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June 18, 2008

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

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

Dear Mr. Larson:

The American Gastroenterological Association (“AGA”) is the largest society of gastroenterologists, representing more than 16,000 physicians, scientists and other health care professionals dedicated to the care of patients with digestive disorders. The AGA is pleased to provide its comments to the Centers for Medicare and Medicaid Services (CMS) on CAG-00396N, the issue of coverage for Computed Tomographic Colonography (CTC) for colorectal cancer (CRC) screening.

This year an estimated 147,000 Americans will be diagnosed with colorectal cancer and 56,500 will die from this disease, with an approximate 1 in 18 lifetime probability of developing colorectal cancer. The larger tragedy behind these numbers is that colorectal cancer is one of the most treatable cancers if it is detected in its early stages. Our members, along with the members of our sister societies in gastroenterology – the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG) – have been at the forefront of providing CRC screening.

Colonoscopy remains the gold standard for the detection and prevention of CRC, as it is the only test that can both detect and remove cancerous lesions. Increased efforts to educate the public on the importance of screening for colorectal cancer and expanded coverage of colorectal cancer screenings will greatly reduce the mortality rates from this disease.

At a time when compliance with screening recommendations for colorectal cancer with any test still are discouragingly low, there are differing opinions as to how the nation should promote screening tests. Approximately 18-50% of adults over age 50 report receiving screening tests, depending on age and gender¹. As a result, only 37% of cases are diagnosed when the disease is still localized; diagnosis at later disease stages results in substantially lower survival. Thus, given the current low uptake rate in testing, and in view of the significant health benefits achieved through early detection of CRC, additional methods to increase appropriate CRC screening are essential to combating this life threatening, yet preventable and treatable disease. Ongoing debate about screening strategies is likely to continue for the foreseeable future, because not only are access, preference, and use of current tests shifting, but also new technologies are being introduced into clinical practice.

The limitations of CTC cannot be ignored and must be taken under advisement in the development of a coverage policy for CTC. Concerns related to test sensitivity, specificity, reporting, training and technology requirements, radiation exposure, and appropriate

¹ Cooper, G, Kou, T., Underuse of Colorectal Cancer Screening in a Cohort of Medicare Beneficiaries, 112 *Cancer* (2007) 293-299.

surveillance intervals are well documented. While the AGA is confident that CMS has conducted a thorough review of the data and related issues, these issues **must** be taken into consideration in developing a coverage policy to mitigate the likely effects of ignoring these issues.

However, we recognize that CTC, if performed properly, can advance the goal of increasing CRC screening rates, and thus reduce the incidence of mortality from this disease. Therefore, the AGA supports coverage for screening CTC **if** CMS requires, as a “condition of coverage” physician completion of a CTC Certification Program that meets the necessary standards related to technology, training, and reporting of all polyps. In addition, the AGA recommends the development of an "episode-based" period of CTC screening to increase the appropriate follow up care based on an evaluation of the CTC results, patient history and an assessment of the CRC risk factors. Participation in a CTC Certification Program can be implemented through CMS’ policy regarding Coverage with Evidence Development (CED), specifically Coverage with Appropriateness Determination (CAD).

The comments contained herein reflect the conditions that, if applied to a coverage policy, would constitute AGA’s approval of CTC as a viable screening option for CRC.

Overview of Conditions

Condition 1: Establish CTC Standards

Improvements to health outcomes will only occur if the standards for CTC are comparable to those applied to screening mammography. Specifically, standards for CTC must incorporate the three critical factors known to impact test performance including:

- 1) the technology that is used (2D and 3D, minimum of 16 slice CT and low radiation);
- 2) adequate training of the physician who is providing the service; and
- 3) the reporting of all polyps in a standardized format.

