
Health Technology Clinical Committee**Findings and Coverage Decision****Topic: Computed Tomographic Colonography (CTC)****Meeting Date: February 15, 2008****Final Adoption: August 15, 2008****Number and Coverage Topic**

20080215B – Computed Tomographic Colonography (CTC)

HTCC Coverage Determination

Computed Tomographic Colonography (CTC) for routine colorectal cancer screening is **not a covered benefit**. This decision does not apply to use of CTC for other diagnostic purposes.

HTCC Reimbursement Determination❖ **Limitations of Coverage**

Not Applicable

❖ **Non-Covered Indicators**

Routine Colorectal Cancer screening

❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Uniform Medical Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

Colon cancer is the nation's second leading cause of cancer deaths, and an estimated 52,000 people will die from it this year. Screening can save lives by finding growths before they turn cancerous, yet only about one-half the population gets recommended screening. Current colorectal cancer screening tests include: Fecal Occult Blood testing, Barium enema, Sigmoidoscopy, and conventional or optical colonoscopy (OC).

CTC has been proposed as a less invasive alternative to conventional colonoscopy to screen for colorectal cancer, with the potential to induce more individuals to get screened. Colonoscopies, considered a gold standard test, are recommended every 10 years for everyone over 50 and more frequently after polyps are found or for high risk individuals. Optical colonoscopy involves taking laxatives to cleanse the bowel and sedation for the procedure. A tube is inserted in the rectum and snaked through the large intestines by a gastroenterologist. Generally, any polyps that are spotted, regardless of size, are taken out in the process. CTC involves taking laxatives to cleanse the bowel and inflating the colon with air or gas using a small tube inserted in the rectum. A CT scanner is used to

take a series of X-rays of the colon and a computer to create a 3-D view. A radiologist then checks the images for suspicious polyps. If any polyps need to be removed, the patient must then have a regular colonoscopy.

Benefits are thought to include an increase in patient compliance for screening recommendations and less risk of bowel perforation than conventional colonoscopy. Harms may include bowel perforation and radiation exposure, accuracy of the imaging tests leading to false results, the need for an additional procedure, conventional colonoscopy, if the CTC finds polyps that need removed and the inability of the screening to view polyps that are less than 5mm.

Summary of Committee Findings

The HTCC reviewed and considered the CT Colonography technology assessment report, information provided by the Administrator, and public and agency comments. A key overall benefit question committee members focused on: would adding CTC to the currently available methods to screen for colorectal cancer reduce cancer deaths. Factors considered related to the impact of CTC on cancer deaths, in addition to the safety and efficacy data include whether there was demonstrated patient preference, access to alternatives, and an impact on screening rates. Some evidence (expert opinion) supports the concept that current providers cannot accommodate optical screening if all patients were screened, therefore arguing for additional methods. Anecdotal and agency utilization do not demonstrate a provider access issue that creates a barrier for individuals to receive CRC screening. Limited patient preference data was gathered from the studies that showed approximately equal, though slightly greater preference for CTC (48%) compared to OC (41%) with 10% having no preference. No study evaluated the key concern of the impact of CTC on overall population screening rates. Based on the evidence presented on safety, efficacy and cost-effectiveness, committee voted for non-coverage.

Effectiveness: Effectiveness was a key area of discussion for committee members. Factors that were important in the discussion included: overall reduction in CRC mortality; equipment and reader training variation; and specificity (true negative, false positive); sensitivity (small polyps, medium polyps, and large polyps). Over-arching discussion included the appropriate comparator and its evidence level. According to National Cancer institute, fecal occult blood testing is the only cancer screening that is proven by randomized control trials to reduce colorectal cancer deaths is completely non-invasive, and very inexpensive. Optical colonoscopy is often the comparator for CTC and is cited as a gold standard, but its relative effectiveness at the overall goal of reducing colorectal cancer is not proven by same quality studies.

