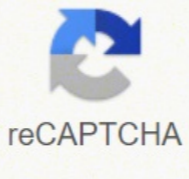
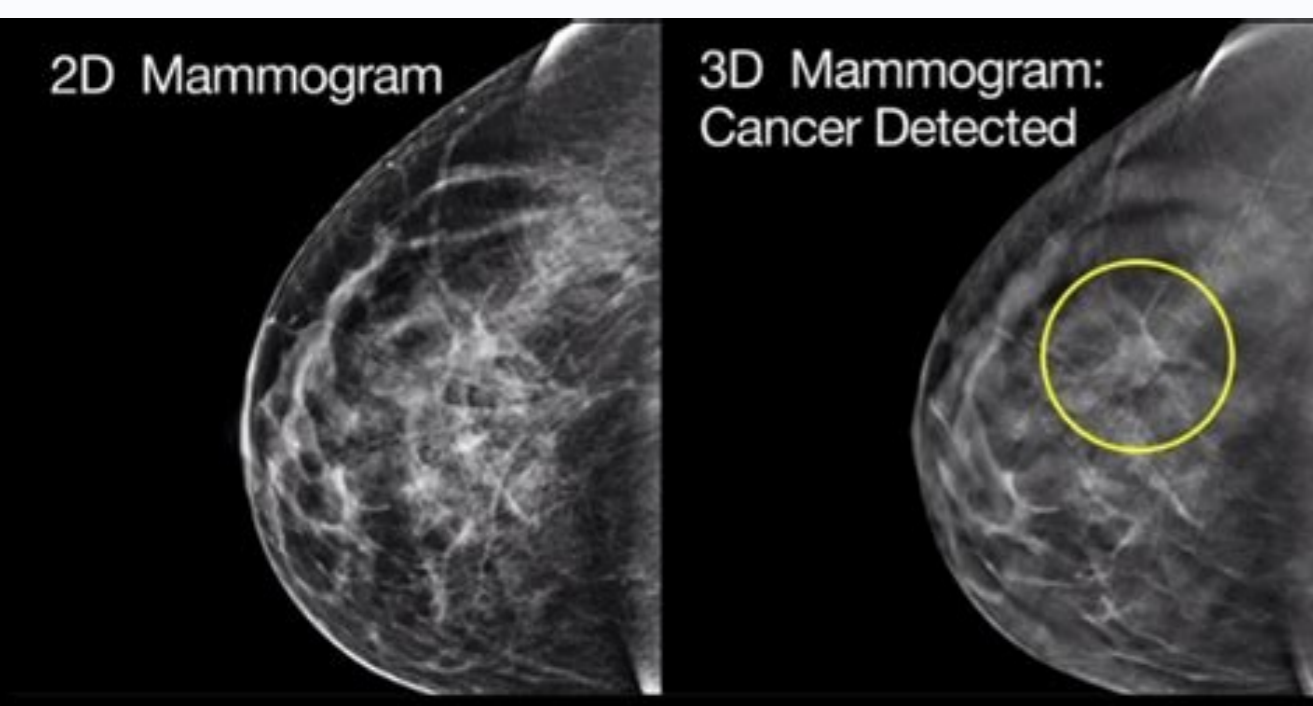




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Breast Cancer Version 2.2015

Clinical Practice Guidelines in Oncology

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Overview

The American Cancer Society estimates that 234,193 Americans will be diagnosed with invasive breast cancer and 40,730 will die of the disease in the United States in 2015.¹ Breast cancer is the most frequently diagnosed cancer globally and the leading cause of cancer-related death in women.²

The lifetime risk of breast cancer for women in the United States has increased from 1 in 11 in the 1970s to 1 in 8 in 2013, a change related to shifting

Abstract

Breast cancer is the most common malignancy in women in the United States and is second only to lung cancer as a cause of cancer death. The overall management of breast cancer includes the treatment of local disease with surgery, radiation therapy, or both, and the treatment of systemic disease with cytotoxic chemotherapy, endocrine therapy, biologic therapy, or combinations of these. This portion of the NCCN Guidelines discusses recommendations specific to the locoregional management of clinical stage I, II, and IIIA (T1N1M0) tumors. (J Natl Compr Canc Netw 2015;13:448-475)

NCCN Categories of Evidence and Consensus

Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise noted.

