October 18, 2013

Executive Name
Address

Re: Formulary Exclusion of Single-Tablet Regimens for Individuals Living With HIV

Dear Mr/Ms. X:

We are writing to express our serious concern about the absence of single-tablet regimens (STRs) for the treatment of HIV on your formularies. Based on a preliminary review, it appears that your plans exclude STRs in several states, which is inconsistent with the current standard of care for HIV. A majority of public and private health insurance plans cover STRs, including the state benchmark plans that set the minimum standard for mandatory Qualified Health Plan (QHP) pharmaceutical coverage under the Affordable Care Act (ACA).

We urge you to immediately amend your formularies to include all STRs, in tiers that will allow people with HIV access to these essential medications, and to update your plan profiles in the Marketplaces to reflect this change. These medications play an important role in the management of HIV infection for a majority of people with HIV who are on treatment; their exclusion from QHP formularies creates a second class of health insurance coverage for individuals purchasing coverage through the Marketplaces.

Advances in HIV care and treatment have transformed HIV/AIDS from a deadly disease to a manageable chronic health condition. Consequently, the HIV standard of care in the United States is to offer treatment to all individuals testing positive, as failure to suppress the virus early in its progression causes irreparable and costly harm to the immune system.\(^1,2\) Development of STRs (that significantly reduce daily pill burden) has further improved management of HIV. Utilization of STRs has increased adherence and improved health outcomes, as well as reduced transmission rates and healthcare expenditures.\(^3,4,5\) In fact, STRs have been shown to reduce hospitalization-related costs by 23% and overall medical costs by 17%.\(^3\) Some of the preferred HIV treatment regimens recommended by the Department of Health and Human Services and International Antiviral Society-USA in their respective guidelines for antiretroviral treatment are available as STRs. Most of the co-formulated products are no more expensive than their component parts and can be of greater value when the benefit to treatment adherence is considered.

With the enactment of the ACA, tens of thousands of individuals living with HIV will now have access to the QHPs you offer. By limiting access to STRs, individuals living with HIV enrolled in your plans will not have access to the simplified drug regimens that promote treatment adherence. This could place them at greater risk for developing more serious HIV-related complications jeopardizing their health and leading to the need for more costly medical interventions, as well as increasing the risk of transmission. In addition, failing to cover STRs will result in extremely dangerous disruptions in treatment for those who are currently uninsured, yet receiving access to these medications through state AIDS Drug Assistance Programs or patient assistance programs (both of which cover STRs), as they transition to QHP coverage.
Plans are required to have clear policies and procedures in place that allow enrollees to request coverage for drugs that are not on formularies (45 CFR § 156.122(c)). However, these processes can be labor intensive, lengthy, and lead to increases in overall health care costs due to the harmful consequences of a potential coverage delay or denial, and the increased administrative burden on an already strained health care system. It also unreasonably deters enrollees (and potential enrollees) from seeking much needed health insurance, as this deviation from the states’ benchmarks will likely have the effect of actively discouraging individuals living with HIV from enrolling in these plans. This may even amount to unlawful discrimination under the ACA. Under 45 CFR § 147.104(e), insurers may not “employ marketing or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.” A benefit design that excludes essential medications for the treatment of HIV violates this regulation.

We strongly urge you to amend your formulary by adding STRs to your drug formularies so that your QHP coverage supports today’s standard of HIV care. We also urge you to ensure that these medications are available at reasonable cost sharing levels to ensure access to the treatment that is critical to keeping people with HIV healthy.

Thank you for your prompt attention to these matters. Should you have any questions or wish to further discuss these matters, please contact Robert Greenwald at rgreenwa@law.harvard.edu or (617) 390-2584.

Respectfully Submitted by the Steering Committee of the HIV Health Care Access Working Group,


cc: Kathleen Sebelius, Secretary, Department of Health and Human Services
Gary Cohen, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight, Department of Health and Human Services

---

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