Importance of Robust Coverage for HIV/AIDS Products

Patients with HIV/AIDS require access to critical and life-saving medications. While there is no cure for HIV/AIDS, the disease can be managed with the appropriate oversight and delivery of care. Antiviral medications developed over the past decade have dramatically increased the life expectancy for HIV/AIDS patients. Additionally, combination products have become critical options for HIV/AIDS patients as these therapies can reduce pill burden and increase adherence.

Benchmark Coverage for HIV/AIDS Therapies

Meaningful access to medicines requires both broad formularies and affordable cost sharing. Information on cost sharing and the use of utilization management techniques such as prior authorization will be available starting in October 2013 when open enrollment begins. Currently, it is only possible to directly assess the required number of medicines to be included in the formularies in each state through an analysis of Essential Health Benefit (EHB) coverage requirements. For this analysis, requirements for coverage of two of the many classes of medicines used to treat patients with HIV/AIDS highlights the risk that plan formularies may provide poor coverage of HIV/AIDS medicines in some states. To comply with EHB requirements, plans must cover at least the number of medicines in each USP category and class as the state-selected benchmark plan. However, benchmark plan coverage differs widely, leaving patients in some states vulnerable to limited formularies. For example:

- Even in states where the benchmark plan offers generous coverage, there is a risk that combination therapies may not be covered due to the way combination products are counted.
- Essential Health Benefit (EHB) plans in a significant majority of states will have to cover all medicines in the two HIV/AIDS classes (see appendix).
- EHB plans in 48 states (including DC) will be required to cover all Protease Inhibitors currently on the market.
- EHB plans in 7 states would be permitted to cover fewer than 75 percent of therapies in the class of other antiretrovirals (or antiretrovirals with different mechanisms of action that are currently not classified based on the USP classification system).

Formulary Standards and Counting Rules

The EHB counting standards ignore some key distinctions between medicines, potentially leading to Exchange plans having narrower formularies than the benchmark plans. For example, these standards fail to recognize the importance of combination therapies, extended release medicines, and newly approved medicines. While these requirements may help plans manage costs, they may fail to protect patient access to critical medicines.

<u>Combination Therapies</u>. Most combination therapies will not be counted towards meeting EHB standards if the individual components are already covered by a plan, leaving plans with less incentive to cover these products.

 Over the previous decade, combination products have become increasingly vital treatment options for serious conditions, such as HIV/AIDS. Combination therapies reduce pill burden and increase compliance for patients, who are often taking multiple medicines several times per day.

<u>Extended Release Medicines</u>. Similar to combination products, CMS does not recognize differences between extended release and conventional dosage forms of a single medicine.

• These products allow patients to take medications less frequently, which increases adherence and helps patients maintain better control of their condition.

Coverage for HIV/AIDS Medicines Under Essential Health Benefits

<u>Newly Approved Medicines</u>. The Department of Health and Human Services has not released guidance related to coverage of newly approved medicines or coverage of medicines that are FDA-approved in the middle of the benefit year.

- While plans have flexibility to add new medicines to their formulary mid-year, it is not required.
- Plans also could remove a medicine when adding a new medicine to the formulary (subject to state law), as long as they cover the required number of medicines in the class.

Role for States in Ensuring Good Coverage

The Affordable Care Act (ACA) requires EHB plans to offer coverage typical of the employer market and that does not discriminate against individuals because of their age, disability, or expected length of life. States play a critical role in meeting these standards by choosing a benchmark plan, reviewing plan formularies, and providing oversight to ensure that plans meet non-discrimination standards. There are several options for states to minimize the risk for discrimination. First, states can undertake non-discrimination reviews that encompass medication tier placement, cost sharing and utilization management. Non-discrimination reviews should ensure that EHB plan formularies enable patients to receive the standard of care for HIV. Second, states can incorporate other oversight activities, such as distribution of a class of medicines across formulary tiers. Third, states can provide oversight to ensure a timely and fair appeals process for individuals seeking access to a medication that is not on their plan's formulary. These activities could limit the potential for plans to discriminate against patients with specific chronic conditions and could also help prevent plans from providing a much narrower benefit package than is typically seen in the employer market.

Appendix: Benchmark Coverage by State

