



June 18, 2008

Coverage and Analysis Group  
Attn: Mr. William Larson  
7500 Security Blvd  
Mail Stop-C-1-09-06  
Baltimore, Md 21244

**Re: NCA Tracking Sheet for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)**

Dear Mr. Larson:

The American College of Radiology (ACR), representing over 32,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, the Society of Gastrointestinal Radiology (SGR), and the Society of Computed Body Tomography and Magnetic Resonance (SCBT) are pleased to submit comments in response to the National Coverage Analysis (NCA) for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N). We appreciate the opportunity to provide comments in this important coverage making process and welcome further dialogue in developing a medically appropriate national policy.

Colorectal cancer (CRC) is the third most common cancer diagnosed among men and women in the United States and the second leading cause of death from cancer. CRC can be prevented by the detection and removal of adenomatous polyps. The ACR, SGR, and SCBT fully support national coverage for CTC as a non-invasive screening tool for CRC for quality patient care and the fight against colorectal cancer, as there are sufficient data and clinical evidence.

The American Cancer Society recently released their joint guideline with ACR and the United States Multi-Society Task Force on colorectal cancer entitled, "*Screening and Surveillance for Early Detection of Colorectal Cancer and Adenomatous Polyps*" (Levin et al 2008). The new guidelines emphasized that the primary goal of colorectal screening is cancer prevention. For the first time, tests were grouped into two major categories: tests that primarily detect cancer and tests that detect adenomatous polyps and cancer. It was the strong opinion of the multi-disciplinary expert panel that exams designed to both prevent and detect cancer should be encouraged if resources are available. This guideline concluded that there is compelling evidence to support CTC for screening for adenomatous polyps and cancers in average-risk patients over age 50 years.

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In addition to the current literature, the American College of Radiology Imaging Network (ACRIN) released the results of its multicenter National CTC Trial (ACRIN 6664) on September 28, 2007. This trial was conducted in 15 centers across the United States and included more than 2,500 patients, designed to determine the ability of CTC in detecting colonic polyps in an asymptomatic screening population. The trial concludes that CTC accurately detects colorectal neoplasia among average-risk persons and that broad application of this relatively non-invasive technique as a primary test option appears highly feasible and may serve to enhance compliance with current CRC screening recommendations. The ACRIN findings will be published in August or September, 2008, and the results are very positive for screening CTC.

## **I. Validation Trials**

To date, clinical trial results of CTC have been validated predominantly using colonoscopy as the reference standard. During the evolution of the CTC technical advances from 1995 to 2005, a range of results were reported in different cohorts of patients using different techniques (Hara et al, 1997; Fenlon et al, 1999; Yee et al, 2001; Fletcher et al, 2000; McFarland et al, 2002; Pineau et al, 2003; Macari et al, 2004; Johnson et al, 2003).

Early validation trials of predominantly polyp-rich patient cohorts demonstrated encouraging results with the sensitivity to detect 10 mm and greater polyps of approximately 90% (Fenlon et al, 1999; Yee et al, 2001). However, several large trials that followed demonstrated less favorable results. Specifically in the multicenter trials of 600 patients of Cotton et al (Cotton et al, 2004) and 614 patients of Rockey et al (Rockey et al, 2005), sensitivities to detect the 10 mm and greater polyps ranged from 55 to 59%. These efforts did not evaluate asymptomatic patients and did not use the latest technological advances of stool tagging or 3D as primary imaging review. Detection of sessile or flat lesions has been variable, ranging from sensitivities of 13%-65% in early CTC studies (Fidler et al, 2002) to 80% when using MDCT and combined 3D-2D polyp detection (Pickhardt et al, AJR, 2004).

