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August 21, 2015

Linda K. Wiant, Pharm. D.
Chief, Medical Assistance Plans
Division of Medicaid
2 Peachtree Street, N.W.
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Atlanta, GA 30303

Sent via email: lwiant@dch.ga.gov

Dear Dr. Wiant:

I am writing on behalf of the HIV Medicine Association (HIVMA) to strongly urge Georgia Medicaid to reconsider the proposal to change the status of three antiretroviral medications (Complera[®], Stribild[®] and Triumeq[®]) to non-preferred status with prior authorization.ⁱ HIVMA represents more than 5,000 HIV clinicians who work on the frontlines of the HIV epidemic in communities across the country, including nearly 60 physicians in Georgia.

Remarkable advances have led to highly effective treatment for HIV infection, and it is now definitively clear that early and sustained treatment resulting in viral suppression is critical to keep patients healthy, mitigate long-term complications and reduce the spread of this infectious disease.^{ii,iii,iv} The epidemic in Georgia is among the nation's worst. According to the most recent CDC data (from 2013), Georgia ranks 2nd among states in rate of new HIV diagnoses, and Atlanta ranks 5th among metropolitan areas. Unfortunately, too few people with HIV are benefiting from HIV treatment in Georgia and throughout the U.S. For Georgia, it is estimated that fewer than 40% of people with HIV in the state achieve viral suppression, with young people faring even worse.^v According to the new National HIV/AIDS Strategy, by 2020, 80% of persons diagnosed with HIV should be virally suppressed.^{vi} The Georgia Medicaid program will play a key role in helping the state achieve these goals.

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.^{vii} The guidelines are outlined in a living document that is updated as new research and treatment options become available. Georgia Medicaid is proposing to restrict access to two medications that are recommended as first line options for treatment naïve patients and one that is an alternative for patients who meet certain clinical criteria. They are all single tablet regimens (STR) that simplify pill burden, which has been linked to lower hospitalization rates, reduced health care costs and improved treatment adherence and outcomes.^{viii,ix,x} In addition, for Stribild[®] some of its component parts are not available outside of the STR.

Limiting access to these medications will restrict access to the preferred HIV treatment for some Medicaid beneficiaries with HIV and possibly permanently limit their future treatment options. Unlike some other conditions, step-therapy – or requiring patients to try and fail on less expensive treatment before allowing coverage for newer, sometimes more expensive treatment—is never appropriate for patients with HIV. HIV treatment failure results in the selection of drug resistant virus that limits future therapeutic options, and causes damage to the immune system. Likewise, prior authorization requirements impose treatment delays and administrative burdens on clinics that are substantial and detract from their ability to care for patients.

Many HIV-infected patients have serious co-occurring conditions in addition to unique physiological factors that determine the HIV antiretroviral agents that will most effectively suppress the virus. HIV clinicians and their patients must have unimpeded access to the range of medications available to quickly and successfully treat HIV. In recognition of this – the Medicare Part D program requires its drug plans to cover all FDA-approved antiretroviral drugs and bars plans from applying utilization management to antiretroviral drugs.

While we appreciate the challenges of managing prescription drug costs, we believe any short term sacrifice in cost will be more than repaid by decreases in other areas of healthcare utilization, and improvements in drug adherence, viral suppression, and consequent new HIV infections averted. We strongly urge Georgia Medicaid to promote high quality HIV care for Georgia’s Medicaid beneficiaries by leaving these decisions to HIV clinicians and their patients.

Thank you for considering our recommendations and please feel free to contact me through the HIVMA executive director Andrea Weddle at aweddle@hivma.org.

Sincerely,



Adaora Adimora, MD, MPH
Chair, HIVMA Board of Directors

ⁱ Georgia Department of Community Health. The Drug Utilization Review Board Reviewed the Following New Drugs and Supplemental Rebate Classes on June 4, 2015. Online at: https://dch.georgia.gov/sites/dch.georgia.gov/files/June%202015%20DURB_Recommendations_Final.pdf.

ⁱⁱ INSIGHT START Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med. Jul 20 2015. Online at: <http://www.ncbi.nlm.nih.gov/pubmed/26192873>.

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- ⁱⁱⁱ Temprano ANRS 12136 Study Group. A trial of early antiretrovirals and isoniazid preventive therapy in Africa. *N Engl J Med*. Jul 20 2015. Online at: <http://www.ncbi.nlm.nih.gov/pubmed/26193126>.
- ^{iv} Statement by the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents Regarding Results from the START and TEMPRANO Trials. July 28, 2015. Online at: <https://aidsinfo.nih.gov/news/1592/statement-from-adult-arv-guideline-panel---start-and-temprano-trials>.
- ^v Georgia Department of Health. HIV Care Continuum. Online at: <http://dph.georgia.gov/hiv-care-continuum>.
- ^{vi} White House Office of National AIDS Policy. National HIV/AIDS Strategy for the United States: Updated to 2020. July 30, 2015. Online at: <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/overview/>.
- ^{vii} 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. Online at: <https://aidsinfo.nih.gov/guidelines>.
- ^{viii} Cohen CJ, JL Meyers, KL Davis. 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.
- ^{ix} Nachega JB et al. Lower pill burden and once-daily dosing antiretroviral treatment regimens for HIV infection: a meta-analysis of randomized controlled trials. *Clin Infect Dis*. 2014 May;58(9).
- ^x Sweet D et al. Real world medication persistence with single versus multiple tablet regimens for HIV-1 treatment. *J Int AIDS Soc*. 2014 Nov 2; 17.