Condition 2: Establish Certification Programs

The AGA believes that the concerns related to the reporting of findings, training and technology can be effectively mitigated through the development of Certification Program(s) for CTC. Such program(s) would ensure physicians have achieved and maintained competency in reading and interpreting CTC scans, and that any facility that offers CTC employs appropriate technology and safety measures for doing so. Requiring participation in a CTC Certification Program can be implemented through CMS’ policy regarding Coverage with Evidence Development (CED), specifically Coverage with Appropriateness Determination (CAD).²

Condition 3: Define Appropriate Episodes of Care

The AGA recommends that CMS define an appropriate episode of care for screening via CTC as a means of ensuring an appropriate cross-specialty care model, which would be in place when a gastroenterologist or radiologist performs CTC. An episode of care should include documentation of the test, examination of findings,

² By statute, CMS may only authorize payment for those items or services which are “reasonable and necessary” for the diagnosis or treatment of illness or are “reasonable and necessary for the prevention of illness”. 42 USC §1395y(a)(1)(A)(B). According to the National Coverage Determination (NCD) Guidance issued by CMS, an NCD can be issued with a Coverage with Appropriateness Determination (CAD) where “there is adequate evidence to determine that an item or service is reasonable and necessary under [42 USC §1395y(a)(1)(A)], but that additional clinical data is needed . . . to ensure that the item or service is being provided to appropriate patients in the manner described in the NCD.” As further discussed in the Guidance, CMS has noted particular concerns that may lead to a CAD. Those concerns include: “if the newly covered item or service should be restricted for use by providers with specific training or credentials”. In this regard, CTC appears to be an appropriate candidate for CAD and these concerns could be addressed through an appropriate certification program.

and to whom the findings and recommendations for follow-up care/surveillance are provided. The recommendations for follow-up must also be documented and communicated to the patient.

Discussion

The AGA supports a comprehensive strategy aimed at increasing overall CRC screening rates; CTC can be a component of that strategy.

Early detection, through screening, is effective in decreasing the morbidity and mortality rates associated with CRC. The AGA recognizes that some patients forgo recommended CRC screening due to concerns of potential perforation and sedation-related risks during colonoscopy. While the incidence of such is small, approving CTC as an alternative option for CRC screening under a CAD protocol may help us to reach a percentage of the population that otherwise is not being screened, thereby leaving a number of cancers undetected.

Patients planning for a CTC screening test must complete a colon cleansing prep, comparable to a colonoscopy. Thus, a patient with a positive CTC finding could be referred for a colonoscopy on the same day; both a CTC and colonoscopy could be performed during an "episode-based" period of CTC screening. The AGA believes this is the optimal model for inclusion of CTC from the perspective of patient efficacy, quality and resource consumption. Gastroenterologists are well equipped to provide this seamless model of care.

The AGA believes the following conditions must be addressed by CMS in their consideration of a coverage policy for CTC:

Condition 1: Establish CTC Standards

Addressing the CTC Sensitivity Issues through Appropriate Training

The AGA recognizes that early detection of CRC is a priority public health goal. The potential for increasing screening participation is a significant benefit of CTC, particularly when the test reliably identifies polyps. However, CTC screening that fails to reliably identify polyps, and/or reporting protocols that recommend non-reporting of lesions <5mm, present significant public health risks. The AGA recommends that any CTC coverage policy incorporate standards that would require the appropriate training for physicians performing CTC as a condition of coverage.

It is reported that the National CT Colonography Trial / ACRIN 6664 study, which has been submitted for publication, will demonstrate that training of physicians administering CTC, the technology utilized, the management of diminutive (<6mm) and small (6-10mm) lesions, and the timing of CTC are all factors that need to be appropriately controlled to ensure that CTC is an effective screening technology³. False negatives are a concern for CTC. Studies to date have demonstrated variability in the sensitivity of CTC, including variability in sensitivity for polyps ≥6mm and <10mm. Preliminary data released in September 2007 regarding the ACRIN 6664 study appear to demonstrate that CTC can achieve a greater sensitivity for polyps ≥6mm under the circumstances of this study. This increased sensitivity is important, as false negatives do not advance the public health goal of CRC screening. Moreover, to the extent those who receive CTC would have otherwise received colonoscopy, false negatives present significant additional treatment costs that would otherwise not be incurred and potentially life-years that will be lost. Simply put, false negatives will increase CRC treatment costs and may increase mortality rates if CRC is not detected early⁴.

³ Barnes E. ACRIN trial shows VC ready for widespread use.
<http://www.auntminnie.com/index.asp?sec=sup&sub=vco&pag=dis&itemid=77711>, September 28, 2007.

⁴ Hur C, Chung DC, Schoen RE, Gazelle GS., The management of small polyps found by virtual colonoscopy: results of a decision analysis. *Clin Gastroenterol Hepatol*, (2007) 5(2):237-244.

In 2007, the AGA issued minimum training standards that address many of the factors related to training and technology requirements that can impact test performance issues (as has the American College of Radiology [ACR])^{5,6}. The AGA will further its work by establishing programs to ensure these standards are met.