During this first decade of effort, two meta-analyses were done to review the CTC trial results (Mulhall et al, 2005). The most comprehensive meta-analysis of Mulhall et al evaluated 33 studies encompassing 6,393 patients. On a per patient basis, CTC sensitivity and specificity for 10 mm and greater polyps was found to be 85-93% and 97% respectively (Mulhall et al, 2005). Pooled sensitivity and specificity for small polyps (6-9 mm) was 70-86% and 86-93%, respectively. Halligan et al reported the sensitivity of CTC to detect invasive colorectal cancer was 96% (Halligan et al, 2005).

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One of the first large CTC trials which evaluated an asymptomatic cohort of screening patients was the Pickhardt et al trial of 1,233 patients (Pickhardt et al, 2003). This trial introduced the novel techniques of stool tagging with electronic subtraction and 3D as a primary imaging review. This trial also used the “enhanced” reference standard of segmental unblinding of CTC results during colonoscopy. Namely, each colonic segment was evaluated by the colonoscopist initially, followed by a second look at the colonic segment if the disclosed CTC results demonstrated a significant lesion. This trial reported sensitivities to detect patients with adenomas at size thresholds of > 6 mm and > 10 mm of 88.7% and 93.8%, respectively; specificities at these two size thresholds were reported at 79.6% and 96.0%, respectively (Pickhardt et al, 2003). Based on the segmental unblinding methodology, misrates at the original colonoscopy (before CTC results were disclosed) could be evaluated. A subsequent analysis of these results demonstrated that colonoscopy missed 10% of adenomas greater than 10 mm (Pickhardt et al, Ann Intern Med, 2004).

Additional trial results with screening cohorts in the United States and Europe are currently being completed and reviewed for publication. In a recently finished Germany screening trial led by Graser et al (Graser et al, 2006) and an ongoing Navy trial in the United States led by Cash et al (Cash et al, 2006), the results of diagnostic performance have been similar to Pickhardt et al (Pickhardt, et al, 2003). Regge et al reported recently the results of the completed Italian Multicenter Polyp Accuracy CTC study group (IMPACT) of 934 asymptomatic patients at increased family or personal risk for colorectal neoplasia (Regge, 2007). Using low dose techniques of < 50 mAs, sensitivities and specificities for patients with > 6 mm versus > 10 mm polyps were 84.2% and 90.4% versus 90.7% and 84.6%, respectively (Regge, 2007).

### **ACRIN Trial**

The National CT Colonography Trial supported by the National Cancer Institute and administered by the American College of Radiology Imaging Network (ACRIN) sought to evaluate the accuracy of CTC in a screening population using optical colonoscopy as the gold standard. Fifteen different medical centers participated nationally—including both private practice and academic centers. The trial recruited 2600 asymptomatic individuals that were prescheduled for screening colonoscopy. A full bowel prep, stool and fluid tagging and state of the art CT scanners and techniques were utilized. Trained and tested radiologists reported all lesions 5 mm or larger.

Complete data were available for 2531 (97%) participants. For adenomas 1 cm or larger the per patient estimates for sensitivity, specificity, positive and negative predictive values and area under the receiver operating characteristic curve were  $0.90 \pm 0.03$ ,  $0.86 \pm 0.02$ ,  $0.23 \pm 0.02$ ,  $0.99 \pm <0.01$  and  $0.89 \pm 0.02$ , respectively. Per-patient sensitivity

estimates ranged from 67%-100% (7 of 15 readers detected all large lesions). Per-polyp sensitivity for large neoplasia was  $0.84 \pm 0.04$ , indicating 16% of large lesions detected on colonoscopy were not seen on CTC. Per-patient sensitivity estimates in detecting adenomas  $\geq 6$  mm, was 0.78.

CTC screening identified 90% of asymptomatic patients with neoplasia  $\geq 10$  mm in diameter. These findings augment previously published data regarding the role of CTC in average-risk CRC screening.

