May 31, 2016

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RE: Coverage of HIV medications under fee-for-service Medicaid

Dear Ms. Moody:

Thank you for meeting with us recently to discuss our concerns about HIV medication access in the fee-for-service Illinois Medicaid program. We are writing to comment on the upcoming review of the HIV medication class by the Drugs & Therapeutics Committee.

Single-tablet regimens (STRs) for the treatment of HIV have revolutionized HIV care. However, in April 2016, the Illinois Department of Healthcare and Family Services (HFS) began requiring prior authorization (PA) for the STR Atripla. As a result, none of the six FDA-approved STRs are available through fee-for-service Medicaid without PA. *Illinois is one of the only states that requires PA for all STRs.* Furthermore, Illinois Medicaid managed care plans almost uniformly allow access to STRs without PAs. Illinois fee-for-service Medicaid is significantly out-of-step with other states and its own Medicaid managed care subcontractors.

As providers treating large numbers of Medicaid recipients living with HIV who are highly vulnerable, we believe STRs are critical to improving the health of people living with HIV and lowering costs for the state. We urge you to allow access to all STRs without prior authorization, and most importantly, to the three STRs that are listed as "recommended" by the U.S. Department of Health and Human Services' HIV treatment guidelines.[1] The three are Stribild, Genvoya and Triumeq.

We ask HFS to consider the following factors when developing the preferred drug list.

[1] 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. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf.

Large numbers of Medicaid recipients living with HIV are not receiving HIV medications. One factor dissuading people from treatment is regimen complexity. Lack of adherence to HIV medications is a significant crisis among Medicaid programs nationally. Zhang and others showed that 44% of Medicaid recipients living with HIV in 14 Southern states did not take *any* HIV medications in a given year, and an additional 22% received sub-optimal treatment (an incomplete HIV regimen or intermittent treatment).[2] In Illinois, just 55% of people diagnosed with HIV were retained in care, and just 41% are virally suppressed.[3] Lack of access to STRs contributes to therapeutic fatigue and dropping out of care.

As a result, many Medicaid recipients living with HIV are not virally suppressed and are more likely to transmit HIV, increasing costs for the state. Untreated, most HIV-positive people have ongoing viral replication increasing their risk of transmitting HIV to others. In fact, groundbreaking research in 2011 showed that HIV treatment is a form of prevention; people with undetectable viral loads are up to 96% less likely to transmit HIV to their partners.[4] Increasing the number of people living with HIV who are virally suppressed will reduce the number of new HIV infections in Illinois (currently about 1,700 per year), and in turn reduce costs for Medicaid. Every individual who contracts HIV costs an estimated $326,000 in lifetime medical care, much of which will be paid by Medicaid because new cases are concentrated among very low-income people.[5]

Adherence is critical for good HIV care ... The DHHS HIV treatment guidelines point out that good adherence is essential for the treatment of HIV.

> Strict adherence to antiretroviral therapy (ART) is key to sustained HIV suppression, reduced risk of drug resistance, improved overall health, quality of life, and survival, as well as decreased risk of HIV transmission. Conversely, poor adherence is the major cause of therapeutic failure. Achieving adherence to ART is a critical determinant of long-term outcome in HIV infected patients.[6]

The guidelines further note,

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[2] Zhang S, McGoy SL, Dawes D, Fransua M, Rust G, Satcher D (2014) The Potential for Elimination of Racial-Ethnic Disparities in HIV Treatment Initiation in the Medicaid Population among 14 Southern States. PLoS ONE 9(4): e96148. doi:10.1371/journal.pone.0096148

[3] Illinois Department of Public Health, "HIV Care Continuum, 2014 Illinois HIV/AIDS Epidemiology Profile," accessed 5/26/16 from http://www.dph.illinois.gov/sites/default/files/publications/1-22-16-OHP-HIV-factsheet-Care-Continuum.pdf

[4] Cohen MS and others, Prevention of HIV-1 Infection with Early Antiretroviral Therapy, N Engl J Med 2011; 365:493-505August 11, 2011DOI: 10.1056/NEJMoa1105243.

[5] Schackman BR and others, The lifetime medical cost savings from preventing HIV in the United States, Medical Care, 2015 Apr;53(4):293-301.

[6] Guidelines, K-1, citations omitted.

> From a patient perspective, nonadherence is often a consequence of one or more behavioral, structural, and psychosocial barriers (e.g., depression and other mental illnesses, neurocognitive impairment, low health literacy, low levels of social support, stressful life events, high levels of alcohol consumption and active substance use, homelessness, poverty, nondisclosure of HIV serostatus, denial, stigma, and inconsistent access to medications).[7]

In our experience as health care providers treating Medicaid recipients and highly vulnerable populations in Illinois, the preceding statement describes many of the Medicaid patients we treat. Because of these factors, adherence is a major challenge for many people with HIV, particularly if they are low-income and struggling to meet their daily needs.

