

## Medicaid Antiretroviral Drug Coverage Issues

June 28, 2016

**Early and uninterrupted access to effective HIV treatment is critical to individual and to public health. Medicaid is the largest federal payer of health care for people living with HIV covering at least 50% of people living with HIV in care and plays a critical role in maximizing health outcomes for people with HIV and in improving public health.**

- It is definitively clear that early and sustained treatment resulting in viral suppression is critical to keep individuals with HIV healthy, mitigate and contain costs of long-term complications and reduce the spread of HIV.
- Studies have proven that individuals with HIV who initiate treatment early and who achieve and maintain viral suppression have better health outcomes and are much less likely to experience serious AIDS and serious non-AIDS events.
- In addition to early and sustained viral suppression improving health outcomes for people living with HIV, individuals who are viral suppressed are significantly less likely to transmit HIV to others – a risk reduction of 96%.

See:

- [January 2016 Updates to DHHS ARV Guidelines](#)
- [QUESTIONS AND ANSWERS The START HIV Treatment Study](#)
- [TEMPRANO Trial Results](#)
- Cohen, M, et al. [Prevention of HIV-1 Infection with Early Antiretroviral Therapy](#). N Engl J Med 2011; 365:493-505 August 11, 2011 DOI: 10.1056/NEJMoa1105243.

**A growing number of state FFS Medicaid programs and Medicaid Managed Care Organizations (MCO) are placing harmful restrictions on antiretroviral drugs. Unpublished data from a study conducted by the HIV Medicine Association of Ryan White-funded medical providers, found that a majority of providers reported their patients had been denied coverage for an antiretroviral drug by a Medicaid FFS or MCO. As a comparison, analysis conducted by Avalere Health indicates that restrictions on antiretroviral drugs in the employer market are minimal.**

### Examples of Restrictions

**Illinois Fee for Service Medicaid** – Illinois Medicaid does not cover any of the Single Tablet Regimens on its state Medicaid FFS preferred drug list. See [letter from Illinois clinicians and advocates](#).

**Horizon NJ Health (Medicaid MCO)** - Providers report being denied coverage for Single Tablet Regimens, e.g., Prezcoix (darunavir/cobicistat) and Triumeq (abacavir/dolutegravir /lamivudine) even after filing appeals. The Director of Pharmacy has confirmed that some of the single tablet regimens are non-preferred but the component parts are available. They require patients to try and fail on prior therapy for a reasonable period of time based on the nature of the drug therapy before non-preferred drugs may be covered. This practice, Step Therapy, is never appropriate for the management of HIV treatment because treatment failure results in the development of drug resistance leaving patients with fewer treatment options. Patients with

drug resistant virus also may transmit drug resistance to others leaving individuals newly infected with HIV with fewer treatment options.

**State Fee for Service Plans Operated by Goold:** Restricting ARV access by not placing all STRs on Preferred Drug List in the states of Iowa, Maine, Mississippi, Ohio, Pennsylvania and West Virginia. In Georgia, recently removed four of the six preferred drugs on the treatment guidelines. Only one has a component that is used to treat treatment naïve patients, according to the treatment guidelines.

**Utah:** Review of Preferred Drug List in near future.

**Oregon:** Proposed to restrict STR access but advocates and providers opposed and for the time being no changes.

**Optima Health (Managed Care-VA):** Restrict Stribild and Tivicay

**Select Health (Managed Care-SC):** STRs are non preferred

### PrEP Examples

**Arizona Medicaid** - the Arizona HIV Prevention Program has reported that Arizona Health Care Cost Containment System (AHCCCS) fee-for-service beneficiaries have been denied access to Truvada when it is prescribed as pre-exposure prophylaxis (PrEP). The AHCCCS fee-for-service PBM, Optum Rx, has indicated that AHCCCS does not have published PrEP-specific criteria and that a fee-for-service medical provider requesting Truvada for PrEP would initiate a prior authorization request using the generic Optum Rx prior authorization form found at [https://www.uhcmedicaresolutions.com/Individual/Medication\\_Prior\\_Authorization\\_Request\\_Form.pdf](https://www.uhcmedicaresolutions.com/Individual/Medication_Prior_Authorization_Request_Form.pdf). Following this PA process, several individuals have been denied access to Truvada for PrEP.

**Florida Medicaid** – Providers and consumers have reported significant challenges accessing Truvada when it is prescribed for PrEP through Florida’s Medicaid managed care plans. While plan utilization management policies and procedures vary by plan, there are several plans that place prior authorization on Truvada when prescribed to HIV-negative individuals and providers and individuals have reported that these prior authorization requests are often denied. Elaine Elmore, the CMS Health Insurance Specialist for Region 4 recently confirmed the variation in PrEP coverage policies among Florida Medicaid managed care plans at a HRSA Regions 4 and 6 HIV/AIDS Summit.

For more information on transmitted drug resistance:

- [Transmitted HIV Resistance Rate Close to 20% in Large Study of US MSM](#)
- [AIDSInfo Drug Resistance](#)

**Due to the complexities and rapid evolution in HIV treatment standards, the U.S. Department of Health and Human Service’s maintains *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents* that are widely recognized as setting the standard for**

**HIV treatment in the U.S, including for the Ryan White HIV/AIDS Program and other federal programs.**

- The DHHS treatment guidelines were first released in 1998 and have since been maintained by a working group of the National Institutes of Health’s Office of AIDS Research Advisory Council (OARAC).
- The NIH working group updates the guidelines as new data becomes available and new antiretroviral drugs are approved.
- The guidelines were updated in January 2016 to recommend initiating treatment as soon as possible depending on patient readiness based on the results of the START trial and TEMPRANO trials.
- The combination drug regimens recommended for treatment initiation in the DHHS guidelines are available as single tablet or multi-tablet regimens and these medications are more likely to be on non-preferred drug lists for states or MCOs that restrict access to antiretroviral drugs.