### **CTC vs OC Trial: Comparison of Detection Rates of Advanced Adenomas**

A recent study demonstrated the efficacy of CTC to properly select patients who would benefit from therapeutic colonoscopy. Kim et al recently reported results of a two pronged study comparing screening with primary CTC in 3,120 patients (with selective recommendation for colonoscopy for patients with detected polyps 6 mm or greater in size) to screening with primary optical colonoscopy in 3,163 patients (Kim, 2007). The two groups were similar, other than a slightly higher proportion of individuals with a family history in the optical colonoscopy group. Both groups reported a similar detection rate of advanced adenomas (3.2% in the CTC group and 3.4% in the OC group), however the total number of polypectomies was over four times higher in the optical colonoscopy group compared to the CTC group (2,434 vs 561, respectively) (Kim, 2007). This study demonstrates that CTC, using a size threshold of 6mm or greater polyps to recommend therapeutic colonoscopy, can lead to efficient removal of advanced adenomas.

## **II. CTC Practice Guidelines and Quality Assurance**

Since its introduction in the mid-1990s, there have been rapid advances in CTC technique, CT scanner technology, imaging workstations and display, and contrast tagging of residual colonic fluid and stool. Several large trials utilizing these new methods, including the DOD study and the recently completed ACRIN 6664 National CT Colonography Trial have demonstrated significant improvements in the performance of CTC in comparison to early clinical studies.

Based on the results of numerous CTC studies, the first society-sponsored practice guidelines for CT colonography were developed by the American College of Radiology (ACR) in 2005, followed by the American Gastroenterological Association (AGA) standards in 2007 (Rockey et al, 2007). These guidelines relate to all aspects of the CT colonography exam, including indications, qualifications of participating personnel, CT and interpretive technique, and quality control and safety programs. A summary of the salient points relating to these recommendations follows:



## Appropriateness Criteria

The ACR recommends the use of CTC for the following indications: (i) as an alternative for colon cancer screening in asymptomatic adults age 50 or over, (ii) for those unwilling to undergo other primary screening modalities, and (iii) following incomplete endoscopy. Earlier in 2006, the European Society of Gastrointestinal and Abdominal Radiology issued a consensus statement that CTC may be considered a primary colorectal cancer screening tool, when validated local expertise is in place (Taylor et al, 2007). Additionally, in May of this year, the American Medical Association Physician Consortium for Performance Improvement also issued a draft for public comment of their Preventative Care & Screening Physician Performance Measurement Set, listing CTC at five year intervals among their current recommended colorectal cancer screening tests (The Physician Consortium for Performance Improvement, 2008). In addition to screening, the ACR also endorses the use of CTC as a diagnostic exam in symptomatic patients or those at increased risk for routine endoscopy. In all of these scenarios, CTC is a means of extending complete full structural screening to the millions of Americans who do not currently undergo screening for colorectal cancer, due to a variety of reasons (e.g., incomplete endoscopy, anticoagulation, fear of endoscopy, convenience, prolonged endoscopic wait times or limited local capacity, etc.).

## Qualifications for Personnel

The ACR recommendations stipulate that certified radiologic technologists operate the CT scanners, and other personnel be familiar with the operation of other required equipment (CTC rectal tubes and automatic insufflation devices).

Because reader training and experience is one of the most important factors affecting the diagnostic performance of CT colonography (Bodily et al, 2005; Doshi et al, 2007; Fidler et al, 2004; Gluecker et al, 2002; Gluecker et al, 2004; Slater et al, 2006; Soto et al, 2005; Taylor et al, 2004; Van Dam et al, 2004), the ACR, AGA, and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) have developed guidelines and consensus statements regarding the minimum training necessary to interpret CTC (Rockey et al, 2007; Taylor et al, 2007).

The American College of Radiology (ACR) recommends that physicians supervising and interpreting CTC should have reviewed at least 50 endoscopically-confirmed cases performed for a variety of indications (screening, symptomatic, incomplete endoscopy) and using a variety of scanning methods (e.g., with/without oral tagging, intravenous contrast), and states that cases can be reviewed in a number of settings, as long as review requires full interactivity with the CTC dataset and the search for colorectal neoplasia.