… and STRs promote adherence and prevent incomplete treatment that lead to resistance. We firmly believe that allowing wider access to STRs will improve adherence. The DHHS HIV treatment guidelines note:

> Simple, once-daily regimens, including those with low pill burden, without a food requirement, and few side effects or toxicities, are associated with higher levels of adherence. Many currently available ARV regimens are much easier to take and better tolerated than older regimens. Studies have shown that patients taking once-daily regimens have higher rates of adherence than those taking twice-daily dosing regimens.[8]

In fact, all HIV medication regimens listed as "recommended" by the DHHS guidelines are once-daily. Three of the five regimens are STRs (Stribild, Genvoya and Triumeq) – all of which require prior authorization under fee-for-service Medicaid. In addition, many of our patients are currently on Atripla, and would potentially need PA if they are switched to fee-for-service Medicaid.

Because they improve adherence and eliminate viral mutation risks, STRs significantly lower the cost of care for PLHIV. Three studies in particular show the impact of STRs on lowering the overall cost of care:

[7] Guidelines, K-1, citations omitted.
[8] Guidelines, K-1, citations omitted.

- People living with HIV who were commercially insured and receiving a single pill a day were 24% less likely to be hospitalized than patients receiving three or more pills per day.[9]
- In a second study of Medicaid recipients, STRs resulted in a 23% reduction in hospitalizations and a 17% reduction in overall health care costs. Patients on STRs were significantly more likely to be highly adherent (>95% of doses taken) than patients on two or more HIV medications.[10]
- A study of VA patients showed that 75% of patients on STRs were highly adherent, compared to 56% taking more than one HIV pill. Moreover, STR recipients had a 21% greater likelihood of having undetectable viral loads, were 31% less likely to be hospitalized and had 45% fewer hospitalizations.[11]
- A cost efficacy study that compared STRs vs. multi-tablet generic regimens also substantial price reductions of generic medications in the U.S."[12]

Furthermore, HIV is unique; it is highly likely to mutate when individuals are non-adherent to medications. In fact, it's more dangerous and costly for patients to take partial treatment than no treatment at all, because the virus could rapidly mutate and become resistant to a whole class of HIV medications, severely limiting future treatment options and increasing hospitalizations.[13] Unlike other conditions where STRs may represent a convenience for patients, STRs are vital to preventing HIV mutation. The guidelines note:

> For many chronic diseases, such as diabetes or hypertension, drug regimens remain effective even after treatment is resumed following a period of interruption. In the case of HIV infection, however, loss of virologic control as a consequence of non-adherence to ART may lead to emergence of drug resistance and loss of future treatment options.[14]

Despite efforts by providers to educate patients on the importance of taking all HIV medications, in our experience, we find it is all too common for patients to leave the pharmacy

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[9] Sax PE, Meyers JL, Mugavero M, Davis KL. Adherence to Antiretroviral Treatment and Correlation with Risk of Hospitalization among Commercially Insured HIV Patients in the United States. Ross JS, ed. PLoS ONE. 2012;7(2):e31591.

[10] Cohen CJ, Meyers JL, Davis KL. Association between daily antiretroviral pill burden and treatment adherence, hospitalization risk, and other healthcare utilization and costs in a US Medicaid population with HIV. BMJ Open. 2013;3(8):e003028.

[11] Rao GA, Sutton SS, Hardin J, et al. Impact of highly active antiretroviral therapy regimen on adherence and risk of hospitalization in veterans with HIV/AIDS. 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Denver, abstract H-1464, 2013.

[12] Sweet DE, Alitice FL, Cohen CJ, Vandewalle B. Cost-effectiveness of single tablet versus multiple tablet regimens for the treatment of HIV-1 infection in the United States. PLoS One. 11(1):e01427821.

[13] Cohen C, Davis K, Meyers J. Association of partial adherence (PA) to antiretroviral therapy with hospitalizations and healthcare costs in anHIV population. Journal of the International AIDS Society. 2012;15(Suppl 4):18060.

[14] Guildelines, K-1.

with just one or two of three medications because the pharmacy is out of stock. Since they are just one pill, STRs completely eliminate this serious problem.

We offer the following recommendations to HFS as it develops the HIV preferred drug list:

1. **Allow unrestricted access to widely-used DHHS-recommended STRs.** The most frequently prescribed "recommended" and "alternative" regimens for HIV treatment — as recommended by the DHHS HIV treatment guidelines — should remain available without restrictions such as prior authorizations. Limiting access to all combination HIV medications creates needless barriers for patients and an unnecessary burden for providers.

2. **Create clear prior authorization criteria.** If HFS does require PA for some medications, there should be clear, published medical criteria that the patient must meet to receive the medication. Social factors – such as co-occurring mental illness, substance use, homelessness, age – should be consider for providing STRs to promote adherence.

3. **"Breaking up" single-tablet HIV medications will save little money.** In fact, requiring patients to take the components separately could increase costs by reducing adherence, increasing viral mutations and resulting in additional hospitalizations.

4. **Consider all health care costs to the state when developing the PDL.** When determining which drugs will require prior authorization, 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 significantly lowers the overall cost of medical care for people living with HIV.

5. **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. We are most willing to serve in this capacity.

Thank you for reviewing this information. Please contact John Peller, President/CEO, AIDS Foundation of Chicago, at jpeller@aidschicago.org or 312-334-0921 if you would like additional information.

Sincerely,

(Organizational affiliation for identification purposes only)
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