Clinical trials: NCCN believes that the best management for any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

Please Note

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) are a statement of consensus of the authors regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult the NCCN Guidelines[®] is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. The National Comprehensive Cancer Network[®] (NCCN[®]) makes no representation or warranties of any kind regarding their content, use, or application and disclaims any responsibility for their applications or use in any way. The full NCCN Guidelines for Breast Cancer are not printed in this issue of JNCCN but can be accessed online at NCCN.org.

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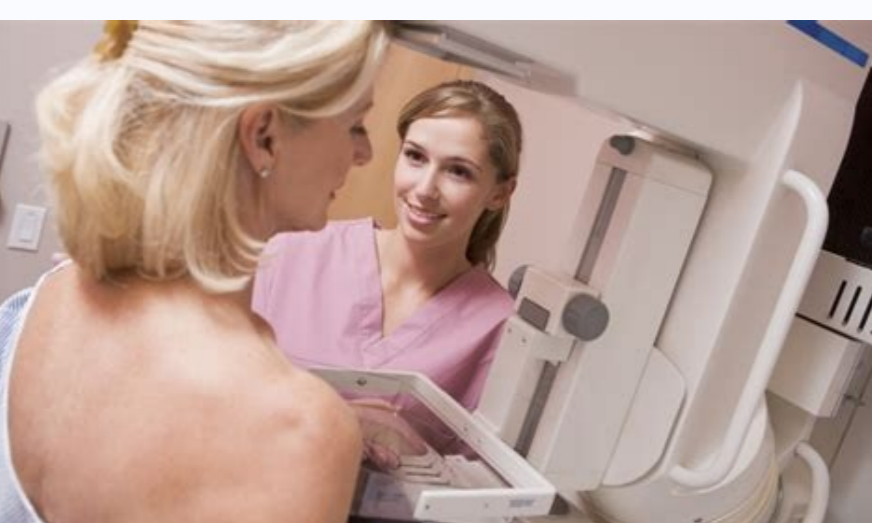
Disclosures for the NCCN Breast Cancer Panel

At the beginning of each NCCN Guidelines panel meeting, panel members review all potential conflicts of interest. NCCN, in keeping with its commitment to public transparency, publishes these disclosures for panel members, staff, and NCCN itself.

Individual disclosures for the NCCN Breast Cancer Panel members can be found on page 475. (The most recent version of these guidelines and accompanying disclosures are available on the NCCN Web site at NCCN.org.)

These guidelines are also available on the Internet. For the latest update, visit NCCN.org.

Comparison of Breast Cancer Screening Guidelines (January 2015)						
Recommended	ACOG	ACR/SBI	ACS	AMA	NCCN	USPSTF
Age to Start Mammograms	40	40	45 Individual choice 40-44	40	40	50
Age to Stop Mammograms	Annual as long as woman in good health	When life expectancy is <5-7 years	When life expectancy <10 years	When life expectancy <10 years	Upper age limit not established	74
Interval	Annual	Annual	Annual 45-54; 1-2 years 55+	Annual	Annual	2 years
Tomo-synthesis (3-D Mammography)	Further study to confirm whether cost-effective replacement for digital mammography alone as first-line screening	No longer investigational; represents an advance in breast imaging	Improvement in detection, lower chance of recall	Silent	Promising; definitive studies pending	Insufficient evidence to support routine use; grade "I"
Notes	Tomosynthesis shown to improve key screening parameters compared to digital mammography	40-44 Opportunity to begin screening; 45-54 Annual exam; 55+ 1-2 years Transition to biennial or opportunity for annual exam	Eligible at age 40, if they choose and their doctors agree; annual at 50		40-49 Grade "C" Individual decision; 50-74 Grade "B" Biennial screening; 75+ Grade "I" Insufficient evidence	