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These recommendations are based on numerous learning studies that demonstrate that CT colonography interpretation requires a minimum of 50 cases to achieve expert levels of performance in most cases (Bodily et al, 2005; Gluecker et al, 2002; Spinzi et al, 2001; Thomeer et al, 2003).

To meet the educational needs for CTC training, multiple large-scale, didactic and intensive hands-on training courses are now being offered by specialty and scientific societies, individual university programs, vendor-specific courses, and the ACR training facility. In 2008, 10-15 CME certified courses were given to train and provide certification of the 50 case review. These courses emphasize the major categories of colorectal morphologies, including polypoid, pedunculated, flat or sessile polyps, as well as advanced mural cancers.

Both ACR and AGA guidelines call for board-certified radiologists to review CTC datasets for potential extracolonic findings and to report those of potential medical significance, along with practice recommendations for further workup.

### **CT and Interpretive Technique**

Many of the early trials in CT colonography that demonstrated wide interobserver variability suffered from poor CT technique (e.g., single detector CT; thick, 5 mm slices) (Cotton et al, 2004; Johnson et al, 2003). Both the ACR and AGA guidelines call for use of a high spatial resolution, low-radiation dose technique in CT colonography, which has been validated in numerous studies. Both ACR and AGA recommend slice thickness of  $\leq 3$  mm (Taylor et al, 2003) and use of a  $\geq 4$ -slice multidetector CT (Hara et al, 2001). Radiation dose should be roughly equivalent to barium enema, and adjusted to patient size (so that greater dose reduction can be achieved in smaller patients). Additionally, CTC datasets should be examined on specialized computer workstations that permit simultaneous axial and multiplanar reformatted viewing, the generation of 3D endoluminal images, interactive adjustment of window-level, and simultaneous display of supine and prone data. Both AGA and ACR practice guidelines call for primary 2D or 3D search of potential lesions, with a well-defined algorithm for characterization of suspicious polyps or cancers.

### **Small Polyps**

Currently, the reporting of polyps based on size category should follow the recent American Cancer Society (ACS) guidelines (Levin et al, 2008). As per the ACS guidelines, polyps  $\geq 6$  mm should be reported and these patients should be offered polypectomy at colonoscopy as an option, however clinical management may vary depending on the age, risk to undergo colonoscopy or other significant co-morbidities.

The issues of diminutive polyps  $\leq 5$  mm remains controversial. As per the ACS guidelines, these lesions harbor a very low risk of advanced neoplasia ranging up to 1.7% (Moravec et al, 2007). The benefits of immediate polypectomy vs short term surveillance of these low risk neoplasms need to be balanced with the considerations of cost and complications of polypectomy. Namely, Levin et al reported in a retrospective review of 16,318 patients of Kaiser Permanente, 82 serious complications (5 in 1,000); 95% of these complications followed biopsy or removal of polyps and 62% of polyps removed were less than 10 mm (Levin et al, 2006). Various policies have been published on the management of lesions detected at CTC (American College of Radiology, 2006; Van Dam et al, 2004; Rockey, 2007; Rex et al, 2006). Currently longitudinal data on the natural history of small colorectal polyps is being collected with CTC surveillance studies. For current clinical practice, appropriate patient management of lesions detected at CTC will need to incorporate the clinical context of patient age, comorbidity, colorectal symptoms, and size and number of polyps. Further multi-disciplinary consensus agreements for clinical management are now being pursued, possibly within the efforts of the Colorectal Round Table.

### **Quality Control and Radiation Dose**

Advances in both technology and physician training have helped not only to greatly improve the sensitivity and specificity of CTC, but also to make the diagnostic performance of CTC more uniform at different institutions involved in multicenter studies. These advances have proven critical for demonstrating that CTC can be applied outside of academic centers and, subsequently, this has led to multisociety endorsement of CTC as a screening test for colorectal cancer, in addition to the development of multisociety guidelines and standards.

