

## CMS Denies Medicare Reimbursement Eligibility for Virtual Colonoscopies

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The Centers for Medicare and Medicaid Services (CMS) recently issued a memorandum stating that it would not approve monetary reimbursement for Medicare-eligible individuals who undergo a virtual colonoscopy noting “[t]he evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test.”<sup>1</sup> The agency’s decision will either somewhat silence or enhance the controversy that has mounted for years among various medical professionals regarding whether the CT scans are as effective as conventional colonoscopy.

### Incidence of Colorectal Cancer and Screening Tests

Colorectal cancer is one of the most commonly diagnosed cancers and a leading cause of cancer deaths in the United States.<sup>2</sup> In 2005, the most recent year for which statistics are available, nearly 142,000 men and women were diagnosed with the disease and approximately 53,000 died as a result.<sup>3</sup> Unlike some other forms of cancer, early detection and intervention has been proven to improve survival rates.<sup>4</sup> The highest rates of incidence are found in individuals located in the Midwest and Southern states and those over the age of 50 with a family history of colorectal cancer and a presence of polyps in the colon.<sup>5</sup> Most colorectal cancers begin as precancerous polyps, abnormal growths in the colon or rectum<sup>6</sup> and often do not include symptoms until cancerous tissue is present in the body.<sup>7</sup>

Though medical professionals and celebrities alike have bombarded the nation with information and statistics regarding the positive effects of being screened for early signs of colorectal cancer, many men and women remain hesitant to undergo a colonoscopy due to an “ick” factor being associated with the procedure. Traditionally, it has been recommended that people start the screening process at or around the age of 50. However, a recent study has revealed that

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<sup>1</sup> Centers for Medicare and Medicaid Svcs., *Decision Memo for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)*, May 12, 2009, <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=220&>.

<sup>2</sup> *Id.*; see also Centers for Dis. Control and Prev., *Colorectal (Colon) Cancer: Statistics*, <http://www.cdc.gov/cancer/colorectal/statistics/> (last updated Jan. 9, 2009).

<sup>3</sup> Centers for Dis. Control and Prev., *Colorectal (Colon) Cancer: Statistics*, <http://www.cdc.gov/cancer/colorectal/statistics/> (last updated Jan. 9, 2009) (citing U.S. Cancer Stat. Working Group, *United States Cancer Statistics: 1999-2005 Incidence and Mortality Web-based Report*, 2009, <http://www.cdc.gov/uscs>).

<sup>4</sup> *Id.*

<sup>5</sup> See Centers for Dis. Control and Prev., *Colorectal (Colon) Cancer: Comparing Colorectal Cancer in Different U.S. States*, <http://www.cdc.gov/cancer/colorectal/statistics/state.htm> (last updated Mar. 19, 2009); Nat. Lib. of Med. and Nat. Inst. of Health, *Colorectal Cancer*, MEDLINE PLUS, <http://www.nlm.nih.gov/medlineplus/print/colorectalcancer.html> (last updated June 19, 2009).

<sup>6</sup> Centers for Dis. Control and Prev., *Colorectal Cancer Screening and Early Detection (brochure)*, <http://www.cdc.gov/cancer/colorectal/pdf/CCSilencebrochure.pdf>.

<sup>7</sup> *Id.* Symptoms to watch for include blood in the stool, a change in bowel habits, general stomach discomfort, frequent gas pains, or weight loss.

colorectal cancer rates are beginning to rise in younger individuals—as much as 2 percent per year for some age groups.<sup>8</sup>