[PubMed Abstract] Pickhardt PJ. However, the FIT-DNA test also was more likely to identify an abnormality when none was actually present (that is, it had more false-positive results, which can lead to unnecessary colonoscopies). [PubMed Abstract] Brenner H, Stock C, Hoffmeister M. Several screening tests have been developed to help doctors find colorectal cancer before symptoms begin, when it may be more treatable. One technique is capsule colonoscopy (also called capsule endoscopy), in which a person swallows a pill-like capsule that contains a tiny wireless camera. Both polyps and colorectal cancers can bleed, and stool tests check for tiny amounts of blood in feces (stool) that cannot be seen visually. For example, measuring three protein biomarkers in stool—hemoglobin, calprotectin, and serpin family F member 2—improved the ability of FIT to detect advanced lesions (including colorectal cancer) by 35% without reducing its specificity (30). New England Journal of Medicine 2004; 351(26):2704-2714. FIT-DNA detects hemoglobin, along with certain DNA biomarkers. Cancer Statistics, 2021. [PubMed Abstract] Shapiro JA, Bobo JK, Church TR, et al. Researchers have developed an ultrasensitive antibody-linked CTC detection technology to capture colorectal epithelial cells associated with colorectal tumors and adenomas in blood samples (25). People who have a positive finding with these tests are advised to have a colonoscopy. Lesions may appear as raised polyps, or, less commonly, they may appear flat or slightly indented. Like the shorter sigmoidoscope, the colonoscope is inserted through the anus into the rectum and the colon as air is pumped into the colon to expand it so the doctor can see the colon lining more clearly. Colorectal cancer is the third most common type of non-skin cancer in both men (after prostate cancer and lung cancer) and women (after breast cancer and lung cancer). [PubMed Abstract] Rex DK, Boland CR, Dominitz JA, et al. Sigmoidoscopy. Cancer 2019; 125(21):3828-3835. International Journal of Colorectal Disease 2017; 32(5):741-743. Specific information about Medicare benefits for colorectal cancer screening is available on the Medicare website. [PubMed Abstract] Virostko J, Capasso A, Yankelov TE, Goodgame B. That is, colorectal cancer screening may be a form of cancer prevention in addition to early detection. American Journal of Gastroenterology 2005; 100(6):1393-1403. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. Drawing of the front of the abdomen that shows the four sections of the colon: the ascending colon, the transverse colon, the descending colon, and the sigmoid colon. Novel circulating tumor cell assay for detection of colorectal adenomas and cancer. An individual's decision about which test to have may depend on: the person's age, medical history, family history, and general health potential harms of the test the preparation required for the test whether sedation may be needed for the test the follow-up care needed after the test the convenience of the test the cost of the test and the availability of insurance coverage The table below summarizes key features of the different colorectal screening tests that people may want to consider when choosing a test. If gFOBT or FIT is the only type of colorectal cancer screening test performed, experts generally recommend testing every year or two (10). In one study of people who were at average risk of developing colon cancer and had no symptoms of colon problems (11), the FIT-DNA test was more sensitive than the FIT test. Clinical trials have shown that having sigmoidoscopy lowers the risks of developing and dying from colorectal cancer (12-16). The lower colon must be cleared of stool before sigmoidoscopy, but the preparation is not very extensive. People should check with their health insurance provider to determine their colorectal cancer screening coverage and what their out-of-pocket expenses may be if the test finds an abnormality that needs to be followed up. Among new approaches to colorectal cancer screening that are being explored are ways to improve visualization of the colon. Fecal DNA versus fecal occult blood for colorectal-cancer screening in an average-risk population. In this test, the rectum and entire