### **Quality Control**

Quality control is an essential and recognized aspect of all CT colonography and colon cancer screening regimens. Routine monitoring of CT equipment along with low dose techniques recommended by the ACR (American College of Radiology, 2005) should be performed (see below). ACR practice guidelines state that colon cleansing and distention should allow adequate visualization of the colon and rectum. Each segment should be distended and free of most fluid. Suboptimal visualization of any segment of the colon should be scanned again. An ACR Committee on Quality Assurance for CTC was formed in 2006 to define key parameters to promote quality assurance.

## **Radiation Dose**

It is critical to keep the radiation dose imparted at CTC efficient. Several investigators have reported successful use of low dose CTC protocols (Macari et al, 2002; Iannaccone et al, 2003; Van Gelder et al, 2004; Cohnen et al, 2004). In 2002, a study of 105 patients was performed with the CT scan protocol of 1 mm slice thickness and low dose of 50 effective mAs (Macari et al, 2002). The total effective dose to the patients for both supine and prone imaging of the abdomen and pelvis was 5.0 mSv for men and 7.8 mSv for women, which is comparable to dose ranges of barium enema. Excellent sensitivity of 90% for 1 cm polyps was achieved (Macari et al, 2002). In 2003, further dose reduction was achieved in a cohort of 158 patients predominantly at increased risk of colorectal neoplasia, using 10 effective mAs and a slightly thicker slice thickness of 2.5 mm (Iannaccone et al, 2003). This protocol resulted in total effective doses to the patients of 1.8 mSv in men and 2.4 mSv in women. In this study, there was 100% sensitivity for all 22 cancers, 100% sensitivity for the thirteen 10 mm and greater polyps, and 83% sensitivity for the 6-9 mm (20/24) polyps. The recent ACRIN trial also used low dose techniques of 50 effective mAs for normal-sized patients, but appropriately modulated dose for smaller and larger patients (to keep image quality constant).

Recent reports have discussed the controversy of low radiation dose exposure (Brenner et al, 2005; Amis et al, 2007). Brenner et al recently addressed the issue of radiation dose screening with CT colonography and concluded that the benefit-risk ratio was high and that cancer risks were very rare (Brenner et al, 2005). Brenner concluded that potential lifetime cancer risk for one CTC exam at 50 was 0.14% (0.07% if 70), which could be reduced by factors of five or ten with optimized low dose protocols (Brenner et al, 2005). However, most estimates of the potential cancer risk have assumed a linear non-threshold model by extrapolating from atomic bomb survivors, but there is controversy over whether this model applies for low dose exposures over limited body regions. Recently the American College of Radiology created a Blue Ribbon Panel on Radiation Dose in Medicine and published recommendations and quality initiatives for the safe use of ionizing radiation, including CT, in clinical practice (Amis et al, 2007). In its practice guidelines for CT colonography, ACR describes routine use of low-dose non-contrast technique, as well as modulation of technique for patients of different sizes as important elements of dose reduction and CT colonography exam quality.

## **III. Cost Effectiveness**

The cost-effectiveness of CT colonography is highly sensitive to the polyp detection rate, especially at the greater than 10mm threshold. In a US study using sensitivities of 82% and 91% for 6-9mm and 10mm and greater polyps respectively, compared to no screening at all CTC is very cost-effective at either 5 or 10-year intervals at \$8,000-\$17,000 per life-year prolonged (Vijan et al, 2007).

When compared to other screening modalities such as flexible sigmoidoscopy every five years, CTC was both cheaper and more effective. In the case of flexible sigmoidoscopy with fecal occult blood testing, CTC was still the dominant screening strategy. CTC every five years compared to annual FOBT alone was found to be more expensive, but more effective at a cost of \$22,000 per additional life-year saved (Vijan et al, 2007). These favorable comparisons to tests already recommended by multiple established guidelines (American Cancer Society, American College of Gastroenterology and Gastrointestinal Consortium) and approved for colorectal cancer screening suggest that CTC is a viable option for colorectal screening in those that prefer it (Woolf et al, 1996; Winawer et al, 1997; Smith et al, 2001).

