Gilead to Restrict Hepatitis C Patient Assistance Program

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Gilead Sciences will limit enrollment to its patient assistance program (PAP) for hepatitis C virus (HCV) drugs Sovaldi (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir), The Wall Street Journal reports.

The drug maker claims it is taking this step to push back against tight-fisted payers, arguing that even though it has given insurance companies and state Medicaid programs substantial discounts on the drugs over the past few months, many are continuing to restrict patient access to the treatments.

PAPs help people obtain medications when they lack insurance coverage or the financial means to access them. However, with Gilead's new hep C drugs costing up to $94,000 per treatment, many insurers have been reluctant to pay, instead referring patients to Gilead's Support Path programs as an alternative.

Gilead claims it has been picking up the cost of hep C treatments from payers far more than it anticipated, mostly as a result of insurance restrictions that keep all but the sickest HCV patients from accessing the drugs.

Gilead seeks to pressure payers to expand their hep C treatment coverage criteria to everyone. The company will limit enrollment to its PAP program if patients' insurance payers hold back on the drugs for reasons like having "less severe" hep C, or are instead offering exclusive coverage to a competing drug (i.e. AbbVie's Viekira Pak).

Gilead also will limit PAP enrollment if a patient's insurance plan requires step therapy, which involves using an older hep C treatment before trying newer drugs, or if plans restrict access to the treatments based on alcohol testing or other clinical criteria.

Advocates arguing against Gilead's decision claim the move puts sick patients in the middle of the battle between big pharma and insurance payers.

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