The AGA anticipates that, if appropriately trained, both gastroenterologists and radiologists will perform CTC in a manner that will further the public health benefit of reliable CRC screening. Incorporating standards that would establish competency thresholds for providing physicians performing CTC as a condition of coverage would help to ensure a quality CTC exam.

The AGA understands that the National CT Colonography Trial / ACRIN 6664 will associate a sensitivity with CTC for lesions >6mm that is higher than previously reported. However, the AGA also recognizes that clinical trials provide a very controlled set of circumstances. Results obtained in actual practice are sometimes less favorable than the results obtained during a clinical trial.

It is reported that ACRIN radiologists were obligated to either read 500 cases or attend a day and a half long training session, and pass a certification exam in which they detected 90% of adenomas 1cm or larger in 50 cases. As noted above, some of the increased sensitivity in the ACRIN study appears to be attributed to more stringent training and experience requirements for ACRIN study interpreters.

The AGA agrees that rigorous training and proper technique are essential to ensuring that CTC achieves appropriate sensitivity, specificity and performance. The AGA recommends that coverage be predicated on the adherence or compliance with training standards for physicians who will administer CTC (such as the AGA or ACR standards), including one that requires a process where the interpreter demonstrates ongoing maintenance of competency.

Addressing Sensitivity Issues through Mandated Technology Standards

The AGA recommends that any CTC coverage policy incorporate standards that would require the appropriate technology as a condition of coverage. There is a need to establish minimum standards for the technology used in performing CTC. The literature shows that multi-detector-row (multi-slice) helical CT scanners that facilitate faster image acquisition and thinner sections, with collimation <5mm, and a scan acquired within a single breath hold of <30 seconds, are important in assuring appropriate performance.⁷ Reconstructed axial or multiplanar 2-dimensional images for detection of an abnormality should be used with 3-dimensional reformatting software cleared by the U.S. Food and Drug Administration for use as a screening tool in detecting colon cancer and confirmation of an abnormality.

Addressing the Concern about Radiation Exposure

The potential for harm from radiation is difficult to assess given the uncertainty of true risks of low levels of radiation exposure. Although it is a challenge to define precise risk estimates related to low doses of radiation exposure, the ionizing radiation exposure from a single abdominal or chest CT may be associated with elevated risk

⁵ Rockey DC, Barish M, Brill JV, Cash BD, et al. Standards for Gastroenterologists for Performing and Interpreting Diagnostic Computed Tomographic Colonography. *Gastroenterology* 2007; 133: 1005-1024.

⁶ ACR Practice Guideline for the Performance of Computed Tomography (CT) Colonography in Adults. ACR Practice Guideline 59, Res.29-2005, Amended 2006, 445-450.

⁷ Taskar V, Clayton N, Atkins M, et al., Breath-holding time in normal subjects, snorers, and sleep apnea patients. *Chest*, (1995) 107(4):959-62.

for DNA damage and cancer formation.⁸ A CTC in a 50-year-old individual with an estimated dose of 7 to 13mSV might add an additional 0.044% to the lifetime risk of colon cancer.⁹ These estimates are subject to great uncertainty due to the uncertain effects of low dose radiation.

The Need for Mandated Reporting of All Polyps

It is the position of the AGA that all polyps identified by CTC be documented and reported. As noted above, there is a concern that CTC has low sensitivity for polyps of ≤ 6 mm as well as significant concerns with the identification of flat and depressed lesions and the risk that they may pose.¹⁰ Early detection of CRC is a significant benefit of CTC, but only when the test reliably identifies polyps. CTC screening that fails to reliably identify polyps for removal presents significant public health risks.

While reports suggest that polyps smaller than 5mm need not be reported,¹¹ there is no large scale study or evidence to support such a position. In fact, the natural history of small polyps is unknown. Not reporting and ignoring small polyps could potentially place the patient at risk for CRC, contrary to the ultimate purpose of CTC for screening. While more frequent CTC screening may help address those concerns, the impact of small polyps has not been fully studied. For that reason, the AGA is working with NIH to promote a study of the natural history of small polyps. Until the history of polyps is determined, the AGA¹², along with ACG¹³ and ASGE, believe that all small and diminutive polyps identified on CTC must be documented and reported. Patients **must** be informed of the results, and patients in consultation with their physician should determine whether or not to remove the polyps.¹⁴

There is a clear need to determine what threshold of size constitutes a clinically relevant lesion for reporting. The AGA encourages efforts to study and obtain data to help the medical community better understand the natural evolution of polyps/lesions. The AGA supports and will collaborate in the development of a registry that will assist in obtaining this important information.

