April 2, 2014

Tamara Syrek Jensen, JD
Acting Director
Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Proposed Decision Memo for Screening for Hepatitis C Virus (HCV) in Adults (CAG-00436N)

Dear Ms. Jensen,

The American College of Gastroenterology (ACG) appreciates the opportunity to offer comments in response to the Centers for Medicare and Medicaid Services’ (CMS) proposed coverage for screening for Hepatitis C virus (HCV) dated March 4, 2014.

The ACG is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, our organization currently includes over 13,000 physicians among its membership of health care providers of gastroenterology specialty care. We focus on the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of ACG have been, and continue to be, promoting evidence-based medicine and optimizing quality of patient care.

The ACG commends CMS for proposing to screen individuals according to the U.S. Preventives Service Task Force recommended guidelines as well as the Centers for Disease Control’s (CDC) recommendations. It is clear that HCV is a major public health problem, with the vast majority of cases presenting no symptoms of the disease. The Federal Government has a tremendous opportunity to screen all Medicare beneficiaries – the population at most risk of having HCV – before these patients experience chronic liver disease such as cirrhosis. These diseases lead to liver failure, cancer, transplants, and even death.

The ACG also urges CMS to amend these coverage guidelines to allow all eligible Medicare providers to order an HCV screening test. The current draft as written will likely inhibit the intended goal of the recommended guidelines—to find and treat the 2.7 to 3.9 million persons in the United States with HCV.

BACKGROUND

CMS proposes to cover screening for HCV with the appropriate U.S. Food and Drug Administration (FDA) approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the beneficiary’s primary
care physician or practitioner within the context of a primary care setting, and performed by an eligible Medicare provider for these services, for beneficiaries who meet either of the following conditions.

- A screening test is covered for adults at high risk for HCV infection. “High risk” is defined as persons with a current or past history of illicit injection drug use; and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high risk persons is covered annually only for persons who have had continued illicit injection drug use since the prior negative screening test.
- A single screening test is covered for adults who do not meet the high risk as defined above, but who were born from 1945 through 1965.

The determination of “high risk for HCV” is identified by the primary care physician or practitioner who assesses the patient’s history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

For the purposes of this decision memorandum, CMS notes that a “primary care setting” is defined as “the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.” Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

CMS also defines a “primary care” physician consistent the Social Security Act, which ” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

CMS does stipulate that the screening test does not have to be performed by a primary care practitioner but the test is best coordinated by the primary care physician who can authorize a referral.

GASTROENTEROLOGISTS AS A PRIMARY CARE PHYSICIAN: ROLE EXPANDING TO SCREEEN AND TREAT HCV

As a subspecialty of internal medicine, many gastroenterologists serve as a primary care physician for patients with chronic gastrointestinal conditions such as irritable bowel syndrome (IBS), inflammatory bowel diseases (IBD) such as Crohn’s and ulcerative colitis, gastroesophageal reflux disease (GERD). This includes obesity and alcohol counseling, as well as screening, diagnosing, and treating other diseases. The ACG continues to urge CMS to consider the role of the specialists in primary care services as opposed to focusing on the provider’s specialty designation. This is especially important if CMS continues to believe that there are shortages of primary care physicians available for Medicare beneficiaries today.
Many experts and medical societies like the ACG believe that community-based gastroenterologists will begin to manage and treat an increasing number of patients with chronic HCV in the future.

The ACG has responded to this epidemic by educating our clinician-members on HCV and how to effectively incorporate screening and treating patients in their practices. The ACG convened an expert task force to develop educational material and guidelines for members on the risk factors of HCV, the importance of screening individuals, and how to effectively treat patients with HCV. The ACG also provides members with patient educational materials and other patient-friendly resources. In recognizing the need help properly train and educate our members, the ACG also offers best practices courses and other events tailored to recognizing HCV risk-factors in patients, the importance of screening, the recommended screening guidelines, and finally the medical science on treatment options available for patients.

As an example, many experts cite a study recently published in the *American Journal of Gastroenterology*, where during a 3-month period, 500 people, 50 – 65 years old, who received a colonoscopy were offered a test for viral hepatitis. Patients answered questions about vaccination, exposure, diagnoses, and risk factors related to viral hepatitis, and blood samples were collected. Patients who tested positive for antibodies to HCV or hepatitis B surface antigen (HBsAg) were contacted for further testing and possible therapy. As a result, 376 people (158 men) agreed to be tested, thus demonstrating the potential role the gastroenterology can play in increasing HCV screening rates. (Am J Gastroenterol 2013; 108:981–989; doi: 10.1038/ajg.2013.50; published online 19 March 2013).

Clearly, there is an opportunity to use gastroenterologists as a path toward increasing HCV screening rates.

