Presidential Advisory Council on
HIV/AIDS

June 9, 2015

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madame Secretary:

As the members of your Presidential Advisory Council on HIV/AIDS (PACHA), we write to advise you regarding our concerns with current public and private insurance practices for the diagnosis and treatment of hepatitis C virus (HCV). High HIV and HCV co-infection rates make this an important and urgent issue demanding our attention. We respectfully offer guidance as to steps the federal government could take to mount an effective response to the HCV epidemic in light of significant new treatment advances.

While it is appreciated that the price of new therapies can create a short-term financial challenge for federal and state budgets, increased competition has dramatically reduced new HCV treatment costs. Despite this, extremely restrictive policies remain in place in many insurance programs. Access to appropriate treatment for HCV is highly cost-effective and crucial to reducing morbidity and mortality levels. In addition, a high percentage of patients undergoing successful HCV treatment with recently-approved medications will experience virologic cure for HCV, which will, in turn, reduce future transmissions and new cases of HCV.

HCV is a Serious Health Concern that Results in Thousands of Deaths in the U.S. Each Year

HCV is a serious and widespread personal and public health issue across the country. It claims thousands of lives each year, including many people who are co-infected with HIV and HCV. About one quarter of HIV-infected persons in the United States are also infected with HCV. People who are co-infected with HIV and HCV have a threefold greater risk of progression to cirrhosis or decompensated liver disease than HCV-monoinfected patients.[i]

In 2007, more than 15,000 people died from HCV related causes, and the mortality rate is increasing; in 2013, nearly 20,000 deaths were attributed to HCV. Models estimate that, if left untreated, there will be a peak of "38,600 incident cases of end-stage liver disease; 3200 referrals for [liver] transplant; and 36,100 deaths"[ii] between 2030 and 2035.

Medications Can Now Cure HCV and Prevent the Further Spread of the Disease

Fortunately, new all-oral treatment regimens can effectively cure HCV (produce sustained virologic response [SVR]) in most individuals in 8 to 24 weeks, with the length of treatment depending on the person's HCV genotype/strain and the presence of existing liver damage. The new drugs are far more effective than older medications, which were not nearly as successful in curing HCV and often produced disabling side effects.[iii] Curing HCV decreases the risk of severe complications such as liver cancer, liver failure, and the need for liver transplant by more than 80%, which saves lives and reduces long-term costs. In addition, treatment and cure are also prevention; successful treatment can dramatically reduce the number of new cases of HCV.

Current Clinical Recommendations for HCV Treatment

While new HCV medications come at a price, with current regimens costing anywhere from $34,000 (8 weeks of treatment, assuming a 46% gross-to-net discount) to $94,500 (12 weeks of treatment without rebate), their promise has led to new treatment guidelines that call for expanded access to the cure. The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) maintain recommendations for *Testing, Managing and Treating Hepatitis C,* an online document that is updated as new treatments and research become available (see http://hcvguidelines.org/). The current AASLD and IDSA guidance recommends treating all HCV-infected persons except for those with limited life expectancy of less than 12 months.[iv]

Current Restrictions to Access to HCV Treatments Are Unreasonable and Discriminatory

While insurers have discretion to establish certain limitations on the provision of drugs, they are not permitted to excessively or unreasonably restrict coverage of effective treatments for patients with HCV. Limitations must be based on clinical evidence and current treatment recommendations. Common arbitrary exclusions not supported by medical evidence that should be eliminated include: requiring diagnosis of advanced liver disease, requiring periods of substance use abstinence, and requiring HCV medications to be prescribed only by specific medical provider specialties.