colon are examined using a colonoscope, a flexible lighted tube with a lens for viewing and a tool for removing tissue. Clinical and Translational Gastroenterology 2019; 10(10):e00088. The US Preventive Services Task Force (USPSTF) considers the following methods to be acceptable screening tests for colorectal cancer: Stool tests. The major risk factors for colorectal cancer are older age and having certain inherited conditions (such as Lynch syndrome and familial adenomatous polyposis), but several other factors have also been associated with increased risk, including a family history of the disease, excessive alcohol use, obesity, being physically inactive, cigarette smoking, and, possibly, diet. Virtual colonoscopy may also miss small polyps (18). American Journal of Gastroenterology 2017; 112(7):1016-1030. In DCBE, a series of x-ray images of the entire colon and rectum is taken after the patient is given an enema with a barium solution. Colorectal-cancer incidence and mortality with screening flexible sigmoidoscopy. If an abnormality is found during sigmoidoscopy, a biopsy or polypectomy may be performed during the test, and a follow-up colonoscopy may be recommended. During sigmoidoscopy, abnormal growths in the rectum and sigmoid colon can be removed for analysis (biopsied). Noninvasive testing for colorectal cancer: A review. In a proof-of-concept study, this blood-based CTC test was able to distinguish between patients with colorectal adenomas or cancer and people without cancer (26). As with standard colonoscopy, a thorough cleansing of the colon is necessary before this test. There is no evidence yet that this test can reduce deaths from colorectal cancer. Double-contrast barium enema (DCBE). The camera takes pictures of the inside of the digestive tract and sends them to a small recorder that is worn on the patient's waist or shoulder. Sedation needed? The preparation for colonoscopy requires a thorough cleansing of the entire colon before the test. [PubMed Abstract] Deng L, Fang H, Tso VK, et al. A meta-analysis of six observational studies reported that screening with colonoscopy substantially reduces the risks of developing and dying from colorectal cancer (17). DCBE is rarely used for colorectal cancer screening; however, it may be used for people who cannot undergo standard colonoscopy—for example, because they are at particular risk for complications. Single-specimen gFOBT done in a doctor's office. [PubMed Abstract] Wu JC, Tseng PY, Tsai WS, et al. Dietary restrictions are typically not required for FIT. In addition, people with a history of inflammatory bowel disease (such as ulcerative colitis or Crohn disease) have a higher risk of colorectal cancer than people without such conditions. These tests most often include a colonoscopy if it has not already been done, such as in the case of stool blood testing. (Blood in stool may also indicate the presence of conditions that are not cancer, such as hemorrhoids.) Currently, three types of stool tests are approved by the US Food and Drug Administration (FDA) to screen for colorectal cancer: guaiac FOBT (gFOBT); the fecal immunochemical (or immunochemical) test (FIT, also known as iFOBT); and multitargeted stool DNA testing (also known as FIT-DNA). The DNA comes from cells in the lining of the colon and rectum that are shed and collect in stool as it passes through the large intestine and rectum. Invasive procedure? American Journal of Gastroenterology 2017; 112(11):1728-1735. The cecum, ascending colon, and transverse colon make up the upper, or proximal, colon; the descending colon and sigmoid colon make up the lower, or distal, colon. Siegel RL, Miller KD, Fuchs HE, Jemal A. [PubMed Abstract] Kehm RD, Yang W, Tehranifar P, Terry MB. However, this approach has not been shown to be an effective way to screen for colorectal cancer (19). The pictures are then viewed on a computer by the doctor to check for signs of disease. Researchers have also identified small molecules, called metabolites, in urine that may signal the presence of colorectal polyps and tumors (27, 28). Colorectal cancer screening: Recommendations for physicians and patients from the U.S. Multi-Society Task Force on colorectal cancer. Accuracy of screening for

