January 5, 2016

Shevaun Harris
Bureau Chief of Medicaid Policy

Arlene Elliott, R.Ph.
Administrator, Pharmacy Policy Section
Medicaid Pharmacy Policy Unit
Agency for Health Care Administration
2727 Mahan Drive, Mail Stop 20
Tallahassee, FL 32308

Sent via email to vern.hamilton@ahca.myflorida.com

Re: Pharmaceutical & Therapeutics Committee Review of Hepatitis C Medications

Dear Administrator Elliott & Bureau Chief Harris:

As the Florida Medicaid Pharmaceutical & Therapeutics Committee will be reviewing hepatitis C agents at its January 15, 2016 meeting, The AIDS Institute is pleased to submit comments on the importance of patient access to hepatitis C treatments through Florida’s Medicaid program. The AIDS Institute, based in Tampa, Florida, is a national nonprofit organization that focuses on public policy, research, advocacy and education. We are dedicated to ensuring that people living with HIV, hepatitis, and other chronic conditions in Florida and throughout the nation have access to high quality and affordable health care. We ask that Florida’s Medicaid program allow full access to all FDA approved hepatitis C direct acting agents by placing all these medications on the Preferred Drug List (PDL), and remove the current restrictions in place that limit patient access to these medications in accordance with the Center for Medicaid and CHIP Services’ November 5, 2015 guidance sent to all state Medicaid programs.

Overview of Hepatitis C

Hepatitis C is a blood-borne liver infection caused by the Hepatitis C virus (HCV). For some people, hepatitis C is a short-term illness but for 70–85 percent of people who become infected, it becomes a long-term, chronic infection. Chronic Hepatitis C is a serious disease than can result in long-term health problems, even death. Approximately 19,368¹ people died in 2013 from hepatitis C related liver disease.² Nationwide, nearly 3.2 million people are living with hepatitis C, however, as many as 75 percent have not been diagnosed.

¹ Current information indicates this represents a fraction of deaths attributable in whole or in part to chronic hepatitis C
² http://www.cdc.gov/hepatitis/hcv/statisticshcv.htm
There have been differing estimates on the number of individuals living with hepatitis C who are enrolled in Medicaid. A September 2015 Milliman study concluded that of the 2.67 million people living with hepatitis C approximately 457,000 or 17 percent of them are on Medicaid.\(^3\) The Senate Wyden-Grassley Report released in December 2015 indicates that there are approximately 698,000 enrollees in Medicaid with hepatitis C.\(^4\)

According to the Florida Department of Health, approximately 318,000 people are living with hepatitis C in Florida. New hepatitis C direct acting agents provide a cure for nearly all patients after an 8 to 12 week course of treatment. These new hepatitis C medications provide individuals with a cure to their once life-long inhibiting disease. However, it is critical that individuals receive access to these treatments in order to receive the benefits that they offer. It should be noted that only those individuals who are diagnosed are aware of their infection and would be currently eligible to access treatment. As mentioned above, most people living with hepatitis C are unaware of their infection. Diagnosing people with hepatitis C will take several years, so those eligible to receive treatment will be spread out over many years.

Since hepatitis C is an infectious disease, curing it now prevents further infections and additional costs down the road for ongoing treatment. Previous therapies came with potentially debilitating side effects and were effective in less than fifty percent of patients who endured the treatment. Without effective treatment, patients suffered greatly as their disease progressed. Many hepatitis C patients required liver transplants or died while waiting for a matching liver donor; others progressed with serious complications from the disease, including liver cancer. A recent report by Milliman on the clinical burden of hepatitis C projects that the incremental cost of hepatitis C to the U.S. health care system is projected to be $115 billion over the next decade. The report estimates that, in the absence of a cure for hepatitis C, more than 350,000 patients would be living with advanced stages of the disease – including 100,000 more with cirrhosis of the liver and 250,000 more patients with end stage liver disease – by 2025. Government programs would bear a significant share of this burden. The Medicare program would spend an additional $30.4 billion, while Medicaid would incur additional spending of $21.5 billion.\(^5\)

Thankfully, today, people with hepatitis C will no longer have to suffer from the effects of their disease and these costs on the healthcare system will be reduced as there are cure drugs available, if people living with hepatitis C have access to them.