The AGA is aware that the ACR is conducting a pilot test of a CT Colonography Registry, which may represent an opportunity for the radiology and gastroenterology community to work together toward a common goal. By requiring the adequate reporting of CTC findings as part of coverage with appropriateness determination

⁸ Lobrich M, Rief N, Kuhne M, et al., In vivo formation and repair of DNA double-strand breaks after computed tomography examinations, *Proc Natl Acad Sci USA* 102 (2005), 8984–8989.

⁹ Brenner DJ, Georgsson MA. Mass screening with CT colonography: should the radiation exposure be of concern? *Gastroenterology* 2005; 129 (1): 328-37.

¹⁰ Soetikno RM, Kaltenbach T, Rouse RV et al. Prevalence of Nonpolypoid (Flat and Depressed) Colorectal Neoplasms in Asymptomatic and Symptomatic Adults *JAMA* 2008; 299 (9): 1027 - 1035.

¹¹ Pickhardt, P.J., CT Colonography (virtual colonoscopy) for primary colorectal screening: Challenges Facing Clinical Implementation, *Abdominal Imaging* (2005) 30:1-4.

¹² Lieberman DA. Cost-effectiveness model for colon cancer screening. *Gastroenterology* (1995) 109:1781–1790.

¹³ Rex DK. PRO: patients 14 with polyps smaller than 1 cm on computed tomographic colonography should be offered colonoscopy and polypectomy, *Am J Gastroenterol* (2005) 100:1903–1905, 1907–1908 15.

¹⁴ In contrast, the ACR guidelines suggest that patients with one or two polyps 6 to 9 mm in size be offered “CTC surveillance” in three years as an alternative to polypectomy. Zalis ME, Barish MA, Choi JR, et al.; Working Group on Virtual Colonoscopy. CT colonography reporting and data system: a consensus proposal, *Radiology* (2005) 236:3–9. This “watch and wait” policy was reported to result in almost 20 times the number of colorectal cancers and more than five times the number of deaths compared to prompt polypectomy. Pickhardt PJ, Taylor AJ, Kim DH, Reichelderfer M, Gopal DV, Pfau PR. Screening for colorectal neoplasia with CT colonography: initial experience from the first year of coverage by third-party payers. *Radiology* (2006) 241:417–425.

requirements, CMS will be able to develop the evidence for the appropriate use of CTC, for referrals from CTC to colonoscopy and polypectomy, and to achieve the ultimate goal of increased early detection of CRC.

Condition 2: Establish CTC Certification

Training, Technology and Reporting Can be Coordinated through a CTC Certification Program as a Requirement of Coverage

The coverage policy could achieve all of the above goals, appropriate training, appropriate technology and appropriate reporting, through a coverage policy that requires the physician to participate in a CTC Certification Program. The AGA recognizes that CMS is not an organization that determines whether a physician is appropriately trained or credentialed and looks to medical specialty societies and other appropriate entities to establish and track the competency and accreditation standards that must be met to ensure quality and improved outcomes.

The AGA is working to facilitate the development of a CTC Certification Program that includes training, technology and reporting as requirements as a means of enabling individual physicians and practices to become certified CTC providers, thereby allowing CMS to include CTC certification as a condition of coverage. Development of a Certification Program will allow CMS to ensure that coverage of CTC screening only takes place where the manner of screening is consistent with the recent consensus recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer^{15, 16} and is consistent with CMS' long-standing policy that a service is reasonable and necessary when it improves health outcomes.

The basic elements of a CTC Certification Program have been developed. For example, physician training programs have been developed by the AGA and the ACR. A standard reporting model for CTC findings comparable to the Breast Imaging Reporting and Data System (BI-RADS[®]), has been developed by the ACR¹⁷. In addition, there are industry standards regarding CT technology.

