HIV Section Medication Formulary Workgroup (HSMFW)
Summary of Email Vote on June 2023 Action Items

Dr. Joanne Urban sent an email to members on June 20, 2023. HSMFW members were asked to provide feedback on the addition of dolutegravir/lamivudine to the Test and Treat Formulary. The deadline for feedback was June 29, 2023.

The following information was provided in the original email:

Dolutegravir/lamivudine for Test and Treat

- Dolutegravir/lamivudine is a recommended regimen option for initial treatment of HIV infection except if HIV RNA is > 500,000 copies/mL, patient has hepatitis B virus (HBV) coinfection or antiretroviral therapy (ART) is initiated before resistance test results are available.
    - This regimen is a preferred option in patients for whom a tenofovir-containing regimen should be avoided (e.g., due to kidney disease)
- Since there is no tenofovir component, there is only 1 drug (lamivudine) with activity against HBV
    - If a patient with chronic HBV infection is placed on a single HBV drug regimen, there is risk of rapid development of lamivudine-resistant HBV
- Current guidelines DO NOT recommend dolutegravir/lamivudine as an option for rapid antiretroviral initiation (i.e., Test and Treat) when baseline labs including HIV RNA, resistance test results and hepatitis B serologies are not available

Adult/Adolescent Antiretroviral Treatment Guidelines from Department of Health and Human Services

https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/table-7-antiretroviral-regimen?view=full

An ARV regimen should be started before HIV drug resistance results are available (e.g., in a person with acute HIV) or when ART is being initiated rapidly.	**Avoid NNRTI-based regimens and DTG/3TC.** **Avoid ABC.** **Recommended ARV Regimens in Persons Without Exposure to CAB-LA PrEP** • BIC/TAF/FTC • DTG plus (TAF or TDF)[a] plus (3TC or FTC) • (DRV/r or DRV/c) plus (TAF or TDF)[a] plus (3TC or FTC) **Recommended ARV Regimen in Persons on CAB-LA PrEP Prior to HIV Acquisition** • (DRV/r or DRV/c) plus (TAF or TDF)[a] plus (3TC or FTC)	Transmitted mutations conferring NNRTI and NRTI resistance are more likely than mutations associated with PI or INSTI resistance. HLA-B*5701 results may not be available rapidly, thus ABC is not recommended. Transmitted resistance to DRV, BIC, and DTG is rare, and these drugs have high barriers to resistance. Mutations conferring resistance to INSTIs have been seen in association with CAB-LA PrEP. CAB-LA has a very long half-life, and drug exposure may persist at levels suboptimal to prevent infection and may select for resistant virus.

Rapid ART Initiation Guidelines-Clinical Guidelines Program-NY State Department of Health AIDS Institute

https://www.hivguidelines.org/antiretroviral-therapy/when-to-start-plus-rapid-start/

Medications to Avoid		
• Abacavir (ABC) • Rilpivirine (RPV) • Efavirenz (EFV) • Dolutegravir/lamivudine (DTG/3TC)	• ABC should be avoided unless a patient is confirmed to be HLA-B*5701 negative. • RPV should be administered only in patients with a confirmed CD4 count ≥200 cells/mm^3 and an HIV RNA level <100,000 copies/mL. • EFV is not as well tolerated as other ARVs, and NNRTIs have higher rates of resistance than other classes. • DTG/3TC requires baseline resistance testing and is not recommended when HBV status is unknown.	A3

Excerpt from the NYDOH AI Guidelines General Principles in Choosing a Regimen for Rapid ART Initiation section.

- The 2-drug ART regimen of dolutegravir/lamivudine (DTG/3TC) should not be used for rapid ART because a baseline HIV genotypic resistance profile and hepatitis B virus status are required before prescription of this regimen (see the NYSDOH AI guideline Selecting an Initial ART Regimen). In the STAT study, 131 participants newly diagnosed with HIV initiated ART with DTG/3TC within 14 days of their diagnosis and before availability of baseline laboratory testing results. The ART regimen was modified in 8 participants (6.1%), 5 of whom had HBV infection and 1 who had the M184V mutation at baseline. Although the majority of participants (98%) were virally suppressed at 24 weeks, this was a single-arm study, viral load test results were not available for 20 participants (15%) at 24 weeks, and participants with a baseline viral load ≥500,000 copies/mL were less likely to achieve viral suppression at 24 weeks than those with a baseline viral load <500,000 copies/mL [Rolle, et al. 2021].