**Medicaid Access to Hepatitis C Treatments**

Currently, Florida Medicaid requires an extensive process in order to access hepatitis C medications. A lengthy and burdensome prior authorization process is required that limits drug access by Medicaid beneficiaries for drugs that are both on and off of the PDL. The prior authorization forms and drug criteria forms are requiring information about beneficiary drug/alcohol usage as well as metavir fibrosis score of F3 or F4. Clinically speaking, it is imperative that physicians are afforded the ability to make medication determinations for their patients. There are a number of medications that are “cure drugs” for hepatitis C patients, and soon there will


be even more. However, there is not a one size fits all model for these patients. What works for one patient may not work for another patient and therefore, we are asking that you place all clinically appropriate current and future medications to treat hepatitis C on your PDL. As detailed in the CMS guidance, below, Florida’s current requirements are not appropriate and therefore, we are asking that you remove these burdensome restrictions so patients who are living with hepatitis C can get the necessary treatment to cure them of hepatitis C. According to the Florida Agency for Healthcare Administration, only 4,200 Medicaid beneficiaries in Florida were treated with the new hepatitis C direct acting agents between January 1, 2014—August 7, 2015. While we are cognizant of the cost of these medications, treatment of HCV is cost-effective in almost all patients.

CMS Guidance

On November 5, 2015, CMS issued guidance to remind state Medicaid programs, which in Florida is over 61 percent funded by the federal government, of their obligation to cover all FDA approved medications manufactured by companies that participate in Medicaid rebate program, and any limitations must be based on clinical outcomes.

In the letter, CMS wrote:

“When establishing formularies, states must ensure compliance with the requirements in section 1927(d)(4), including the requirements of section 1927(d)(4)(C) of the Act. Under this provision, a covered outpatient drug may only be excluded with respect to the treatment of a specific disease or condition for an identified population if, based on the drug’s labeling, or in the case of a drug the prescribed use of which is not approved under the FFDCA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

Accordingly, to the extent that states provide coverage of prescription drugs, they are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.”

CMS stated they are concerned:

“that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavih fibrosis score F3, while a number of states are requiring metavih fibrosis scores of F4. Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. In addition, several states are requiring that prescriptions for DAA HCV drugs must be prescribed by, or in consultation with specific provider types...”

1705 DeSole St., NW, Suite 700, Washington, DC 20036-202 835 8373 - fax 202 835 8368
17 Davis Blvd. Suite 403, Tampa, FL 33606 - 813 258 5929 – fax 813 258 5939
www.theaidsinstitute.org
As further discussed below, we believe patient access to the hepatitis C cure drugs that Florida currently allows in its Medicaid program falls short of that which is described by CMS in its guidance. Therefore, we are requesting that you review the current access restrictions and make the necessary changes so that Florida Medicaid will be in accordance with the CMS guidance and Medicaid beneficiaries with hepatitis C can gain access to the hepatitis C cure medications in a timely fashion.

FDA Labeling & Clinical Guidelines

As mentioned in the CMS guidance, states can only limit access to medications as long as they are included in the FDA approved labeling for that medication. The limitations that Florida Medicaid has instituted, including progressed liver fibrosis and abstention from drug or alcohol use, are not included in the FDA’s approved labeling for the hepatitis C curative drugs.

The CMS guidance also discusses the importance of following the most appropriate clinical guidelines in making treatment decisions. Two leading expert organizations, the American Association for the Study for Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), have recently released their treatment guidelines, “Recommendations for Testing, Managing, and Treating Hepatitis C.” They concluded that the treatment for hepatitis C would benefit nearly all of those who are chronically infected and the goal should be to treat all patients as promptly as feasible to improve their health and to reduce hepatitis C transmission. The professional guidance for treating hepatitis C is clear—treatment is recommended and beneficial for all patients with hepatitis C, unless they have a short life expectancy.