Stage of Liver Disease

Mandating that patients have advanced liver disease for treatment authorization (including invasive, expensive, and often inaccessible diagnostic procedures, such as elastography tests), denies early access to a cure. It requires individuals to be seriously ill from a chronic, infectious, life-threatening disease before they can be offered the cure. HCV treatment is an evidence-based intervention to prevent liver disease progression and a significant proportion of those with earlier stages of fibrosis will progress to cirrhosis in the absence of treatment. Policies should promote early treatment access for all HCV-infected patients. Earlier treatment is better tolerated, has a better chance of positive outcome (SVR), and, irrespective of the stage of liver disease, provides benefits to (a) patients (including dramatic reductions in all-cause mortality[v] and substantially improved quality of physical, emotional, and social health[vi]), and (b) the public health (reducing the risk of HCV transmission to uninfected people).

Substance Use Abstinence

Requiring periods of abstention from substance use denies treatment to individuals who can derive the greatest benefits from new treatments. Alcohol and other substance use accelerate liver disease progression in people with HCV, making those with substance disorders a high priority for treatment. People who inject drugs pose a risk of transmission through shared injection equipment if left untreated. Moreover, as noted in treatment guidelines from the Veterans Administration, "[t]here are no published data supporting a minimum length of abstinence as an inclusion criterion for HCV antiviral treatment. Patients with active substance- or alcohol-use disorders should be considered for therapy on a case-by-case basis and care should be coordinated with substance-use treatment specialists." In addition, there is strong evidence that alcohol consumption and injection drug use are poor proxies for measuring risk of non-adherence. A recent systematic review and meta-analysis of research on interferon-based HCV treatment in people who inject drugs (PWID) found "high adherence, low discontinuation of therapy, and a low rate of reinfection," with SVR rates comparable to those observed in "real-life" treatment cohorts.[vii]

Authorized Prescriber Specialty

Qualified HCV prescribers should not be defined solely by specialty training. Licensed clinicians with experience treating HCV, regardless of specialty training, should be able to prescribe HCV treatment. This includes clinicians who receive training through telemedicine networks (e.g., Project ECHO) and work in coordination with an organized care system. Limiting HCV medication prescription only to gastroenterologists, hepatologists, or infectious disease specialists unnecessarily restricts access and disrupts continuity of care. This restriction also disproportionately affects patients in areas where there is a shortage of specialist providers, which includes many urban as well as rural areas of the country. Given that there is no clinical evidence to support restrictions based on specialty type, patients should be allowed to work with the qualified health care providers who they are most comfortable with and are more conveniently accessible.

Drug Manufacturer Exclusivity Deals

Finally, many insurers have negotiated rebates and exclusivity deals with pharmaceutical manufacturers to reduce the cost of HCV treatment. Exclusivity deals should not unduly restrict access to appropriate treatment and interfere with the ability of patients and their providers to make medical decisions. Insurers should consider deals in which a certain HCV medication would be a preferred medication but if, for whatever reason, an alternative treatment is recommended, patients should be allowed access to alternative treatments with no additional restrictive criteria. In New York's Medicaid program, as a result of an exclusivity deal, everyone able to use the preferred HCV medication is guaranteed immediate access to the medication; people living with HIV and others who require the non-preferred treatment, however, must wait until their HCV progresses to an advanced stage of liver disease. Such unfair and discriminatory access to treatment practices should not be permitted within Medicaid or any other insurance program.

Recommendations to Update Insurers' Treatment Access and Prior Authorization Criteria

- Increase CDC funding to support scaled up viral hepatitis screening and ensure that such funding targets populations most affected to produce the greatest overall impact.

- Ensure that CMS issues guidance to state Medicaid programs about the importance of updating treatment access and prior authorization criteria to reflect evidence-based care and to eliminate discriminatory policies that unreasonably delay or otherwise deny treatment access to individuals living with HCV in Medicaid fee-for-service and managed care plans. These discriminatory policies include restrictive clinical criteria requirements, certification requirements that unreasonably limit qualified providers and delay treatment, failure to individually assess requests for prior authorizations based on medical need, and delayed treatment based on needed access to non-preferred treatment.