This is especially important for patients who are not interested in the use of optical colonoscopy as an initial screening test. About 50 percent of eligible persons participate in screening for colorectal cancer. There is large potential for CTC to screen individuals who would otherwise not be screened.

Much research on cost effectiveness has focused on direct comparisons of optical colonoscopy to CT colonography. This ignores the significant portion of patients who are screened by barium enema, fecal occult blood test, flexible sigmoidoscopy, or not screened at all. In addition there are indirect costs and costs borne by patients that are not accounted for by these studies. One way that costs can be saved in the screening and follow-up process is if a positive CTC were immediately followed by an optical colonoscopy on the same day. This provides for efficiencies where the patient makes only one trip to the site and both studies can be done with the same bowel preparation. Where such centers are available, they may greatly increase adherence to follow-up after the diagnostic evaluation and, therefore, better economic viability of CTC.

#### **IV. Additive CTC Study and Studies CTC Replaces**

CTC is an ideal additive study after an incomplete colonoscopy for whatever the reason of incomplete inspection. It can be performed safely and can be performed on the same day, thus eliminating the need for a second bowel preparation. In terms of screening, CTC can replace the DCBE. It is better tolerated by patients and has shown a higher sensitivity for polyp detection. CTC will not replace optical colonoscopy but may improve colon cancer screening by allowing more patients to undergo effective colon cancer screening.

#### **V. How Often Screening CTC Performed**

CTC appears to be more effective in polyp detection than double contrast barium enema (DCBE). There are several studies that show similar sensitivity of CTC to colonoscopy

for the detection of colorectal polyps  $\geq 10$  mm. Based on the most recent data evaluating the effectiveness of CTC, the American Cancer Society recommends a screening interval of 5 years between negative CTC interpretations. This appears to be a reasonable time interval given that the current ACS recommendation for DCBE is five years and for colonoscopy 10 years. The American College of Radiology supports this time interval.

Polypectomy is the preferred treatment for CTC detected polyps measuring  $\geq 6$  mm, as long as the patient is a suitable candidate for endoscopic removal of the polyp identified at CTC. If the patient is at high risk for sedation or polypectomy, surveillance could be performed. The exact surveillance intervals will be at the discretion of treating physicians.

## **VI. Patient Population**

There are several evidence-based guidelines which, with minor variations, categorize individuals into specific risk groups with correlated recommendations for management. Screening identifies individuals who are more likely to have colorectal cancer or adenomatous polyps from among those without signs or symptoms of the disease. Based on age related risk, all individuals without other risk factors who are 50 years or older are considered at average risk.

Those with a single first-degree relative (mother, father, sister, brother, or child) who have had colorectal neoplasia before age 60 or multiple first-degree relatives with neoplasia diagnosed at any age are defined as at increased or above average risk. Individuals with a long-standing history of inflammatory bowel disease or from families with defined genetic syndromes are at high risk. Surveillance involves the ongoing monitoring of people with previously diagnosed colorectal neoplasm or inflammatory bowel disease. The degree of risk may be related to the underlying or prior pathology. Diagnostic examinations are performed on symptomatic individuals or as a follow-up to a prior but less definitive screening study. These individuals, by definition, are considered at greater risk to harbor colorectal neoplasia.

In general, the screening guidelines for CTC are similar to those for colonoscopy. However, patients with a history of chronic ulcerative colitis or Crohn's colitis are likely better screened with colonoscopy, related to the higher likelihood of an abnormality being detected requiring biopsy and histologic evaluation.

## **VII. Future Technologies**

### **Current Status of Computer-Aided Detection for CT Colonography**

The purpose of computer-aided detection (CAD) is to locate possible polyps automatically and annotate the images or present a list of image locations. The reader of CTC reviews the output of the CAD and makes the final diagnosis. Additionally, software tools for measurement of polyp size, volume, and automated comparison of supine and prone polyp candidate localization, are sometimes considered tools which are part of CAD. At least five major entities (academic or commercial) have developed and tested CAD systems.