Medicaid has an obligation to follow the best available science and not institute prior authorization policies based on cost containment concerns that bar people from medically necessary treatment. Additionally, Florida Medicaid cannot justify restricting access to hepatitis C drugs due to allegations of the diversion of drugs used to treat another infectious disease. We question why drugs to treat hepatitis C patients are being singled out and no other drug classes. It appears that this could be due to stigma and discrimination.

Evidence of Stage 3 or Stage 4 Hepatic Fibrosis

Restricting access to treatment only to those suffering from advanced liver disease and who face imminent harm contradicts best scientific and medical evidence. The HCV Guidelines recommend treating all hepatitis C-infected patients regardless of current liver fibrosis level with the new medical therapies, including patients with F0 to F2 fibrosis. AASLD/IDSA endorse treating patients with hepatitis C as the standard of care. According to the guidelines, which quotes the committee panel co-chair Raymond Chung, MD, “There are also expanding data on the benefits of HCV treatment for patients with all stages of disease, including mild liver disease.” The AASLD & IDSA, citing the abundant scientific literature in their guidance document, which includes studies that show there is a better chance of suppressed viral suppression if treatment commences earlier.

It is widely known that failure to treat hepatitis C will lead to other medical problems. Since no test can perfectly distinguish F2 from F3 or F3 from F4, limiting access to F3/F4 really means directing treatment to only cirrhotic patients. If we wait until advanced fibrosis we will need to do life-long screening for HCC [hepatocellular

---

7 Hcvguidelines.org
carcinoma] every six months, this will be expensive, logistically difficult, and cause patient anxiety. Thus it is clear that requiring an F3 or F4 is clinically inappropriate and therefore we are requesting that you remove such references from your drug criteria requirements. Hepatitis C treatment that leads to a cure is the only evidence-based intervention to prevent liver disease progression.

**Drug/Alcohol Usage Restrictions**

The AASLD & IDSA’s guidelines document *“Recommendations for Testing, Managing, and Treating Hepatitis C,”* notes that excluding people from hepatitis C therapy based on the amount of alcohol they drink is not supported by data. In fact, curing hepatitis C in people who drink heavily is imperative to mitigate liver damage. While alcohol can worsen liver damage in general, there is no evidence that alcohol use counteracts the efficacy of hepatitis C treatment medications in curing the disease. AASLD/IDSA’s guidelines also notes that

“[t]here is strong evidence from various settings in which persons who inject drugs have demonstrated adherence to treatment and low rates of reinfection, countering arguments that have been commonly used to limit access to this patient population [...] Conversely, there are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete [hepatitis C] therapy.

These requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy. Scale up of [hepatitis C] treatment in persons who inject drugs is necessary to positively impact the [hepatitis C] epidemic in the United States and globally.”

The decision to treat people with hepatitis C who use drugs and/or alcohol should rest with their treating provider, who can best determine if the patient will be adherent to the treatment regimen.

**Conclusion**

These new hepatitis C agents are phenomenal drugs as they are providing individuals with a cure to their once life-long inhibiting disease. However, it is critical that individuals receive access to these treatments. Florida’s Medicaid beneficiaries with hepatitis C, who include the state’s most poor and vulnerable, should be able to access this treatment to better their healthcare outcomes. While the initial cost may be high, it must be remembered that these medications are a cure for an infectious and deadly disease and therefore, will save the system money in the long run.

In summary we urge you to:

- Include all current and new hepatitis C curative drugs on the preferred drug list
- Lift the onerous Prior Authorization requirements to comply with the CMS guidance and the AASLD/IDSA treatment guidelines

---

8 “Lost Opportunities in Hepatitis C Care,” Camilla S. Graham, MD, MPH, May 2015 Presentation at the PACHA meeting
In so doing Florida will help end this widespread silent epidemic. Hepatitis C is an infectious disease and we have an opportunity to cure it. Providing all hepatitis C patients with access to a cure is the most effective way to eliminate the virus at a population level.

We look forward to following your deliberations on January 15th and what steps Florida Medicaid is taking to address this issue. We thank you for your time and attention to our letter, and would be pleased to meet to further discuss these important matters.

Sincerely,

Michael Ruppal
Executive Director

cc: Justin Senior, Deputy Secretary