See:

- [DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents](#)
- [DHHS Guideline Recommendations Only](#)
- [DHHS Guideline Tables](#)
- [FDA Approved HIV Medicines](#)

**HIV is a chronic condition requiring strict adherence to life-long treatment, which makes selecting an effective and highly tolerable treatment regimen critical. A number of factors are considered in selecting the appropriate treatment regimen for an individual patient, including tolerability, co-morbidities, adherence, drug-drug interactions, pill burden and affordability for the patient.**

- The newer antiretroviral therapies are more effective at suppressing HIV and have better tolerability and safety profiles. *See Cihlar, T and Fordyce, M. [Current status and prospects of HIV treatment](#). *Current Opinion in Virology* 2016; 18:50-56.*
- Pill burden is an important consideration when identifying the most effective treatment regimen for individuals with HIV to promote treatment adherence, reduce the potential for treatment interruptions due to delayed refills for one or more prescriptions and to reduce out of pocket costs for patients.
- From Section K-1 Adherence to Antiretroviral Therapy in [DHHS Treatment Guidelines](#): “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,<sup>1,2</sup> as well as decreased risk of HIV transmission.<sup>3</sup> 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.”

“Characteristics of one or more components of the prescribed regimen can affect adherence. 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. However, data to support or refute the superiority of fixed-dose combination product of 1-pill versus 3-pills (of individual drug products), once-daily regimens—as might be required for the use of some soon-to-be available generic-based ARV regimens—are limited.”

### **Lower pill burden improves treatment adherence.**

Studies indicate that lower bill burden, including through single tablet regimens or multi-tablet regimens, support improved adherence and can be associated with reduced hospitalization rates and increased viral suppression rates and lower health costs when drug and other medical costs are considered.

See:

Nachega, J, et al. Lower Pill Burden and Once-Daily Antiretroviral Treatment Regimens for HIV Infection: A Meta-Analysis of Randomized Controlled Trials. *Clin Infect Dis.* (2014) 58 (9): 1297-1307. doi: 10.1093/cid/ciu046

Sutton SS, et al. Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks. *Am J Manag Care.* 2016 Apr;22(4):242-8.

Sutton S, et al. Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy. *Pharmacotherapy.* 2016 Apr;36(4):385-401. doi: 10.1002/phar.1728. Epub 2016 Apr 13.

Sweet DE, et al. Cost-Effectiveness of Single- Versus Generic Multiple-Tablet Regimens for Treatment of HIV-1 Infection in the United States. *PLoS One.* 2016 Jan 25;11(1):e0147821. doi: 10.1371/journal.pone.0147821. eCollection 2016.

Clay, PG, et al. *Medicine (Baltimore).* Meta-Analysis of Studies Comparing Single and Multi-Tablet Fixed Dose Combination HIV Treatment Regimens. 2015 Oct;94(42):e1677. doi: 10.1097/MD.0000000000001677.

**Medicaid and Medicaid MCO prior authorization approvals should be based on the DHHS Antiretroviral Guidelines and take into consideration the treating physician’s recommendation. Individuals with HIV should be eligible for a 72-hour emergency supply of their prescribed antiretroviral drug while awaiting consideration – particularly for individuals who are already taking the medication.**

- Selecting the right treatment regimen that will be most effective for an individual living with HIV has long-term implications for his or her health and in terms of costs to the health care system. The cost of treatment failure is high as patients are likely to develop drug resistant virus that is more difficult and costly to treat.
- Patients managed by experienced HIV providers have better health outcomes and receive more cost effective care.

- Medicaid prior authorization determinations are frequently made by staff without HIV experience or using algorithms that do not take into account unique patient characteristics, particularly for treatment experienced individuals.
- Drug treatment interruptions can result in the development of drug resistance and should be avoided whenever possible.

**See:**

- HIVMA. [Identifying Providers Qualified to Manage the Longitudinal Treatment of Patients with HIV Infection and Resources to Support Quality HIV Care](#). March 2013.

**As more states move to restrict access to newer antiretroviral drugs, it is important to reiterate key Medicaid drug coverage policies as was done in [Medicaid Drug Rebate Program Notice Release No. 172 Assuring Medicaid Beneficiaries Access to Hepatitis C \(HCV\) Drugs](#).**

Highlighted text from HCV coverage notice:

- CMS is concerned that some states are restricting access contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs.
- While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes, such practices must The effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments.
- CMS encourages states to exercise sound clinical judgment and utilize available resources to determine their coverage policies. These resources include pharmacy and therapeutics (P&T) committees, drug utilization review (DUR) boards, and comparative analysis of the costs to treat HCV patients in light of the efficacy of these newer regimens in terms of cure rates, when compared to those of preexistent therapies.
- Medicaid managed care organizations (MCOs) or other managed care arrangements' conditions should not be more restrictive than coverage under the states' fee-for-service (FFS) programs.
- Drugs under the approved state plan must be available to individuals enrolled in Medicaid managed care arrangements. As with their FFS program, states are urged to carefully monitor drug coverage policies of their MCOs to ensure enrollees have appropriate access. States have the option to include these drugs in the managed care contracts and capitation rates or to "carve out" drugs.