The AGA is exploring possibilities for developing a "third party" CTC Certification Program that implements the CTC standards based on recommendations by the AGA and ACR. The CTC Certification Program will address the concern that test performance will vary unless it is restricted for use by providers with specific training or credentials.¹⁸ A Certification Program should require that physicians participating in the CTC training programs meet certain proficiency standards, such as gaining proficiency in a designated time frame, participating in continuing education and demonstrating maintenance of competency. Similarly, the certification organization could require verification of the technology that will be used by the physician in performing CTCs. The AGA supports facility accreditation by entities such as the American College of Radiology or the Intersocietal Commission for the Accreditation of Computed Tomography Laboratories.

The AGA understands that enforcing certification requirements on single physicians may be difficult. However, the coverage with appropriateness determination policy will facilitate the CTC certification process. By submitting a claim for CTC screening services, the physician will, in effect, certify his or her CTC training. In addition, as a

¹⁵ 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) 58:130–160.

¹⁶ See CMS Guidance, *National Coverage Determinations with Data Collection as Condition of Coverage: Coverage with Evidence Development.*

¹⁷ Zalis ME, Barish MA, Choi JR, et al.; Working Group on Virtual Colonoscopy. CT colonography reporting and data system: a consensus proposal. *Radiology* (2005) 236:3–9.

¹⁸ *Ibid*

requirement of coverage with appropriateness determination, the physician will be required to report all polyps identified on the CTC examination.

The Coverage Policy Can Mitigate the Likelihood of Unnecessary Tests

The current level of CRC screening which, by definition, is only performed in the absence of signs and symptoms, is too low. Because CTC requires patient compliance (through adequate cathartic preparation) it is possible that the ability of a physician to “over” perform CTCs is remote. Nevertheless, the coverage policy can mitigate the likelihood that physicians will perform unnecessary tests. For example, the coverage policy could limit the frequency of covered CTCs that are provided as a screening test.

The State of Washington Health Technology Assessment Report found only one CTC screening strategy to be marginally more effective than colonoscopy every ten years, and that strategy is to perform CTC every five years with colonoscopy referral for polyps ≥ 6 mm.¹⁹ CTC every 10 years is more expensive and less effective in preventing cases of cancer (47 vs. 52 in a lifetime cohort of 1,000 individuals) and cancer deaths (24 vs. 26).²⁰ Thus, CMS could limit coverage for CTC, in the absence of polyps, to every five years. Once polyps are detected on CTC, the appropriate follow-up examination from a patient care and resource consumption perspective is colonoscopy.

As discussed above, screening, by definition, is a service performed on the patient in the absence of signs and symptoms. CTC produces images not only of the colon, but of the surrounding internal organs. To date, clinical trials have not directly assessed a net health benefit due to the detection and treatment of extracolonic findings generated by CTC. While various studies have reported the incidence of extracolonic findings, such findings would entail further workup and diagnostic testing of incidental findings, findings that are not covered by the CRC screening benefit as established by the Congress under 42 CFR 410.37.

Condition 3: Define Appropriate Episodes of Care

The Coverage Policy Should Address Follow-Up Care by Defining an "Episode-Based" Period of CTC Screening

The AGA recommends a coverage policy that encourages rapid follow-up procedures and which correspondingly would not create a disincentive for physicians who refer those procedures. The above discussion provides a plan for addressing issues related to the sensitivity and reliability of CTC for effective CRC screening. However, even if CTC increases the number of individuals screened for CRC, and screening is appropriately performed, that increase will only be effective in decreasing CRC mortality if those individuals receive the appropriate follow-up care when necessary. Although there is some discussion about the amount of follow-up care that would be required, the State of Washington Health Technology Assessment Report indicates that follow up colonoscopy would occur in roughly 10.3% of all cases if the cut-off point were ≥ 6 mm.²¹ However, other studies have reported the rates may be significantly higher, with referral rates ranging from 30 to 51%.^{22,23} High referral rates make CTC much less cost-effective than colonoscopy. Thus, the CMS

¹⁹ Washington State Health Care Authority Health Technology Assessment Program, Computed Tomographic Colonography, February 1, 2008.

²⁰ Vijan S, Hwang I, Inadomi J, et al. The Cost-Effectiveness of CT Colonography in Screening for Colorectal Neoplasia. *Am J Gastroenterol* (2007) 102:380–390.

²¹ Washington State Health Care Authority Health Technology Assessment Program, Computed Tomographic Colonography, February 1, 2008.

²² Pickhardt PJ, Choi JR, Hwang I, et al. Computed tomographic virtual colonoscopy to screen for colorectal neoplasia in asymptomatic adults. *N Engl J Med* 2003; 349: 2191-2000.

