COLON HEALTH CENTERS
OF AMERICA, LLC

June 13, 2008

Mr. William Larson, MA
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

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

Dear Mr. Larson:

I strongly urge CMS to initiate national coverage for Virtual Colonoscopy (VC). However, I believe that the only appropriate way to provide VC is in the setting of a comprehensive colorectal cancer screening process, i.e., VC with the opportunity for a same-day, same-prep therapeutic colonoscopy (polypectomy) for those with discovered polyps.

VC is now a proven screening test based on numerous regional and national randomized controlled trials, including ACRIN 6664. Further, VC is clearly more effective than three of the four covered CRC screening tests (FOBT, Flexible Sigmoidoscopy, and Barium Enema), and is as effective as Screening Colonoscopy. [There is a tendency to think of colonoscopy as the perfect "gold standard" test when in actuality it is only 90% sensitive in detecting significant polyps. With new technologies and reading techniques, VC at least matches this sensitivity, and may soon exceed it. For example, the VC studies demonstrate numerous polyps and cancers that were detected on VC, but missed on colonoscopy.]

However, the major problem with VC is the lack of therapeutic options when polyps are discovered. In the setting of stand-alone VC, these patients will very likely be forced to make an appointment with a colonoscopist on a subsequent day—and even worse—be forced to take a second colon prep in order to have the polyps removed. This is not only an unacceptable inconvenience for Medicare beneficiaries, but will likely result in many patients refusing to perform the second prep and not getting their pre-cancerous polyps removed.

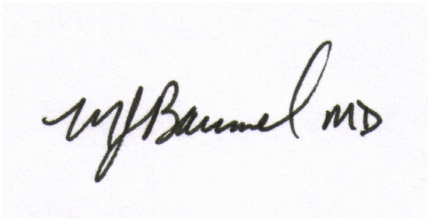
Because of this, VC should only be allowed in an integrated program, whereby VC results are available immediately following the test and same-day therapeutic colonoscopy is definitively made available to all patients with significant polyps. Such comprehensive programs allow for all of the benefits of VC (easier, safer, no sedation, and less expensive) while overcoming the major deficit (lack of therapeutic option).

Furthermore, these comprehensive programs allow for a progressive "episode-of-care" reimbursement strategy, i.e. a single bundled reimbursement for the entire screening process: VC for all, followed by same-day, same-prep therapeutic colonoscopy in those with significant polyps. I understand that CMS is moving in the direction of episode-of-care reimbursement strategies.

In summary, I urge CMS to help save lives by covering VC in the Medicare program, but to do so in the only way that make sense for patients, within a comprehensive screening program that allows for same-day, same-prep therapeutic colonoscopy, and a bundled, episode-of-care reimbursement

Thank you for your consideration.

Sincerely yours,



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