



Price Of PrEP Forces Patients, Providers To Consider Coverage Limits

By John Wilkerson
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The price of pre-exposure prophylaxis is forcing patients, providers and payers to consider the possibility of coverage restrictions on an expensive HIV prophylaxis under FDA review, 18 months before a generic of the one PrEP drug already on the market is expected to be approved.

Insurance coverage of PrEP is a swirl of policies, and cost and clinical considerations, and the debate over coverage restrictions will play out against [the backdrop of President Donald Trump's pledge to end the HIV epidemic by 2030](#). Price is driving the coverage debate, and complicating factors include an Obamacare policy that led to mandatory coverage of Truvada in people at risk of infection, clinical trial results that show the new drug, Descovy, is a little safer than the existing version, Truvada, and differences between PrEP and HIV treatment regimens that limit the importance of Descovy's lower toxicity.

The annual list price of Descovy is \$21,000. The drug already is approved to treat HIV, and it is expected to be approved to prevent infections -- [an FDA advisory panel this month recommended](#) the approval of Descovy as PrEP. Truvada, the current PrEP, has a similar list price, which has risen significantly since its approval in 2004.

In response to Trump's HIV initiative, Gilead agreed to provide PrEP up to 200,000 individuals each year until Descovy goes generic. More than 1 million Americans are at high risk for HIV infection.

Teva plans to market a generic version of Truvada on Sept. 30 of next year, months before private insurers and Medicaid [will have to provide PrEP for free to patients at high risk of HIV infection](#) thanks to an Obamacare measure. That coverage requirement was triggered by a U.S. Preventive Services Task Force recommendation.

Insurers pay rebated prices that are significantly lower than list prices when more than one drug is available, and the price of the first generic at first will likely be slightly less than Truvada because the first generic gets six months on the market without additional generic competitors.

Descovy is less likely to hurt livers or thin bones, but otherwise the two drugs work about the same.

Tim Horn, director of medication access and pricing at the National Alliance of State and Territorial AIDS Directors, said clinical trial results do not indicate that everyone needs the slightly safer Descovy. Based on current data, Horn's group does not intend to push back on commercial insurers or Medicaid programs that prefer generic Truvada over Descovy for preventing infections, provided they include safeguards for those who need Descovy.

State AIDS directors are not patient advocates, who historically have urged coverage of new drugs regardless of price. However, patient advocates increasingly are having difficulties maintaining that approach.

Jeremiah Johnson, HIV project director at the Treatment Action Group, said he is open to discussing the possibility of limiting Descovy to people with liver damage or osteoporosis, though he said that attitude is probably uncommon among patient advocates. Johnson dislikes coverage restrictions, and he said insurers can make it difficult to get drugs even when there are coverage mandates.

However, he said high prices slow the uptake of HIV preventive drugs, and the main goal of his organization -- and the Trump initiative -- is to get PrEP to everyone who needs it.

"We must deal with dirty tricks on all sides by corporate entities," he said.

Carl Schmid, deputy executive director of the AIDS Institute, said he would reserve comment until FDA approves Descovy.

"How does someone know if they are going to have these issues in advance of taking the drug?" he asked. "I was on Truvada (for my hepatitis B) and I developed severe kidney issues, but no one could have predicted that in advance." W. David Hardy, adjunct professor of medicine at Johns Hopkins and chair of the HIV Medicine Association, said there are reliable tests for detecting liver damage and osteoporosis, and he said damage to kidneys and bones caused by PrEP is reversible.

Descovy avoids some of the side effects of Truvada by delivering about 90 percent less of the active ingredient into the blood compared to Truvada and instead delivers the drug to the T cells that HIV infects. That makes the drug useful for treating HIV in patients who are already infected and must take the drug daily the rest of their lives.

However, PrEP is used on and off because patients stop taking the drug when risky behavior subsides, allowing damaged kidneys and bones time to heal. Also, PrEP is primarily used in patients between the ages of 25 and 40, and kidney damage and osteoporosis is uncommon in that age bracket. Hardy said he worries that Gilead, which makes both Truvada and Descovy, might create a two-class system in the minds of patients.

"One thing that Gilead may try to do is make it look like Descovy is the safer and therefore preferable option and kind of create a two-class system where the more expensive medication is looked upon as safer and just as effective, and Truvada, when it goes generic, is looked upon as cheaper but not as safe," Hardy said. -- *John Wilkerson* (jwilkerson@iwnews.com)