The most common and best screening test for colorectal cancer at present is a traditional colonoscopy.<sup>9</sup> Preparation for the procedure typically begins the day before with the individual drinking only clear liquids and consuming special laxatives to cleanse the colon.<sup>10</sup> Preparation for the procedure has been cited as being the worst part of the entire process.<sup>11</sup> On the day of the exam, patients are given sedation medication and are, for the most part, unaware the procedure is taking place. As the patient lies on his or her left side, a long, flexible scope (colonoscope) is inserted through the rectum and advanced to the other end of the large intestine.<sup>12</sup> Affixed with a camera, the scope bends around the curves of the colon allowing the physician to check for any abnormalities.<sup>13</sup> If the doctor sees something that may be unusual, small amounts of tissue can be removed for a biopsy, and polyps or other abnormal growths can be identified and removed.<sup>14</sup> The procedure is performed on an outpatient basis and generally takes less than 60 minutes to complete.<sup>15</sup>

Often referred to as CT (computerized tomographic) colonography, a virtual colonoscopy is a non-invasive procedure that utilizes MRI or CT scans to produce images of the colon and rectum.<sup>16</sup> Although patients must undergo similar bowel-cleansing procedures as they would for a traditional colonoscopy, the virtual test is typically performed without sedation and without a scope in a radiology department of a hospital or medical center.<sup>17</sup> The patient will be situated on his or her side or back, on a narrow table, while a small tube is inserted into the rectum pumping air to inflate the colon so that it is easier for the physician to see.<sup>18</sup> Once completed, the table slides into a tunnel through the machine, much like an MRI, where images are taken of the

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<sup>8</sup> See Jill U. Adams, *Colorectal Cancer Rates Are Rising in Younger People*, L.A. TIMES, June 22, 2009, <http://www.latimes.com/features/health/la-he-closer22-2009jun22,0,3729887.story>. The new study found that the rate in white men ages 20 to 49 was 8.4 cases out of every 100,000 people during 1992 to 1995. Ten years later, the rate had risen to 10.2 – a 21 percent increase.

<sup>9</sup> David H. Kim, M.D., et al., *CT Colonography versus Colonoscopy for the Detection of Advanced Neoplasia*, 357 NEW ENG. J. MED. 1403, 1407 (Oct. 2007); Palo Alto Med. Found., *Colon Cancer Screening*, (Sept. 2006), available at <http://www.pamf.org/health/guidelines/ColonCancer.pdf>; see also Nat. Colorectal Cancer Res. All., *Get Tested: Colonoscopy*, [http://www.eifoundation.org/national/nccra/get\\_tested/colonoscopy.html](http://www.eifoundation.org/national/nccra/get_tested/colonoscopy.html) (NCCRA was co-founded by CBS Evening News Anchor Katie Couric after her husband Jay Monahan passed away at the age of 42 from colorectal cancer).

<sup>10</sup> *Id.*

<sup>11</sup> See e.g., Miranda Hitti, *Colonoscopy Prep Worse than Procedure*, WEBMD, May 16, 2008, <http://www.webmd.com/colorectal-cancer/news/20080516/colonoscopy-prep-worse-than-procedure>; Daniel J. DeNoon, *Virtual Colonoscopy, Real Accuracy: Study ‘Validates’ CT Scans for Colon Cancer Screening, but Worries Linger*, WEBMD, Sept. 17, 2008, <http://www.webmd.com/colorectal-cancer/news/20080917/virtual-colonoscopy-real-accuracy>.

<sup>12</sup> WebMD, *The Basics of Colonoscopy*, <http://www.webmd.com/digestive-disorders/colonoscopy>.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*; see also Nat. Colorectal Cancer Res. All., *Get Tested: Colonoscopy*, [http://www.eifoundation.org/national/nccra/get\\_tested/colonoscopy.html](http://www.eifoundation.org/national/nccra/get_tested/colonoscopy.html).

<sup>16</sup> Nat. Lib. of Med. and Nat. Inst. of Health, *Medical Encyclopedia: Virtual Colonoscopy*, MEDLINE PLUS, <http://www.nlm.nih.gov/medlineplus/print/ency/article/007253.htm> (last updated Mar. 8, 2008).

