



VIRTUAL COLONOSCOPY

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Important reminder

Virtual colonoscopy is a radiology procedure. Effective January 1, 2010, FCHP implemented a radiology management program. FCHP has delegated review of requests (prior authorization) for certain high-tech outpatient radiology procedures, including virtual colonoscopy, to MedSolutions, Inc. for the following products:

- Select Care
- Direct Care
- Fallon Senior Plan
- Commonwealth Care
- Federal Employee Health Benefits Program

FCHP's Care Review Department will review requests (prior authorization) for high-tech outpatient radiology procedures, including virtual colonoscopy, for the following products:

- Fallon Preferred Care (PPO)
- Fallon Senior Plan Preferred
- MassHealth
- NaviCare

Overview

Virtual colonoscopy, also known as computed tomographic colonography (CT colonography or CTC) is a minimally invasive radiological examination of the colon and rectum. Virtual colonoscopy can be performed on commercially available multidetector CT scanners. Virtual colonoscopy requires full purgatory bowel prep similar to the bowel prep for endoscopic colonoscopy. The procedure requires oral contrast and colonic insufflation. No sedation or analgesia is required. Persons who screen positive on virtual colonoscopy require endoscopic colonoscopy to remove or biopsy polyps or lesions.

No prospective, randomized, controlled clinical trials have been performed (nor are any planned) to demonstrate the efficacy of virtual colonoscopy in reducing mortality from colorectal cancer. Given the large, cumulative body of evidence in support of colorectal cancer screening and the value of polypectomy, studies of virtual colonoscopy have focused on the performance of virtual colonoscopy for polyp detection with endoscopic colonoscopy as the reference standard.

Studies by Pickhardt et al. (2003), Johnson et al. (2008), and Graser et al. (2009) provide the most substantial, recent evidence on the performance of virtual

colonoscopy. These studies were consistent in showing a reasonable sensitivity and specificity for polyps 6 mm - 9 mm and 10 mm and larger compared to endoscopic colonoscopy. There is ongoing debate about the clinical significance of 6 mm - 9 mm polyps. At this time, the current Multisociety recommendation is to refer patients with 3 or more polyps 6 mm to 9mm or one or more polyps 10 mm or larger for endoscopic colonoscopy. CT colonography does not appear to have the ability to reliably detect small polyps < 6 mm. (Levin et al. 2008)

Since virtual colonoscopy cannot reliably detect polyps < 6mm, the impact of these polyps in the intervening screening interval is important but unknown at this point. Since all polyps seen on endoscopic colonoscopy are routinely removed, the natural history of these small polyps has not been well characterized. The majority of these very small polyps are likely to be benign; however, Lieberman et al. (2008) noted that 1.7% of polyps < 6mm had advanced histology. Further research on the natural history of polyps < 6mm and their health outcomes is needed

In addition to polyp size, the type of lesion is a factor. Nonpolypoid (flat, depressed or indented) lesions are very difficult to detect with virtual colonoscopy and are more common than originally believed in past accounts. In a study of asymptomatic and symptomatic veterans, Soetikno et al. (2008) reported that the prevalence of nonpolypoid colorectal neoplasms was 9.35% and noted that these "were relatively common lesions diagnosed during routine colonoscopy and had a greater association with carcinoma compared with polypoid neoplasms, irrespective of size." Further research on the natural history of nonpolypoid lesions and their health outcomes is needed.

The rate of referral to endoscopic colonoscopy for polypectomy is another important consideration when using a screening modality such as virtual colonoscopy which does not have therapeutic capabilities. The rate of referral is dependent upon test parameters, such as sensitivity and specificity, and the prevalence of polyps in the targeted screening population. If all individuals with polyps 6 mm are referred to endoscopic colonoscopy as recommended by current guidelines, the referral rates would be 29.7% in the 2003 Pickhardt study (mean age = 57.8 years), 12.9% in the 2007 Kim study (mean age = 57.0 years), and 12% in the 2008 Johnson study (mean age = 58.3 years). Whitlock and colleagues (2008) noted: "On the basis of a referral threshold of any polyp 6 mm or greater, these studies suggest that 1 in 3 to 1 in 8 persons screened with virtual colonoscopy would be referred for colonoscopy."

Polyp studies have shown that the proportion of individuals that have at least one 6 mm polyp increases with age. In a colonoscopy screening study, Liebermann et al. (2008) found the proportion of screening individuals with at least one polyp 6 mm to be 13.8% for individuals aged 50-59 years; 16.9% for individuals aged 60-69 years; 18.5% for individuals aged 70-79 years; and 20.5% for individuals aged 80 years and older. The value of virtual colonoscopy as a screening test that does not have therapeutic options may well be reduced or negated if there is a high rate of referral to endoscopic colonoscopy leading to duplicative tests. Patients need to understand the likelihood of endoscopic colonoscopy and the possible need for two bowel preparations. Further study is needed to examine the cost-effectiveness of screening virtual colonoscopy if 15% to 20% of patients will require endoscopic colonoscopy.