fecal occult blood on a single stool sample obtained by digital rectal examination: A comparison with recommended sampling practice. *Alimentary Pharmacology and Therapeutics* 2014; 48(1):e54. [PubMed Abstract] Wang H, Tso V, Wong C, Sadowski D, Fedorak RN. Experts generally recommend sigmoidoscopy every 5 or 10 years for people at average risk who have had a negative test result (10). Rates of new colorectal cancer cases are decreasing among adults aged 50 years or older due to an increase in screening and to changes in some risk factors (for example, a decline in smoking) (2). *PLoS Medicine* 2012; 9(12):e1001352. *Journal of Medical Screening* 2007; 14(3):132-137. With these tests, stool samples are collected by the patient using a kit, and the samples are returned to the doctor. Colorectal cancer statistics, 2020. Researchers are also trying to improve the sensitivity of stool-based screening for detecting advanced adenomatous polyps, which can potentially become colorectal cancer, by testing for the presence of multiple biomarkers. However, many small polyps may not be likely to become cancer and so taking them out may not be of benefit. Circulating tumour markers can define patients with normal colons, benign polyps, and cancers. In a clinical study, a metabolomic-based urine test was better able to identify patients with adenomas than stool-based tests (29). These so-called circulating tumor cells (CTCs) are rare, however. [PubMed Abstract] Burch JA, Soares-Weiser K, St John DJB, et al. Effect of flexible sigmoidoscopy screening on colorectal cancer incidence and mortality: A randomized clinical trial. *Journal of Clinical Medicine* 2018; 7(2):22. It is important to have colorectal cancer screening. Effect of screening sigmoidoscopy and screening colonoscopy on colorectal cancer incidence and mortality: Systematic review and meta-analysis of randomised controlled trials and observational studies. Antibody conjugated supported lipid bilayer for capturing and purification of viable tumor cells in blood for subsequent cell culture. [PubMed Abstract] Collins JF, Lieberman DA, Durbin TE, Weiss DG; Veterans Affairs Cooperative Study #380 Group. Once-only sigmoidoscopy in colorectal cancer screening: Follow-up findings of the Italian Randomized Controlled Trial–SCORE. If polyps or other abnormal growths are found during a virtual colonoscopy, a standard colonoscopy must usually be performed to remove them. Because virtual colonoscopy also produces images of areas outside the colon and rectum it can lead to the unintentional discovery of medical findings in these areas that require additional follow-up procedures. Most colorectal cancers begin as a growth, or lesion, in the tissue that lines the inner surface of the colon or rectum. *JNCI Cancer Spectrum* 2019; 3(3):pkz038. *JAMA* 2021; 325(19):1965-1977. [PubMed Abstract] Schoen RE, Pinsky PF, Weissfeld JL, et al. Randomized trials have shown that gFOBT, when performed every 1 to 2 years in people aged 50 to 80 years, can help reduce the number of deaths due to colorectal cancer (7, 8). Once-only flexible sigmoidoscopy screening in prevention of colorectal cancer: A multicentre randomised controlled trial. ACG clinical guidelines: Colorectal cancer screening 2021. [PubMed Abstract] Segnan N, Armaroli P, Bonelli L, et al. The barium helps to outline the colon and the rectum on the images. *Lancet* 2010; 375(9726):1624-1633. *Annals of Internal Medicine* 2019; 171(9):643-654. Medicare covers several colorectal cancer screening tests for its beneficiaries. However, a certain type of polyp known as an adenoma is more likely to become a cancer. Other methods. [PubMed Abstract] US Preventive Services Task Force, Davidson KW, Barry MJ, et al. In this test, the rectum and sigmoid colon are examined using a sigmoidoscope, a flexible lighted tube with a lens for viewing and a tool for removing tissue. *CA: A Cancer Journal for Clinicians* 2020; 70(3):145-164. Cleansing of the colon is still necessary before this test. However, Medicare and some insurance companies currently do not pay for the costs of virtual colonoscopy. Most patients receive some form of sedation during the test. [PubMed Abstract] Shaukat A, Kahi CJ, Burke CA, et al. Effect of flexible sigmoidoscopy-based screening on incidence and mortality of colorectal cancer: A systematic review and meta-analysis of randomized controlled trials. *Parts of the colon. Journal of the National Cancer Institute* 2011; 103(17):1310-1322. Because gFOBT can also detect heme in some foods (for example, red meat), people must avoid certain foods before having this test. Clinical validation of a novel urine-based metabolomic test for the detection of