Equipment variation and reader/provider training – the report appropriately identified a current level of equipment and training for study inclusion. However, the current community standard is not uniform- there is variation in both equipment and training levels and the ability to enforce requirements for a population screening test by state payers is limited – the result is likely lower equipment and reader training and commensurate results. Regarding specificity: the evidence report demonstrated clinically equivalent ability to identify individuals without cancer (relatively high true negative and low false positive, about equal to optical colonoscopy – see evidence table page 32). Regarding sensitivity (true positive and false negatives) the evidence was mixed and dependent on the polyp size – small polyps were disregarded by the group; medium polyps detection based on 3 moderate quality studies found approximately equal numbers of cancer to optical colonoscopy; and the large polyp group also found approximately equal numbers of cancer to optical colonoscopy-see evidence

table page 55. However, one study's results were not pooled, and this lowered the sensitivity of virtual colonoscopy by 10% which was clinically relevant to some committee members. It was noted that sensitivity findings were based on centers and individuals having good training and equipment that may not be reflective of the providers that would service the state agency population. A majority of committee members found that the current scientific evidence is sufficient to demonstrate that in some or all cases, CTC is equivalent in efficacy.

Safety: Key health outcomes important to the safety considerations for CTC were: invasiveness; bowel perforation; radiation exposure (accumulation); and extra-colonic findings. CTC is an invasive procedure due to bowel preparation (cleansing and air pressure through rectal tube to inflate colon), though different degree to optical colonoscopy. This is a key distinction for whether it involves some risk and related to whether the unpleasant aspect of screening is reduced enough to induce more individuals to get screened. Both CTC and OC have small risk of bowel perforation, but CTC rate is smaller as calculated by evidence report (.08 for CTC versus .13 for OC).

Radiation exposure is higher with CTC than OC, but this is expected because of test. Key issue is level of exposure and long term risk related to additive exposure for population screening every five years - long term effect is unknown and significant clinical debate on exposure risk – FDA estimate one new cancer per 2000 for standard dose abdominal CT. Evidence review comparisons: chest x-ray is .02; Low dose CTC is .5; abdominal CTC is 10-radiation worker exposure limit is 20 per year. Extra-colonic findings can be beneficial if clinically significant, but most findings are not and those produce additional unnecessary testing and strain for patients. Evidence report indicates between 6 and 8% of tests in studies had extra-colonic finding with 0.3% of patients found to have extra-colonic cancers. Committee members found that both tests had safety related trade-offs, though likely low risk; evidence supported a finding that CTC was either equivalent or more safe than optical colonoscopy.

Cost: Due to the close findings related to safety and effectiveness, cost outcomes were important, including; the cost of the procedure; referral rate to additional procedures (optical colonoscopy); and extra-colonic findings. The technology report cost findings included: not currently priced (national/Medicare), most private payers do not reimburse, estimate cost \$522 for CTC and \$523 OC. Technology report cost conclusions included: break even at half price of OC; low value if same or higher price than OC; higher value if one-third the cost of OC. Agency utilization data indicated that FoBT: \$7, OC: \$723; CTC\$912. Current screening costs with CTC annually are 10 million; and to screen the same population with CTC would increase costs to between 26 to 30 million.

Regarding additional tests required upon a CTC finding: the technology report rate of referral for follow up in studies was 14% and the referral rate for HCA paid CTC's was 40%. Limited information on cost of extra-colonic findings was presented in the tech report estimated at about \$2-\$34 per screening. Cost became a key element of discussion - for some committee members, if costs were lowered to one-third of OC, then this essentially equivalent option would become beneficial. Limited current reimbursement experience is that the cost is higher than CTC. Committee members found that current evidence either indicated that there CTC was less cost effective than alternatives or that there was insufficient evidence to make a conclusion about cost-effectiveness.

Committee Authority

The Washington State [Health Technology Clinical Committee \(HTCC\)](#), an independent committee of 11 health practitioners, determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Evidence includes a report concerning the technology provided by a company specializing in objective reviews of pertinent scientific literature; information submitted by the affected state agencies; and public comment. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be reviewed at the determination of the HCA Administrator.