

Colorectal Cancer Screening Fact Sheet

Patients age 50 or older should be screened for colorectal cancer

- Colorectal cancer (CRC) is the 2nd leading cause of cancer death in the U.S., with over 140,000 expected to be diagnosed with CRC in 2018. More than 50,000 people in the U.S. die annually of CRC.¹
- CRC screening is generally recommended for all average-risk patients aged 50-75, with individualized plans made for patients aged 76-85 based on the patient's overall health and prior screening history.²
- People who have a family member with colorectal cancer or polyps are at increased risk and might need to start colorectal cancer screening before age 50.³
- The American Cancer Society recently released its 2018 guideline which recommends that average-risk adults aged 45 years and older start colorectal cancer screening.⁴
 - The change in starting age is designated as a "qualified recommendation," because there is less direct evidence related to CRC screening in adults aged 45-49 since most studies only include adults over 50.
 - The recommendation for adults aged 50 years and older is designated as a "strong recommendation," based on the greater strength of the evidence and the judgment of the overall benefit.
- African Americans have the highest death rates from CRC when compared with all other racial groups in the United States. The American College of Gastroenterology (ACG) and the American Society for Gastrointestinal Endoscopy (ASGE) recommend CRC screening in African Americans to begin at age 45.
- When CRC is found early, the 5-year relative survival rate is about 90 percent, yet 1 in 3 people in the U.S. who should be tested for colorectal cancer have never been screened.⁴

Colonoscopy is the most effective screening test for CRC

- Preventing cancer is always better than finding cancer.
- Colonoscopy is the gold standard of CRC screening methods because it can both detect and remove pre-cancerous polyps. It is the only suitable test for people who have risk factors such as family history of CRC.³
- In 2017, the U.S. Multi-Society Task Force on Colorectal Cancer (MSTF) recommended that physicians offer colonoscopy first with annual fecal immunohistochemical testing (FIT) offered to patients who decline colonoscopy, followed by second-tier tests for patients who decline FIT.⁵
 - First-tier options are colonoscopy every 10 years or annual FIT.⁵
 - Second-tier options include CT colonography every 5 years, FIT-fecal DNA test (Cologuard®) every three years, or flexible sigmoidoscopy every five to 10 years.⁵

Medicare patients may face co-insurance charges after initial CRC screening

- Medicare will cover 100 percent of the initial CRC screening test chosen by a patient.⁶
- If the initial test is positive, then subsequent testing may result in a large patient deductible and/or co-insurance bill because the second test would be considered a diagnostic or therapeutic service under Medicare billing codes.⁶

¹ American Cancer Society. Cancer Statistics Center: Colorectum. <https://cancerstatisticscenter.cancer.org/#!/cancer-site/Colorectum>. Accessed July 12, 2018.

² US Preventive Services Task Force. Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement. JAMA, 2016;315(23):2564–2575. <http://doi.org/10.1001/jama.2016.5989>.

³ American Society for Gastrointestinal Endoscopy. Media backgrounder on Colorectal Cancer Screening. <https://www.asge.org/home/about-asge/newsroom/media-backgrounders-detail/colorectal-cancer-screening>. Accessed July 12, 2018.

⁴ American Cancer Society. American Cancer Society Updates Colorectal Cancer Screening <http://pressroom.cancer.org/releases?item=770>. Accessed July 12, 2018.

⁵ Rex D, Boland C, Dominitz J et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer. The American Journal of Gastroenterology 2017;112:1016-1030. <http://doi.org/10.1038/ajg.2017.174>.

⁶ American Cancer Society. Colorectal Cancer: Early Detection, Diagnosis, and Staging: Insurance Coverage for Colorectal Cancer Screening. <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-coverage-laws.html>. Accessed July 12, 2018.

What Patients Should Know About Cologuard®

Cologuard® is only recommended for patients of average risk

- Cologuard® is a stool DNA-based test that detects molecular markers of altered DNA that are contained in cells shed by CRC or advanced adenomas into the stool. Cologuard® also utilizes a FIT test that incorporates an Enzyme-Linked Immunosorbent Assay to quantify Hemoglobin in stool.⁷ All positive test results should lead to a colonoscopy.⁷
- Cologuard® is approved for patients age 50 years and older who are at average risk for colon cancer and is not intended to replace diagnostic colonoscopy or surveillance colonoscopy in high-risk patients.⁷
- Cologuard® is NOT approved for patients with high risk, including those who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:
 - Personal history of polyps;
 - Inflammatory Bowel Disease;
 - Chronic ulcerative colitis;
 - Crohn's disease;
 - Familial adenomatous polyposis; and
 - Family history of CRC.⁷

Colonoscopy finds more cancer and polyps than Cologuard®

- A 2014 study in the New England Journal of Medicine of nearly 10,000 patients found that screening colonoscopy was more effective than Cologuard® at detecting CRC and polyps.⁸
 - Cologuard® detected 92.3 percent of the colorectal cancers detected by screening colonoscopy.⁸
 - The sensitivity of Cologuard® for detecting advanced polyps with high-grade dysplasia was 69.2 percent and 42.4 percent for detecting advanced precancerous lesions.⁸
 - 20 to 30 percent of colorectal cancers likely arise through the serrated polyp pathway.⁹ Cologuard® was only 42.4 percent sensitive at detecting serrated polyps >1cm.⁸
 - The lower specificity (86.6 percent) of Cologuard® leads to a very high false positive rate (13.4 percent).⁸

Patients may face co-insurance charges for follow-up colonoscopy

- Medicare will cover 100 percent of the Cologuard® screening test.⁶
 - If a Cologuard® test is positive, then the recommended follow-up colonoscopy could result in a large patient deductible and/or co-insurance bill because it would be considered a diagnostic or therapeutic colonoscopy under Medicare billing codes.⁶
- Cologuard® is covered by many private insurers, but patients could pay approximately \$600 if not covered.⁵

⁷ U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED). https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017b.pdf. Accessed July 12, 2018.

⁸ Imperiale T, Ransohoff D, Itzkowitz S, et al. Multitarget Stool DNA Testing for Colorectal-Cancer Screening. *New England Journal of Medicine*, 2014;370:1287-1297.

⁹ Makkar R, Pai R, Burke C. *Cleveland Clinic Journal of Medicine*. 2012 December;79(12):865-871. <http://doi.org/10.3949/ccjm.79a.12034>.