colonic polyps on Chinese population. *New England Journal of Medicine* 2012; 366(25):2345-2357. Experts recommend colonoscopy every 10 years for people at average risk as long as their test results are negative. Virtual colonoscopy, also called computed tomographic (CT) colonography, is a screening method that uses special x-ray equipment (a CT scanner) to produce a series of pictures of the colon and the rectum from outside the body. Information about ongoing clinical trials that are studying methods for colorectal cancer screening can be found in NCI's clinical trials database. [PubMed Abstract] Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. *Journal of General Internal Medicine* 2012; 27(9):1150-1158. Recent trends in the age at diagnosis of colorectal cancer in the US National Cancer Data Base, 2004-2015. *CA: A Cancer Journal for Clinicians* 2018; 68(4):250-281. You may also contact NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for assistance with searching the clinical trials database. gFOBT uses a chemical to detect heme, a component of the blood protein hemoglobin. In the case of permitted digital reproduction, please credit the National Cancer Institute as the source and link to the original NCI product using the original product's title; e.g., "Screening Tests to Detect Colorectal Cancer and Polyps was originally published by the National Cancer Institute." In 2021, an estimated 149,500 people in the United States will be diagnosed with colorectal cancer and 52,980 people will die from it (1). In the United States, colorectal cancer is most common in adults aged 65 to 74. Raised polyps may be attached to the inner surface of the colon or rectum with a stalk (pedunculated polyps), or they may grow along the surface without a stalk (sessile polyps). Colorectal polyps are common in people older than 50 years of age, and most do not become cancer. *CA: A Cancer Journal for Clinicians* 2021; 71(1):7-33. During colonoscopy, any abnormal growths in the entire colon and the rectum can be removed. Preparation (colon cleansing) needed? *British Journal of Cancer* 2011; 105(2):239-245. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *American Journal of Gastroenterology* 2021; 116(3):458-479. *Annals of Internal Medicine* 2005; 142(2):81-85. Doctors sometimes perform a single-specimen gFOBT on a stool sample collected during a digital rectal examination as part of a routine physical examination. Test Diet and medication changes before test? [PubMed Abstract] Deng L, Ismond K, Liu Z, et al. Newer studies have shown that FIT can detect more colorectal cancers than gFOBT (that is, it is more sensitive) (9). [PubMed Abstract] Tsai WS, You JF, Hung HY, et al. Colorectal cancer (cancer that develops in the colon and/or the rectum) is a disease in which abnormal cells in the colon or rectum divide uncontrollably, ultimately forming a malignant tumor. Screening for colorectal cancer in asymptomatic average-risk adults: A guidance statement from the American College of Physicians. 40 years of change in age- and stage-specific cancer incidence rates in US women and men. [PubMed Abstract] Zapka J, Klabunde CN, Taplin S, et al. Also shown are the small intestine, the cecum, and the rectum. *Annals of Internal Medicine* 2021; doi: 10.7326/M20-8270. If an abnormality is detected during virtual colonoscopy, the patient will be referred for a standard colonoscopy. *BMJ* 2014; 348:g2467. Missed lesions at CT colonography: Lessons learned. Experts generally suggest FIT-DNA testing at least every 3 years (6). [PubMed Abstract] Siegel RL, Miller KD, Goding Sauer A, et al. [PubMed Abstract] Mead R, Duku M, Bhandari P, Cree IA. A blood test for an altered gene called SEPT9 is FDA approved to be used to screen adults 50 years or older at average risk for colorectal cancer who have been offered and have a history of not completing colorectal cancer screening. If a screening test finds an abnormality (a lesion or tumor), additional tests may be needed. [PubMed Abstract] Atkin WS, Edwards R, Kralj-Hans I, et al. This method is currently approved for patients with an incomplete colonoscopy and for detection of colon polyps in patients with evidence of lower GI bleeding but not as a stand-alone screening test. One new approach to colorectal cancer screening is to look for cells released by colorectal polyps and tumors into the bloodstream (24). This instrument is inserted through the anus into the rectum and sigmoid colon as air is pumped into the colon to expand it so the doctor can see the colon lining more clearly. The cecum, colon, rectum, and anal canal make up the large intestine. Urinary metabolomics to identify a unique biomarker panel for