²³ Hara AK, Johnson CD, Reed JE, et al. Detection of colorectal polyps with CT colonography: initial assessment of sensitivity and specificity. *Radiology* 199; 205: 59-65.

coverage policy should take into consideration what follow up procedures are covered if polyps ≤ 9 mm are discovered during CTC.

The coverage policy should recognize that a significant advantage of colonoscopy is that detection and removal of polyps can occur during the same procedure. The AGA recommends that the coverage policy include coverage for follow-up procedures during the CTC screening episode, including colonoscopies performed if polyps, regardless of size, are discovered during the CTC examination. The inclusion of colonoscopy as a screening benefit during the CTC screening episode will allow for the consultation by the physician with the patient as to the management of the CTC findings.

By using an episode-based period of CTC screening, the coverage policy would recognize the significant advantage of colonoscopy—i.e. the detection and removal of polyps during the same procedure. With CTC, removal of identified polyps must take place through a second procedure. Proper bowel preparation is an important factor in the success of colonoscopy. Because patient adherence to appropriate follow-up care may be improved if colonoscopy and polypectomy can take place on the same day of, and in rapid succession to, the CTC, an episode-based CTC screening benefit would ensure rapid succession of colonoscopy and polypectomies, when appropriate.

While both appropriately trained radiologists and gastroenterologists could perform CTC, gastroenterologists could perform any necessary follow-up procedures, a distinct advantage that could encourage patient adherence with follow-up procedures. The opportunity to increase CRC screening and prevention should not be stymied by an inability to refer follow-up care quickly and efficiently regardless of the location or relationship of the physicians involved.²⁴ In addition, the policy should allow for colonoscopy as a screening benefit if the physician and patient want to follow up on polyps < 10 mm.

Summary

In sum, the AGA recommends that CTC be covered as a colorectal cancer screening benefit for Medicare beneficiaries as long as the conditions enumerated above are satisfied. The coverage policy should mandate the training, technology and reporting prerequisites necessary to increase the likelihood that screening CTC will improve detection and that the CRC burden will not increase as a result of the false negative results associated with inadequate training or inappropriate technology. In addition, the AGA recommends standard reporting of all polyps in order to develop the evidence as to the appropriate use of referrals from CTC to colonoscopy and polypectomy.

The AGA's endorsement of coverage for CTC under the circumstances described herein should not be interpreted as suggesting that CTC should replace colonoscopy. Colonoscopy remains the gold standard for the detection of CRC and the removal of lesions; CTC will help a portion of the population get screened that otherwise would not be screened.

However, given the gap in patient compliance with current screening guidelines, CTC could be an acceptable screening test if the coverage policy addresses those factors that impact test performance. The AGA believes the coverage policy should address training for physicians, appropriate technology requirements and the required reporting of all polyps. The decision as to whether to remove diminutive and small polyps identified on CTC – or to implement a surveillance approach – should be an informed decision made between the patient and their physicians. The screening interval for CTC should be based on an analysis of the implications of the published literature and the pending results of the ACRIN 6664 trial on CRC morbidity and mortality.

Recognizing the improved quality of care that resulted from the development and implementation of quality standards for mammography tests, the AGA believes that quality standards need to be incorporated in the

²⁴ For instance, if the gastroenterologist performed the CTC at an ASC, he/she should not be prohibited from providing the follow up care at his/her practice. Provided that the coverage conditions are appropriate, the CTC and follow up care would not have a risk of overuse. Therefore, CTC and follow up care such as colonoscopy or polypectomy should not be classified as Designated Health Services. The rationale for this distinction would be similar to that which was used for excluding mammography as a Designated Health Service.

coverage policy for screening CTC. Provided that the key issues which could limit screening CTC test performance are addressed in the coverage policy, the AGA would endorse a decision to provide coverage for screening CTC for Medicare beneficiaries.

We appreciate the opportunity to provide input on this important issue. If you have any questions or need additional information, please contact Jennifer Conte, Senior Director of Clinical Practice and Reimbursement at the AGA via phone at 301-941-2641 or at JConte@gastro.org.

Sincerely,

A handwritten signature in blue ink that reads "Robert Sandler". The signature is fluid and cursive, with the first name "Robert" and last name "Sandler" clearly legible.

Robert S. Sandler, MD, MPH, AGAF
President, AGA Institute