



GE Healthcare

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March 13, 2009

Charlene Frizzera, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd, Room 314G
Baltimore, MD 21244-1850

**Re: Proposed Decision Memo for Screening Computed Tomography Colongraphy (CTC)
for Colorectal Cancer (CAG-00396N)**

Dear Ms. Frizzera:

GE Healthcare appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) February 11, 2009 proposed coverage decision memo for screening CT Colonography (CTC) for colorectal cancer (CRC).

GE Healthcare, a \$17 billion unit of General Electric Company with headquarters in the United Kingdom, has expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, performance improvement, drug discovery, and biopharmaceuticals manufacturing technologies. GE Healthcare's broad range of products and services enables healthcare providers to offer patients earlier and better diagnosis and treatment of cancer, heart disease, neurological diseases, and other conditions to improve the quality and length of life. Worldwide, GE Healthcare employs more than 50,000 people committed to serving healthcare professionals and their patients in more than 100 countries.

It is significant to recognize that we are advocating that CMS reconsider its non-coverage recommendation for CTC during National Colorectal Cancer Awareness Month. Colorectal cancer is the third most diagnosed cancer in the United States and the second leading cause of death from cancer. The disease kills as many as breast cancer and AIDS combined and 1 in every 18 Americans will be diagnosed with colorectal cancer in their lifetime with an increasing incidence correlated with older age. This loss of life is tragic considering that the disease is almost always preventable through routine screening and is highly treatable.

GE Healthcare recognizes and supports the initiation of this national coverage analysis and we fully support a Medicare CRC screening program that includes a range of alternatives that maximizes patient compliance. Specifically, **GE Healthcare strongly supports national Medicare coverage of CTC as a clinically effective, more patient acceptable alternative for CRC screening.** GE Healthcare believes there are five critical topics regarding the CMS proposed decision of non-coverage for CRC screening with CTC that require elaboration:

- Adding CTC as an alternative will support increased CRC screening compliance
- CTC is a clinically effective CRC screening alternative
- CMS does not have the legal authority to incorporate cost effectiveness as an assessment criteria in its screening coverage decision making
- MedCAC inappropriately considered cost-effectiveness information
- There are several concerns regarding the Agency for Healthcare Research and Quality (AHRQ) cost-effectiveness analysis that must be remedied

Adding CTC as alternative will support increased CRC screening compliance

We all share the common goal to increase CRC screening compliance rates beyond the 50% level, a participation plateau that has not improved in many years. Since the issuance of this proposed decision, President Obama and the Office of Management and Budget in its overview of the 2010 federal budget specifically mention increased funding for disease prevention, specifically highlighting the low CRC screening rates.¹ As a department of the Executive Branch, CMS is responsible for helping to achieve these objectives of increased prevention and screening and can do so by adding CTC as an alternative for CRC screening.

Several key stakeholder groups advocate CTC as a CRC screening alternative. Clinical guidelines issued jointly by the American Cancer Society (ACS), the US Multi Society Task Force on Colorectal Cancer, and the American College of Radiology (ACR) which support CTC screening for colorectal cancer, and was a catalyst for CMS initiating its coverage analysis. Importantly, these guidelines whose primary goal is colon cancer prevention, include CTC as an acceptable *option* for the early detection of CRC and adenomatous polyps for asymptomatic adults aged 50 years and older.² These guidelines were influenced by the preliminary results of the American College of Radiology Imaging Network (ACRIN) prospective, multi-center national CTC trial. The preliminary findings demonstrated the clinical efficacy of CTC compared to optical colonoscopy (OC) and its *potential to enhance colon cancer screening compliance.* ACS guidelines for the early detection of colorectal cancer have emphasized options, and will continue to do so to enhance access to and uptake of screening, according to the ACS. Specifically the guidelines state, "it is our hope that these new recommendations will facilitate increased

¹ Office of Management and Budget. Jumpstarting the Economy and Investing for the Future. Available at: http://www.whitehouse.gov/omb/assets/fy2010_new_era/Jumpstarting_The_Economy.pdf. Accessed March 5, 2009.