**ADULTS AT HIGH RISK OF HCV INFECTION**

The ACG urges CMS to expand the eligible Medicare providers who may order an HCV screening test in adults at high risk for HCV infection.

According to CMS’ proposed decision memo, the determination of “high risk for HCV” is identified by the primary care physician or practitioner who assesses the patient’s history, which is part of any complete medical history. Under this scenario, the GI clinician would be able to assess the Medicare beneficiary’s risk of having HCV but could not order the HCV screening test. In addition, the GI clinician could be serving in what is effectively a “primary care” role for the Medicare beneficiary, depending upon the symptoms or conditions of that particular beneficiary. Yet even as a de facto primary care provider, our members would not be able to order a screening test simply because he/she does not fall into the definition of a “primary care physician” due to the provider’s Medicare specialty designation. Not only does this process seem unnecessary, but it has significant patient care implications, as the beneficiary would be required to first see a primary care provider for the referral, then follow-up and get the screening test (either in the primary care office or back in the GI clinician’s office), and incur other copayments and cost-sharing. The memo as written appears counter to the goals of discovering who among the Medicare population is living with HCV infection.
CMS also notes that a “primary care setting” would exclude emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice care. The ACG urges CMS to consider the potential increase in screening rates that would occur if physicians were empowered to order HCV screenings for patients that are present in these other care settings. As the article in the *American Journal Of Gastroenterology* demonstrates, CMS should look across the spectrum of health care settings in order to find the millions of Medicare beneficiaries infected with HCV. By only enabling these physicians to assess the risk-factors in order to provide the rationale for a HCV, but not allowing them the opportunity to order a test for HCV, this coverage decision (in its current structure) may leave many Medicare beneficiaries at the status quo— at high-risk, but not getting screened and treated.

**ASYMPOMATIC MEDICARE BENEFICIARIES BORN FROM 1945-1965**

The ACG urges CMS to expand the eligible Medicare providers who may order an HCV screening test in adults born from 1945-1965.

CMS notes that veterans and baby boomers are most at risk for HCV. Baby boomers – which make up about 30% of the U.S. population – account for 2/3 of the people with HCV in the U.S. Also, CMS notes that roughly 85-90% of those infected with HCV are asymptomatic, with the same percentage of these individuals considered to have “chronic HCV.” While the ACG commends CMS’ decision to cover HCV screening by a birth cohort, we believe CMS’ proposed coverage memo unnecessarily impedes the shared goal of finding these asymptomatic Medicare beneficiaries infected with HCV.

As discussed above, the gastrointestinal clinician plays an important primary-care role in treating patients, regardless of specialty designation. It is important to recognize that many Medicare beneficiaries already have chronic conditions, and therefore use a specialist treating those conditions as their primary care providers. The ACG agrees with CMS that primary care plays an integral role in the coordination of preventive benefits. However, for HCV screening purposes, this assumes an asymptomatic Medicare beneficiary would see a primary care provider for an unrelated issue, the primary care provider will recommend a screening, and the beneficiary would follow-up with getting screened. Given the importance of finding and treating asymptomatic Medicare beneficiaries with HCV, the ACG urges CMS to expand definition of the Medicare provider eligible to order an HCV screening test, while also broadening the range of care settings (where an HCV screening may be ordered from) to include those settings where the Medicare beneficiary may already be seeking treating for related/unrelated health care services.

CMS cites medical literature in this memo concluding HCV screening is in fact cost-effective. There are unfortunately ethnic and racial disparities in HCV as well. Since CMS believes that HCV screening is cost-effective, there is little economic incentive to limit which Medicare provider may order an HCV screening test. The goal of a birth-cohort screening recommendation is to screen as many eligible beneficiaries as possible, especially if there are racial and ethnic disparities, as there are in HCV. ACG
urges CMS to recognize that the provider and setting best able to reach these asymptomatic individuals is where these individuals are already seeking care.

**HCV SCREENING CODES**

ACG commends CMS for publishing this proposed decision memo to begin screening Medicare beneficiaries for HCV. CMS notes that HCV screening is not currently covered by Medicare even though the vast majority of HCV-infected persons in the U.S. are baby boomers. This coverage determination, coupled with well trained Medicare providers and recent advances in treating HCV, can effectively wipe-out a disease that the Federal Government has labeled the “silent epidemic.”

The ACG recommends that CMS implement an HCV screening “G-codes” to assist providers, Medicare claims administrators, and CMS in assessing the effect of this coverage determination. Similar to screening colonoscopy in Medicare, CMS could have separate “G-Codes” for high-risk individuals as well as average-risk individuals in the Medicare program.

**CONCLUSION**

The ACG welcomes the opportunity to work with CMS on developing these coverage determinations. Please contact Brad Conway, Vice President of Public Policy, Coverage & Reimbursement at 301.263.9000 or bconway@gi.org to discuss further.

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