



Infectious Diseases Society of America



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August 19, 2014

Marilyn B. Tavenner, RN, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicaid Restrictions on Providers Treating HCV

Dear Administrator Tavenner:

In response to action taken by some State Medicaid programs to restrict the specialties of providers who can prescribe drug therapies to treat hepatitis C virus (HCV), the Infectious Diseases Society of America (IDSAs) and the HIV Medicine Association (HIVMA) appeal to the CMS Administrator to recommend that Infectious Diseases (ID) Specialists and other HIV providers¹ be covered prescribers of all HCV medications.

IDSAs represents more than 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education and research in the area of ID. The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the U.S. and abroad. Our members care for patients of all ages with serious infections, including people living with HCV, HIV and AIDS. Within IDSAs, HIVMA represents more than 5,000 clinicians and researchers on the front lines of the HIV/AIDS epidemic whose clinical management and research on common co-morbidities of HIV infection includes HCV and hepatitis B co-infection.

ID and HIV specialists are ideally positioned to address this "silent epidemic," leveraging the advances in the treatment of HCV with the emergence of protease inhibitor-based therapies that are similar to HIV treatment. ID specialists are leaders in all aspects of HCV as evidenced below.

- A majority of the physician members serving on the FDA Antiviral Drugs Advisory Committee that makes recommendations regarding the approval of new HCV medications are ID specialists.
- ID and HIV specialists conduct HCV-related clinical and basic research, and many acquired experience prescribing the new HCV medications to their patients enrolled in clinical trials that generated the evidence base for FDA approval.
- ID and HIV specialists are intimately familiar with the mechanisms of action of these advanced therapies that are similar to those used to treat other infectious diseases, including HIV, and are well qualified to manage the complications that may arise with the regimens that call for combining these advanced therapies.

¹ See *Identifying Providers Qualified to Manage the Longitudinal Treatment of Patients with HIV Infection and Resources to Support Quality HIV Care*. Updated March 2013. Online at <http://www.hivma.org/Defining-HIV-Expertise.aspx>.

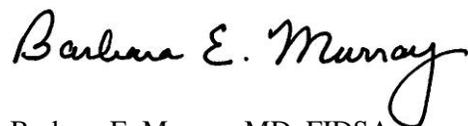
Not all hepatologists have experience managing HCV, and many have little experience managing the complex care of HCV and HIV co-infected patients since a majority are cared for by ID or HIV specialists. In addition, HCV is an infectious disease that is eradicated with antiviral therapy. Infectious diseases providers are national leaders in the efforts to use anti-infective agents responsibly (stewardship) and are well positioned to ensure the most cost-effective use of these new medicines, much as they already do for other antimicrobial agents.

In the U.S., nearly 4 million persons are estimated to be infected with HCV and approximately half are unaware of their status. Approximately 20,000 individuals are newly infected each year.^{2,3} Research supporting the cost effectiveness of HCV screening led the U.S. Preventive Services Task Force's to elevate its HCV screening recommendations and the Centers for Medicare and Medicaid Services (CMS) to incorporate HCV screening coverage into the Annual Wellness Visit. Furthermore, the Department of Health and Human Services' (HHS) action plan for the prevention, care and treatment of viral hepatitis aims to raise awareness of this "silent epidemic" and reduce the number of new HCV infection cases in alignment with the Healthy People 2020 objectives.⁴

With the large burden of HCV in the general population, efforts to expand the availability and the clinical expertise of providers are an essential complement to more effective screening and in fighting this insidious killer. **IDSA, in collaboration with the American Association for the Study of Liver Diseases (AASLD), is leading the way in providing timely clinical guidance (see <http://www.hcvguidelines.org/>).** The guidance is a living document maintained to assist prescribers on the appropriate treatment for specific patient populations that covers or will cover which regimens to use, when and in whom to use them, and how to monitor HCV patients during and after treatment. **Many of the guidance panel members are excluded from prescribing the new HCV medications according to the specialty restrictions that some Medicaid programs are implementing.**

Given the scope and severity of the HCV epidemic, we consider denial of HCV care provided by ID and HIV specialists to be an unreasonable and unjustified limitation of access to high quality care for those who need it most. Therefore, we strongly urge CMS to support our appeal to state Medicaid programs to include ID and HIV specialists as authorized prescribers of drug therapies to treat HCV.

Respectfully,



Barbara E. Murray, MD, FIDSA
President, IDSA



Joel Gallant, MD, MPH
Chair, HIVMA

CC: Cindy Mann, JD, Director, Center for Medicaid and CHIP Services

² Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. *Ann Intern Med* 2006;144:705–14.

³ CDC. Surveillance for acute viral hepatitis—United States, 2008. Available at: <http://www.cdc.gov/hepatitis/Statistics/2008Surveillance/index.htm>.

⁴ "Combating the Silent Epidemic of Viral Hepatitis: Action Plan for Prevention, Care and Treatment of Viral Hepatitis." Department of Health & Human Services. May 12, 2011. Accessed on August 4, 2014 at <http://www.hhs.gov/ash/initiatives/hepatitis>