² Levin B, Lieberman DA, McFarland B et al. Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. CA Cancer J Clin 2008 March 5.

rates of CRC screening and that referring clinicians find these new guidelines ease some of the challenges they have experienced in promoting CRC screening to their patients.”² Also, twenty-six states plus the District of Columbia legislate CRC coverage in accordance with these ACS guidelines that include CTC³. With a Medicare non-coverage decision, Medicare patients, whom may have chosen CTC prior to entering the Medicare program, would be forced to choose a more invasive or less accurate screening procedure or forgo screening.

The American College of Gastroenterology believes CTC provides an acceptable screening option for patients, particularly for those who may not seek a screening procedure due to some aversion to existing options. They recently updated their screening guidelines and endorse CT Colonography for patients who decline colonoscopy⁴. In addition, new data has recently emerged that suggests that among U.S. patients, there is evidence of a willingness to pay for CRC screening that could translate to improved screening compliance that is necessary to save more lives from colorectal cancer.⁵ This data and the multiple sets of guidelines support the premise that adding CTC to the list of available screening tools would increase compliance.

CTC is a clinically effective CRC screening alternative

We believe there are sufficient data and clinical evidence to support CTC screening coverage under Medicare as evidenced by the ACRIN trial. In September 2008, *The New England Journal of Medicine* published the final results of the clinical data collected from 2,531 asymptomatic participants enrolled in 15 centers across the U.S., making it the largest and most comprehensive CTC screening trial to date. The results found that CTC screening identified 90% of patients with adenomas and cancers measuring 10 mm or more in diameter, supporting and extending previously published data regarding the role of CTC in screening patients with an average risk of colorectal cancer.⁶

Two respected U.S. Health Technology Assessment organizations also recognize the clinical value of CTC as a CRC screening alternative. The February 2009 ECRI Institute Evidence report indicates that CT Colonography “... has a sensitivity of 91%...” for screening asymptomatic, average-risk individuals⁷ and has been shown to be more sensitive than other screening methods already covered by Medicare, such as flexible sigmoidoscopy and

³ American Cancer Society. Colorectal Cancer Facts & Figures 2008-2010. Available at: http://www.cancer.org/downloads/STT/F861708_finalforweb.pdf. Accessed March 11, 2009.

⁴ Rex DK, Johnson DA, Anderson JC, Schoenfeld PS, Burke CA, Inadomi JM. American college of gastroenterology guidelines for colorectal cancer screening 2008. *Am J Gastroenterol.* 2009;104:739-50.

⁵ Marshall DA, Johnson FR, Kulin NA et al. How do physician assessments of patient preferences for colorectal cancer screening tests differ from actual preferences? A comparison in Canada and the United States using a stated-choice survey. *Health Econ.* 2009.

⁶ Johnson, CD, M.D., M.M.M., Chen, MH, Ph.D., et al, Accuracy of CT Colonography for Detection of Large Adenomas and Cancers, *New England Journal of Medicine*, 2008; 359:1207-1217.

⁷ ECRI Institute. Computed Tomographic (CT) Colonography for Colorectal Cancer Screening and Diagnosis. Available at: <https://members2.ecri.org/Components/EvidenceReports/Documents/IssueFiles/TX1990.pdf>. Accessed March 5, 2009.

double contrast barium enema^{8,9}. The rigorous health technology assessment organization, Blue Cross Blue Shield Technology Evaluation Center (TEC), also recently concluded that CTC meets all five TEC criteria for the purpose of colon cancer screening which address regulatory approval, health outcomes, procedure alternatives, and provider settings¹⁰.

