Chase Brexton Health Care

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Submitted for Public Comment: Maryland Prescription Drug Affordability Board

Dear Members of the Maryland Prescription Drug Affordability Board:

As Chief Medical Officer and Director of the Infectious Disease Center of Excellence at Chase Brexton Health Care, I am writing to express our concerns about the potentially significant negative impact establishing an upper payment limit on manufacturers of medications would have on the treatment and reduction of HIV in Maryland. Further, challenging access to Biktarvy and having to switch patients to non-preferred drug options could result in increased costs.

There are over 31,000 people living with HIV (PWH) in Maryland. PWH are disproportionally more likely to have psychosocial barriers to care, be in a lower-than-average financial class, have other medical comorbid conditions, and have a substance use disorder. These burdens result in patients with complex care issues, including difficulty taking medications regularly, trouble remaining adherent to treatment plans, and struggles remaining in care.

Biktarvy is the most prescribed medication to treat HIV in the United States. At Chase Brexton Health Care, 60 percent of our PWH patients are on this drug. To understand why, we need to understand the basics of how HIV is treated: HIV is a virus that can quickly adjust to its environment. When exposed to medications, HIV can mutate and become resistant to such drugs, which allows the virus to survive even in the most challenging environments. With very few exceptions, HIV needs to be treated with a "cocktail," a prescription of three different drugs, and that "cocktail" needs to be taken daily as prescribed. When using three fully susceptible drugs regularly, the virus is under so much treatment pressure that it no longer can develop resistance and the treatment is successful. If the medications are not taken regularly, we refer to it as poor- or non-adherence, and the virus thrives.

Biktarvy addresses many of the HIV treatment challenges:

- First, **Biktarvy is a single tablet regimen (STR) that contains three active drugs**, effectively combining the "cocktail" into one pill, it only has to be **taken once daily**, and it **causes very few side effects** compared to most other HIV drugs. Studies have shown that the fewer pills someone needs to take and the less side effects those drugs cause, the more likely the patient is to take their medications regularly, decreasing the risk of developing resistance and treatment failure.
- Secondly, every drug has its own threshold to be able to develop resistance to the virus. Some are more forgiving to non-adherence and others are less. **Biktarvy has a high barrier to resistance compared to many other drugs** making it a very favorable drug to treat even patients who do not take their medication daily for any reason (such as ongoing substance use, or homelessness). Each time a patient develops

resistance to a drug, their treatment regimen needs to be changed. And often that results in simple single tablet regimens not being possible options anymore. This results in patients having to go on multidrug regimens, leading to increased daily pill burden and increased cost. Biktarvy is very favorable in that regard as it is less likely to fail due to development of resistance reducing the risk of patients needed to be switched to another more complex and more expensive regimen.

- Lastly, many HIV drugs tend to have many and often severe interactions with other medications. This is less of a concern for young and otherwise healthy individuals. However, compared to the general population, PWH are more likely to have other comorbid conditions, such as diabetes, hypertension, or substance use disorder. It can be challenging to find a regimen that works with the other medications an individual is taking. **Biktarvy is compatible with most commonly used medications** and makes this a favorable choice for people on other treatment regimens.

The Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, developed by the Department of Health and Human Services (DHHS), refer to Biktarvy as the preferred drug for the treatment of HIV. The medications listed by the Maryland Prescription Drug Affordability Board as Proposed Therapeutic Alternatives, posted April 10, 2024, contains many second- and third choice drugs that are not comparable to Biktarvy. Further, most of the listed options are not considered preferred regimens by the DHHS guidelines and have specific issues making them unfavorable options for our patient population in Baltimore City.

I would like to comment on three of the listed to explain why they are less favorable and more likely to cause issues leading to treatment failure.

1. Triumeq is also an STR that contains three active drugs, including the medication abacavir. **Abacavir can cause severe/life-threatening immune hypersensitivity reactions** in certain people and requires testing prior to being prescribed to determine if it can be used safely. Further, abacavir has been shown in studies to **increase the risk of cardiovascular events**, including heart attacks and strokes making this an unfavorable choice, especially in patients with other cardiovascular comorbidities and risk factors.
2. Genvoya is an STR that contains three drugs plus one so-called booster drug. That booster drug increases the half-life of one of the drugs, allowing for patients to take Genvoya only once daily. However, that booster drug increases the half-life of many other medications as well, **causing drug-to-drug interactions** with many commonly used medications, including statins very frequently used to treat high cholesterol and steroids used to treat asthma and many other conditions. Further, the drugs **in Genvoya have a low barrier to resistance increasing the risk of drug resistant HIV mutations** if not taken regularly. Genvoya is more likely to fail due to resistance than Biktarvy.
3. Sustiva is not an STR; it is a single drug that needs to be paired with two other active agents to be a complete regimen. Increased pill burden means an increased risk of poor adherence. Further, Sustiva **is**

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one of the oldest drugs on the list, having received FDA authorization in 1998 and **is rich in side effects**, causing neuropsychiatric changes in over 50 percent of patients including insomnia, aggression, depression, anxiety, paranoia, and psychosis. All of these side effects are reasons patients may be resistant to taking Sustiva regularly, making this an outdated and unfavorable option. Sustiva also causes **drug-to-drug interactions** with many commonly used drugs, making it difficult to use in patients taking other medications. **Sustiva has a very low barrier to mutations**, making it one of the easiest HIV drugs to develop a resistance to. Finally, Sustiva was removed as a first line option from the HIV treatment guidelines years ago. With the advances in medicine today, it should not be on any preferred drug list.

Challenging access to Biktarvy and having to switch patients to non-preferred drug options could result in increased costs. If the patient is placed on non-preferred drug options, it will lead to increases in complications from drug-to-drug interaction and increases in resistance due to worsened adherence. These factors will ultimately lead to an increase in new drugs prescribed, and therefore an increase in overall cost.

The task before the Board is a delicate matter and the Board needs to consider all potential consequences. The complexities in the field of Infectious Disease medicine make this decision to reduce access to Biktarvy all the more profound. With more than 13 years of experience as an Infectious Disease doctor, I understand my patients and take immense care in prescribing medications that will provide them the most favorable outcomes and success in their treatment plan.

Biktarvy has research-proven advantages over all listed alternative options, making it a preferred choice for most patients. **It has a high barrier to resistance, is easy to take, causing minimal or no side effects which improves adherence, and causes no drug-to-drug interactions with most commonly prescribed medications.**

In thinking not only of my patients but of the treatment of HIV statewide, I would recommend careful consideration and reflection on the significant impact changing access to Biktarvy could have on HIV treatment, undetectable/untransmittable rates, and overall infection reduction within the state of Maryland.

Sincerely,

Sebastian Ruhs, MD, PhD
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Chief Medical Officer

CC: Patrick Mutch, CEO, Chase Brexton Health Care
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