CMS Issues Important Guidance on HCV Treatment Access

November 6, 2015 By NASTAD

On Thursday, November 5th, the Centers for Medicare and Medicaid Services (CMS) released guidance to states with regard to access restrictions on direct acting anti-viral treatments for hepatitis C in state Medicaid programs. The guidance follows state and national advocacy challenging Medicaid restrictions that have served as a major barrier to access to a hepatitis C cure. NASTAD along with other partners have urged CMS to take this corrective action.

The guidance reiterates federal Medicaid law with regard to drug coverage, providing that:

- States must provide access to all outpatient drugs covered under rebate agreements with drug manufacturers, with limited exceptions (the manufacturers of the new hepatitis C treatments are covered by these agreements).

- States have discretion to establish limitations on coverage - for example, through preferred drug lists and use of prior authorization - however, these practices must be to ensure access to clinically appropriate treatment, not to deny access to effective, medically necessary treatments.

- CMS notes that limiting access to treatment to individuals with a fibrosis score of F3 or F4, requiring a period of abstinence from drug and alcohol use, or significantly limiting the types of providers able to prescribe hepatitis C drugs are examples of unreasonable restrictions on access to treatment.

- CMS encourages states to ensure that coverage policies are informed by clinical recommendations, including by reference to treatment guidelines put forth by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America

(IDSA) and the International Antiviral Society-USA (IAS-USA). This is particularly important given recent updates to these treatment guidelines emphasizing that, with limited exceptions, treatment is recommended for all patients diagnosed with hepatitis C.

- CMS notes concerns about variation between fee-for-service and Medicaid managed care plans and reminds states that Medicaid managed care plans may not use a standard for determining medical necessity that is more restrictive than is used in the state plan.

NASTAD applauds this action and looks forward to increased access to treatment for all people living with hepatitis C.

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