With respect to CMS' concerns regarding the 'generalizability' to the Medicare population GE Healthcare feels this concern is less significant as CRC screening is a benefit for patients 50 years and older and Medicare coverage may also include younger disabled populations. In addition, screening only Medicare subjects is not practical for comprehensive study within a prospective clinical trial, as demonstrated by the government sponsored ACRIN 6664 trial. Although not specifically studied in the ACRIN trial, CTC may actually be more appropriate and successful in the older Medicare population, given the potential for poor tolerance of the OC procedure secondary to an increased incidence of colonic outpouching (diverticulosis) and colonic redundancy, which can be associated with painful coiling of the colonoscope and potential perforation.¹¹

Relative to CMS questions regarding radiation harms, GE Healthcare recognizes concerns about potential risk associated with ionizing radiation in medical imaging and remains committed to developing safe and effective devices that improve net health outcomes for patients. The benefit to patients from diagnostic information delivered with CT imaging systems need to be balanced against associated radiation doses. When prescribing a CT scan, the trained physician must make this determination. In their analysis of mass screening for colorectal cancer using CT colonography, Brenner and Georgsson¹² found a favorable clinical balance: "in terms of radiation exposure, the benefit-risk ratio potentially is large for CTC". Recent information communicated to MedCAC on patient dose from the multi-centric, multi-vendor ACRIN 6664 screening that utilized current CT imaging technologies and clinical protocols indicated that effective dose range was between 5-8 mSv¹³. The potential risk is even lower for the Medicare population due to the decreasing radiosensitivity of abdominal organs that occurs with increasing age. With over 60 million annual CT exams in the US, CT has demonstrated itself as a safe and effective tool that delivers the high detail images needed for accurate diagnosis and medical care.

We believe CMS' concerns related to site patient dose variance will be addressed through facility accreditation processes that will be mandated for advanced imaging modalities via

⁸ Winawer, Sidney J., M.D., et al. A Comparison of Colonoscopy and Double-Contrast Barium Enema for Surveillance after Polypectomy. *New England Journal of Medicine*, 2000; 342:1766-72.

⁹ Imperiale TF, Wagner DR, Lin CY, Larkin GN, Rogge JD, Ransohoff DF. Risk of advanced proximal neoplasms in asymptomatic adults according to the distal colorectal findings. *N Engl J Med* 2000 July 20;343(3):169-74.

¹⁰ Blue Cross Blue Shield Association. CTC Colonography ("Virtual Colonoscopy") for Colon Cancer Screening. Available at: <http://www.bcbs.com/blueresources/tec/press/ct-colonography-virtual.html>. Accessed March 5, 2009.

¹¹ Ko CW, Sonnenberg A. Comparing risks and benefits of colorectal cancer screening in elderly patients. *Gastroenterology* 2005 October;129(4):1163-70.

¹² Brenner DJ, Georgsson MA. Mass screening with CT colonography: should the radiation exposure be of concern? *Gastroenterology* 2005 July;129(1):328-37.

¹³ CMS: Centers for Medicare and Medicaid Services Medicare Evidence Development and Coverage Advisory Committee RE: Screening Computed Tomography Colonography (CTC). Available at: <http://www.cms.hhs.gov/FACA/downloadads/id45c.pdf>. Accessed: March 5, 2009.

the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Operator and physician training as well as formal accreditation programs play the key role in minimizing dose, reducing variance and assuring quality.

In response to stakeholder questions about long-term effects of low-level excess radiation, GE Healthcare's products and many other CT scanners record examination parameters to facilitate both patient examination reporting and broad, long-term longitudinal studies to assess population trending. GE Healthcare actively collaborates with other industry partners and professional societies who are committed to responsible, safe, and effective use of imaging technology to reduce colorectal cancer mortality. An example of this collaboration is the creation of a new DICOM standards-based dose report being incorporated on CT image systems that enables exam dose information to be recorded, networked, and available for future reference, trending, and analyses.

CMS does not have the legal authority to use cost-effectiveness in evaluating CTC

Contrary to the view of CMS in the proposed decision memorandum, there is simply no authority in the Social Security Act or other applicable law (and CMS cites none) that allows consideration of cost-effectiveness when determining that a procedure or service is covered by Medicare for colorectal cancer screening. This lack of authority is confirmed by applicable CMS guidance and by a review of Medicare statutory provisions:

- CMS Guidance

The agency has issued a final guidance document that states “[c]ost effectiveness is not a factor CMS considers in making NCDs . . . the cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD.”¹⁴ This CMS guidance makes no exception for colorectal cancer screening technology or any other type of health care intervention.