The major clinical challenge is to evaluate the impact of CAD in an actual clinical interpretive setting. Preliminary results in CT colonography CAD are encouraging. There is evidence that high sensitivity and a low number of false positive detections per examination are achievable. Based on recent clinical CAD studies, CAD improved non-expert reader sensitivity with a minimal effect on reading time and false positive rate. Some results suggest that CAD may decrease interobserver variability in exam performance sensitivity. If this trend is proven in larger clinical trials, CAD will become an integral and important tool which will likely become part of every CTC visualization software package. Appropriate training in how to use CAD may be a key to its success.

## **VIII. CTC Screening Programs Currently in Progress**

The ACR is aware of at least three major U.S. institutions that have large volume screening programs for colorectal cancer using CT colonography (CTC). These three institutions are the University of Wisconsin, Walter Reed Army Medical Center and the National Naval Medical Center. The programs have been in place for 4-5+ years ranging in a patient load of 1400 to 2400 per year. The patient demographic generally is made up of an equal amount of men and women ranging in ages from 50-79 primarily in the average risk category. Radiologists interpret the CTC studies and have received specific training to read these studies, have met a minimum required set of reads in training before interpreting in the screening program and improve their skills as they increase the volume of cases read on a regular basis. The two military programs are funded under the militaries' own health care budgets. Walter Reed Army Medical Center says that their screening program has been a great success and recently deployed CTC screening programs to eight other army medical centers. They also are working with the Department of Veteran's Administration to deploy CT colonography screening throughout the VA health system. Walter Reed has indicated that when military members go outside of their program, TriCare does pay for CT colonography. The University of Wisconsin has worked with Wisconsin Physician's Service (WPS) to pay for CTC as a screening study under its private plan. At the University of Wisconsin,



several third party payers have provided coverage for colorectal screening. Pickhardt et al reported very positive first year results of screening 1,100 patients in this system, with 99 percent insurance coverage provided (Pickhardt et al, 2006).

In addition, there are 15 sites that participate in the ACRIN trial plus other major institutions such as Mayo Clinic, Massachusetts General Hospital, and University of Chicago that provide screening of colorectal cancers using CTC. Admittedly these programs are lower volume because of lack of coverage by the payers and the patients pay out-of-pocket.

Currently, Medicare pays for diagnostic CTC in 47 states under their local coverage decisions (LCDs) primarily for the indication of failed colonoscopy (Knechtges et al, 2007). In addition to the local Medicare policies, there are several private payers that are covering diagnostic CTC.

Medicare and private payers have recognized CT colonography as an important diagnostic study for the detection of colorectal cancer. Two major governmental health care programs and one major private payer, in addition to self-pay patients have found CTC to be highly beneficial as a screening exam for colorectal cancer. It is projected that access to patients and availability of this study by a multitude of sites would not be a significant problem with increase in demand.

## **IX. Conclusion**

In light of the American Cancer Society guidelines, existing strength in literature, current screening programs, and the compelling ACRIN findings, the ACR, SGR, and SCBT strongly support national coverage of screening CTC. In addition to the existing cogent evidence identifying CTC as a valuable screening tool and the developing data, we are committed to quality of patient care and the development of programs that ensure consistent levels of performance and quality assurance measures. To this end, the ACR has dedicated resources for quality assurance and validation including the ACR Blue Ribbon Panel on Radiation Dose, CTC Practice Guidelines, and the interactive hands-on training ACR Education Center.

The ACR, SGR, and SCBT appreciate the opportunity to provide these comments. Should CMS have any questions or comments, we would welcome further dialogue and are eager to assist in this important Medicare coverage process. Please do not hesitate to call Pam Kassing at (800) 227-5463, ext. 4544 or Anita Pennington at ext. 4923.

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