detecting colorectal cancer: A multicenter study. The capsule passes out of the body during a bowel movement. Evaluation of colorectal cancer incidence trends in the United States (2000-2014). A colonoscopy to follow up on a screening test with a positive result, such as an abnormal stool test or even a lesion detected on a screening colonoscopy, is considered to be a diagnostic exam and may not be covered (or not covered as fully as a screening colonoscopy). However, incidence is increasing among younger adults (2-4) for reasons that are not known. An analysis of US population-based cancer registry data from NCI's Surveillance, Epidemiology, and End Results (SEER) program for 2000 to 2014 shows that, each year over this period, the incidence of colorectal cancer increased 2.7% among 20- to 39-year-olds and 1.7% among 40- to 49-year-olds while decreasing 0.5% among 50- to 59-year-olds, 3.3% among 60- to 69-year-olds, and 3.8% among 70- to 79-year-olds (5). Although the percentage increases were higher in the younger age groups than the older age groups, fewer colorectal cancers were still diagnosed in younger people than older people (for example, for 2000 to 2014, 22.5 colorectal cancers were diagnosed per 100,000 people aged 40 to 49 years, compared with 128.6 colorectal cancers diagnosed per 100,000 people aged 60 to 69 years). [PubMed Abstract] If you would like to reproduce some or all of this content, see Reuse of NCI Information for guidance about copyright and permissions. People are usually not sedated for this test. [PubMed Abstract] Ouyang DL, Chen JJ, Getzenberg RH, Schoen RE. Clinical validation of a multitarget fecal immunochemical test for colorectal cancer screening: A diagnostic test accuracy study. [PubMed Abstract] Qaseem A, Crandall CJ, Mustafa RA, et al. Test frequency Additional considerations Stool tests Yes for gFOBT, no for FIT or FIT-DNA No No No Every year to every 3 years, depending on the test Follow-up colonoscopy will likely be needed if test is positive Sigmoidoscopy Yes Yes Yes (less extensive than for colonoscopy) Usually no Every 5 to 10 years, possibly with more frequent FIT Abnormal tissue can be removed during exam Very small risk of tearing or perforation of the lining of the colon Not widely available in United States (23) Colonoscopy Yes Yes Yes Every 10 years Abnormal tissue can be removed during exam Small risk of tearing or perforation of the lining of the colon Virtual colonoscopy No No Yes No Every 5 years Follow-up colonoscopy will likely be needed if test is positive Not widely available and may not be covered by insurance Can find abnormalities outside the colon that may need follow-up Involves exposure to small amount of radiation Colorectal cancer screening is a preventive service that the Health Insurance Marketplace and many other health plans are required to cover. *Biomaterials* 2013; 34(21):5191-5199. Diagnostic accuracy of faecal occult blood tests used in screening for colorectal cancer: A systematic review. Screening colonoscopy in the US: Attitudes and practices of primary care physicians. [PubMed Abstract] Elmuzzor BJ, Hayward RA, Schoenfeld PS, et al. A computer then assembles these pictures into detailed images that can show polyps and other abnormalities. Several other tests to screen for colorectal cancer exist, although these are not generally recommended. Blood-based DNA test (liquid biopsy). *JAMA* 2014; 312(6):606-615. [PubMed Abstract] Holme Ø, Løberg M, Kalager M, et al. [PubMed Abstract] Ansa BE, Coughlin SS, Alema-Mensah E, Smith SA. A comparison of fecal immunochemical and high-sensitivity guaiac tests for colorectal cancer screening. People who are screened with sigmoidoscopy may also be tested every few years with FIT. Colonoscopy. Development and validation of a highly sensitive urine-based test to identify patients with colonic adenomatous polyps. If an abnormality is found during a standard colonoscopy, a biopsy or polypectomy may be performed during the test to determine whether cancer is present. *Cancer Epidemiology, Biomarkers & Prevention* 2019; 28(8):1283-1291. It is the second leading cause of cancer death in the United States after lung cancer. This test is another method of visualizing the colon from outside the body. Different tests have different advantages and disadvantages, and people should talk with their health care provider about which test is best for them. Some insurers consider a screening colonoscopy that reveals a polyp that must be removed to be a diagnostic exam and charge accordingly. [PubMed Abstract] Wolf AMD, Fontham ETH, Church TR, et al. *Abdominal Imaging* 2013; 38(1):82-97.

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