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

colon.<sup>19</sup> The process takes approximately 20 minutes to complete.<sup>20</sup> It must be noted that a CT colonography is strictly a diagnostic procedure; if any abnormal polyps are detected, a conventional colonoscopy will be required to remove the possibly cancerous tissue.<sup>21</sup> Additionally, some insurance companies may not cover the virtual procedure as a screening test.<sup>22</sup>

### The Face Off Between Physician Groups

Those primarily responsible for performing traditional colonoscopy procedures, gastroenterologists or surgeons specializing in the gastrointestinal system, state virtual colonography examinations fail to detect smaller polyps that may be cancerous, should not be performed for those who are at a higher risk of colon cancer, and would require a traditional colonoscopy to remove abnormal tissue—thereby increasing the expense of having two procedures performed.<sup>23</sup> Current research has found that virtual scans can detect approximately 90 percent of polyps at least 10 millimeters in size.<sup>24</sup>

Pro-virtual colonoscopy scans, namely radiologists who perform the procedures, note the “better, safer, faster, [and] cheaper”<sup>25</sup> procedure may ultimately lead more people to get screened and result in fewer deaths.<sup>26</sup> Further, the CT scans see more than just the colon or intestine.

“Colonoscopy cannot look outside the colon. CT colonography does,” says physician and internal medicine expert Robert Fletcher, professor emeritus at Harvard University.<sup>27</sup> “So there is an opportunity among patients age 50 and older to be able to look for other abnormalities that maybe asymptomatic but may cause harm in the future. We can look for...tumors in other body parts.”<sup>28</sup> Though Professor Fletcher makes the claim, there have been no published reports on the uses of CT colonography to detect other physical anomalies.

Although the American Cancer Society, the American College of Radiology, and the United States Multi-Society Task Force on Colorectal Cancer embrace CT colonography as an option on the list of colon cancer screening procedures, GI physicians remain reluctant to endorse the virtual exam.

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<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> See RadiologyInfo, *CT Colonography*, [http://www.radiologyinfo.org/en/info.cfm?PG=ct\\_colo](http://www.radiologyinfo.org/en/info.cfm?PG=ct_colo).

<sup>22</sup> *Id.*

<sup>23</sup> DeNoon, *supra* note 11; see also Salynn Boyles, *Virtual Colonoscopy: Who Should Get It?*, WEBMD, June 16, 2009, <http://www.webmd.com/colorectal-cancer/news/20090616/virtual-colonoscopy-who-should-get-it>.

<sup>24</sup> *Id.* See also David H. Kim, M.D., et al., *CT Colonography versus Colonoscopy for the Detection of Advanced Neoplasia*, 357 NEW ENG. J. MED. 1403, 1411 (Oct. 2007) (concluding that both the virtual and standard screening methods resulted in similar detection rates for cancerous tissue).

<sup>25</sup> Andrew Pollack, *Medicare Blow to Virtual Colonoscopies*, N.Y. Times, Feb. 13, 2009, <http://www.nytimes.com/2009/02/13/health/policy/13colon.html>.

<sup>26</sup> Nat. Cancer Inst., *Large, Multi-Center Trial Demonstrates Comparable Accuracy for Virtual Colonoscopy and Standard Colonoscopy*, Sept. 17, 2008, <http://www.cancer.gov/newscenter/pressreleases/VirtualColonoscopyRelease>.

<sup>27</sup> See DeNoon, *supra* note 11.

<sup>28</sup> *Id.*

Thus, it can be concluded that a small victory was won by the gastrointestinal medical professionals when CMS recently decided to deny coverage of CT colonography for cancer screening. Medicare currently covers colorectal cancer screening for beneficiaries over 50 undergoing traditional colonoscopy and several other tests and procedures.<sup>29</sup>

### The CMS Decision to Deny Payment for Virtual Colonoscopies

On February 11, 2009, CMS issued a proposed decision memorandum stating that the agency was considering denying coverage eligibility for CT colonography.<sup>30</sup> The agency based its preliminary decision on a review of medical literature, information presented during a Medicare Evidence Development and Coverage Advisory Committee meeting in November, 2008, and public comments submitted as of that date.<sup>31</sup> After CMS published its 21-page memo, the agency commenced a 30-day public comment period before issuing a final decision.<sup>32</sup>

