UNIVERSITY of MARYLAND EASTERN SHORE

SCHOOL *of* PHARMACY *and* HEALTH PROFESSIONS

Dear Prescription Drug Affordability Board,

I am an AAHIV certified pharmacist practicing in the area of HIV care on the Eastern Shore of Maryland. I urge you to be very cautious with your evaluation and suggestions for modification to use of Biktarvy within the state of Maryland. As with all specialties, HIV has much nuance and recommendations should be made with consultation of those with expertise in the area.

The assessment of Biktarvy as a drug is potentially unaffordable is misguided. The reason it is at the top of the list for total dollars spent is due to its popularity, any HIV treatment with similar numbers of prescriptions would be in the exact same position before this Board.* Biktarvy is a popular drug because of its efficacy, and tolerability.[1] Biktarvy is one of 3 Single Tablet Regimens (STRs) on the DHHS guidelines list of preferred initial regimens.[1] It attained that status years ago and has replaced older regimens that are not as well tolerated. Biktarvy is a highly active combination regimen that retains activity even in the presence of some mutations.[2] It can be safely administered rapidly to patients without the need for extensive and delayed lab testing.[3] HIV treatment has progressed to a phase where we can keep people healthy on tolerable medications, as the STR with proven efficacy and tolerability, Biktarvy has become the primary treatment utilized by HIV experts.

Recommended Initial Regimens for Most People with HIV

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use. Choice of ART during pregnancy should be guided by recommendations from the Perinatal Guidelines.

For people who do not have a history of CAB-LA use as PrEP, the following regimens are recommended:

INSTI plus Two NRTIs

- BIC/TAF/FTC **(AI)**[a]
- DTG/ABC/3TC **(AI)**—**if HLA-B*5701 negative**
- DTG plus (TAF or TDF)[c] plus (FTC or 3TC) **(AI)**

INSTI plus One NRTI

- DTG/3TC **(AI),** except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available

For people with HIV and a history of CAB-LA use as PrEP, INSTI genotypic resistance testing should be performed before the start of ART. If treatment is begun prior to results of genotypic testing, the following regimen is recommended:

- DRV/c[b] or DRV/r with (TAF or TDF)[c] plus (FTC or 3TC)—pending the results of the genotype test **(AIII)**

DHHS Guidelines 2024: Table 6 Recommended Initial Regimens[1]

We appreciate that Triumeq and Dovato are proposed as alternatives for Biktarvy, however, the regular use of both of these medications have requirements for labs, including delays for resistance testing or genetic testing.[1] These delays in therapy can prevent uptake of treatment and have shown worse outcomes for patients. Additionally, Triumeq's massive tablet size limits its acceptability and use.[4]

Genvoya and Stribild's size are also on the larger size, however their real drawback is the CYP450-3A4 boosting agent. This booster causes many drug interactions and makes overall care for the patient difficult and at times potentially dangerous.[1] The integrase inhibitor, elvitegravir, in these medications does not have the same durability against missed doses and resistance as bictegravir, also making them less preferred regimens.[1] It should be noted, that these regimens are not less expensive than Biktarvy, but are less effective AND pose risks to the patient.

Descovy is not a complete therapy and would be the NRTI backbone of another product.[1] Commonly it would be combined with Tivicay. This is a great treatment, but it has the noted drawback of not being a STR. This creates the possibility of errors in prescribing and dispensing, which in turn, can lead to the development of resistance. This combination therapy also is more expensive that the STR of Biktarvy.

Isentress is a less potent and less robust integrase inhibitor than bictegravir and dolutegravir.[1] It also requires combination with a dual NRTI backbone like Descovy. This combination makes the overall treatment more expensive than Biktarvy.

The protease inhibitor class, including Reyataz and Prezista, requires boosting with a CYP450-3A4 inhibitor.[1] This presents problematic drug interactions to manage. Additionally, these medications are not being dosed as STRs and combined costs is approximately equivalent to the cost of Biktarvy.

Pifeltro does not have the strong activity of Biktarvy and also requires the addition of the 2 NRTI backbone like Descovy.[1] This combination is about the same cost as Biktarvy.

The only regimen suggested to be an actual cost savings is use of efavirenz along with the 2 NRTI backbone. This medication, while it has extensive experience in practice, also has an extensive adverse effect profile.[1] There are well known psychiatric contraindications to use of this medication and it can cause psychiatric adverse effects.[1,5] Most notably, would be vivid nightmares and dreams.[1,5] These often are so problematic that patients discontinue use of efavirenz.

Overall, while there are other options to the use of Biktarvy, they are not all good options, they do not really result in medication savings, and ultimately cost the system at least as much as Biktarvy. The main reason why Biktarvy costs more than all other HIV medications combined is that we use it much more extensively because it easy to use, durable and a well-tolerated product.

Sincerely,
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References:

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