AIDS FOUNDATION OF CHICAGO

Recommendations to Implement HIV Medication Cost Controls in SMART Act

June 15, 2012

This document was developed in collaboration by AIDS Foundation of Chicago's Medical Advisory Group, with participation from the following individuals: Kristin Keglovitz Baker, PA-C, AAHIVS; David Barker, MD, MPH, FACP; Corinne Blum, MD, AAHIVS; Patricia Langehennig, MD, MPH, AAHIVS; Blake Max, PharmD, AAHIVE; Daliah Mehdi, RN; Art Moswin, MD, FACP, AAHIVS; Richard Novack, MD; Norma Rolfsen, FNP, AAHIVS, AACRN. Contact: John Peller, Vice President of Policy, jpeller@aidschicago.org, (312) 334-0921.

Background: In May 2012, the Illinois General Assembly approved the SMART Act (SB 2840), which contains significant changes to the Medicaid program, including a provision intended to reduce spending on HIV medications.[1] The HIV medical and advocacy community opposes cost controls since HIV medicines are cost-effective and life-saving. The law contains a provision that requires the Illinois Department of Healthcare and Family Services (HFS) to consult with the HIV community when developing cost control proposals. The AIDS Foundation of Chicago (AFC) convened in June 2012 a group of health care providers, people with HIV and advocates to develop recommendations to guide implementation.

We thank the legislature and HFS for agreeing to exempt antiretrovirals from the new limit of four Medicaid prescriptions per month. However many people with HIV have multiple concurrent illnesses and receive more than four non-HIV medicines. Indeed in our experience it is not unusual for patients to take 10 medications for multiple comorbidities.

We are deeply concerned that HFS cost containment efforts will remove access to HIV medicines formulated in combination tablets. We think in many cases doing so will *increase* costs to the state by worsening outcomes for people living with HIV. Combinations of HIV medicines, by improving adherence and preventing partial compliance, improve outcomes of treatment. This has the downstream effect of reducing acute illnesses with expensive emergency room visits, hospitalizations, and long-term-care admissions. People on combinations are 1.6 times more likely to take medications as directed, keeping them healthier.[2] People on combinations have a 24% lower risk of hospitalization than people who take each drug separately,[3] leading to lower costs for medical care over time.

---

[1] 305 ILCS 5/5-5.12(h-5). See Appendix 1 for the text of the provision.

[2] Airoldi M et al. Patient Preference Adherence 2010; 4:115-125.

[3] Sax P, et al. Oral presentation 113, 10th International Congress on Drug Therapy in HIV Infection, 7–11 November 2010, Glasgow, Scotland.

People with HIV who take their medications as directed reduce their viral load and thus the likelihood of transmitting the virus to others. Improved adherence resulting from access to combinations should lead to fewer new HIV infections, lowering future costs to the state.

We offer the following recommendations to HFS:

1. **Allow unrestricted access to some combination HIV medications.** The most frequently prescribed, preferred and alternative regimens for HIV treatment – as recommended by the DHHS HIV treatment guidelines[4] – should remain available without restrictions. Limiting access to all combination HIV medications would create needless barriers for patients and an unnecessary burden for providers. HFS is aware through current dispensing records what the commonly used combinations are currently.

   HIV treatment is highly complex. To achieve the best health outcomes, HFS should allow providers discretion in prescribing and minimize prior approval. As the HHS guidelines note, "Selection of a regimen should be individualized on the basis of virologic efficacy, toxicity, pill burden, dosing frequency, drug-drug interaction potential, resistance testing results, and comorbid conditions….Based on individual patient characteristics and needs, in some instances, an alternative regimen may actually be a preferred regimen for a patient."[5]

2. **"Breaking up" single-tablet HIV medications will currently save little money.** An earlier HFS proposal would have required patients to take as individual pills medications that are currently combined into a single once-daily tablet. The greatest cost-savings will come from future generic versions of medications in once-daily tablets, but few are available currently and the cost difference is insignificant.