The following is a summary of the discussion:

- I agree with the recommendations and guidelines. (Appelbaum)
- I agree. I'm not generally in favor of amending the formulary in ways that are inconsistent with guideline recommendations. Joanne - where can we find the list of the current ARVs on the FL test and treat formulary? (Sherman)
- The current Test & Treat formulary is located here: https://www.floridahealth.gov/diseases-and-conditions/aids/Clinical_Resources/_documents/TestandTreatFormulary.pdf (Iriye)
- Thanks, Jeannette. Since Dovato is already listed there, I'm curious to know its frequency of use in this scenario and also if there have been any reported issues with the samples/vouchers method to acquire the drug for test and treat. (Sherman)
- I would add that while Viiv presents the STAT study to support a proof of concept for using Dovato in rapid start settings It has not been endorsed by DHHS guidelines for such. I would recuse myself from voting on this as I do speak in promotional programs for Viiv in which the STAT data is presented. (Sension)
- I agree with having Test and Treat formulary reflect guidelines. (Gadkowski)
- I agree; stay with the guidelines. (Arons)
- Thank you for the active discussion everyone. I wanted to provide a few things to consider as everyone ponders this request. The Test and Treat program in our state is not limited to new diagnoses. Also, the provider seeing the patient for their test and treat visit are sometimes not a provider who sees patients routinely for HIV care. I would be concerned there could be delay in someone recognizing that a patient was not an appropriate candidate for dolutegravir/lamivudine (e.g., VL > 500,000, Hepatitis B coinfection, resistance). (Urban)
- I agree to remain within HHS guidelines and would not favor its inclusion at this time. (Rodriguez)
- I am OK with either way, adding or not. (Bargar)
- Yes, I agree. The Test and Treat formulary should follow current/ existing guidelines. (Cancel)
- I agree that we stay within the guidelines. (Carscallen)
- I would also agree staying within HHS guidelines and would not favor its inclusion at this time. (Reza)
- Agree will all that formulary should reflect current guidelines (Conde)
- I agree with staying within HHS guidelines and having Test and Treat formulary reflect current guidelines. (Lucero)
- I also agree with following the current guidelines. (Votavo)
- I am torn with this vote because I know Dovato is not on the DHHS guideless for Rapid ART, however, I also know that individualizing ART is so important. I know that ViiV conducted the STAT trial for Rapid Initiation with overall positive outcomes. I do understand there is a boxed warning for those with HBV; however, if I am reading the trial outcomes, only 5 modifications were made due to baseline HBV co-infection at 48 weeks. I realize most have voted not to add, so my vote will not change that outcome. (Sabatino)
- I wanted to share some of my experience in rural North Central Florida: Most of our Test and Treat patients are initially seen by a healthcare provider who is not necessarily an HIV-specialist and therefore has (understandably) limited comfort with different antiretroviral therapies. So T &T patients are largely started on the same antiretroviral regimens. It is at the follow-up visit where patients do see an HIV-specialist where we can fine-tune/adjust the medications if needed. We also

see a fair number of patients in Test and Treat who are returning to care and are not new diagnoses, which may affect our prescribing as well. (Gadkowski)

- I would also agree staying within HHS guidelines and would not favor its inclusion at this time (Anderson)

Kim Molnar, The AIDS Institute, sent an email on June 30, 2023, to HSMFW members asking them to vote on whether to recommend the addition of dolutegravir/lamivudine to the Test and Treat Formulary. Members were asked to submit their vote by Wednesday, July 12, 2023. A reminder email was sent to members on July 7, 2023. Ms. Molnar also followed up with individual members who had not yet cast their vote prior to the deadline.

For voting purposes, abstentions are not counted towards consensus. The results of the vote were as follows:

Do you recommend that dolutegravir/lamivudine be added to the Test & Treat formulary?		
	Response Percent	Response Count
Yes	26.3%	5
No	73.7%	14
Abstain		1

Summary: Dolutegravir/lamivudine was not recommended for addition to the Test and Treat Formulary.

Summary approved by HSMFW vote during Zoom meeting on 9/8/23.