- Amend the *Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation* rule (EHB rule) to require coverage of all HCV medications widely accepted in treatment guidelines or best practices and to allow the use of non-preferred HCV medications with no additional restrictive criteria when requested as medically necessary by patients and their providers.

- Amend the EHB rule to prohibit excessive coinsurance for HCV medications (where no generic equivalent exists) that are widely accepted in treatment guidelines or best practices.

- Require all Marketplaces to ensure that Qualified Health Plans provide complete, accurate, and accessible formulary information in a standard format, including actual out-of-pocket costs imposed on enrollees for treatments of HCV with co-insurance requirements.

- Ensure prompt investigation by HHS of discriminatory practices by Qualified Health Plans against people with HCV and ensure aggressive enforcement of non-discrimination protections in §1557.

- Create a federal report on HCV drug pricing to be issued annually to address concerns over a lack of transparency in drug pricing and in pricing negotiations that often result in higher drug costs. The report should include the price that key federal programs (e.g., Medicare, Veterans Administration, Bureau of Prisons, 340B Drug Pricing Program) pay for new, directly-acting antivirals for HCV as well as, to the extent possible, the price that key state programs (e.g., Medicaid programs, other state agencies such as corrections departments) pay.

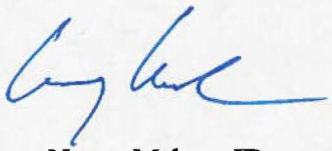
- Require each manufacturer of a prescription drug that costs $10,000 or more annually or per course of treatment to file a report outlining research, development and production costs for the drug; costs of clinical trials and other regulatory costs; costs for materials, manufacturing, and administration attributable to the drug; costs paid by any entity other than the manufacturer or predecessor for research and development; and other costs to acquire the drug.

Conclusion

A cure for HCV exists. But, while some states expand access to life-saving HCV medications, many Americans continue to experience HCV-related liver disease progression and death. We recommend that all state Medicaid programs update their prior authorization and treatment access criteria to reflect the overwhelming evidence that early access to new medications is crucial for individuals living with HCV

and for the public health. We thank you for considering our recommendations and would welcome the opportunity to meet with you to discuss them.

All my best,



Nancy Mahon, JD
Chair

Enclosure
CC: Anne Reid, Karen DeSalvo, and Ron Valdiserri

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[i] Graham CS, Baden LR, Yu E, et al. Influence of human immunodeficiency virus infection on the course of hepatitis C virus infection: a meta-analysis. *Clin Infect Dis*. 2001;33(4):562-569.
[ii] Rein DB, Wittenborn JS, Weinbaum CM, Sabin M, Smith BD, Lesesne SB. "Forecasting the morbidity and mortality associated with prevalent cases of pre-cirrhotic chronic hepatitis C in the United States." Dig Liver Dis. 2011 Jan;43(1):66-72.
[iii] Graham, C M.D., et al., "Hepatitis C Treatment in 2014," presentation to the Massachusetts Viral Hepatitis Advisory Committee, (Feb. 14, 2014).
[iv] (When and in Whom to Initiate HCV Treatment, Page 1). *Note to Draft: Andrea, can you direct me to this document so I can cite it properly?*
[v] van der Meer AJ, Veldt BJ, Feld JJ, et al. Association between sustained virological response and all-cause mortality among patients with chronic hepatitis C and advanced hepatic fibrosis. *JAMA*. 2012;308(24):2584-2593
[vi] Younossi ZM, Stepanova M, Henry L, et al. Effects of sofosbuvir-based treatment, with and without interferon, on outcome and productivity of patients with chronic hepatitis C. Clin Gastroenterol Hepatol. 2013
[vii] Aspinall EJ, Corson S, Doyle, JS, Grebely J, Hutchinson SJ, Dore GJ, Goldberg DJ, Hellard ME. "Treatment of Hepatitis C Virus Infection Among People who Are Actively Injecting Drugs: A Systematic Review and Meta-Analysis." Clinical Infectious Disease. 2013: 57 (suppl 2): S80-S89.