3. **Consider all relevant costs to the state in assessing cost neutrality:** When determining cost neutrality, HFS should include spending on all medical services, including hospitalization, long term care, cost of non-HIV drugs, and administrative spending to implement HIV medication restrictions. As mentioned above, research demonstrates that single tablet regimens improve adherence, which in turn lowers the cost of medical care for people with HIV.[6]

4. **Continue to consult with providers.** We ask that HFS consult with experienced HIV medical providers at least annually to review cost control measures, assess the impact of new medications or medications that become generic, and determine how cost controls are working.

---

[4] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. 1–239. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

[5] DHHS Guidelines, F-1.

[6] Sax P, et al., ibid.

5. **HFS should create a rapidly responsive transparent system for prior approvals,** if prior approvals are implemented for HIV medications. Because HIV providers routinely provide care for other medical conditions we need a timely, responsive system for prior approvals, including a speedy method for escalating appeals if requests are denied.

Recommendations for HIV Drug Manufacturers

Pricing decisions made by drug manufacturers will play a significant and increasing role in decisions made by HFS, ADAP programs, and other public payers regarding continued access to combination products. HIV medications are approximately twice as expensive in the U.S. than in other industrialized nations. Some generics available in developing countries cost one one-hundredth of the average wholesale price for the same patent protected medicines here. While we understand the need for investment in research and development to maintain a vibrant pipeline of new drugs, current pricing levels for combinations will be indefensible as these inexpensive generics enter the U.S. market in the next few years. We strongly urge drug companies to consider reducing the price of combination products to be in-line with the market costs of the individual components if generics were substituted for the patented components as individual entities in order to remove any incentive for payers to deny access to combinations to publically supported patients.

Attachment 1: HIV Medication Provisions in the Illinois Medicaid SMART Act (SB 2480), Changes passed May 2012 (305 ILCS 5/5-5.12) (from Ch. 23, par. 5-5.12)

Sec. 5-5.12. Pharmacy payments.

Note: Only language relevant to HIV medications appears below.

(h-5) On and after July 1, 2012, the Department shall impose utilization controls, including, but not limited to, prior approval on specialty drugs, oncolytic drugs, drugs for the treatment of HIV or AIDS, immunosuppressant drugs, and biological products in order to maximize savings on these drugs. The Department may adjust payment methodologies for non-pharmacy billed drugs in order to incentivize the selection of lower-cost drugs. For drugs for the treatment of AIDS, the Department shall take into consideration the potential for non-adherence by certain populations, and shall develop protocols with organizations or providers primarily serving those with HIV/AIDS, as long as such measures intend to maintain cost neutrality with other utilization management controls such as prior approval.

(j) On and after July 1, 2012, the Department shall impose limitations on prescription drugs such that the Department shall not provide reimbursement for more than 4 prescriptions, including 3 brand name prescriptions, for distinct drugs in a 30-day period, unless prior approval is received for all prescriptions in excess of the 4-prescription limit. Drugs in the

following therapeutic classes shall not be subject to prior approval as a result of the 4-prescription limit: immunosuppressant drugs, oncolytic drugs, and anti-retroviral drugs.

Attachment 2: DHHS Recommended Preferred Combination Regimens

The DHHS guidelines recommend four regimens for patients who have never received HIV treatment and one alternative for pregnant women. Access to these regimens should not be restricted. The combinations are: 1) Atripla (EFV/TDF/FTC), 2) Norvir-boosted Reyataz (ATV/r) + Truvada (TDF/FTC); 3) Norvir-boosted Prezista (DRV/r) + Truvada (TDF/FTC); 4) Isentress (RAL) + Truvada (TDF/FTC); and 5) for pregnant women, Norvir-boosted Kaletra (LPV/r) + Combivir (ZDV/3TC).[7] HFS should also not restrict the availability of the most commonly prescribed alternative HIV regimens, as defined by the DHHS guidelines.

HFS should consider the total cost of a complete treatment regimen when making cost control decisions, since some combination medications must be taken with a third or fourth drug to completely manage HIV. For example, to compare the cost of Atripla (a single tablet regimen) (#1 above) with other drugs, one must look at the cost of all four drugs that make up the second regimen above (Norvir-boosted Reyataz (ATV/r) + Truvada (TDF/FTC)).