Medicaid Plans To Voice Concerns To States About Costly New Hepatitis C Drugs

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Medicaid health plans are readying a public push to voice their worries about new, costly Hepatitis C medications that have recently come onto the market and plan to send a letter to state Medicaid directors this week about developing solutions so that plans and the program remain financially solvent, the head of Medicaid Health Plans of America tells Inside Health Policy.

The drug receiving the most attention, Gilead's Sovaldi, was approved in December by FDA but Medicaid plans had already negotiated their 2014 rates with states, exposing them to millions of dollars in unanticipated costs. Medicaid Health Plans of America CEO Jeff Myers says in addition to making plans whole for 2014 because they need to be paid for treatments that are already being provided, state Medicaid agencies need to figure out how the cost of the medications will be built into future rates.

Insurers are beginning to report the direct financial impact they are seeing from Sovaldi, which costs $84,000 for the 12-week dosage regimen. While cost has been criticized and garnered attention already from lawmakers -- Energy and Commerce Democrats in March sent a letter to Gilead about Sovaldi's pricing and held a briefing with the company earlier this month -- the drug has also been hailed as significantly more effective at curing patients than existing treatments. UnitedHealth Group said during its first quarter earnings call that the company saw $100 million in costs due to the drug. Those costs were borne in Medicare, Medicaid and the commercial market, the company said Thursday (April 17), according to a transcript from Seeking Alpha.

Company executives would not provide much detail on whether those costs were in line with expectations for the first quarter, with United's Dan Schumacher only saying, "It's a multiple of what we expected."

Plans and state Medicaid programs will continue to face challenges as more high-cost, specialty drugs come onto the market, so the two need to work in collaboration to ensure that good outcomes for patients are achieved while also maintaining fiscal solvency for the plans and the Medicaid program, MHPA says. The Medicaid plans argue that the true cost of a patient's treatment with Sovaldi will be more than $84,000 because the drug can be taken in combination with other drugs and treatment could extend to more than 12 weeks depending on a patient's response.

Myers says the plans want to work with the states and CMS to figure out a way that plans are made whole for 2014, for example through supplemental funding or a retrospective rate adjustment through the states. For 2015, plans are still thinking about the exact course they would want the states to take, but Myers suggests that they should use clinical review committees to best figure out how to treat the population and how the drug price is factored into capitated rates.
The plans say clinical guidelines for the drug do not yet exist, and those that will be issued going forward must be based on the best clinical evidence and evidence-based outcomes data. The guidelines also must account for adherence, the stage of disease, prognosis and potential for future morbidity. States should use clinical review committees to look at all of the different therapies being used -- either on or off label -- and make sound decisions going into 2015, Myers says.

Matt Salo, head of the National Association of Medicaid Directors, says states do have the choice to renegotiate rates with plans, or they could put in a risk corridor where plans would get paid more based on their enrollees' utilization of the medication. Some states could just carve the drug out so Medicaid would pay for it directly, but Salo says this would be "kind of an extreme thing to do."

"It flies in the face of integration," he said. While states have to cover the drug because of Medicaid's open formulary requirements, he added that they could also use techniques, such as prior authorization and preferred drug lists, to manage utilization.

Myers says that if states are moving in a direction where they take responsibility for the cost of the medication and directly negotiate with the manufacturers, then plans should be actively involved in making sure that beneficiaries stay on their medication regimen. He cautioned against states using a carve-out where the plans don't administer anything, as health plans should play a role in managing the beneficiary's care.

"Medicaid health plans already serve an important role in medical management and care coordination to help ensure patients comply and adhere to the course of treatment," MHPA argues. "Plans ensure appropriate use and drug distribution and access to the drug. Health plans have experience with other illnesses -- such as tuberculosis and HIV -- that are high cost and require intensive medical management."

Carl Schmid, deputy executive director of the AIDS Institute, said the group generally doesn't take positions on drug pricing but they do feel it's dangerous to get into a discussion about withholding drugs from patients. The group has increasingly gotten involved in issues related to Hepatitis C drugs, arguing that they are often subject to tiering mechanisms by plans in the exchanges that result in prohibitive cost-sharing for patients.

With respect to the exchanges and the new Hepatitis C drugs, one industry source says the implications for qualified health plans will likely be a bigger question for 2016, when the current essential health benefit benchmark standard is slated to end. CMS outlined an approach for setting essential health benefits that lasts for 2014 and 2015, and the source says that for the "counting" requirements that dictate how many drugs must be covered on QHP formularies, insurers are probably already meeting the count for Hepatitis C drugs based on what was previously on the market.

Schmid notes that while Sovaldi has a base price of $84,000, the drug is subject to Medicaid rebates, which were extended into managed care plans under the Affordable Care Act and were also increased from 15.1 percent to 23.1 percent for branded drugs. He also argues that the new therapy is "a cure" for Hepatitis C patients and while the drug is expensive, it will save money in other parts of the health care system.
"It's a cure. What is the price you put on that?" he says.

Other patient groups have protested Gilead's pricing of the drug. Earlier this year, the AIDS Healthcare Foundation wrote letters to state Medicaid directors asking them to block Sovaldi from inclusion on their drug formularies.

"At $1,000-per-pill, Sovaldi is priced 1,100 percent more than Gilead's most expensive AIDS drug, Stribild, it's four-in-one AIDS drug combination, which was priced at $80 per pill a year ago when it came to market," Michael Weinstein, president of AIDS Healthcare Foundation, said in a statement at the time. "At that time, Stribild's price was 35 percent more than Atripla, the company's best selling combination HIV/AIDS treatment, and made Stribild the highest priced first-line combination AIDS therapy. Now, Gilead has set a new benchmark for unbridled greed with its outrageous price for Sovaldi—a price that some pharmacy industry sources suggest represents a retail markup of 279,000 percent over the cost of actually producing the drug."

Myers takes issue with Gilead's pricing and its justification for the pricing. Even if the drug helps to save money downstream, the plan doesn't necessarily get the value of those cost savings. And with insurance in general, but particularly Medicaid, beneficiaries often move in and out of the program, Myers says. A managed care plan might pay for a beneficiary's drug but that doesn't mean that the beneficiary will stay with that plan, or that the plan will get the future benefit, he says.-- Rachana Dixit (rdixit@iwpnews.com)