- Medicare Statutory Provisions

Social Security Act §1861(ddd), as added by MIPPA §101(a)(1)(B), provides for Medicare coverage of certain “additional preventive services” that are “not otherwise described” in title XVIII of the Social Security Act. Colorectal cancer screening services are among the services that title XVIII describes. Thus, we agree with the CMS assumption in the proposed decision memorandum that coverage of colorectal cancer screening tests must be considered under a different statutory provision --Social Security Act §1861(pp)(1)-- that is dedicated exclusively to coverage of colorectal cancer screening.

¹⁴ Guidance for the Public, Industry and CMS Staff, “Factors CMS Considers in Opening a National Coverage Determination” (April 11, 2006).

That said, the method by which §1861(ddd) provides for the coverage of “additional preventive services” bears on the question of CMS authority to use cost-effectiveness in a coverage decision. Specifically, in the case of the specified class of technologies to which it applies, §1861(ddd) provides that the HHS Secretary must use Medicare’s national coverage process, and, in using this process, “may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.”

Whatever the precise implications of this §1861(ddd) passage, it makes clear that Congress employs explicit language when it means to confer authority for the Secretary to inject economic considerations into Medicare coverage decisions. Such explicit language is lacking in the authorities applicable to colorectal cancer screening tests, and, indeed, as noted above, would be directly inconsistent with CMS’ own guidance document.

We note, in the interest of completeness, that §1861(pp) -- the provision dedicated exclusively to coverage of colorectal cancer screening tests – recognizes authority of the Secretary to apply appropriate “payment limits.” These limits, as the statute elsewhere makes clear,¹⁵ are pertinent only to the methodology for calculating *payment amounts* for services and have no relation to CMS authority to *cover* services. As a federal court recently held, the HHS Secretary lacks authority to use purported coverage limits to supersede otherwise applicable Medicare payment methodologies.¹⁶

MedCAC inappropriately considered cost-effectiveness information

At the MedCAC meeting, the panel received some background from the CMS representative on the relevance of MIPPA section 101 – the provision that enables coverage of “additional preventive services” under Social Security Act §1861(ddd). The MedCAC transcript reads as follows: “... Congress in passing the legislation that authorized coverage for colorectal cancer screening authorized us to look at the cost of these particular technologies in the assessment of coverage of these different technologies”.¹³ This explanation, while well intentioned, may have created some confusion among panel members about the relevance of the new law, and it might possibly have led them to conclude (incorrectly) that this provision impacted how CT colonography was to be considered. As noted above, and as the CMS proposed decision memorandum acknowledges, the statutory authority for this NCD derives from Section 1861(pp) of the Social Security Act, not the MIPPA-enacted provision. Because the MIPPA provision restricts CMS from covering preventive or screening services that are not supported by an evidence grade of “A” or “B” by the USPSTF, we are concerned that MedCAC panel members may have mistakenly concluded that the evidence bearing on CT colonography could not be considered to be adequate for coverage. We believe that a careful and full explanation of the law bearing on this issue was in order at the meeting, and we trust that this matter will be made clear in the final coverage determination. In any event, any CMS decision that relies on the MedCAC findings is suspect.

¹⁵ See, e.g., Social Security Act 1834(d) (“Frequency Limits and Payment for Colorectal Cancer Screening Tests”).

¹⁶ See, *Hays and Dey, L.P. v. Leavitt*, 583 F. Supp. 2d 62 (D.D. 2008) (HHS Secretary could not apply a purported coverage limit based on “least costly alternative” to override Medicare Part B drug payment methodology).