Virtual colonoscopy also detects extracolonic findings that often trigger a diagnostic search. In an asymptomatic screening population, the incidence of unsuspected but potentially important extracolonic findings is approximately 4.5%, but findings of minimal or moderate potential clinical significance, such as cholelithiasis and nephrolithiasis are more common (6% and 8% respectively). (Pickhardt et al. 2006) While there are potential benefits from serendipitous findings, there are also associated risks and costs that need to be considered when these findings are false positives.

Radiation exposure from virtual colonoscopy is also a potential concern since individuals undergoing screening are asymptomatic of the target condition. In a recent position statement issued by the Health Physics Society, the effects of low-dose radiation exposure (defined as below 50 to 100 mSv – a threshold many times higher than typical virtual colonoscopy levels) were considered to be “either too small to be observed or are nonexistent.” Clearly there is a risk from radiation but how large or small the risk is over time has not been well established. Long term follow-up of specific screening populations may provide additional information on the radiation risk from virtual colonoscopy.

Overall, when considering potential benefits and potential harms, there is insufficient evidence to conclude that the use of screening virtual colonoscopy improves health outcomes. Data on the health outcomes and potential benefits and harms of screening colonoscopy are needed from well designed clinical studies. This conclusion is consistent with the U.S. Preventive Services Task Force and the Centers for Medicare & Medicaid Services.

Screening average-risk individuals (i.e. without identifiable risk factors for colorectal cancer) for colorectal cancer is desirable and has been endorsed by the American College of Gastroenterology, the American Gastroenterological Association, the American Cancer Society, and the U.S. Preventive Services Task Force. Different strategies are recommended for screening of people at average-risk and for those at increased risk. There are a range of options available for screening average-risk patients for colorectal cancer, including but not limited to fecal occult blood test, flexible sigmoidoscopy and conventional colonoscopy. Although these screening tests vary, any one, applied in a systematic program of regular screening has the potential to significantly reduce deaths from colorectal cancer. Colonoscopy is the only test recommended for surveillance of patients with increased risk for colorectal cancer, such as those with a family history of colorectal cancer or adenomatous polyps. Colonoscopy is unique in that it is the only screening/surveillance technique that allows the detection and removal of cancerous and pre-cancerous polyps throughout the colon and rectum. Furthermore, it is the final common pathway for all positive screening tests.

Policy

Virtual colonoscopy requires prior authorization. FCHP's Care Review Department will review requests for virtual colonoscopy for Fallon Preferred Care (PPO), Fallon Senior Plan Preferred, MassHealth and NaviCare. MedSolutions, Inc. will review requests for

virtual colonoscopy for Select Care, Direct Care, Fallon Senior Plan, Commonwealth Care and the Federal Employee Health Benefits Program.

FCHP covers diagnostic virtual colonoscopy (CPT code 74261 or 74262) for plan members when endoscopic colonoscopy would ordinarily be indicated (e.g., for signs or symptoms of lower gastrointestinal bleeding) but cannot be performed because:

1. The plan member has a severe medical condition which precludes endoscopic colonoscopy, such as severe heart disease; severe pulmonary disease; uncontrolled diabetes; or uncontrolled hypertension¹
2. The plan member is taking anticoagulant medication and cannot have the anticoagulant withheld²
3. The plan member has failed endoscopic colonoscopy
 - a. Due to diverticular disease, colonic tortuosity or adhesions
 - b. Due to a distal obstructing lesion which prevents passage of the colonoscope proximal to the lesion

There is insufficient evidence to conclude that the use of screening virtual colonoscopy improves health outcomes. Data on the health outcomes are needed from well designed clinical studies. FCHP has determined that screening virtual colonoscopy (CPT code 74263) is not medically necessary.

Codes

Codes	Number	Description
CPT	74261	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; without contrast material
	74262	Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with contrast material(s), including non-contrast images, if performed
	74263	Computed tomographic (CT) colonography, screening, including image postprocessing

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Products to Which This Policy Applies

- FCHP Direct & Select Care
- Fallon Preferred Care (PPO)
- Major Medical
- MassHealth
- Companion Care
- Commonwealth Care

¹ Colonoscopy is a low-risk procedure. Patients with concomitant conditions undergoing colonoscopy may be at increased risk from complications due to sedation/anesthesia. A less invasive technique for evaluation of the colon might be preferred to minimize the risk for possible complications (Yucel et al. (2008)

² Patients who require polypectomy and who are considered at high risk for a thromboembolic event during short-term interruption of warfarin therapy may be considered for bridge therapy with heparin or low molecular weight heparin, according to the procedure described in the American College of Chest Physicians guidelines. (Douketis et al. 2008)

- Ø Fallon Senior Plan
- ⊕ Fallon Senior Plan Preferred
- ⊕ NaviCare
- Ø Summit Elder Care® PACE (With the exception of emergency care, all services for Summit ElderCare® PACE participants must be authorized and arranged by the Summit ElderCare (SE) Interdisciplinary Team (IDT) overseeing the care for that participant. The applicable IDT can be determined by the HCO code on the participant ID card. A Summit ElderCare clinician is always on call and can be reached by dialing any of the site telephone numbers.)

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Committee review dates:

Technology Assessment Subcommittee: 07/27/04; 09/27/05; 06/22/10

Technology Assessment Committee: 08/25/04; 01/31/06, 01/25/11

IMPORTANT NOTE:

Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.