017, from [https://www.uptodate.com/contents/surveillance-after-colorectal-cancer-resection?source=search_result&search=surveillance colonoscopy&selectedTitle=2~150](https://www.uptodate.com/contents/surveillance-after-colorectal-cancer-resection?source=search_result&search=surveillance%20colonoscopy&selectedTitle=2~150)
 15. Retrieved September 20, 2016, from <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM9115.pdf>
 16. National Coverage Determination (NCD) for Colorectal Cancer Screening Tests (210.3). (n.d.). Retrieved September 28, 2017, from <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?CALId=171&CalName=Coding%2BGuidelines%2Bfor%2BUrine%2BCulture&ExpandComments=n&CommentPeriod=0&NCDId=281&ncdver=1&bc=gAQAAAAAQEAAA%3D%3D&>

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.

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