First Generic Truvada Now Available in the United States

Teva's new version of TDF and emtricitabine doesn't offer much of a price break, but that could come next spring.

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A new generic version of Truvada from Teva Pharmaceuticals hit the market this week, but at a price of about $1,455 a month, it undercuts the cost of the brand-name product from Gilead Sciences by only a couple of hundred dollars.

Truvada (tenofovir disoproxil fumarate/emtricitabine) is used for both HIV treatment and pre-exposure prophylaxis (PrEP). Teva also launched a generic version of Atripla (efavirenz/tenofovir disoproxil fumarate/emtricitabine), a combination pill for HIV treatment that was once widely used but has largely been supplanted by newer meds with fewer side effects.

The Food and Drug Administration approved Truvada for HIV treatment in 2004 and for PrEP in 2012. Although tenofovir disoproxil fumarate (TDF) is already off patent, the patent for emtricitabine is not set to expire until September 2021.

As previously reported, Gilead reached an agreement with Teva to give the Israeli company exclusive rights to sell a generic version of Truvada in the United States a year ahead of schedule. Teva's exclusive rights will last for six months, after which other companies may join the market. Generic versions of TDF/emtricitabine are already available in other countries, sold under names such as Tenof-EM, Tavin-EM and Ricovir.

The arrival of generic equivalents of brand-name drugs often leads to dramatic price reductions thanks to increased competition. But this is not necessarily the case when only a single generic version is available.

"Historically, when there's only one generic manufacturer in the field, the price difference is a minuscule 10% to 15%," Tim Horn, the director of medication access and pricing at NASTAD told POZ. "The real savings for all purchasers and payers won't begin until there's robust generic competition."

According to a Teva press release, generic Truvada is expected to be available through retailers

and wholesalers at a Wholesale Acquisition Cost (WAC) of $48.51 per tablet, while the expected WAC of generic Atripla will be $78.86 per tablet.

For generic Truvada, this works out to about $1,455 for a 30-day supply. Brand-name Truvada typically sells for around $1,600 to $1,800 per month. Advocates have argued that the cost of PrEP is one of the barriers to wider access. Generic versions of TDF/emtricitabine in other countries cost about $25 a month.

Many people in the United States do not pay full price for brand-nameTruvada because it is covered by commercial insurance, Medicaid or Medicare.

Thanks to a recommendation by the U.S. Preventive Services Task Force, private insurers will be required to cover PrEP without cost sharing starting in 2021. Some state and local programs provide Truvada for PrEP for free. Gilead offers a patient assistance program for low-income people without insurance and a co-pay card to cover out-of-pocket costs for those with private insurance.

Teva announced that it will also offer a co-pay card for its generic Truvada that will cover $600 worth of out-of-pocket costs for a month's supply. This is the same annual amount as Gilead's co-pay assistance, though Gilead set the benefit at $7,200 per year, with no monthly limit, after some people found that the monthly restriction made it difficult to negotiate insurance deductibles and out-of-pocket maximums.

Given the complexities of the American drug pricing and insurance system—which includes various (often undisclosed) discounts for different payers—some people may find that they have trouble getting coverage for either the new generic version or brand-name Truvada, or they may end up actually paying less for the brand-name product.

Teva's generic version is as safe and effective as brand-name Truvada. People taking either version for PrEP must be tested before starting in order to ensure that they do not already have HIV, and they should undergo regular testing for HIV, sexually transmitted infections and kidney function while using it.

Generic Truvada comes with the same safety concerns, namely decreased kidney function and a small amount of bone loss. However, studies have shown that Truvada is a safe PrEP option for most people. Those with pre-existing kidney or bone problems are advised not to use Truvada. Gilead's Descovy (tenofovir alafenamide/emtricitabine), approved for HIV treatment and PrEP—except for those who are at risk of acquiring HIV via vaginal sex—is easier on the kidneys and bones but more likely to cause elevated blood lipids and weight gain.

The drugs in generic Truvada are also active against hepatitis B virus (HBV), but it is not approved for this indication. People should be tested for HBV before starting Truvada and should be closely monitored after stopping, as this can lead to severe liver disease flare-ups.

Click here to learn more about PrEP.

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