

December 8, 2016

Felicia Norwood, Director
Illinois Department of Healthcare and Family Services
201 South Grand Avenue East, 3rd Floor
Springfield IL 62763-0002

Dear Commissioner Norwood:

The undersigned organizations, who work closely with clients at risk for and living with hepatitis c, are gravely concerned about the criteria for coverage and the prior authorization process for Direct-Acting Antivirals (DAAs) used to treat hepatitis c (HCV). Since the FDA's approval of DAAs used to treat and cure hepatitis c, Illinois HFS has imposed some of the most onerous coverage restrictions in the United States. When combined with a burdensome and non-transparent prior approval process, the restrictive criteria has kept utilization by Medicaid enrollees of these new and life-saving medications extremely low. Restricting access in this way is short-sighted and in conflict with the tenants of adequate and ethical clinical care. As advocates and doctors working with individuals with hepatitis c and witnessing the human and financial damage restricted access creates, we are hoping to initiate a dialogue with the Department about coverage for DAAs for our clients and all Medicaid enrollees.

According to HFS-supplied information, obtained in a July 2016 Freedom of Information Act request, HFS has 9632 enrollees in fee-for-service Medicaid who are infected with hepatitis c. During the same time period only 148 applications for prior authorization were approved. Considering that these medications are recommended by the American Association for the Study of Liver Disease and the Infectious Disease Society of America in their HCV guidelines (<http://hcvguidelines.org>), these rates are disturbingly low. Based on the information we received from HFS, only 1.5 percent of the Medicaid population with HCV is getting medications that are the current standard of care for the disease. By contrast, the HCV guidelines cited above recommend "treatment for all patients with chronic HCV infection" Such low utilization by Medicaid recipients suggests that many, if not most, eligible patients do not have access to this medication, and risk developing advanced liver disease, cirrhosis and liver cancer, all conditions that are devastating to patient health and costly to treat. We believe that the Department's restrictive prior authorization criteria is responsible for this lack of access.

We were heartened to read in the Chicago Tribune, on September 12, 2016, that the Department changed their policy regarding coverage for DAAs to ease some of the coverage restrictions. We also understand that on October 1, 2016, a notice went out to providers stating that "effective with dates of service on or after October 1, 2016, the Department will begin providing prescription coverage for qualifying patients with a Metavir score of F3 down from F4 previously." (HFS Provider notice 9/30/2016).

While we welcome this change to the fibrosis requirement, it has been difficult to ascertain whether the Department has actually implemented this new rule. To date, documentation of stage 4 hepatic fibrosis is still required both in the list of "General Criteria for Prior Approval of Newer DAA for Hep C" and by the Prior Authorization request form, for "Initial Chronic Hepatitis C". We assume that the Department is in

the process of altering these forms to correspond to the change in the criteria. But we have no way of knowing when or how these changes will be implemented and we still see providers and patients unable to ascertain clear rules or to access DAAs despite stage 3 disease.

We hope that in making changes to the criteria for coverage, the Department will take into account the requirements of federal Medicaid Law and the 2015 guidance issued by CMS, as noted here:

1. Under federal Medicaid law, notwithstanding cost, if a drug is FDA-approved, subject to a rebate agreement with the manufacturer, and not in one of the few categories in which a state is allowed to exclude coverage (all of which are met for at least some of the DAAs), **the drug must be made available wherever medically necessary**, although prior authorization (PA) may be imposed. 42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a)(12). The Department's current criteria for PA for DAAs precludes access to medically necessary medications and is therefore illegal.
2. Additionally, federal law requires that all Medicaid-covered services be furnished with "reasonable promptness." Federal regulations under this provision **require that a person be able to apply for Medicaid services without delay**. Federal law also requires that a hearing be offered to anyone denied specific services, with a written notice to the enrollee explaining the reason for the denial and providing information about the means to access a hearing. The Department is not complying with these laws in administering coverage decisions regarding DAAs in its implementation of de facto rationing of these medications in contradiction to federal law and medical standards for treatment.
3. Likewise, the prescription drug coverage, including access to Harvoni™, Epclusa™, and other DAAs, that is made available to an individual eligible under the State Medicaid Plan cannot be less in amount, duration or scope than the coverage made available to any other such individual. 42 U.S.C. § 1396a(a)(10)(B), 42 C.F.R. § 440.240, 42 C.F.R. § 440.230(b) (**requiring states to ensure that the amount, duration, and scope of coverage are reasonably sufficient to achieve the purpose of the service**). This is known as Medicaid's "comparability" requirement. HFS is discriminating among similarly situated Medicaid beneficiaries on the basis of categorical restrictions that are not supported by prevailing clinical standards, in violation of this standard. 42 U.S.C. § 1396a(a)(10)(B)(i)
4. Finally, on November 5, 2015 the Center for Medicaid and CHIP services issued guidance to the states on coverage for DAAs. This document entitled "Assuring State Medicaid Beneficiaries access to Hepatitis C (HCV) Drugs" advises states about coverage access to DAAs for Medicaid beneficiaries. **The guidance notes that States are required to cover HCV medications under the terms of the Social Security Act**. The guidance specifically mentions three limitations which impermissibly restrict access to medications used to treat HCV; the requirement of extensive liver damage as proved by a fibrosis score of 3 or greater, the requirement that a patient remain abstinent from use alcohol or drugs for a specific period of time, and the requirement that the medications be prescribed in consultation with a specialist. Illinois HFS has adopted all three of these requirements. CMS also notes that states should use the [AASLD and IDSA HCV Treatment Guidelines](#) to guide their coverage policies.

Assuming the Department is presently reviewing DAA coverage policies to comport with your reduction in fibrosis severity requirement, we request the opportunity to sit down with you and engage in a discussion about the criteria going forward. Our hope is the criteria can be revised to achieve our mutual priorities, comply with federal law, and avoid litigation. We look forward to hearing from you to set a meeting for further discussion.

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