



Fair Antiretroviral Drug Pricing and Robust Coverage for Antiretrovirals: Critical Factors in Ending the HIV Pandemic

A Joint Statement of the HIV Medicine Association (HIVMA) and the
American Academy of HIV Medicine (AAHIVM)
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Unprecedented scientific achievements have produced effective HIV treatment and prevention tools that allow leaders worldwide to envision an AIDS-free generation three decades into the HIV pandemic. The evidence is overwhelming that early and ongoing access to HIV treatment not only saves the lives of HIV-infected individuals but also dramatically reduces their risk of transmitting the virus, which heightens the urgency to improve access to HIV care and treatment. Of the 1.1 million people living with HIV infection in the U.S., just 37 percent are retained in regular care and only 25 percent have undetectable levels of HIV in their blood.

For too many HIV medical providers working on the frontlines of the HIV pandemic, the vision of a world without AIDS is tempered by the obstacles to accessing HIV care and treatment that remain today. HIV infection is largely a disease of vulnerable populations, especially the very poor, and HIV-infected individuals face many barriers in meeting complex and competing medical, social, and daily living needs. The Centers for Disease Control and Prevention estimates that HIV prevalence in urban areas is seven times higher among heterosexuals with household incomes of less than \$10,000 than those with annual household incomes of \$50,000 or greater. At 2.1 percent, the HIV prevalence in poor urban areas of the U.S. is on par with those in Ethiopia, Angola, and Haiti.

Due to the socioeconomic distribution of the disease, drug accessibility based on price unduly affects individuals with HIV. Twenty-five percent of people with HIV infection are uninsured, with fewer than 15 percent having private insurance coverage. Nearly half rely on Medicaid coverage, but even then a majority only qualifies after becoming disabled by AIDS. For the minority with private coverage or those with Medicare Part D, treatment options are often limited by coverage that places preferred antiretrovirals on higher cost sharing tiers.

While most private and public third-party payers currently cover a majority of antiretroviral medications, some insurers are beginning to implement cost control strategies that we are concerned may lead to restricting coverage to only the lowest cost options within a class. In addition, as more antiretrovirals are available in generic formulations, newer, more effective, and better-tolerated antiretrovirals are at risk of not being covered, or of being priced out of reach of HIV-infected patients. For a subset of patients with HIV infection who develop antiretroviral drug resistance, access to newer drugs and formulations will continue to be the only effective treatment option.

The Patient Protection and Affordable Care Act (ACA) in conjunction with the National HIV/AIDS Strategy offer the opportunity to dramatically improve access to HIV care and treatment; but success will depend on the adequacy of coverage in supporting comprehensive care and treatment, including prescription drugs. Dramatic improvements in viral suppression rates for HIV-infected patients will not be realized if the most effective antiretrovirals are not included in drug formularies, and if they are not available at reasonable costs to third-party payers and to individuals living with HIV infection.

We have growing concerns with antiretroviral pricing. As examples, several years ago, the price for the commonly prescribed Norvir™ (ritonavir) was increased by 400 percent. More recently, a new combination medication, Stribild™ (elvitegravir + cobicistat + tenofovir + emtricitabine), was priced 33 percent higher than the comparable

combination antiretroviral Atripla™ (efavirenz/emtricitabine/tenofovir disoproxil fumarate). With HIV disease still disproportionately affecting the poor in the U.S. and worldwide, decisions such as these restrict access to effective HIV treatment and contribute to HIV-related disparities.

Our organizations appreciate the contributions of pharmaceutical companies to the remarkable scientific advancements in HIV medicine and their commitments to ensuring HIV antiretrovirals are available in resource-poor settings. We also recognize that pharmaceutical companies and insurers have a business model to support, but we believe a balance between profit, access, and public health will produce the highest return on investment.

RECOMMENDATIONS:

AAHIVM and HIVMA support improved access to effective HIV antiretrovirals both domestically and worldwide while also supporting research and development pipelines that play a critical role in realizing the vision of a world without AIDS. We urge:

- pharmaceutical companies to set prices for antiretrovirals at levels that support access for the populations most in need.
- pharmaceutical companies and U.S. policymakers to work with insurers and government payers to ensure that drug formularies include all antiretrovirals, and to ensure antiretrovirals are not subject to burdensome cost-sharing, prior authorization, and other restrictions that limit timely patient access or provider prescription.
- pharmaceutical companies to sustain and expand their co-pay assistance programs so such programs are available for all antiretroviral agents and income eligibility levels set to address the needs of individuals who are not able to access medications due to extraordinary cost-sharing requirements.
- pharmaceutical companies to participate in the HarborPath program that streamlines access to antiretrovirals for people with HIV infection without insurance or with poor drug coverage. Participation by all companies is urgently needed to realize the potential of this important program.
- pharmaceutical companies and U.S. policymakers to continue to support agreements that promote access to antiretrovirals in under-resourced countries by allowing for the manufacturing of generic antiretrovirals outside of the U.S. and offering deep discounts on branded HIV antiretrovirals. Industry and U.S. policymakers should also refrain from blocking the efforts of developing countries to produce generic antiretrovirals to meet the needs of their own citizens, as well as those of HIV-infected individuals in other resource-poor settings.
- pharmaceutical companies to continue to develop pediatric antiretroviral formulations in order to decrease the gap in availability, approval, and access to antiretroviral therapy in pediatric and adolescent populations.
- philanthropists, industry, federal and state government entities, medical providers, and other stakeholders to work together to explore all options for lowering the costs of antiretroviral therapies and to identify solutions to ensure access to HIV treatment for everyone who needs it.

HIV Medicine Association
Andrea Weddle
Executive Director
1300 Wilson Blvd, Suite 300
Arlington, VA 22209
ph 703.299.0915
www.hivma.org

American Academy of HIV Medicine
James Friedman
Executive Director
1705 DeSales Street, NW
Washington, DC 20036
ph 202-659-0699
www.aahivm.org