Finally, during the MedCAC meeting the panel heard testimony from the AHRQ regarding cost-effectiveness that was passed on a draft analysis that contained several analytical errors, including the misrepresentation of costs that overstated CTC procedure costs and understated optical colonoscopy procedure costs. We believe that based on the errors in the AHRQ report and the incorrect guidance that panel members received from CMS regarding the evaluation of cost-effectiveness, the MedCAC panel findings should not be used during the final coverage determination process.

There are concerns regarding the AHRQ cost effectiveness analysis that must be remedied

Although GE Healthcare believes that the Secretary does not have authority to consider cost effectiveness in this coverage decision, we have concerns regarding the AHRQ cost effectiveness analysis. The CMS proposed decision relies in part on an AHRQ cost effectiveness analysis that is improperly designed and based on outdated cost information, which leads AHRQ and CMS to conclude erroneously that CTC is not cost effective. We are concerned that AHRQ's false conclusion about cost effectiveness may have also biased CMS' interpretation of the clinical literature.

AHRQ's study design characterizes CTC as a substitute for currently covered screening technologies (FOBT, flexible sigmoidoscopy, colonoscopy or barium enema). In fact, CTC is intended to augment existing screening technologies, not replace them. A properly designed cost-effectiveness analysis should compare costs and benefits of the current Medicare *screening program* to the costs and benefits of a *screening program* that includes CTC as an alternative screening technology to augment the overall strategy to CRC screening.

AHRQ gave passing and incomplete attention to this fundamental issue in a sensitivity analysis that evaluated how changes in compliance would affect the cost effectiveness of CTC. Not surprising, this analysis clearly demonstrated that the cost-effectiveness ratio of CTC increases dramatically when it results in more patients being screened. A more robust evaluation of CTC on the Medicare's screening program can be constructed from results provided in Table 9 of AHRQ's report; the incremental cost-effectiveness ratio for CTC vs. no screening ranges from \$1,800 to \$9,500 across the two CTC options and three models considered in AHRQ's analysis.

CMS and AHRQ's inconsistent characterization of screening technologies as being substitutes for new technologies on the one hand, and being additive to the screening benefit on the other, is apparent when comparing the current benefit design to AHRQ's analysis. The Medicare screening benefit includes a wide range of choices for Medicare beneficiaries. However, many of these options are not on the "efficient frontier"¹⁷ estimated by AHRQ and should, if logic holds, not be covered on pure cost effectiveness grounds. The fact that Medicare currently covers colorectal cancer screening options that are not efficient

¹⁷ For example, the only two efficient strategies from the CRC-SPIN model are hemoccult SENSE and colonoscopy.

proves that factors other than clinical evidence and cost effectiveness - such as patient choice - are critical elements of coverage decisions.

In addition to being incorrectly designed, AHRQ's analysis also relies on outdated and understated costs for screening colonoscopy.¹⁸ AHRQ estimated the cost of a screening colonoscopy to be \$522.47 based on 2007 data.¹⁹ However, the comparable cost of a screening colonoscopy is \$569.79 based on 2009 data.²⁰

We urge CMS to review the AHRQ analysis based on the additional beneficiaries that can be screened as part of a comprehensive program that includes CTC as an alternative.

In conclusion, GE Healthcare reiterates its **support for CTC as a CRC screening alternative to provide a more patient acceptable, clinically effective test to help policymakers increase the low screening compliance rates to prevent CRC.** We believe there is sufficient clinical evidence, and there are the necessary clinical guidelines and process infrastructure in place to ensure the safe and effective use of CTC in clinical settings.

We appreciate the opportunity to comment on this proposed decision memorandum, and look forward to providing CMS with any additional information that would be of value for the final decision on screening CTC for colorectal cancer.

Sincerely,



Hugh Zettel
GE Healthcare, Strategic Reimbursement Executive

cc:
Carolyn Clancy, MD
Director, Agency for Healthcare Research and Quality

¹⁸ We appreciate AHRQ responding to our previous comment by correctly including anesthesia costs in the cost of a screening colonoscopy in their final report.

¹⁹ \$497.59 inflated by 5% to account for repeat colonoscopies.

²⁰ Outpatient facility payments for optical colonoscopy increased substantially after 2007.