Shortly thereafter, proponents of CT colonography quickly mobilized. More than 350 comments were submitted to CMS by interest groups, many with a financial stake in use of the technology.<sup>33</sup> A write-in campaign was launched by groups of radiologists and manufacturers of CT equipment and several members of the United States House of Representatives signed letters urging CMS to reverse its position.<sup>34</sup> Efforts by supporters of virtual colonoscopy were ultimately unsuccessful.

On May 12, 2009, CMS finalized its decision to deny coverage of CT colonography for cancer screening noting its “pivotal, overarching concern” was the lack of cognizable benefit to Medicare patients.<sup>35</sup> In particular, CMS noted that the mean age of participants in the studies cited in support of virtual colonoscopy coverage was significantly lower than that of Medicare beneficiaries.<sup>36</sup> “There were no studies evaluating this technology in the elderly, nor were there analyses of subgroups of participants over 65 years of age.”<sup>37</sup> A *New England Journal of Medicine* article evaluating the data relied upon by CMS in making its decision noted that the mean age of study participants in the trials was 60.1 years – well below the average age of Medicare beneficiaries.<sup>38</sup>

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<sup>29</sup> See Kate Murphy, Colorectal Cancer Coal., *Medicare Won't Cover CT Colonography*, Feb. 13, 2009, [http://fightcolorectalcancer.org/research\\_news/2009/02/medicare\\_wont\\_cover\\_ct\\_colonography](http://fightcolorectalcancer.org/research_news/2009/02/medicare_wont_cover_ct_colonography).

<sup>30</sup> Centers for Medicare and Medicaid Svcs., *Proposed Decision Memo for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)*, Feb. 11, 2009, <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=220&>.

<sup>31</sup> *Id.*; see also Murphy, *supra* note 29.

<sup>32</sup> *Id.*

<sup>33</sup> Sanket S. Dhruva, et al., *CMS's Landmark Decision on CT Colonography – Examining the Relevant Data*, 360 *NEW ENG. J. MED.* 2699, 2699-700 (June 2009).

<sup>34</sup> *Id.* at 2700.

<sup>35</sup> Centers for Medicare and Medicaid Svcs., *Decision Memo for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)*, at 18, May 12, 2009, <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=220&>; Dhruva, et al., *supra* note 33 at 2699.

<sup>36</sup> *Id.*

<sup>37</sup> Sanket S. Dhruva, et al., *CMS's Landmark Decision on CT Colonography – Examining the Relevant Data*, 360 *NEW ENG. J. MED.* 2699 (June 2009).

<sup>38</sup> *Id.*

Another important factor CMS considered in making its decision is the procedure's cost.<sup>39</sup> The agency is specifically authorized to consider costs of colorectal cancer screening procedures, prostate cancer screening tests, and other preventative services.<sup>40</sup>

The rigid stance taken by CMS regarding CT colonography is a departure from its handling of other, similar past decisions. Approximately two years ago, the agency denied broad coverage of cardiac CT on grounds that there was insufficient evidence of benefit to the Medicare age group.<sup>41</sup> After intense pressure by the cardiac medical community and congressional supporters, CMS ultimately withdrew its decision denying reimbursement and issued an opinion which supported generous coverage.<sup>42</sup>

### Conclusion

The debate surrounding the benefit of virtual colonoscopies will likely continue. Additional studies involving older, Medicare-eligible patients and other subgroups may well gleam positive results that the CMS can rely upon in changing its current position on CT colonography. In the meantime, the most important advice physicians are likely to give individuals is to get screened. How a person gets screened should be an individual decision based on discussions between patients and healthcare providers.

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<sup>39</sup> *Id.* at 2700.

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*